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
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
Overview

• Metabolic risk
• Monitoring & Management
  – how we’re doing
  – guidelines
  – practical strategies
CATIE Results: Weight Gain Per Month of Treatment

- Olanzapine
- Quetiapine
- Risperidone
- Perphenazine
- Ziprasidone
CATIE Results: Metabolic Changes From Baseline

- **Glucose (mg/dL):**
  - Olanzapine: 13.7
  - Quetiapine: 7.5
  - Risperidone: 6.6
  - Perphenazine: 5.4
  - Ziprasidone: 2.9

- **Glycosylated Hg (% HgA1c):**
  - Olanzapine: 0.4
  - Quetiapine: 0.04
  - Risperidone: 0.07
  - Perphenazine: 0.0
  - Ziprasidone: 0.11
Treatment of Early-Onset Schizophrenia Spectrum Disorders (TEOSS)

- 8-19 year old patients diagnosed with 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; \( \geq 20\% \) reduction in total PANSS; and tolerating treatment

Sikich et al, Am J Psychiatry 2008
TEOSS: PANSS Score Change

![Graph showing PANSS Score Change over weeks for Molindone, Olanzapine, and Risperidone]
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%

![Bar chart showing the percentage of patients tested for lipid and glucose testing at baseline and week 12 for pre-guideline and post-guideline cohorts. The chart indicates a significant difference in the testing rates between the two cohorts, with post-guideline cohorts showing higher testing rates.]

^ All four group comparisons significant at p<0.001.

Haupt et al, Am J Psychiatry 2009
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 *

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<th></th>
<th>Start</th>
<th>4 wks</th>
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<th>12 wks</th>
<th>6 mos</th>
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<td>Fasting lipid profile</td>
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* 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](http://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

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

## Management: Lipids

<table>
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<tr>
<th>Risk Category *</th>
<th>LDL Goal (mg/dL)</th>
<th>Initiate Lifestyle Changes (mg/dL)</th>
<th>Consider Drug Therapy</th>
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<td><strong>High risk:</strong></td>
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<td>CAD or CAD equivalents **</td>
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<td>0-1 risk factor</td>
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*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

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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