

A PATIENT-CENTERED APPROACH TO IMPROVE SCREENING FOR THE METABOLIC SIDE EFFECTS OF SECOND- GENERATION ANTIPSYCHOTIC (SGA) MEDICATIONS

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POLL QUESTION

- What best describes your position at the VA?
 - Researcher
 - Clinician
 - Administrator/policymaker
 - Other

POLL QUESTION

- How familiar are you with the recommended screenings for the metabolic side effects of SGA medications?
 - Very familiar
 - Moderately familiar
 - Somewhat familiar
 - A little bit familiar
 - Not familiar at all

BACKGROUND

- Individuals with serious mental illness (SMI) have significantly reduced life expectancy (~25 years of potential life lost).
- Cardiovascular disease (CVD) and Type 2 diabetes are major contributors to morbidity and premature mortality in this population.
- In addition to lifestyle factors, certain medication side effects likely contribute to CVD risk.

BACKGROUND

- Metabolic side effects of second-generation antipsychotic (SGA) medications may contribute to CVD risk
 - Weight gain
 - Hyperglycemia
 - Hyperlipidemia

- Differential metabolic risk across SGAs
 - High risk: Clozapine, olanzapine
 - Intermediate risk: Quetiapine, risperidone/paliperidone
 - Low risk/neutral: Aripiprazole, ziprasidone, asenapine (?), iloperidone (?), lurasidone (?)

FDA WARNING ABOUT METABOLIC SIDE EFFECTS OF SGAS

June 2004

FDA has asked manufacturers of all atypical antipsychotic drugs to add a new warning to the drugs' labels about the increased risk of hyperglycemia and diabetes. Atypical antipsychotics include: Clozaril[®] (clozapine), Risperdal[®] (risperidone), Zyprexa[®] (olanzapine), Seroquel[®] (quetiapine), Geodon[®] (ziprasidone), and Abilify[®] (aripiprazole).

Epidemiologic studies suggest that the risk of hyperglycemia and diabetes is increased in patients taking Clozaril, Risperdal, Zyprexa and Seroquel, although the relationship isn't completely understood. In some cases, the hyperglycemia was extreme and associated with ketoacidosis or hyperosmolar coma or death. Geodon and Abilify weren't marketed at the time the study was conducted.

For some patients, the hyperglycemia resolved when the drug was discontinued, but others required continuing treatment for their diabetes even after they stopped taking the drug.

The warning recommends that patients with diabetes who are started on atypical antipsychotics be monitored regularly for worsening of glucose control.

Patients starting on these drugs who have diabetes risk factors, such as obesity or a family history of diabetes, should have fasting blood glucose testing at the start of treatment and periodically thereafter.

And all patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia, such as excessive thirst, excessive appetite, frequent urination, or weakness. If they develop symptoms of hyperglycemia while on these drugs, they should have a fasting blood glucose test.

RECOMMENDATIONS FOR MONITORING FOR METABOLIC SIDE EFFECTS OF SGAS

Screening parameter	Mt. Sinai Recommendations	ADA et al., Recommendations
Weight and height/BMI/waist circumference	Measure BMI before medication initiation or change and at every visit for the first 6 months after medication initiation or change. When the patient's weight stabilizes, monitor at least quarterly and more often if the patient is overweight. BMI monitoring should be supplemented by measurement and recording of the patient's waist circumference.	Measure weight/BMI before medication initiation or change, at 4, 8, and 12 weeks after medication initiation or change, and quarterly thereafter. Measure waist circumference before medication initiation or change and annually thereafter.
Fasting blood glucose (FPG) or HbA1c	Measure FPG or HbA1c before medication initiation or change. In the absence of symptoms of diabetes or significant weight gain, OR for patients with significant risk factors for diabetes, monitor 4 months later and annually thereafter. In patients who are gaining weight, monitor every 4 months.	Measure FPG before medication initiation or change, 12 weeks after medication initiation or change, and annually thereafter. Monitor more frequently in patients with a higher baseline risk for diabetes.
Lipid panel	In patients with normal LDL levels, obtain lipid profile at least once every 2 years. In patients with LDL levels > 130mg/dl, monitor lipids every 6 months.	Obtain lipid profile before medication initiation or change, 12 weeks after medication initiation or change, and every 5 years thereafter (more frequently if clinically indicated).
Blood pressure	No recommendation.	Measure blood pressure before medication initiation or change, 12 weeks after medication initiation or change, and annually thereafter.

Marder SR et al. *Am J Psychiatry* 2004; 161:1334-49
 ADA et al. *Diabetes Care* 2004; 27(2):596-601.

BACKGROUND

Extent of Monitoring for Metabolic Side Effects of SGAs

Type of monitoring	Baseline studies		Post-guideline studies		Pre-post change
	Number of studies	Rate of testing, % (95% CI)	Number of studies	Rate of testing, % (95% CI)	
Weight	19	47.9 (32.4-63.7)	3	75.9 (37.3-98.7)	28.0
Blood pressure	14	69.8 (50.9-85.8)	3	75.2 (45.6-95.5)	5.4
Glucose	30	44.3 (36.3-52.4)	7	56.1 (43.4-68.3)	11.8
Lipids	23	22.2 (16.4-28.7)	7	37.2 (23.7-51.9)	15.0

Mitchell et al. *Psychological Medicine* 2012; 42:125-147.

BACKGROUND

- Extent of monitoring for metabolic side effects of SGAs is inadequate and was largely unaffected by release of FDA warning and guidelines.
- Certain system- and provider-level efforts to enhance metabolic screening have been implemented in the VA, but
 - Have not been empirically evaluated; and
 - May have limited effectiveness without engaging the patient.

CONCEPTUAL FRAMEWORK

Patient-Centered Care

- Key dimensions
 - Active participation by patients in their own care;
 - Quality of clinician-patient relationship or interaction (therapeutic alliance).

- Linked to positive outcomes
 - Increased adherence to treatment;
 - Improved disease management;
 - Improved health status;
 - Greater patient satisfaction.

Mead and Bower. *Soc Sci Med.* 2000; 51: 1087-1110.

Roter et al. *Arch Intern Med.* 1995;155: 1877–84.

Stewart MA. *CMAJ.* 1995;152: 1423–1433.

RATIONALE

Consumer Health Informatics (CHI)

- VA is a leader in patient-centered CHI
 - Electronic medical record since 1997
 - *MyHealthVet*
 - *PTSD Coach App!*

BACKGROUND

Cognitive Impairments in Individuals with SMI

- Standard website design approaches are inappropriate for individuals with cognitive impairments, e.g.,
 - Attention
 - Memory
 - Visual-spatial processing
 - Information processing
 - Psychomotor skills
 - Executive functioning
- Necessary website modifications include
 - Use of shallow hierarchies;
 - Use of memory aids to support navigation;
 - Minimize need to think abstractly;
 - Avoid distracting decorative features;
 - Use of brief, but explicit labels.

SPECIFIC AIMS

- To determine the effects of exposure to a patient-centered computerized tool, relative to enhanced treatment as usual (e-TAU), on
 - Rates of screening by providers for the metabolic side effects of SGAs;
 - Recognition by providers of metabolic abnormalities associated with SGAs.
 - Self-efficacy in communicating with prescriber and preferences for participating in decision-making around screening.
 - Patterns of patient-provider communication related to screening for metabolic side effects of SGAs.

METHODS

- **Study design:** Randomized, controlled trial.
 - Patient-centered computerized tool (n=120)
 - Enhanced treatment as usual (e-TAU) (n=120)
- **Study sites:** Two outpatient mental health clinics in VAMHCS.
- **Patient inclusion criteria:**
 - Diagnosis (Psychotic disorder , bipolar disorder, major depression, PTSD)
 - Prescribed any SGA by a psychiatrist or NP in the VAMHCS
 - At least 2 visits with prescribing MD/NP in past year
 - Ability to read at a 4th grade reading level
 - Agreement by prescribing MD/NP
 - Patient is clinically stable to participate in study;
 - To have one visit with participant audio taped.

KEY ELEMENTS OF THE INTERVENTION



Introduction

← REPEAT

This short program will tell you about some of the side effects of antipsychotic medications and how you can talk with your mental health provider about getting tested for these side effects.

The topics that you will learn about include:

- Overweight and obesity
- Blood pressure
- Blood sugar
- LDL cholesterol
- HDL cholesterol
- Triglycerides

← PREVIOUS

NEXT →

KEY ELEMENTS OF THE INTERVENTION



Blood Sugar

← REPEAT

High blood sugar from antipsychotic medications is dangerous because it can sometimes lead to diabetes or make diabetes worse, which can increase your risk of health problems such as heart attack and kidney disease.



← PREVIOUS

NEXT →

KEY ELEMENTS OF THE INTERVENTION



Blood Sugar

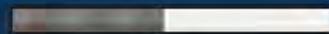
← REPEAT

One way is to measure your blood sugar after you have not eaten anything for at least 8 hours.

This is called fasting blood sugar.



← PREVIOUS



NEXT →

KEY ELEMENTS OF THE INTERVENTION



Additional Information on Blood Sugar

◀ REPEAT

For most people with diabetes, having a fasting blood sugar that is less than 130 mg/dl or a hemoglobin A1c value that is less than 7% will help lower the risk of diabetes-related health problems.



8 / 9

◀ PREVIOUS

NEXT ▶

KEY ELEMENTS OF THE INTERVENTION



Additional Information on Blood Sugar

◀ REPEAT

You should have your blood sugar checked once every year.

If you already have diabetes, talk with your health care provider about getting your blood sugar checked even more often.



1 / 1

← PREVIOUS

NEXT →

KEY ELEMENTS OF THE INTERVENTION



Blood Sugar

← REPEAT

Your medical record shows that you have not had your blood sugar checked in the past 12 months.

Neither you nor your mental health provider knows if your blood sugar is too high.



← PREVIOUS



NEXT →

KEY ELEMENTS OF THE INTERVENTION



Blood Sugar

◀ REPEAT

Your medical record shows that the last time you had your **fasting blood sugar** checked, it was **150 mg/dl**, which is too high.



◀ PREVIOUS



NEXT ▶

KEY ELEMENTS OF THE INTERVENTION



Blood Sugar

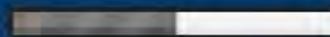
← REPEAT

Your medical record shows that the last time you had your **fasting blood sugar** checked, it was **95 mg/dl**, which is in the normal range.

Keep up the good work!



← PREVIOUS



NEXT →

KEY ELEMENTS OF THE INTERVENTION



Blood Sugar

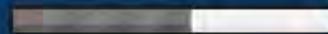
◀ REPEAT

Many people talk with their mental health providers about getting their blood sugar checked.

To get the conversation started, you can give your mental health provider a copy of the report that can be printed at the end of this program.



← PREVIOUS



NEXT →

KEY ELEMENTS OF THE INTERVENTION



← REPEAT

Press the PRINT REPORT button if you would like to receive a written report on the results of each the medical tests that were reviewed in this program.

PRINT REPORT

Remember, you can give one copy of this report to your mental health provider so that you can talk about getting screened for the health problems you learned about today.



← PREVIOUS

NEXT →

KEY ELEMENTS OF THE INTERVENTION

**Antipsychotic Side Effects Screening Report for
John D.
May 17, 2011**

Test	My Test Results	Action Steps Recommended	Next Screening Due
Weight Check every 3 months Goal: A healthy weight	Missing	Talk to your mental health provider <u>today</u> about getting your weight checked	NOW!
Blood Pressure Check every 3 months Goal: Less than 140/90	Missing	Talk to your mental health provider <u>today</u> about getting your blood pressure checked	NOW!
Blood sugar Check every year Goal: HbA1c: Less than 6 Fasting blood sugar: Less than 100	Fasting blood sugar: 90	Keep up the good work! ☺ Talk to your mental health provider <u>today</u> about keeping your blood sugar in the normal range	10/17/11
LDL Cholesterol Check every 2 years Goal: Less than 130	180	Talk to your mental health provider <u>today</u> about whether your LDL cholesterol is still too high	12/15/11
HDL Cholesterol Check every 2 years Goal: Greater than 40 or 50	55	Keep up the good work! ☺ Talk to your mental health provider <u>today</u> about keeping your HDL cholesterol in the normal range	12/15/11
Triglycerides Check every 2 years Goal: Less than 150	200	Talk to your mental health provider <u>today</u> about whether your triglycerides are still too high	12/15/11

PATIENT COPY/MENTAL HEALTH CARE PROVIDER COPY

THE COMPARISON CONDITION (e-TAU)

Weight Gain

Weight gain, which may lead to being overweight or obese, can occur when a person takes in more calories than they use up. Antipsychotic medications may also contribute to this weight gain. Too much of these extra calories, stored as excess body fat, can lead to other health problems.

You should have your weight checked every 3 months by your health care provider.



Elevated Blood Sugar

Some antipsychotic medications may increase your blood sugar levels. Too much sugar in your blood can lead to diabetes, which can increase your risk for heart disease and kidney disease.

Blood sugar that is too low can lead to other health problems.

There are two ways that your health care provider can measure your blood sugar. 'Fasting blood sugar' measures your blood sugar level after 8 hours without food. On the other hand, Hemoglobin A1c tests your average blood sugar level over the last 3 months.

Whichever method is used, you should get your blood sugar tested 1 time every year by your health care provider.

Cholesterol

There are three types of fats in your blood that are important to keep an eye on.

LDL cholesterol is sometimes called "bad" cholesterol. If you have too much, it can build up in your blood stream and can block your blood vessels.

HDL cholesterol is sometimes called "good" cholesterol. This kind of cholesterol prevents build-ups of LDL.

Triglycerides are a naturally produced fat in the body. Normal levels are necessary and healthy.

Antipsychotic medications can sometimes cause an imbalance in one or all of these types of cholesterol that can increase your risk for heart disease.

You should have your LDL and HDL cholesterol and your triglyceride levels checked every 2 years by your health care provider.

High Blood Pressure

Weight gain sometimes causes high blood pressure. Blood pressure is the force of blood flow inside your blood vessels. Too much force causes high blood pressure, also known as hypertension. High blood pressure is dangerous because it makes your heart work too hard and increases your risk of heart attack and stroke.

You should have your blood pressure checked every 3 months by your health care provider.



Use the checklist below to talk with your mental health or other healthcare provider about getting screened for the side effects of antipsychotic medications.

Screening Checklist

- ✓ Weight: every 3 months
- ✓ Blood Pressure: every 3 months
- ✓ Blood Sugar: every year
- ✓ LDL Cholesterol: every 2 years
- ✓ HDL Cholesterol: every 2 years
- ✓ Triglycerides: every 2 years



Getting Screened for the Side Effects of Antipsychotic Medication



Antipsychotic medications are helpful in treating the symptoms of your mental illness. However, these medications can have certain side effects.

This pamphlet describes some of these side effects and how often you should be screened for them.

Make sure to ask your mental health or other health care provider about getting screened for these side effects.

METHODS

Exposure to the Intervention/Comparison Condition

- **Location:** Private room adjacent to prescriber's waiting room.
- **Research staff assistance:** Minimal.
- **Timing:** Immediately prior to outpatient mental health visits with prescribing MD/NP.
- **Frequency:** Up to 3 times, at least 4 months apart, over the one-year study period.

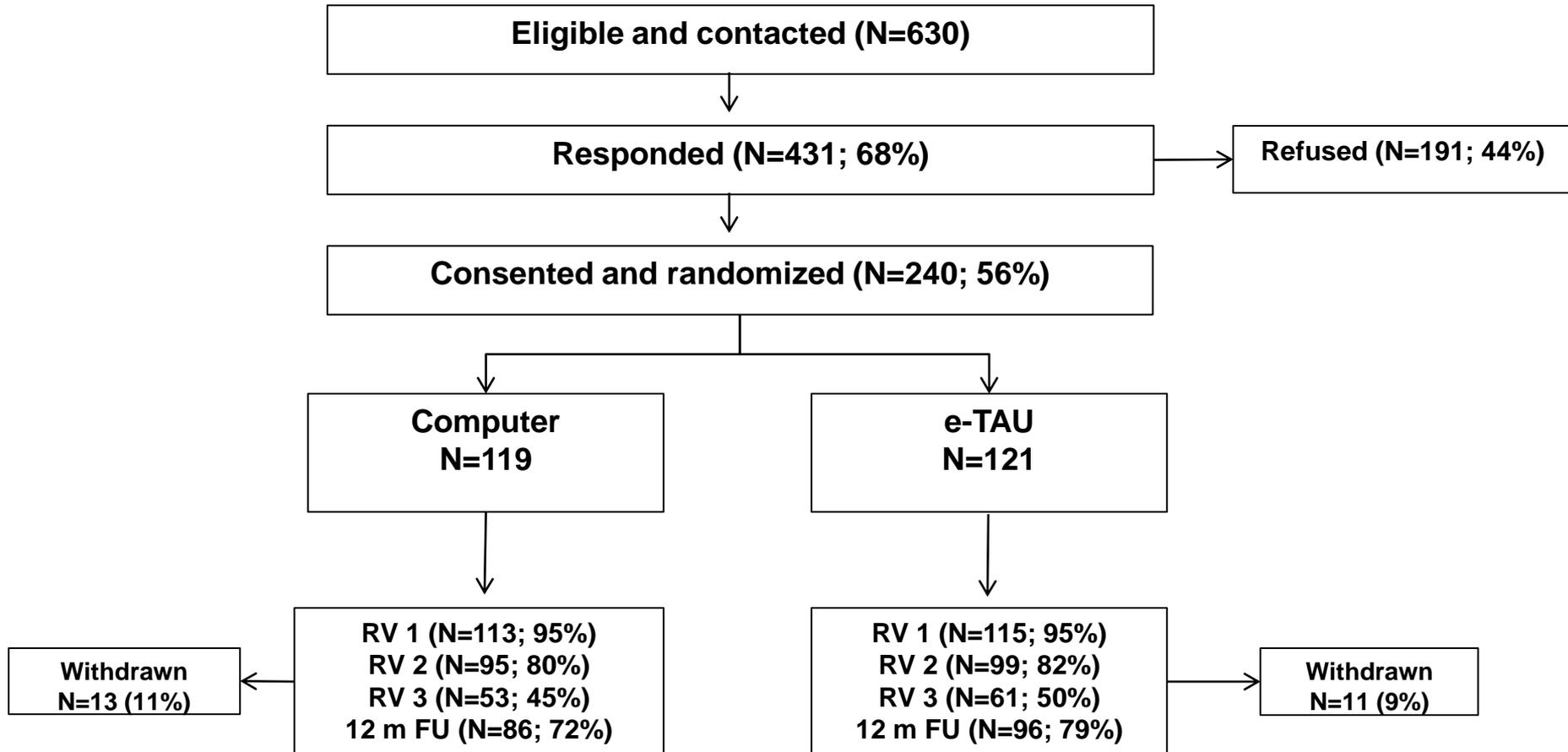
RESULTS

Enrollment of SGA Prescribers

- All eligible SGA prescribers (psychiatrists/nurse practitioners) agreed to participate
 - N= 15 at Baltimore VAMC
 - N= 6 at Perry Point VAMC
- Prescribers consented to have first research visit with any enrolled patient audio taped

RESULTS

Enrollment of Veterans (Goal: N=240)



RESULTS

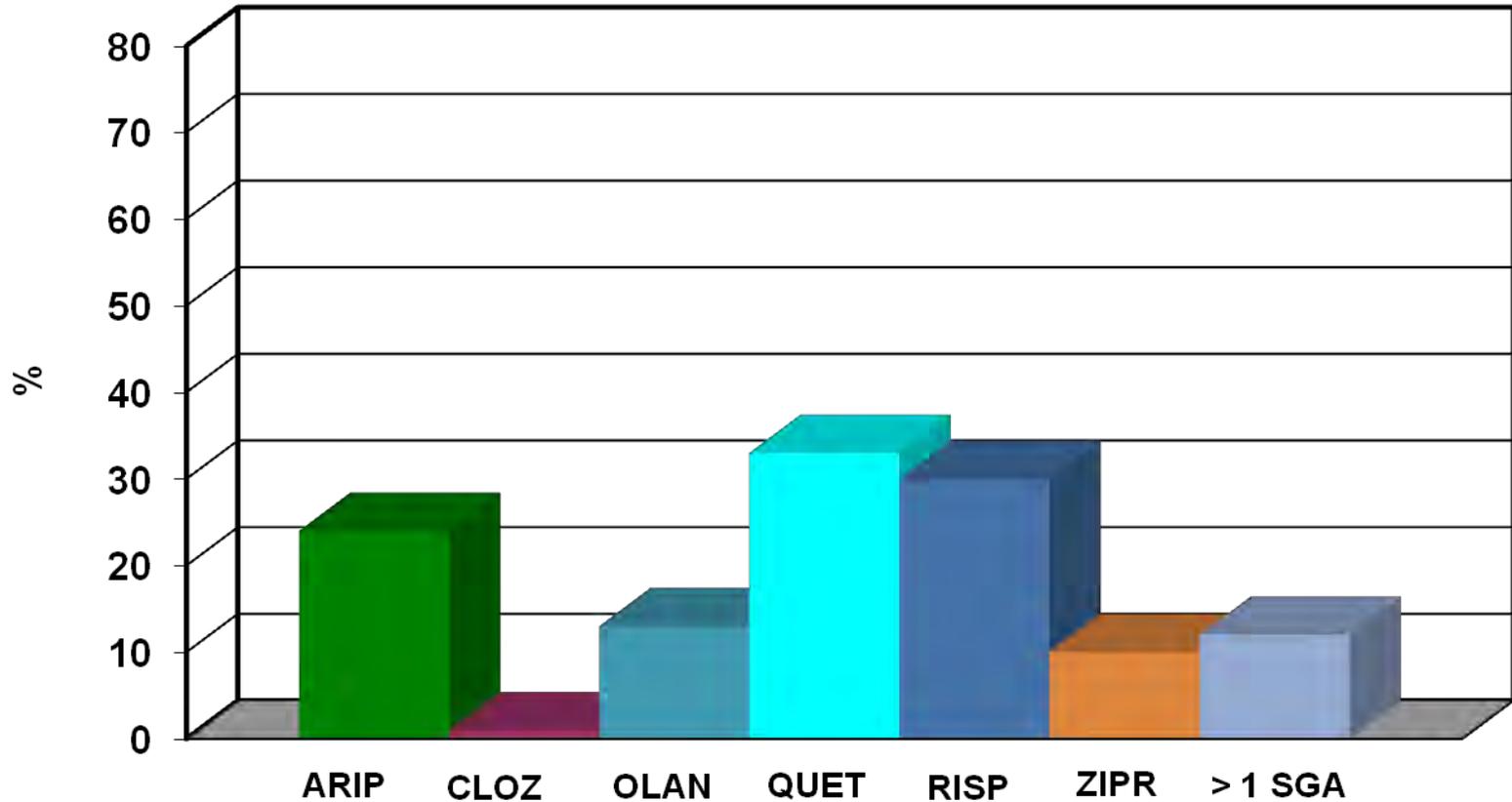
Demographic and Clinical Characteristics (n=240)

Characteristic	Mean (\pm S.D.)/ %
<u>Demographics</u>	
Age	54 (\pm 9) years
Male gender	89%
Non-white race	53%
Unsupervised housing	85%
Ever married	68%
> 12 years education	56%
Working for pay	20%
Military service-connected benefits	56%
Other disability benefits	43%
<u>Primary psychiatric diagnosis</u>	
Psychotic disorder	33%
Bipolar disorder	32%
Major depression	23%
PTSD (only)	12%
<u>BASIS-24 psychiatric symptoms*</u>	
Overall	1.3 (\pm 0.7; range: 0-3.4)
Psychosis	1.0 (\pm 1.0; range: 0-3.8)
Emotional lability	1.8 (\pm 1.1; range: 0-4.0)

* Items rated on a 5-point scale (0-4), with higher scale scores indicating greater symptom frequency/severity.

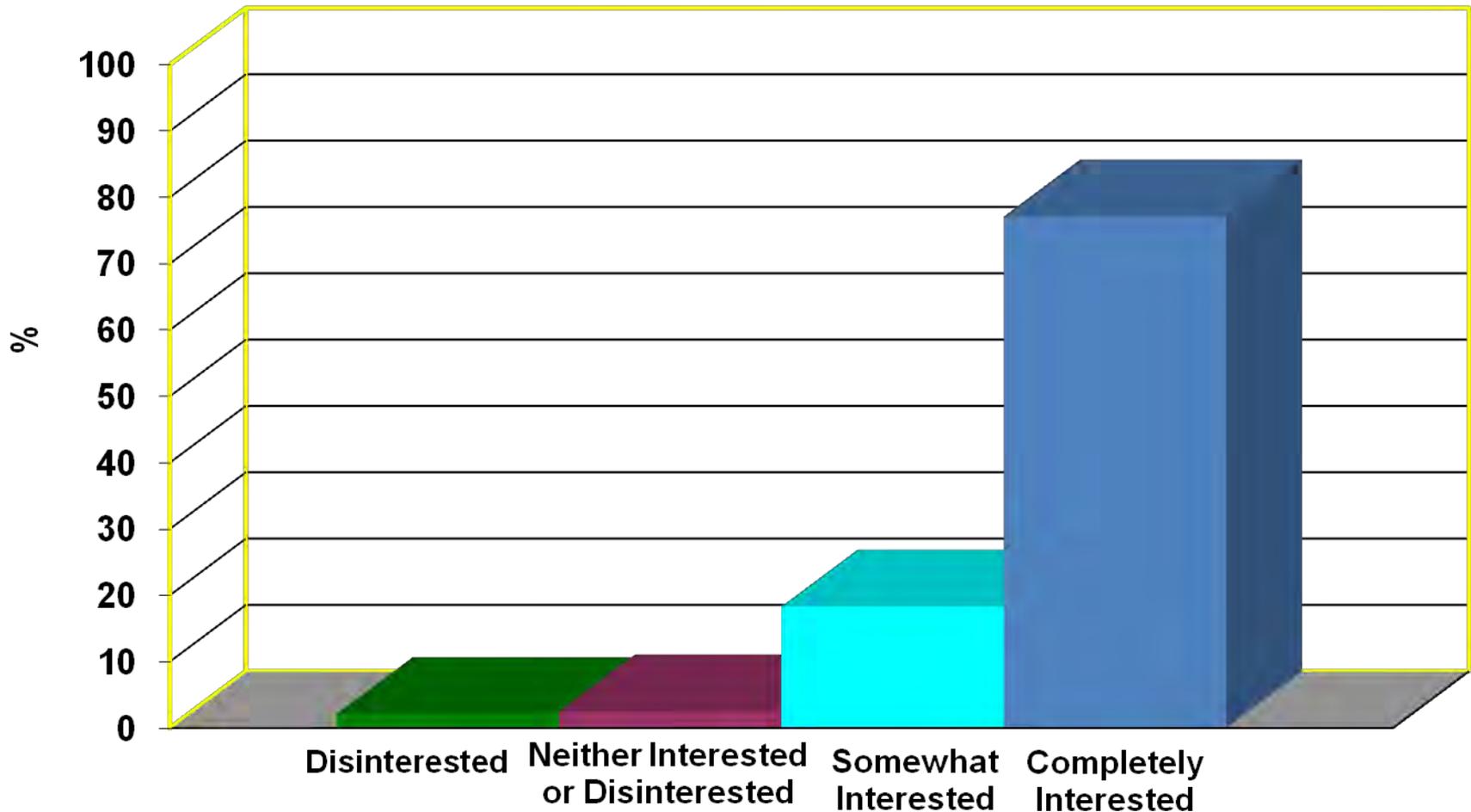
RESULTS

Second-Generation Antipsychotics Prescribed at Baseline (n=240)



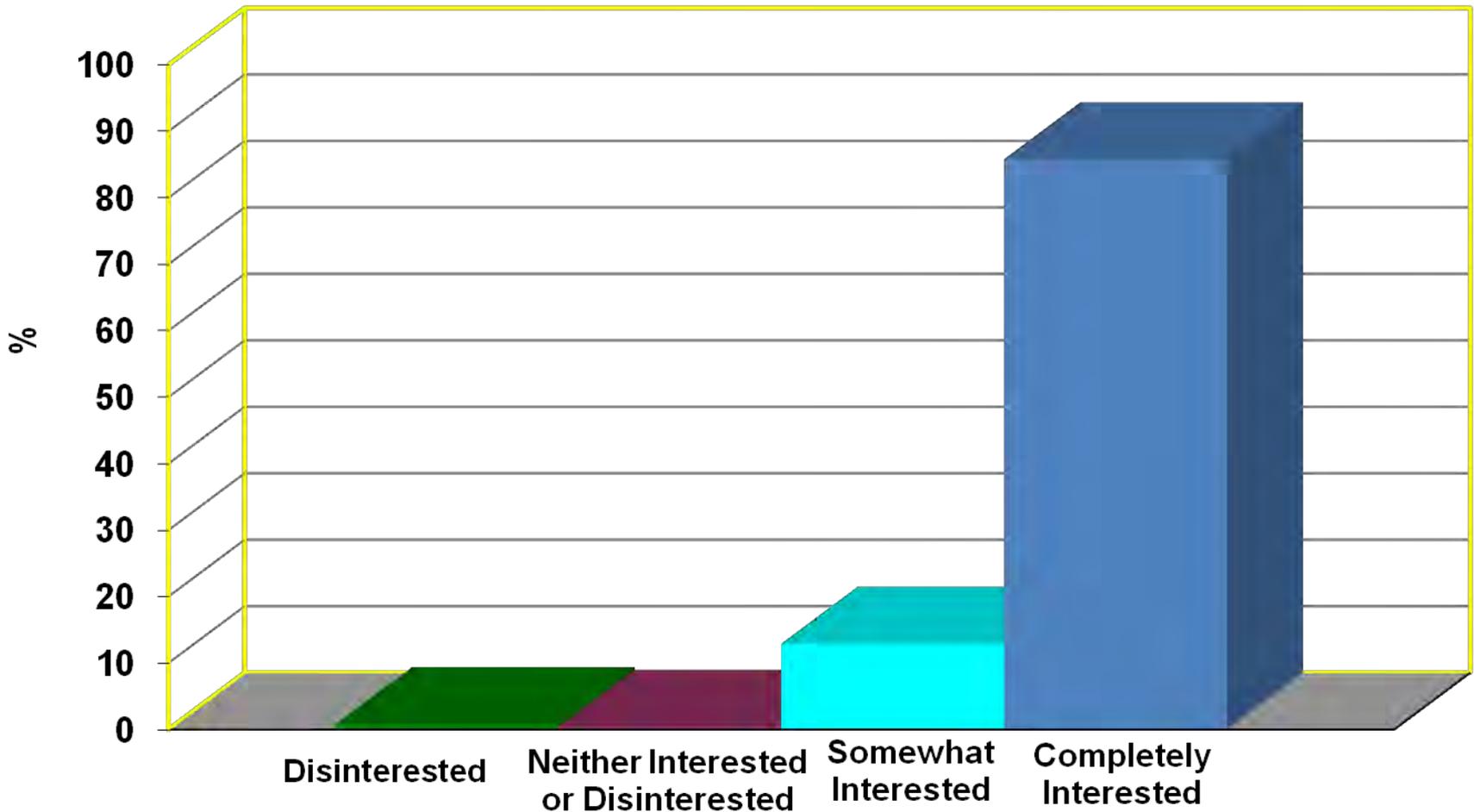
BASELINE PREFERENCES FOR OBTAINING SGA METABOLIC SCREENING (N=240)

...interest in receiving screening for the side effects of antipsychotic medications'...



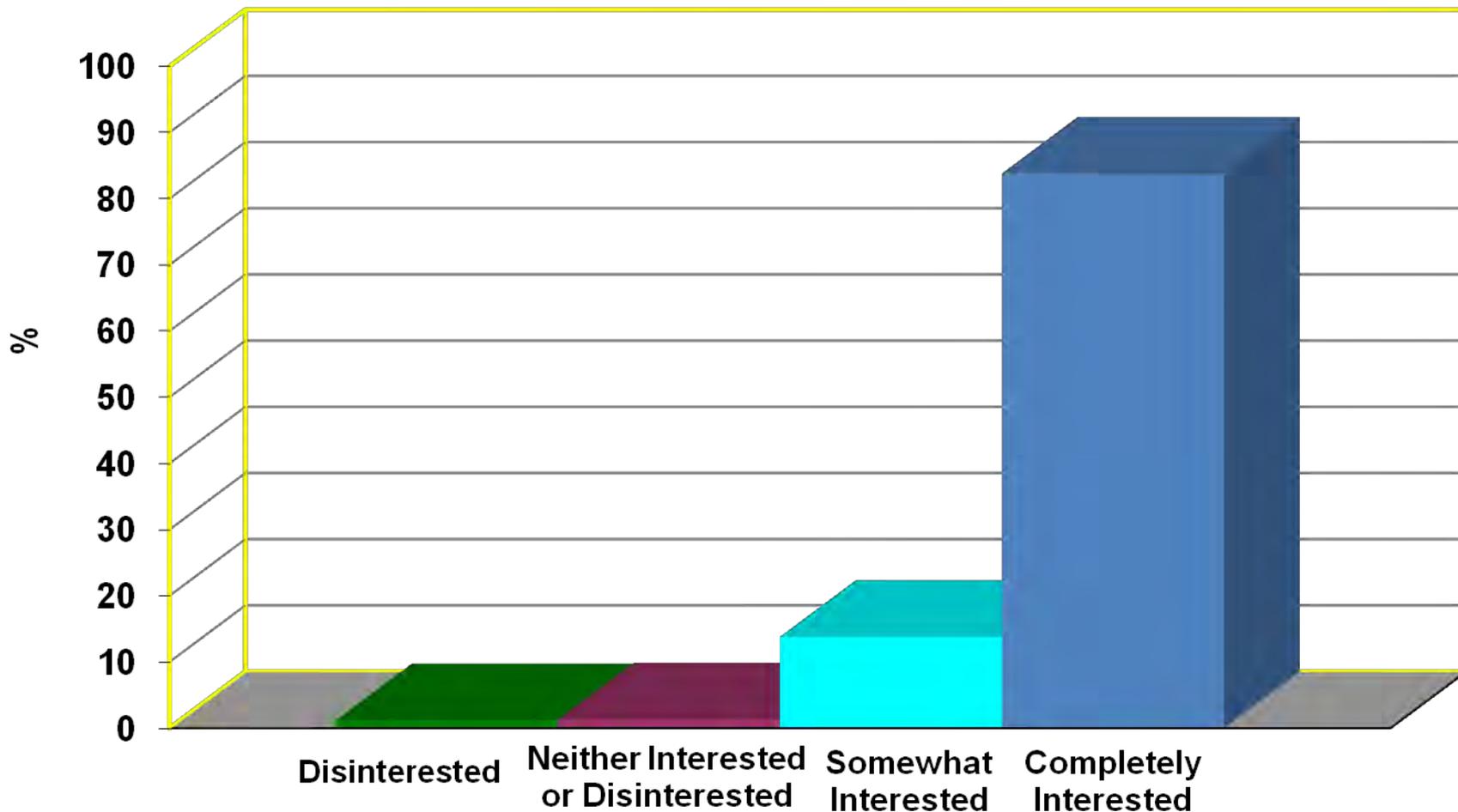
BASELINE PREFERENCES FOR OBTAINING SGA METABOLIC SCREENING (N=240)

...interest in **finding out the results** of screenings for the side effects of antipsychotic medications...



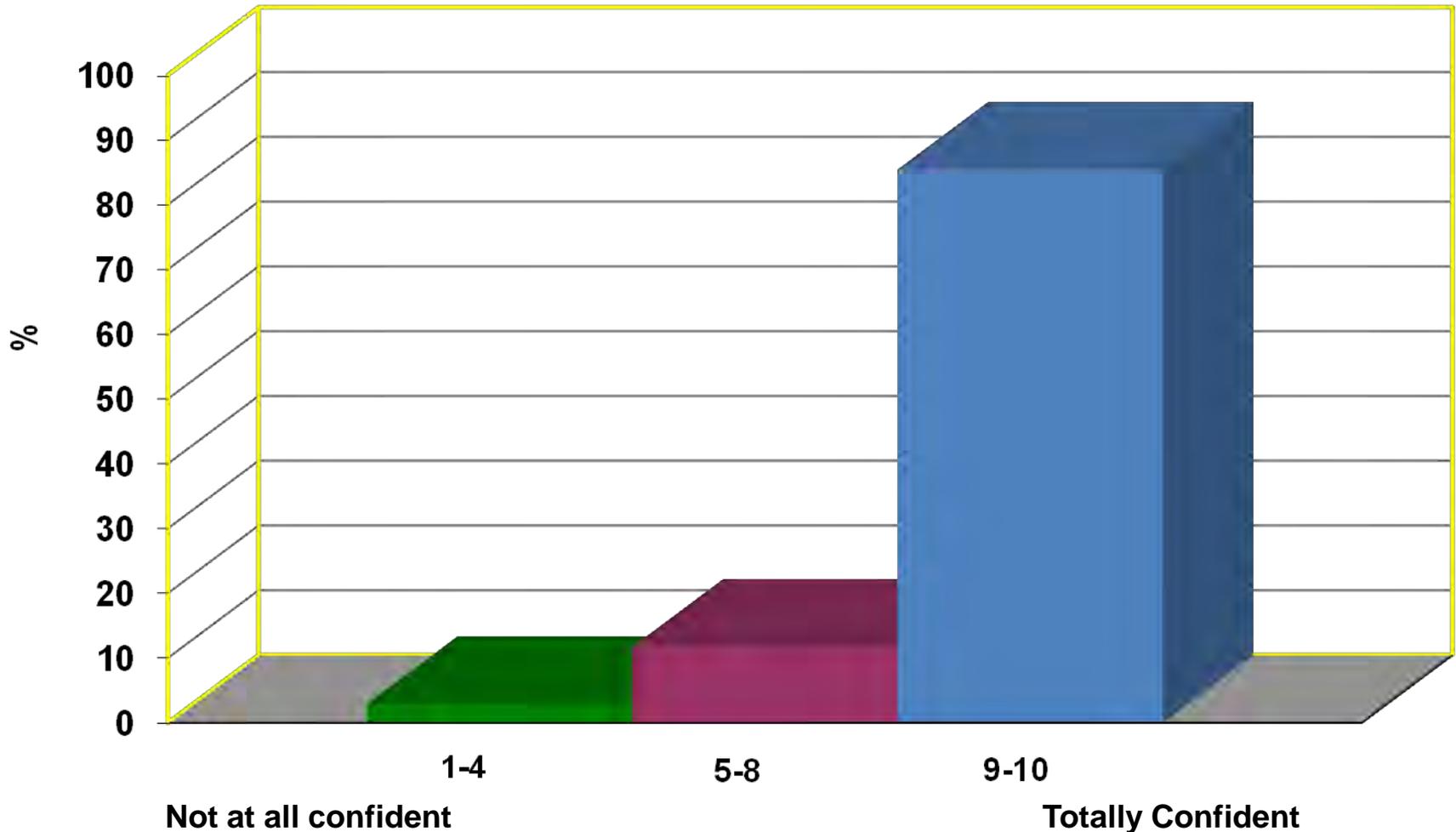
BASELINE PREFERENCES FOR OBTAINING SGA METABOLIC SCREENING (N=240)

...interest in talking with your prescriber about the results of screenings for the side effects of antipsychotic medications...



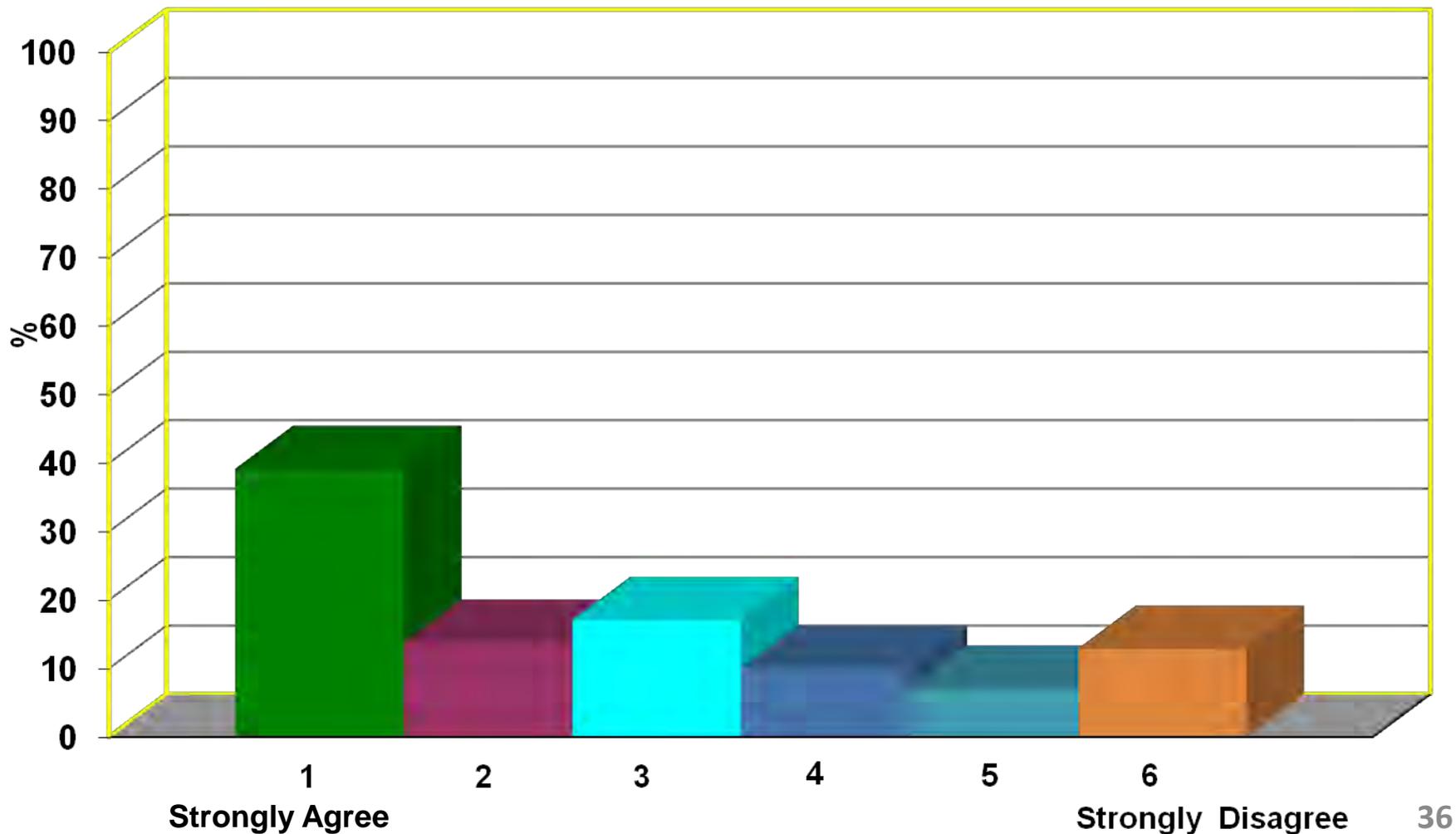
BASELINE SELF-EFFICACY IN COMMUNICATING WITH CLINICIANS ABOUT METABOLIC SIDE EFFECTS OF SGAS (N=240)

... 'how confident are you that you can ask your prescriber about getting screened?' ...



BASELINE PREFERENCES FOR PARTICIPATING IN DECISION-MAKING AROUND METABOLIC SCREENING (N=240)

... 'I prefer to leave decisions about getting screened for antipsychotic side effects up to my prescriber'...



PARTICIPANTS' NEUROCOGNITIVE FUNCTIONING (N=240)

Neurocognitive domain ¹	SGA study (n=240)	Comparison groups ²		
		Schizophrenia (n=56)	Bipolar disorder (n=60)	Healthy control (n=312)
Immediate Memory	84.4 ± 17.0	72.8 ± 14.5	82.6 ± 15.5	92.6 ± 13.2
Language	92.6 ± 8.2	77.6 ± 16.6	89.6 ± 15.5	97.1 ± 16.5
Attention	86.7 ± 17.1	76.6 ± 16.6	84.6 ± 17.1	98.3 ± 16.0

¹ As assessed by the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS).

² From Dickerson et al., *Journal of Nervous and Mental Disease* 2007; 195:566-571.

SPECIFIC AIMS

- To determine the effects of exposure to a patient-centered computerized tool, relative to enhanced treatment as usual (e-TAU), on
 - Rates of screening by providers for the metabolic side effects of SGAs.
 - Recognition by providers of metabolic abnormalities associated with SGAs.
 - Self-efficacy in communicating with prescriber and preferences for participating in decision-making around screening.
 - Patterns of patient-provider communication related to screening for metabolic side effects of SGAs.

THE ROTER INTERACTION ANALYSIS SYSTEM (RIAS)

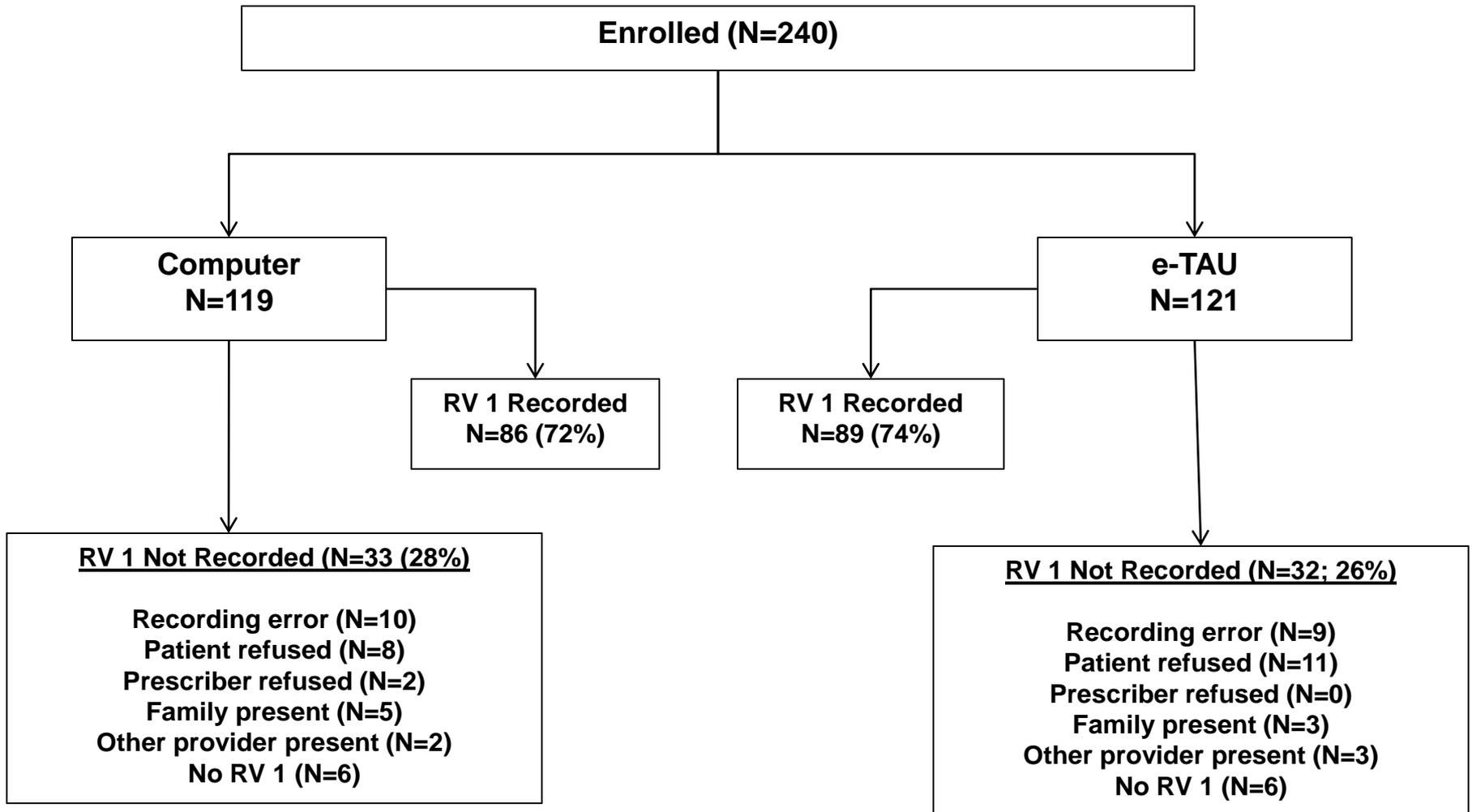
- Communication coding system developed by D. Roter, M.P.H., Dr.PH.
- Applied to audio- or video taped patient-clinician interactions in hundreds of studies worldwide.
 - Not widely used in psychiatric settings.
- Assigns each complete thought ('utterance') to one of 41 categories of communication representing, e.g.,
 - Communication processes e.g., giving information, asking questions by patient vs. clinician;
 - Affective or tonal quality of interaction;
 - 'Patient-centeredness', 'communication control'.

THE ROTER INTERACTION ANALYSIS SYSTEM (RIAS)

- Coding specific to this study
 - Any mention of metabolic parameters by patient or clinician;
 - Who first initiated discussion of metabolic parameters;
 - Who first initiated discussion of metabolic screenings (past, future);
 - Extent of talk about metabolic parameters/screening during visit;
 - Any mention of report, list, pamphlet, etc.

RESULTS

Audio Recording of Research Visit 1 (RV 1)



RESULTS (N=175)

Mentions of Metabolic Parameters/Report

Topic mentioned	Computer (N=86)	e-TAU (N=89)	P value
%, Weight	77%	67%	0.169
%, Blood pressure	50%	48%	0.824
%, Blood sugar	66%	74%	0.254
%, LDL cholesterol	34%	15%	0.003
%, HDL cholesterol	37%	14%	<0.001
%, Triglycerides	33%	17%	0.016
%, Report, list, pamphlet, etc.	49%	20%	< 0.001

RESULTS

First Mention of Metabolic Parameters/Screening by Prescriber

Topic mentioned	Computer (N=86)	e-TAU (N=89)	P value
Any parameter	17/25 (68%)	16/18 (89%)	0.862
Weight	40/66 (61%)	40/60 (67%)	1.00
Blood pressure	28/43 (65%)	26/43 (61%)	0.786
Blood sugar	44/57 (77%)	53/65 (82%)	0.361
LDL cholesterol	23/29 (79%)	11/13 (85%)	0.040
HDL cholesterol	20/31 (65%)	11/12 (92%)	0.106
Triglycerides	23/28 (82%)	13/15 (87%)	0.100
Past metabolic screenings	52/73 (71%)	51/63 (81%)	0.922
Future metabolic screenings	7/8 (88%)	4/9 (45%)	0.366

RESULTS

First Mention of Metabolic Parameters/Screening by Patient

Topic mentioned	Computer (N=86)	e-TAU (N=89)	P value
Any parameter	8/25 (32%)	2/18 (11%)	0.058
Weight	26/66 (39%)	20/60 (33%)	0.376
Blood pressure	15/43 (35%)	17/43 (40%)	0.724
Blood sugar	13/57 (23%)	12/65 (18%)	0.842
LDL cholesterol	6/29 (21%)	2/13 (15%)	0.157
HDL cholesterol	11/31 (35%)	1/12 (8%)	0.004
Triglycerides	5/28 (18%)	2/15 (13%)	0.257
Past metabolic screenings	21/73 (29%)	12/63 (19%)	0.117
Future metabolic screenings	1/8 (12%)	5/9 (55%)	0.103

CONCLUSIONS

- At baseline, veterans with SMI prescribed SGAs expressed high levels of
 - Interest in getting screened for the metabolic side effects of SGAs;
 - Confidence in asking their prescriber about getting screened;
 - Interest in obtaining the results of screenings and discussing them with their prescriber.
- Veterans who had viewed a computer program about the metabolic side effects of SGAs had conversations with their SGA prescribers
 - Consisting of more talk about LDL and HDL cholesterol and triglycerides;
 - Including more mentions of a report or pamphlet about metabolic screenings.

CONCLUSIONS

- Feedback from participants in computer condition has been positive, particularly around
 - Education about metabolic side effects.
 - Provision of personalized screening status/results.
- Potential next steps
 - Examine responses of prescribers (and patients) to findings of metabolic screenings.
 - Consider more widespread implementation of the computerized intervention in VA.

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