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Community Adherence to Schizophrenia Treatment and Safety Monitoring Guidelines

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Abstract

The 2003 Schizophrenia PORT treatment recommendations and Mt. Sinai Conference Safety Monitoring recommendations generated guidelines for pharmacological treatment of schizophrenia and monitoring of antipsychotic side effects. This study examined rate of recommendation adherence and impact of adherence on outcomes of outpatients with schizophrenia or schizoaffective disorder in community mental health centers. Clinical practice was assessed as conformant, non-conformant, or not applicable. Treatment practices were conformant for antipsychotic dose (83%), use of antiparkinsonian (97%), antidepressant (100%), and antianxiety agents (90%), but not clozapine for residual positive symptoms (31%), monitoring weight gain (48%), glucose dysregulation (53%), hyperlipidemia (34%), or extrapyramidal symptoms (11%). Community mental health center treatment practices were largely conformant with 2003 Schizophrenia PORT treatment recommendations. There is less evidence patients who receive treatment in the community are adequately monitored for antipsychotic side effects per Mt. Sinai recommendations.

Keywords

schizophrenia; second generation antipsychotic; adherence; treatment guideline; metabolic side effects

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Conflict of Interest

Robert Buchanan M.D. has served as consultant or on the advisory boards of Abbott, Amgen, Astra-Zeneca, Astellas, Bristol-Meyer-Squibb, Cypress Bioscience, EnVivo. Janssen Pharmaceuticals, Inc., NuPathe, Inc, Pfizer, Roche, Schering-Plough, Solvay Pharmaceutical, Takeda, and Wyeth. Robert Buchanan M.D. is also a DSMB member for Cephalon, Pfizer, and Otsuka. Robert McMahon Ph.D. has consulted for Amgen. Robert Buchanan M.D. and Bernard Fischer M.D. receive royalties from UpToDate Incorporated. For the remaining authors none were declared

Disclosures

Dr. XX has served as consultant or on the advisory boards of Abbott, Amgen, Astra-Zeneca, Astellas, Bristol-Meyer-Squibb, Cypress Bioscience, EnVivo. Janssen Pharmaceuticals, Inc., NuPathe, Inc, Pfizer, Roche, Schering-Plough, Solvay Pharmaceutical, Takeda, and Wyeth. Dr. XX is also a DSMB member for Cephalon, Pfizer, and Otsuka. Dr. YY has consulted for Amgen. Dr. XX and Dr. ZZ receive royalties from UpToDate Incorporated. For the remaining authors no conflicts of interest were declared.

Introduction

The paradigm of adherence to treatment based upon informed science is a general tenet of medicine (Sacket et al., 1996). Professional organizations and government agencies have established guidelines for the treatment of many diseases based upon the current available evidence, including diabetes, hypertension, and hypercholesterolemia (American Diabetes Association 1990; Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure 1977; Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults 1988) but, until recently, there was no general agreement on the best treatments for individuals with schizophrenia (American Psychiatric Association 2004, Lehman et al., 1998; Miller et al., 1999; McEvoy et al., 1999). Of the recently published guidelines or algorithms, the Schizophrenia PORT treatment recommendations are unique in that they are limited to evidence-based guidelines for best practices in the treatment of schizophrenia (Buchanan et al., 2010; Dixon et al., 2010; Lehman et al., 1998; Lehman et al., 2004). These guidelines were based on a review of available empirical data and assessment of the data by an expert panel. There are no comparable set of evidence-based practices for the monitoring of side effects associated with antipsychotic medications. The Mt. Sinai Conference Safety Monitoring recommendations are based upon expert review of the available evidence and consensus expert opinion and provide guidelines for commonly occurring side effects or medical conditions observed in people with schizophrenia.

In a previous study, we evaluated four 1998 Schizophrenia PORT pharmacological treatment recommendations: 1) acute inpatient antipsychotic treatment, 2) acute inpatient antipsychotic dose, 3) maintenance outpatient antipsychotic treatment and 4) maintenance outpatient antipsychotic dose for conformance and outcome (Buchanan et al., 2002). This study was cross-sectional, identified participants by medical record review, and had eligible participants undergo the PORT Mental Health Survey (a quality of life assessment); the majority of participants were treated with first generation antipsychotics. The study found no associations between treatment recommendation conformance and outcome; however, treatment with first generation antipsychotics at doses below the lower end of the recommended dosage range (i.e., less than 300 chlorpromazine equivalents) was associated with increased employment, indicating that those well enough to work probably required less medication. In contrast, outpatients treated with doses above the upper end of the recommended dosage range (i.e., greater than 600 chlorpromazine equivalents) had significantly more positive symptoms, indicating a degree of treatment resistance.

The purpose of this study was to examine the care of people with schizophrenia in community-based clinics to determine if treatment was in compliance with the 2003 Schizophrenia PORT treatment recommendations and side-effect monitoring was in accordance with the Mt. Sinai Conference Safety recommendations. This study is unique since participants were assessed with ratings in person and not solely by chart or database review. Furthermore, we investigated the extent to which conformance with these recommendations affected clinical outcomes including symptoms, quality of life, and severity of medication side-effects.

Methods

Participants

Participants with a chart diagnosis of schizophrenia or schizoaffective disorder, age 18 years or older, and currently being treated with a second generation antipsychotic (clozapine, risperidone, olanzapine, quetiapine, ziprasidone, or aripiprazole) were recruited from four local community mental health centers. Study sites are in suburban areas of Baltimore County Maryland and recruitment was from October 2007 to December 2011. Each clinic has 3–4 psychiatrists and clinics are not affiliated with a medical school. The psychiatrist caseload is typical of mental health clinics with approximately 15–20 patients per day. Possible participants were referred by their clinicians. The Institutional Review Boards of the University of Maryland School of Medicine and the Sheppard Pratt Health System approved the study protocol and informed consent procedures. Written documentation of informed consent and capacity to provide consent was obtained from all participants after study procedures had been fully explained and prior to study participation.

Assessments

Trained research staff completed all assessments. Scheduled reliability meetings for assessments are a routine part of training. Each participant had their psychiatric medication and medical history abstracted from their clinic records. The psychiatric medication history included current medications and medications for the preceding year. If a participant had been treated at the site for less than one year, then the medication history only included medications from the start of their treatment at the clinic. All current medical conditions and their associated treatments were also recorded.

The Brief Psychiatric Rating Scale (BPRS) (Overall and Gorham, 1962) total score and the Clinical Global Impressions (CGI) were used to assess global psychopathology. The BPRS positive symptom items (i.e., conceptual disorganization, hallucinations, unusual thought content, and suspiciousness) and the Scale for the Assessment of Negative Symptoms (SANS) (Anderson, 1982) total score were used to assess positive and negative symptoms, respectively. Cognitive impairment was evaluated with the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) (Gold et al., 1999) and general well-being was measured by the Level of Function Scale (LOF) (Heinrichs et al., 1984) and Quality of Life Interview (QOLI) (Lehman, 1983). The Simpson Angus Scale (SAS) (Simpson and Angus, 1970), Barnes Akathisia Scale (BAS) (Barnes, 1989), and MPRC Involuntary Movement Scale (MIMS) (Cassady et al., 1997) were used to measure movement disorder side-effects, while fasting glucose and lipid profile, prolactin level, EKG, and vital signs (including height, weight, and waist circumference) were collected to assess other side-effects and medical conditions.

Study Design

This was an observational study. Five 2003 Schizophrenia PORT treatment recommendations (Buchanan et al., 2010) and four Mt. Sinai Conference Safety recommendations (Marder et al., 2004) were chosen for conformance assessment. We

selected these recommendations because a conformance evaluation could be conducted through chart review.

The PORT recommendations selected were: 1) antipsychotic outpatient maintenance dose; 2) antiparkinsonian agent use for movement disorders; 3) clozapine for people with residual positive symptoms; 4) antidepressant use in people with co-occurring depression; and 5) anti-anxiety use in people with co-occurring anxiety disorders. The Mount Sinai recommendations selected were monitoring the patient for: 1) increases in weight, BMI, and waist circumference; 2) glucose dysregulation; 3) hyperlipidemia; and 4) movement disorder side-effects.

Conformance was assessed for each recommendation based upon a predetermined algorithm, which consisted of one or more queries (see Table 1 and Table 2). The queries were answered in a stepwise manner until a determination could be made whether current treatment was conformant or non-conformant with the recommendation. If a recommendation did not pertain to an individual participant, then the recommendation was deemed to be “not applicable” for the individual. There were three circumstances under which a Schizophrenia PORT treatment recommendation could be deemed “not applicable”: 1) clozapine for residual positive symptoms if participants did not have a score of 4 or more on at least one of the BPRS positive symptom items; 2) adjunctive antidepressants if major depressive criteria were not met; and 3) adjunctive anti-anxiety agents if generalized anxiety disorder criteria were not met.

The Mt. Sinai Conference Safety recommendations potentially not applicable included the following: 1) glucose dysregulation recommendation if there was no documentation of pre-existing diabetes or risk factors other than antipsychotic treatment; and 2) hyperlipidemia recommendation if the BMI of the participant was less than 25.

Statistical Analysis

Descriptive statistics were used to describe patterns of antipsychotic and other psychotropic medication use. Schizophrenia PORT and Mt. Sinai Conference Safety recommendation conformance rates were categorically evaluated as either yes or no. The effect of conformance on clinical assessments and side effect assessments was evaluated using t-tests or ANOVA.

Results

Seventy-three subjects participated in the study. The demographic characteristics, medication data, and clinical and side effect ratings are presented in Table 3.

Schizophrenia PORT Treatment Recommendations

Schizophrenia PORT treatment recommendation conformance was generally high (83%–100%), except for the use of clozapine for residual positive symptoms which had 31% conformance with the recommendation (see table 4). In terms of antipsychotic dose, 83% of participants were treated within the recommended dose range. Of those outside of the dose range, 50% (6 out of 12) were above and 50% (6 out of 12) were below the recommended

dose. Four of the six individuals whose dose was above the recommended range were treated with olanzapine. Of the two individuals whose treatment was not conformant with the antiparkinsonian recommendation one individual was treated with olanzapine above the recommended dose and the other was treated with risperidone long acting injection within the recommended dose. All of the participants meeting criteria for treatment with an antidepressant were conformant and 90% of participants meeting criteria for treatment with antianxiety medications were conformant.

Conformance with PORT recommendations was minimally associated with clinical outcomes. The only significant association was observed for clozapine treatment for residual positive psychotic symptoms. Individuals who were conformant with clozapine treatment had a significantly lower BPRS positive symptom item and total scores. The BPRS positive symptom item score for conformant individuals was 9.9 ± 4.0 compared to 12.3 ± 2.8 for non-conformant individuals ($t(49) = -2.6$, $p = 0.013$, 95% CI $[-2.5, -2.3]$, effect size -0.3). The BPRS total score for conformant individuals was 36.3 ± 10.3 compared to 41.6 ± 8.0 for non-conformant individuals ($t(49) = -2.1$, $p = 0.046$, 95% CI $[-5.7, -4.9]$, effect size -0.6). Conformance with clozapine treatment recommendations resulted in improved Level of Functioning Scale total score (conformant $= 9.7$, nonconformant $= 18.6$). The other PORT recommendation with a trend toward improvement for conformant individuals was using antianxiety medications for individuals experiencing anxiety. Conformance with the antianxiety medication recommendation trended towards improvement in SANS anhedonia subscale (7.9 ± 4.1 versus 13.0 ± 4.2 ; $t(34) = -1.7$, $p = 0.093$).

Mt. Sinai Safety Recommendations

Conformance with the Mt. Sinai Safety recommendations was generally poor with most recommendations having a conformance rate of approximately 50% or less. Monitoring for extrapyramidal side effects, akathisia, and tardive dyskinesia was especially poor with only 11% conformance to the recommendation (see table 5).

The participants who were conformant for glucose dysregulation monitoring had worse metabolic parameters compared to the non-conformant group. The conformant group weighed more (229 ± 55.7 lbs. versus 202 ± 35.2 lbs.; $F(2,68) = 10.7$, $p < 0.01$); and had larger waist circumference (45.4 ± 5.5 in. versus 42 ± 3.7 in.; $F(2,63) = 17.2$, $p < 0.01$), higher BMI (35.3 ± 8.6 kg/m² versus 30.6 ± 5.2 kg/m²; $F(2,61) = 11.7$, $p < 0.01$), higher VLDL (37.2 ± 16.1 mg/dl versus 34.4 ± 18.9 mg/dl; $F(2,63) = 4.1$, $p = 0.022$), higher triglycerides (195.5 ± 98.0 mg/dl versus 176 ± 96.3 mg/dl; $F(2,61) = 3.54$, $p = 0.035$), and a higher fasting glucose level (112 ± 41.9 mg/dl versus 101 ± 25.0 mg/dl; $F(2,67) = 2.2$, $p = 0.12$).

The participants who were conformant with hyperlipidemia monitoring weighed significantly more than the non-conformant group (230.7 ± 45.3 lbs. versus 217.4 ± 44.5 lbs.; $F(2,69) = 19.1$, $p < 0.01$), had significantly higher waist circumference (45.5 ± 4.9 in. versus 43.8 ± 4.5 in.; $F(2,64) = 21.2$, $p < 0.01$), and significantly higher BMI (36.1 ± 7.7 kg/m² versus 33.3 ± 7.3 kg/m²; $F(2,62) = 17.3$, $p < 0.01$). The conformant group also had significantly lower HDL (46.3 ± 12.3 mg/dl versus 47.9 ± 15.2 mg/dl; $F(2,69) = 3.5$, $p = 0.035$). There was no difference in total cholesterol or triglycerides between the conformant group and non-conformant group for hyperlipidemia monitoring.

The participants who were conformant for weight monitoring weighed significantly more than the non-conformant group (225.9 ± 55.5 lbs. versus 189.8 ± 44.5 lbs.; $t(70)=3.1$, $p=0.003$). Too few participants were monitored for movement disorder sided effects to determine if there was any relationship between conformance and extrapyramidal side effects, akathisia, or tardive dyskinesia.

Discussion

The major finding of our study was that people with schizophrenia treated in outpatient community mental health clinics were generally conformant with the 2003 Schizophrenia PORT treatment recommendations, except for the use of clozapine for the treatment of residual positive symptoms. In contrast, conformance with the Mt. Sinai Conference recommendations for side effect monitoring was generally poor with providers following these recommendations less than fifty percent of the time.

Two other studies have examined the rate of conformance with Schizophrenia PORT pharmacological treatment recommendations in individuals receiving treatment at local community mental health centers. West et al evaluated conformance to the 1998 Schizophrenia PORT treatment recommendations and the APA 1997 Practice Guidelines for the Treatment of Schizophrenia and found similar results: 83% of patients were treated within the target range of antipsychotics, 100% of patients with depression were receiving an antidepressant, and 71% of patients on a second generation antipsychotic were not receiving antiparkinsonian medications (West et al., 2005).

Goldman et al evaluated 1998 Schizophrenia PORT treatment recommendation, Texas Medication Algorithm Project (TMAP), and Expert Consensus Guideline Series conformance in a community mental health clinic (Goldman et al., 2003). In contrast to the current study and West et al (West et al., 2005), they found only 43% of patients had maintenance antipsychotic medication in the recommended range of 300–600 chlorpromazine equivalents per day.

Our observation of poor adherence to the Mount Sinai side effect monitoring guidelines is consistent with previous studies. Cuffel et al found only 8.5% of 8166 patients had baseline lipid profiles 6 months after the ADA/APA Consensus statement was released and only 22.5% had glucose testing after the release of the American Diabetes Association/American Psychiatric Association (ADA/APA) Consensus Statement recommendations (Cuffel et al., 2006). In a Veterans health study evaluating lipid and blood glucose monitoring, 59% of veterans had their lipids monitored in the following 12 months after switching second generation antipsychotics. The veterans also had 80% monitoring of fasting blood glucose and 31% monitoring for hemoglobin A1C (Hsu et al., 2008). The CATIE study found the prevalence of metabolic syndrome to be approximately 40% depending upon the criteria used to define metabolic syndrome and found the associated diseases of metabolic syndrome – diabetes, hypertension, and dyslipidemia - had a high rates of non-treatment in the schizophrenia population (McEvoy et al., 2005; Nasrallah et al., 2006). The present study, Hsu et al, and Cuffel et al all show very poor conformance to guidelines for monitoring physical health of individuals with schizophrenia in general psychiatric practice, which is

important given the side effect profile of second generation antipsychotic medications and concurrent medical comorbidities. Mortality for individuals with schizophrenia is higher compared to the general population and this difference can be directly attributed to an increased risk of death from comorbid medical conditions (Saha et al., 2007).

This is the first study to directly evaluate conformance to PORT and Mt. Sinai guideline recommendations of treatment and medical monitoring in the same population. Overall there was little relationship between conformance to the Schizophrenia 2003 PORT treatment recommendations, Mt. Sinai Safety Conference recommendations, symptom scores, cognitive measures, side effect evaluations, or quality of life rating scales. The only significant relationship between 2003 Schizophrenia PORT treatment recommendation conformance and outcome was for the clozapine treatment recommendation. Conformance was associated with lower BPRS positive symptom item and BPRS total scores. The observed benefit of conformance with the clozapine treatment recommendations was statistically and clinically significant and supports the importance of clozapine as a treatment option for people with continued positive symptoms. Clozapine continues to be underutilized in clinical practice despite clearly having a beneficial effect on treatment resistant symptoms (Conley et al., 2005; Joober and Boksa 2010; Nielsen et al., 2010; Rosenheck et al., 1999). Conformant participants also had a numerically, but not statistically, higher Quality of Life Interview global score and Level of Functioning Scale total score; these results are consistent with prior studies evaluating clozapine and quality of life (Rosenheck et al., 1999).

In a previous Medicaid database study, Dickey et al (Dickey et al., 2006) found adherence to the 1998 Schizophrenia PORT antipsychotic dosage recommendations were generally unrelated to measures of health status. Physical health was better, but not significantly, in the group whose dose was within the guideline recommendations. Patients in the high dose group had more non-movement-related side effects.

Stiles et al (Stiles et al., 2009) evaluated APA practice guidelines for schizophrenia using a Medicaid database and found treatment consistent with the recommended guidelines was associated with a small, but significant, reduction in mental health symptoms. In a review of psychiatric guidelines on provider performance and patient outcomes, there was insufficient evidence to draw firm conclusions on the effects of implementing specific psychiatric guidelines (Weinmann et al., 2007).

Although the rate of conformance with the Mt. Sinai Conference Safety Monitoring recommendations was low, participants who were conformant with the weight gain and obesity, glucose dysregulation, and hyperlipidemia recommendations had significantly elevated weight, waist circumference, and BMI compared to the non-conformant group. Other side effect measures were also elevated for those who were conformant with these recommendations. For the weight gain and obesity recommendation, the conformant group had significantly higher cholesterol and higher LDL. The conformant group for the glucose dysregulation recommendation had significantly elevated VLDL and elevated triglycerides, but lower HDL with no difference in glucose levels between groups. Conformant participants for the hyperlipidemia recommendation had significantly lower HDL compared

to the nonconformant and not applicable group. A plausible explanation for this finding is that patients who presented with objective indices for risks factors of metabolic disorders were more likely to be monitored than those without abnormal indices, i.e., in the context of limited resources, patients who were most in need received the required monitoring services.

Tosh et al (Tosh et al., 2010), working with the Cochrane Schizophrenia Group, evaluated all randomized or quasi-randomized clinical trials focusing upon physical health monitoring versus standard of care or comparing self-monitoring versus monitoring by a health professional or simple versus complex monitoring or specific versus non-specific checks or once only versus regular checks or comparison of different guidance. There were no studies that fulfilled the review criteria, so they could not evaluate the impact of health monitoring on quality of life. The impact of monitoring physical health as a means to reduce morbidity and mortality and improve quality of life is not clear, but at this time conformance to recommendations evaluating side effects is poor.

Guidelines for medical treatment based upon empirical evidence are meant to improve medical care and patient outcomes. Refinement of medical guidelines is a continuous process of improvement. Since this study was completed the 2009 Schizophrenia PORT Recommendations have been published. There are slight differences between the recommendations evaluated for the 2003 Schizophrenia PORT recommendations and the 2009 Schizophrenia PORT recommendations. The 2009 recommendations differ by not recommending adjunctive treatment with antidepressants or anti-anxiety medications due to insufficient evidence to support their use in schizophrenia.

This is the first study to evaluate, through direct patient assessment, how conformance to treatment and side effect monitoring recommendations affected psychiatric symptoms, medical outcomes, and quality of life. It is critically important to determine if conformance to recommended treatment and monitoring guidelines alters patient outcomes and if these effects are clinically significant. Borenstein (1998) argues that many studies make the unfortunate mistake of equating clinical significance with statistical significance. Treatment guidelines and recommendations are based upon these primary studies. Therefore, in order to provide appropriate guidance to clinicians, guideline authors should strive to ensure that treatment and monitoring recommendations lead to clinically meaningful differences in the care of patients.

This study suggests poor patient outcomes are not prevented by conformance to recommended side effect monitoring guidelines, but, rather, poor outcomes may encourage late conformance to side effect monitoring guidelines. In addition, the population at risk for these side effects would probably benefit from increased monitoring. They often have difficulty obtaining medical care and some of the participants may already have undiagnosed medical issues, specifically metabolic abnormalities, at the time of their participation in the study. One way to enhance side effect monitoring and increase diagnosis of medical illnesses would be to have primary care physicians embedded in mental health clinics. This would ensure that appropriate referral, diagnosis, and treatment are easily completed in the same clinic where mental health services are administered.

Due to the cross-sectional design of the study the impact of more adherent monitoring practices over time could not be evaluated, but this would be an important area of future research. It is unclear if prospective implementation of these guidelines is most pertinent to overall patient well-being. The medications used to treat psychotic symptoms have a plethora of side effects, specifically metabolic, and this current study does not address the question of conformance and non conformance secondary to side effects from medication. Conformance to the PORT recommendations may have been affected by patient's inability to tolerate side effects. As with other areas of medicine, psychiatry is continuously weighing the risks and benefits of treatment. Future studies are needed to address the impact of conformance to recommended guidelines and guidelines need to be continuously revised and updated so guidelines accurately reflect the link between guideline conformance and outcomes of patient health.

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Table 1

Schizophrenia 2003 Port Treatment Recommendations Conformance Algorithms

1. Antipsychotic Outpatient Maintenance Dose	Conformant	Non Conformant
a. Is antipsychotic dose within its specified range?	Yes	No

2. Adjunctive Antiparkinsonian Agents	Conformant	Non Conformant
a. Patient is treated with second generation antipsychotic and is not prescribed an anti- Parkinsonian agent.	Yes	No – Go to b
b. Patient has score of 2 or more on one or more SAS items.	Yes	No – Go to c
c. Patient has a score of 2 or more on the BAS Global Clinical Assessment of akathisia item.	Yes	No

3. Residual Positive Symptoms and Clozapine Treatment	Conformant	Non Conformant
a. One or more of the four BPRS positive psychotic symptoms is 4 or more.	Yes – Go to b	No – Not Applicable
b. Individual had adequate trial of two different classes of antipsychotic medication.	Yes – Go to c	No
c. Individual is prescribed clozapine.	Yes –Go to d	No
d. Clozapine dose is greater than 600 mg per day.	Yes	No – Go to e
e. A clozapine level has been collected.	Yes – Go to f	No
f. Clozapine blood level is greater than 350 ng/ml or clozapine and norclozapine blood level is greater than 450 ng/ml.	Yes	No

4. Adjunctive Antidepressants	Conformant	Non Conformant
a. Patient meets SCID criteria for major depressive disorder or has met criteria in the past year.	Yes – Go to b	No – Not Applicable
b. Patient is prescribed an antidepressant medication.	Yes	No

5. Adjunctive Anti-Anxiety Medications	Conformant	Non Conformant
a. Patient currently meets SCID criteria for generalized anxiety disorder or has met those criteria in the past year.	Yes – Go to b	No – Not Applicable
b. Patient is prescribed an anti-anxiety medication.	Yes	No

Table 2**Mt. Sinai Safety Conference Recommendations Conformance Algorithms**

1. Weight Gain and Obesity	Conformant	Non Conformant
a. Patient has been on the same antipsychotic medication for greater than one year.	Yes – Go to b	No – Go to f
b. Patient has been on the same antipsychotic medication for greater than one year.	Yes – Go to c	No
c. Patient has weight recorded in the previous 12 months.	Yes – Go to d	No
d. Patient BMI calculated in previous 12 months.	Yes – Go to e	No
e. Patient waist circumference measured in previous 12 months.	Yes	No
f. Patient has been started on a new antipsychotic medication within the last 12 months.	Yes – Go to g	No
g. Patient has height recorded.	Yes – Go to h	No
h. Patient weight recorded monthly for the first six months on the new medication.	Yes – Go to i	No
i. Patient BMI calculated monthly for the first six months on the new medication.	Yes – Go to j	No
j. Patient waist circumference measured at initiation of the new medication.	Yes	No

2. Glucose Dysregulation	Conformant	Non Conformant
a. Patient has been on the same medication for greater than one year.	Yes – Go to b	No – Go to d
b. Patient has diabetes or risk factors for diabetes at time of assessment	Yes – Go to c	No – Not Applicable
c. Glucose measure obtained within the preceding 12 months	Yes	No
d. Patient has been started on new antipsychotic medication in the past 12 months and has been on this medication for at least 4 months.	Yes – Go to e	No – Not Applicable
e. Patient has diabetes or risk factors for diabetes.	Yes – Go to f	No – Go to g
f. Glucose measure was obtained at baseline and since the start of the new antipsychotic medication.	Yes	No
g. Patient has been started on new antipsychotic medication within last 12 months, does not have risk factors for diabetes, and glucose measure was obtained at baseline.	Yes	No

3. Hyperlipidemia	Conformant	Non Conformant
a. Patient has been on the same antipsychotic medication for more than one year.	Yes – Go to b	No – Go to d
b. Patient has BMI greater than 25.	Yes – Go to c	No – Not Applicable
c. Lipid panel was obtained in the past 12 months.	Yes	No
d. Patient has started a new antipsychotic medication within the last 12 months and a lipid panel was obtained at baseline.	Yes	No

4. Extrapyramidal Side Effects, Akathisia, and Tardive Dyskinesia	Conformant	Non Conformant
a. Patient has been on the same antipsychotic Medication(s) for greater than 1 year.	Yes – Go to b	No – Go to f
b. Patient has been on the same or lower dose of antipsychotic medication(s) for greater than 1 year.	Yes – Go to d	No – Go to c
c. Patient has been on the same antipsychotic medication(s) for greater than 1 year and the dosage increases have been less than 25%.	Yes – Go to d	No – Go to e
d. Patient has been examined for parkinsonian signs and abnormal involuntary movements within the preceding 12 months.	Yes	No
e. Patient has been on the same antipsychotic medications for greater than 1 year and dosage increases have been greater than or equal to 25% and the patient has been examined for parkinsonian signs and abnormal involuntary movements within the preceding 12 months.	Yes	No
f. Patient has been started on a new antipsychotic medication in the past year and the patient has been examined for parkinsonian signs and abnormal involuntary movements at baseline and two weeks after the antipsychotic medication dose has stabilized.	Yes	No

Table 3

Baseline Demographic and Clinical Characteristics (N=73)

		M (SD) or %
	Age (yrs)	50.2 (8.6)
	Gender (female)	38.4%
	Race (white)	71.2%
Second Generation Antipsychotics (SGAs)	aripiprazole	11.0%
	clozapine	42.5%
	olanzapine	24.7%
	quetiapine	12.3%
	risperidone	27.4%
	ziprasidone	5.5%
	Multiple SGAs	23.3%
BPRS	Anxiety-Depression	9.4 (3.8)
	Anergia	7.1 (2.4)
	Negative Symptoms	6.0 (2.3)
	Psychosis	9.9 (3.8)
	Activation	4.8 (1.4)
	Hostile-Suspiciousness	5.7 (2.4)
	BPRS Total Score	36.5 (9.2)
SANS	Affective Flattening or Blunting	6.9 (4.5)
	Alogia	1.9 (1.8)
	Avolition-Apathy	7.5 (4.0)
	Anhedonia-Asociality	7.8 (4.8)
	SANS Total Score	23.4 (11.5)
CGI	Severity	4.0 (0.7)
	Global	2.4 (2.0)
LOFS	LOF Total Score	20.1 (5.7)
Simpson-Angus	Total Score	2.8 (2.3)
RBANS	Immediate Memory	76.3 (20.0)
	Visuospatial	80.2 (18.0)
	Language	86.6 (11.5)
	Attention	74.2 (17.4)
	Delayed Memory	78.4 (19.6)
	Total Score	73.6 (15.1)
BAS	Total Score	1.0 (1.9)
MIMS	Global Akathisia	0.1 (0.4)
	Global Dyskinesia	0.5 (0.8)
	Global Parkinsonian	0.04 (0.27)

Brief Psychiatric Rating Scale (BRPS), Scale for the Assessment of Negative Symptoms (SANS), Clinical Global Impression (CGI), Level of Functioning Scale (LOFS), Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), Barnes Akathisia Scale (BAS), Maryland Involuntary Movement Scale (MIMS)

Table 4

Conformance to Schizophrenia 2003 Port Recommendations

Schizophrenia 2003 PORT Recommendation	Proportion Conformant	N
1. Maintenance Outpatient Antipsychotic Dose	0.83	73
2. Adjunctive Antiparkinsonian Agents	0.97	73
3. Residual Positive Symptoms and Clozapine Treatment	0.31	39
4. Adjunctive Antidepressants	1.00	19
5. Adjunctive Antianxiety Agents	0.90	21

Table 5

Conformance to Mt. Sinai Safety Conference Recommendations

Mt. Sinai Safety Conference Recommendation	Proportion Conformant	N
1. Weight Gain and Obesity	0.48	73
2. Glucose Dysregulation	0.53	60
3. Hyperlipidemias	0.34	59
4. Extrapyramidal Side Effects, Akathisia, and Tardive Dyskinesia	0.11	72