MIAMI Project:
MIRECC Initiative on Antipsychotic Management Improvement

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MIAMI Journey

- 1998-2000
  - Increased recognition of the metabolic effects of second-generation antipsychotic medications
- 2003
  - VA/DOD Clinical Practice Guideline for the Management of Diabetes Mellitus in Primary Care
- 2004
  - Consensus guidelines for physical health monitoring of patients with schizophrenia (Am J Psych, 2004)
  - ADA consensus conference on antipsychotic drugs and obesity and diabetes (Diabetes Care, 2004)
  - Updated VA/DOD Clinical Practice Guidelines for Management of Psychosis

MIAMI Journey

- 2003-2008
  - Emerging evidence that despite the various guidelines, rates of metabolic monitoring were fairly low
- 2007 - VA OIG Report: Healthcare Inspection: Atypical Antipsychotic Medications and Diabetes Screening and Management. Recommendations included:
  - Implement and document weight reduction strategies
  - Improve treatment and documentation of interventions for elevated fasting blood glucose levels
  - Implement interventions to maintain blood pressures less than 140/90 for younger patients without diabetes who are prescribed atypical antipsychotic medications
  - Achieve target blood glucose levels for younger patients with diabetes who are prescribed atypical antipsychotic medication

MIAMI Journey

- 2008 - VA Office of Mental Health Services: Report of the Workgroup on Atypical Antipsychotic Medications and Diabetes Screening and Management.
  - Assure access by primary care and mental health clinicians to guidance documents
  - Ensure mental health clinics are able to follow recommendations for monitoring of metabolic risk factors
  - Improve coordination of care between primary care and mental health for patients treated with antipsychotic medication
  - Improve referral of patients with identified metabolic risk factors to *MOVE!* or other wellness programs

MIAMI Journey

- 2009 - MIAMI Project is funded: VA Office of Mental Health Services Initiative
- 2-year national program designed to implement recommendations from the Atypical Antipsychotics Workgroup
- Administered by the VISN 22 and 16 MIRECCs in conjunction with Mental Health QUERI
- Project Goals: improve monitoring for and management of physical health problems among veterans taking atypical antipsychotic medications
  - Improve adherence to guidelines around metabolic monitoring for antipsychotic medication
  - Decrease the number of veterans who are prescribed antipsychotic medications who are obese
  - Increase the use of weight interventions among veterans who are prescribed antipsychotic medications and are obese

MIAMI Activities

- Develop and disseminate effective tools for implementing antipsychotic monitoring programs
- Educate champions who will go back to their facilities/VISNs and educate others
- Assist with implementation of metabolic monitoring/management at VA clinics
- Utilize VHS DSS and VA Corporate Data Warehouse to evaluate change in monitoring in VA

MIAMI Resources: Practice Guidelines and Wellness Resources

- vaww.mirecc.va.gov/miamiproject/
  - Includes background information regarding MIAMI
- vaww.mirecc.va.gov/miamiproject/guidelines.asp
  - Clinical practice guidelines for obesity, diabetes, hypertension, dyslipidemia, and atypical antipsychotics
- vaww.mirecc.va.gov/miamiproject/resources.asp
  - EQUIP Wellness Manual
  - Food and Physical Activity Diary
  - BMI Chart

MIAMI Resources: Educational Tools

- vaww.mirecc.va.gov/miamiproject/education.asp
  - Metabolic Monitoring and Management for Patients Taking Antipsychotic Medications: Guidance for VHA Primary Care Providers
  - A poster including essential information regarding metabolic monitoring and management
  - Educational slides to help promote awareness of the problem and educate other clinicians
  - Downloadable powerpoint presentations from 2010 MIAMI Conference

MIAMI Resources: Technical Assistance Center (TAC)

- vaww.mirecc.va.gov/miamiproject/technical_assistance_center.asp
- Goal of center is to support sites implementing routine monitoring
- Located in Little Rock at CeMHOR
  - Monday thru Friday
  - 8:00-4:30
  - Phone: 1-888-357-1978
  - Email: vhalitmiamiproject@va.gov

TAC Services

- Clinical consultations
  - Metabolic Effects of Antipsychotic Medications
  - Current Monitoring and Management Guidelines
- Advice about implementation strategies
  - General – how to get started, who to involve
  - Specific – how to manage a particular challenge at a specific site
- Advice re: wellness resources for individuals with SMI
  - Accessing programs
  - How they fit with monitoring/management programs
  - How to engage veterans in these programs

TAC Services

- Central repository for implementation tools
  - Sites can send tools to TAC to share with other sites
  - Distribution of “hardcopy” tools
- “Connector” between sites and between sites and experts

Improving the Health of Veterans Prescribed Antipsychotic Medications: Recommendations for Monitoring and Management

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VA VISN-22 MIRECC

UCLA Department of Psychiatry

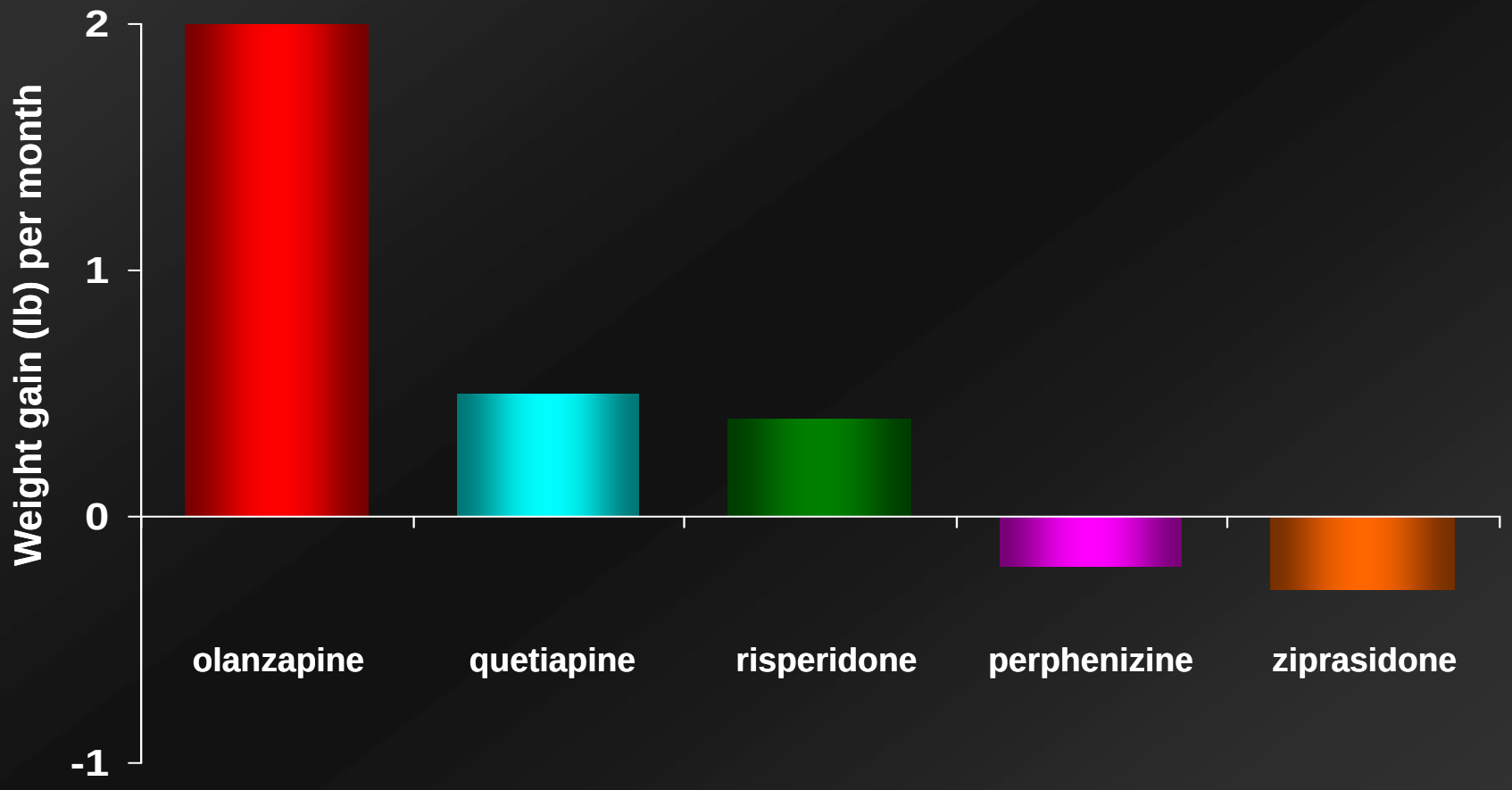
June, 2010

MIAMI project

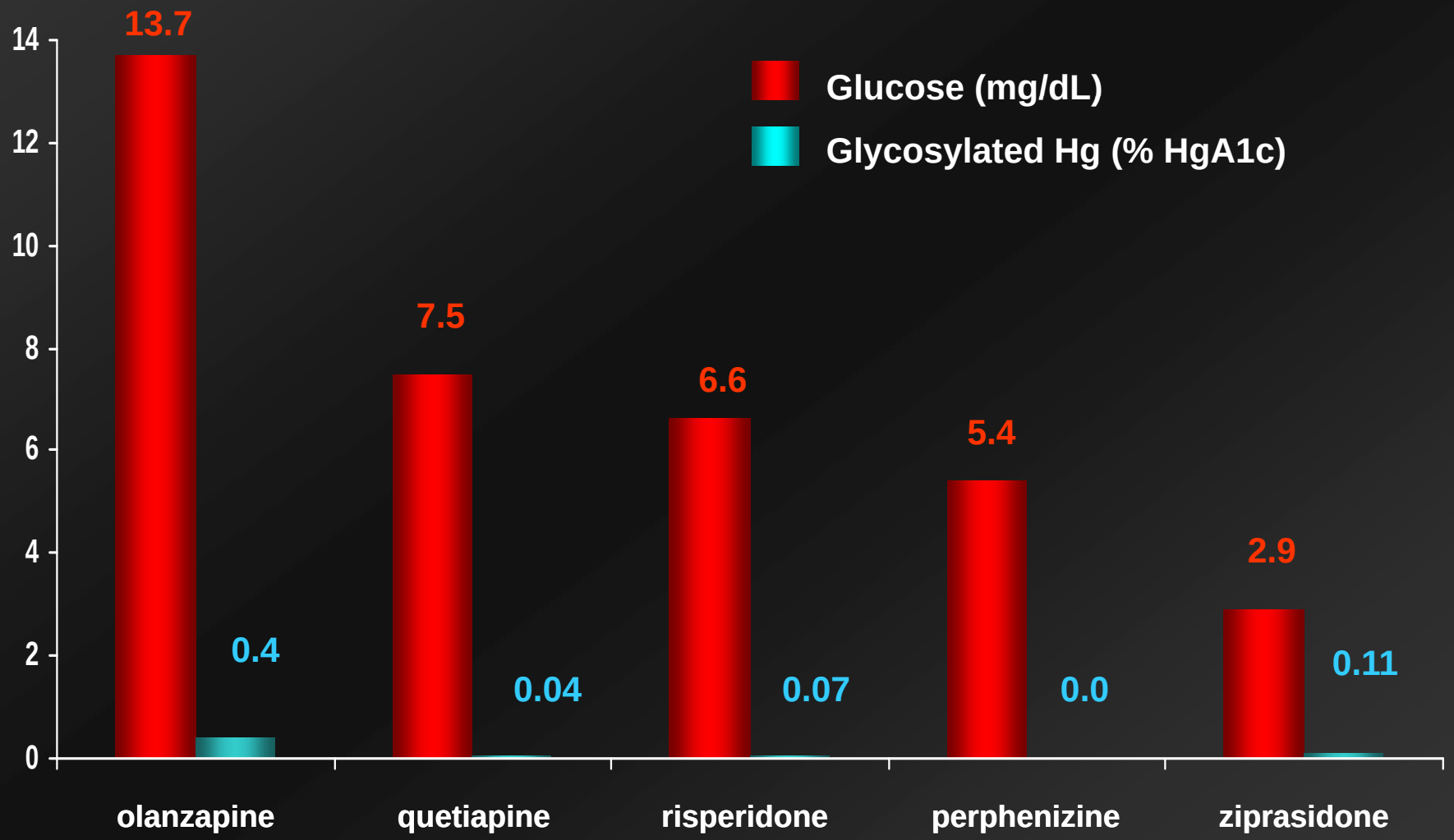
Overview

- **Metabolic risk**
- **Monitoring & Management**
  - **how we're doing**
  - **guidelines**
  - **practical strategies**

CATIE Results:
Weight Gain Per Month of Treatment



CATIE Results: Metabolic Changes From Baseline

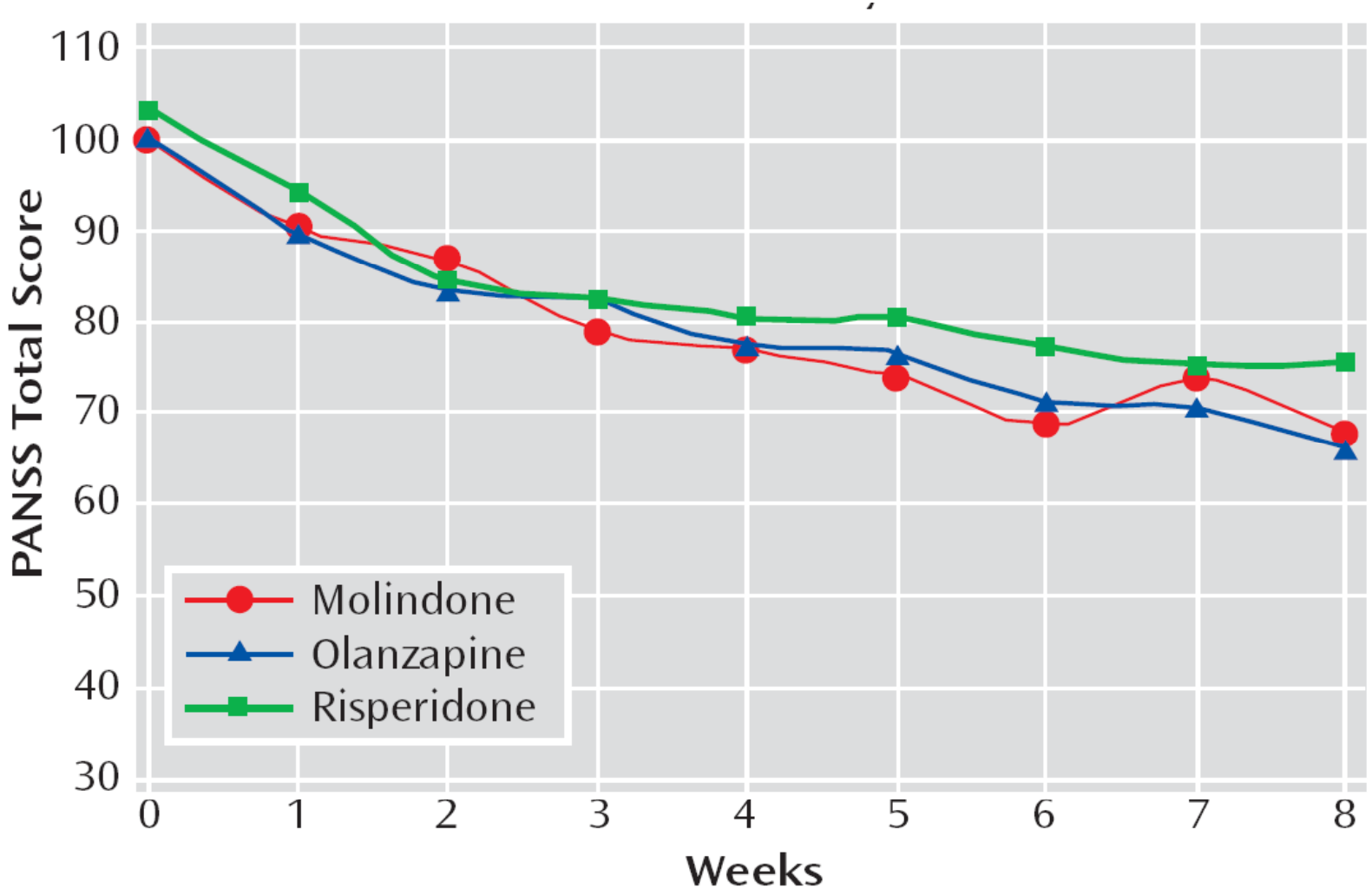


Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS)

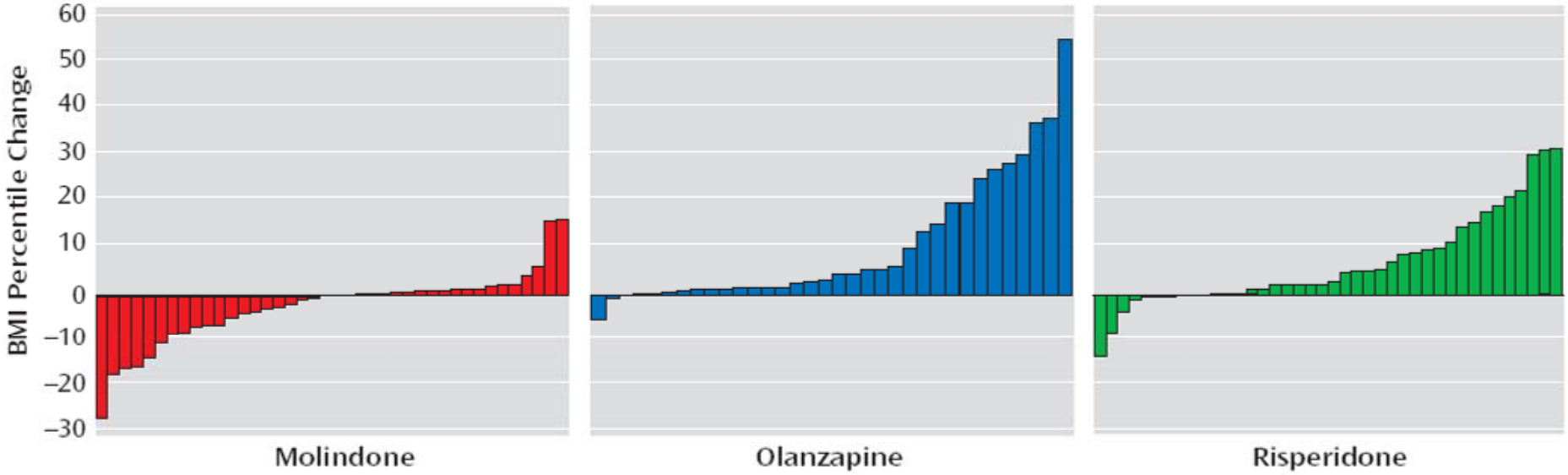
- **8-19 year old patients this schizophrenia**
- **randomly assigned to molindone 10-140 mg, olanzapine 2.5-20 mg, or risperidone 0.5-6 mg**
- **8 weeks**
- **Primary outcome was responder status**
  - **much or very much improved on CGI; ≥20% reduction in total PANSS; and tolerating treatment**

Sikich et al, Am J Psychiatry 2008

TEOSS: PANSS Score Change



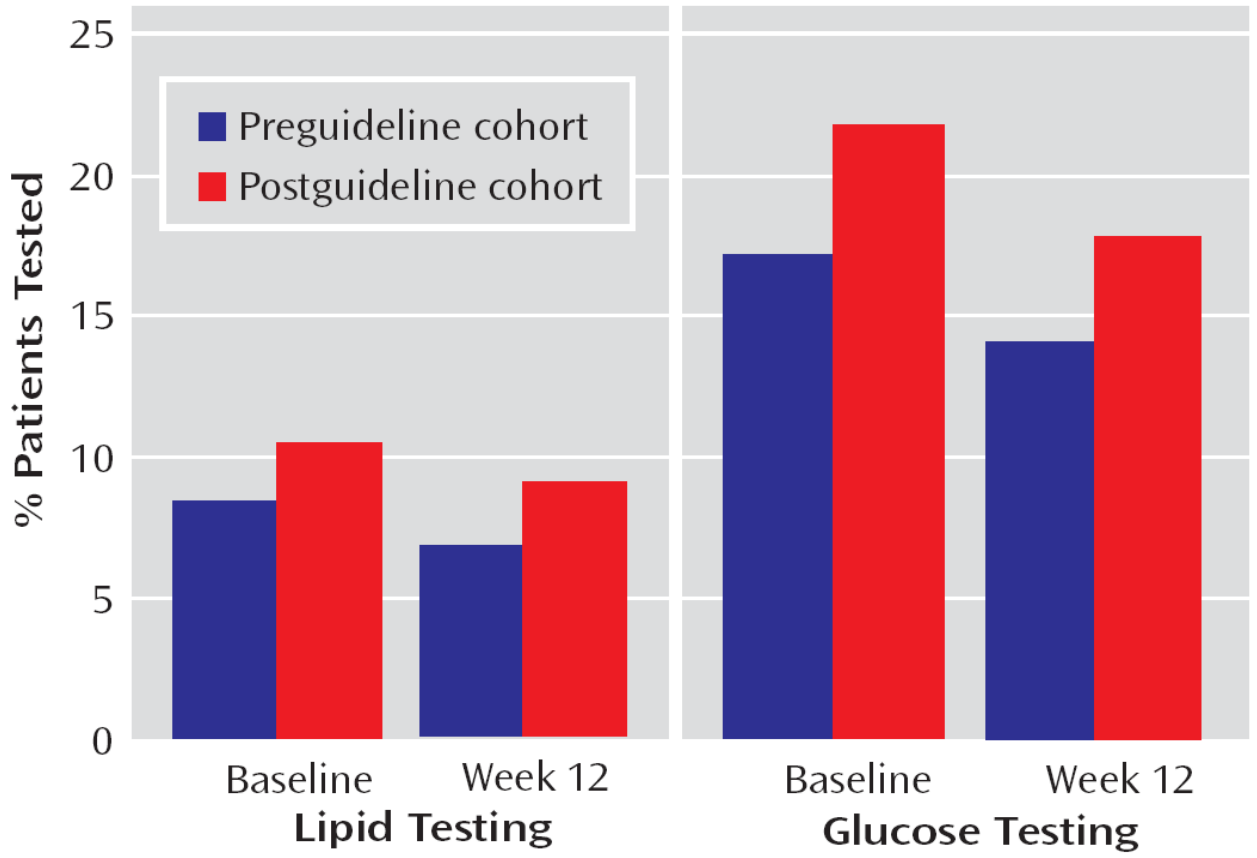
TEOSS: BMI Percentile Change for Each Patient



Monitoring in the U.S.

- Highly variable
- In most public mental health settings, medical care and mental health are separate
- In settings like VA, patients have full access to primary care, but monitoring is still a problem
- Monitoring during 1st month
  - Medicaid 2005 (Morrato et al, Arch Gen Psychiatry 2010)
  - glucose: antipsychotic = 28% vs. albuterol = 31%
  - lipid panel: antipsychotic = 12% vs. albuterol = 11%

Glucose & Lipid Testing at Baseline and 12 weeks (2004)



[a] All four group comparisons significant at $p<0.001$.

Haupt et al, Am J Psychiatry 2009


CHEMIN DE FER
DE L'OUEST

Physical Health Monitoring

- **Where should it occur?**
- **Who should monitor?**
- **What should be monitored and how often?**

Where Should It Occur?

- Patients may see a mental health clinician more often than a primary care clinician
- Primary care clinicians may not be aware of the risks associated with psychiatric illness
- Patients may have limited access to primary care clinicians
- Psychiatric settings may lack tools for monitoring – including scales and pressure cuffs

Who Should Monitor?

- **Psychiatrists may be reluctant to monitor medical problems when they are uncomfortable intervening**
- **Psychiatrists and other medical specialists tend to do poorly in routine monitoring**
- **Many public and private settings have no infrastructure for monitoring**

ADA Consensus on Antipsychotic Drugs and Obesity and Diabetes: Monitoring Protocol *

	Start	4 wks	8 wks	12 wks	6 mos	12 mos
Weight (BMI)	X	X	X	X	X	X
Waist circumference	X					X
Blood pressure	X			X		X
Fasting glucose	X			X		X
Fasting lipid profile	X			X		X

* More frequent assessments can be warranted based on clinical status

Diabetes Care. 27:596-601, 2004

Mount Sinai Consensus Conference on Antipsychotic Prescribing (October, 2002)

- **Organizers**
  - Susan Essock
  - Alexander Miller
  - Steve Marder
- **Antipsychotic Experts**
  - Jeffrey Lieberman
  - John Davis
  - Bob Buchanan
  - Nina Schooler
  - John Kane
  - Dan Casey
  - Nancy Covell
  - Donna Wirshing
  - Scott Stroup
  - Catherine Craig
  - Ellen Weissman
  - Steven Shon
- **Medical Experts**
  - Len Pogach
  - Bonnie Davis
  - Xavier Pi-Suney
  - J. Thomas Bigger
  - Steve Yevich
  - David Kleinberg
  - Alan Friedman

Weight Monitoring

- Clinics that manage patients with schizophrenia should be able to weigh patients at every visit
- Mental health clinicians should monitor BMI of every patient
  - weigh patients at every visit
  - calculate BMI
- BMI monitoring may be supplemented by knowledge of the patient's waist circumference
  - intervene if waist circumference is greater than 35" for a woman or 40" for a man
- Clinicians should encourage patients to monitor their own weight

Weight Monitoring

- Patients should be weighed at every visit for the first six months following a medication change
- The relative risk of weight gain among antipsychotics should be a consideration in drug selection for patients who have BMI greater than 25
- Unless a patient is underweight (BMI<18.5), a weight gain of 1 BMI unit indicates a need for an intervention
- Interventions include closer monitoring of weight, engagement in a weight management program, or changes in antipsychotic medication
- The clinician should consider switching to medication with less weight gain liability

Diabetes Monitoring

- **Mental health practitioners should be aware of risk factors for diabetes for all patients with schizophrenia.**
- **A baseline measure of glucose should be collected for all patients before starting a new antipsychotic. A fasting glucose is preferred, but HbA1C is sufficient if fasting glucose is not feasible.**

Diabetes Monitoring (cont)

- **Psychiatrists should inform patients of the symptoms of diabetes and ask them to contact a medical clinician if they occur.**
- **Mental health clinicians should assure that patients with diagnosed diabetes are followed by a medical clinician who is knowledgeable about diabetes.**
- **The psychiatrist and medical clinician should communicate when medication changes are instituted that may affect the control of the patient's diabetes.**

Lipid Monitoring

- Mental health clinicians should be aware of lipid profiles for all patients with schizophrenia
- Psychiatrists should follow National Cholesterol Education Program (NCEP) guidelines to identify patients at high risk for cardiovascular disease
  - www.nhlbi.nih.gov/about/ncep
- If a lipid panel is not available, one should be obtained and reviewed

Lipid Monitoring (cont)

- **Mental health clinicians should assure that NCEP guidelines are followed for patients with abnormal cholesterol (total, LDL, HDL) and triglyceride levels.**
- **When patients with abnormal levels are identified they should be referred to a medical clinician or, in the absence of such a clinician, treatment may be implemented by the psychiatrist.**

Guidelines for Monitoring

Monitoring	APA	ADA / APA	Mt. Sinai
Body weight and height	BMI every visit for 6 months; quarterly thereafter	BMI at baseline; every 4 weeks for the 12 weeks; quarterly thereafter	BMI at baseline; at every visit for next 6 mos; quarterly when stable
Fasting glucose or HgA1c	Fasting plasma glucose at baseline. Fasting plasma glucose or HbA1c at 4 months after initiating new treatment and annually thereafter	Fasting plasma glucose at baseline, 12 weeks and annually thereafter	Fasting plasma glucose or HbA1c before initiating an antipsychotic, annually thereafter
Lipid panel	At least every 5 years	Baseline; at 12 weeks; every 5 years	Every 2 years or more often if levels are in the normal range and every 6 months if LDL levels are >130mg/dL

Diabetes Care, Vol 27, No 1, February 2004. *Am J Psychiatry.* 161:2, February 2004 Supplement.
Am J Psychiatry. 2004; 161:1334-1349.

Goal: Lower Risk for Cardiovascular Disease

- **Blood cholesterol**
  - **10% ↓ = 30% ↓ in CHD (200-180)**
- **High blood pressure (> 140 SBP or 90 DBP)**
  - **4-6 mm Hg ↓ = 16% ↓ in CHD & 42% ↓ in stroke**
- **Cigarette smoking cessation**
  - **50%-70% ↓ in CHD**
- **Maintenance of ideal body weight (BMI = 25)**
  - **35%-55% ↓ in CHD**
- **Maintenance of active lifestyle (20-min walk daily)**
  - **35%-55% ↓ in CHD**

Hennekens CH. *Circulation.* 1998;97:1095-1102.

Management: Lipids

Risk Category *	LDL Goal (mg/dL)	Initiate Lifestyle Changes (mg/dL)	Consider Drug Therapy
High risk: CAD or CAD equivalents **	< 100	≥100	≥130
Moderately high risk: 2+ risk factors	< 130	≥130	≥130
Moderate risk: 2+ risk factors	< 130	≥130	≥160
Low risk: 0-1 risk factor	< 160	≥160	≥190

*Risk factors: tobacco, HTN, family history, age (> 45 ♂, > 55 ♀), HDL (< 40 ♂, < 50 ♀)
**CAD equivalents: diabetes, abdominal aortic aneurysm, peripheral or coronary artery disease, carotid stenosis

Management: Blood Pressure

- **BP 120-139 / 80-89**
  - counsel on diet and exercise
  - re-evaluate medications
  - recheck at next visit
- **BP > 130/80**
  - refer to primary care if patient has any of these:
    - diabetes
    - chronic kidney disease
    - cerebrovascular disease
    - coronary artery disease
- **BP > 140 / 90**
  - refer to primary care

Management: Fasting Glucose

- **110-126 mg/dl or > 126 with HgbA1c < 7%**
  - **counsel on diet/exercise**
  - **re-evaluate medications**
  - **recheck blood sugar at a reasonable interval**
- **126-199 with HgbA1c > 7%**
  - **refer to primary care**
- **> 200 or symptoms of diabetes**
  - **urgent visit at primary care**

Management: Weight

- Risk of weight gain should be considered in medication choice for patients with BMI > 25
- Intervene when
  - weight gain of 1 BMI unit, or
  - BMI > 30
- (1) Provide a weight management program
  - group and individual education
- (2) Change patient's antipsychotic medication
  - consider switching to medication with less weight gain liability

Body Mass Index

BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	BMI
HEIGHT (Inches) / WEIGHT (Pounds)																							
58"	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	
59"	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	
60"	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	
61"	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	
62"	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	
63"	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	
64"	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	
65"	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	
66"	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	
67"	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	
68"	125	131	138	144	151	158	164	171	177	184	190	197	204	210	216	223	230	236	243	249	256	262	
69"	128	135	142	149	155	162	169	176	182	189	196	203	210	216	223	230	236	243	250	257	263	270	
70"	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	
71"	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	
72"	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	
73"	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	
74"	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	
75"	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	
76"	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	
	HEALTHY WEIGHT						OVERWEIGHT					OBESE											

Source: National Institutes of Health; http://win.niddk.nih.gov/statistics/index.htm#table

Weight Management Programs Are Effective

- **Group and individual psychoeducation improves weight in people with serious mental illness**
  - **numerous controlled research trials**
- **Weight loss is modest: average 5 lbs**
- **Modest weight loss has been associated with health benefits**

EQUIP Weight Management Program

- Patients referred by clinician
- Sixteen, 45-minute sessions
- Minimum once-weekly sessions
- 8 - 10 participants per group
- Patients can join program at any point during the 16 session cycle
  - should complete all 16 sessions
  - should repeat program as needed
- To be discussed by Amy Cohen

Changing Medication Can Cause Weight Loss

- **CATIE study**
  - **1493 patients, 57 sites**
  - **18 months**
- **Among patients who gained more than 7% in Phase 1, the following lost more than 7%**
  - **olanzapine: 0%**
  - **quetiapine: 7%**
  - **risperidone: 20%**
  - **ziprasidone: 42%**

Changing from Olanzapine to Aripiprazole Causes Weight Loss

- Newcomer et al 2008
- Overweight patients on olanzapine
- Switch to aripiprazole vs. remain on olanzapine
  - randomized controlled trial, n=173, 16 weeks
- Results
  - weight change (pounds): -4.0 vs. +3.1
  - lost more than 7%: 11% vs. 3%
  - lipids improved, glucose unchanged
  - CGI-Improvement: no change - minimal improvement

Metformin and Lifestyle Intervention for Antipsychotic Weight Gain

- **128 patients with schizophrenia who gained 10% of weight on antipsychotics**
- **Randomized to placebo, life style intervention, metformin (750 mg / day), or metformin plus life style intervention**
- **12 week weight change:**
  - **placebo: +4.8%**
  - **lifestyle alone: -2.2%**
  - **metformin alone: -4.9%**
  - **metformin plus lifestyle: -7.3%**

Wu et al, JAMA 2008

Other Approaches

- **Reserve antipsychotics with metabolic side effects for illnesses where there is an adequate evidence base**
  - **recent VA study that 60% of antipsychotic prescriptions were for off label uses**
  - **quetiapine**
- **Be cautious using other medications with weight gain liability and limited effectiveness**
  - **valproate**

Education

- Clinicians and managers
- Patient, family, caregivers
  - knowledgeable about medications and the risk for weight gain, diabetes, and cardiovascular disease
- Patients
  - chart their own weight
  - weight and blood pressure can be monitored at home
  - pursue recommended diet and exercise

Summary

- **Individuals taking antipsychotic medication are at a high risk for weight gain, metabolic syndrome, and cardiovascular disease**
- **Monitoring**
  - **weight: at every visit & at home**
  - **metabolic syndrome: blood pressure, glucose, lipids**
- **Interventions**
  - **medication change**
  - **weight management groups**
  - **referral to primary care**