

Rates and Predictors of Metabolic Laboratory Test Monitoring in MOBILITY, a Large Pragmatic Trial of Youth Prescribed Second-Generation Antipsychotics

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INTRODUCTION

- Monitoring of metabolic laboratory tests in youth prescribed second-generation antipsychotics is recommended by both the American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry. However, 25% or fewer child and adolescent psychiatrists adhere to this recommendation.¹
- With this in mind, we examined site, demographic, and clinical predictors of metabolic laboratory monitoring in MOBILITY (Metformin for Overweight & Obese Children and Adolescents with Bipolar Spectrum Disorders Treated with Second-Generation Antipsychotics), a large, pragmatic trial of youth prescribed second-generation antipsychotics (SGA).

METHODS

- Study Design**
- Overweight or obese (≥85th percentile of body mass index (BMI) for age and sex) youth ages 8-19 years with a current or past diagnosis of a bipolar spectrum disorder who are continuing or starting treatment with an SGA and are receiving mental health care at one of 40 sites in the United States were enrolled in a large pragmatic trial (MOBILITY) and randomized to either a healthy lifestyle intervention and metformin vs. a lifestyle intervention alone.

- Predictors of metabolic laboratory test monitoring**
- Site factors included site type (academic vs. community mental health center) and presence (vs. absence) of onsite phlebotomy.
 - Patient factors included demographic and clinical characteristics as well as insurance status (private vs. public).

- Statistical Methods**
- We evaluated potential site- and patient-level predictors of monitoring baseline metabolic lab measures (obtained within 3 months prior to or following enrollment in MOBILITY).
 - Categorical and continuous variables were assessed using Fisher's exact tests and independent-samples t-tests, respectively.

RESULTS

- In our sample of 553 adolescents with at least one data point, the overall rate of any metabolic laboratory test (e.g., glucose, lipids, insulin, or hemoglobin A1c levels) was 73.2%, although rates for specific measures varied. Among patients for whom lab tests were available, 31.8% met criteria for metabolic syndrome (three of five possible criteria are required, and three of these are based on serum laboratory measures)².
- Rates of lab tests were higher among patients enrolled at academic institutions (76.4%), vs. community mental health centers (69.5%).
- Rates were higher among White patients (76.5%), vs. non-White patients (66.7%), and among those with a prior diagnosis of anxiety (80.0%) vs. no anxiety diagnosis (69.5%). Rates were lower among patients with ADHD (66.8%) vs. no ADHD (77.5%) and those identifying as Hispanic (60.3%) vs. non-Hispanic (75.0%).
- Sex, age, baseline BMI as well as Clinical Global Assessment Scale (CGAS), Young Mania Rating Scale, and modified 5-item Children's Depression Ratings Scale-Revised (CDRS-R) scores were similar in patients with and without lab tests.

CONCLUSIONS

- The overall rate of metabolic lab test monitoring in MOBILITY is higher than reported in standard clinical care³, perhaps due to an increased awareness of the metabolic side effects of SGAs from study participation.
- Patients with lab tests commonly meet criteria for components of metabolic syndrome.
- However, metabolic syndrome criteria may be overlooked in this population, if labs are not regularly obtained.
- Future studies examining caregiver and clinician characteristics associated with metabolic laboratory monitoring are needed.

Over 26% of patients in this pragmatic trial did not get the recommended metabolic lab monitoring.

Rates of monitoring were lower among ADHD, non-White, and Hispanic patients as well as those enrolled at community mental health centers.

Criteria for metabolic syndrome are under-recognized in this population.

Table 1. Rates of metabolic labs obtained (N=553)

Any Labs Present, n (%)	404 (73.2)
Glucose	401 (72.6)
Triglycerides	369 (66.9)
HDL Cholesterol	365 (66.1)
Insulin	296 (53.6)
Hemoglobin A1c	308 (55.8)

Table 2. Rates of meeting criteria for components of metabolic syndrome (among those with tests)

Glucose ≥ 100	14.4%
Triglycerides ≥ 110	40.0%
HDL Cholesterol <40	29.0%
Metabolic Syndrome	31.8%

Table 3. Associations of potential continuous risk factors to rates of metabolic labs

	Labs Obtained		Labs Not Obtained		p
	mean	sd	mean	sd	
BMI	29.2	5.9	28.8	5.9	0.534
Age	13.9	2.8	13.6	2.9	0.326
CGI Severity	3.8	0.9	3.8	0.9	0.681
CGAS	57.2	11.0	58.3	11.2	0.318
YMRS	7.7	6.8	7.6	7.2	0.882
Core CDRS	11.0	5.1	12.0	5.5	0.057



Table 4. Associations of potential categorical risk factors with rates of metabolic labs

		N	%	Metabolic Labs Obtained	Odds Ratio	95% CI	p
BMI %ile	85-95	184	33.3%	74.5%	0.92	(0.61 -- 1.38)	0.685
	>95	368	66.7%	72.8%			
Sex	Female	258	46.7%	75.2%	1.21	(0.83 -- 1.76)	0.184
	Male	295	53.3%	71.5%			
Insurance	Public	190	56.7%	70.6%	0.76	(0.5 -- 1.16)	0.242
	Private	145	43.3%	75.9%			
Lab Onsite	Yes	293	53.5%	70.6%	0.76	(0.52 -- 1.11)	0.176
	No	255	46.5%	76.1%			
Academic Site	Yes	297	53.7%	76.4%	1.42	(0.97 -- 2.07)	0.015
	No	256	46.3%	69.5%			
White/Caucasian	Yes	375	67.9%	76.5%	1.61	(1.09 -- 2.39)	0.012
	No	177	32.1%	66.7%			
Hispanic	Yes	63	11.4%	60.3%	0.62	(0.42 -- 0.92)	0.016
	No	488	88.6%	75.0%			
Bipolar	Yes	147	30.6%	72.1%	1.00	(0.65 -- 1.54)	1.000
	No	334	69.4%	72.2%			
Impulse Control	Yes	29	6.0%	65.5%	0.72	(0.33 -- 1.59)	0.400
	No	452	94.0%	72.6%			
Autism	Yes	52	10.8%	65.4%	0.70	(0.38 -- 1.29)	0.255
	No	429	89.2%	73.0%			
Depression	Yes	283	58.8%	71.0%	0.87	(0.58 -- 1.31)	0.537
	No	198	41.2%	73.7%			
ADHD	Yes	161	40.1%	66.8%	0.58	(0.39 -- 0.88)	0.011
	No	240	59.9%	77.5%			
Trauma	Yes	64	13.3%	75.0%	1.18	(0.65 -- 2.17)	0.655
	No	417	86.7%	71.7%			
Anxiety	Yes	120	24.9%	80.0%	1.75	(1.06 -- 2.89)	0.026
	No	361	75.1%	69.5%			
OCD	Yes	19	4.0%	89.5%	3.40	(0.77 -- 14.92)	0.116
	No	462	96.0%	71.4%			

DISCLOSURES: Dr. DelBello receives research support from NIH, PCORI, Acadia, Allergan, Janssen, Johnson and Johnson, Lundbeck, Otsuka, Pfizer, and Sunovion. She is also a consultant, on the advisory board, or has received honoraria for speaking for Alkermes, Allergan, Assurex, CMEology, Janssen, Johnson and Johnson, Lundbeck, Myriad, Neuronetics, Otsuka, Pfizer, Sunovion, and Supernus. Dr. Correll has been a consultant and/or advisor to or has received honoraria from: Alkermes, Allergan, Angelini, Boehringer-Ingelheim, Gedeon Richter, Gerson Lehrman Group, Indivior, IntraCellular Therapies, Janssen/J&J, LB Pharma, Lundbeck, MedAvante-ProPhase, Medscape, Merck, Neurocrine, Noven, Otsuka, Pfizer, Recordati, Rovi, Servier, Sumitomo Dainippon, Sunovion, Supernus, Takeda, and Teva. He has provided expert testimony for Bristol-Myers Squibb, Janssen, and Otsuka. He served on a Data Safety Monitoring Board for Boehringer-Ingelheim, Lundbeck, Rovi, Supernus, and Teva. He received royalties from UpToDate and grant support from Janssen and Takeda. He is also a shareholder of LB Pharma. Dr. Patel is an employee of Humana Healthcare Research, Inc. Dr. Welge and Mr. Blom receive research support from NIH and PCORI. Ms. Klein and Ms. Dyce receive research support from PCORI.



References:

- McLaren, JL, Brunette, MF, McHugo GJ, Drake RE, Daviss WB (2017). *Psychiatric Services* 68(9), 958-961.
- Grundy, SM, Cleeman, JI, Daniels, SR, et al; National Heart, Lung, and Blood Institute (2005). *Circulation* 2005;112(17):2735-2752.
- Kioko, E, Williams K, Newhouse, B (2016). *Archives of Psychiatric Nursing* 30(6), 671-677.

