Psychotropics and Foster Care: Challenge or Opportunity?

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Objectives

At the conclusion of this presentation, the participant will be able to:

- **Cite specific challenges in the use of psychiatric medications in foster children.**
- **Compare challenges posed to pre-authorization and monitoring programs by pediatric patients with those posed by adolescent patients.**
- **Discuss newer data on diabetes and metabolic issues related to antipsychotic use.**
- **Formulate an ongoing monitoring plan for antipsychotic treatment.**

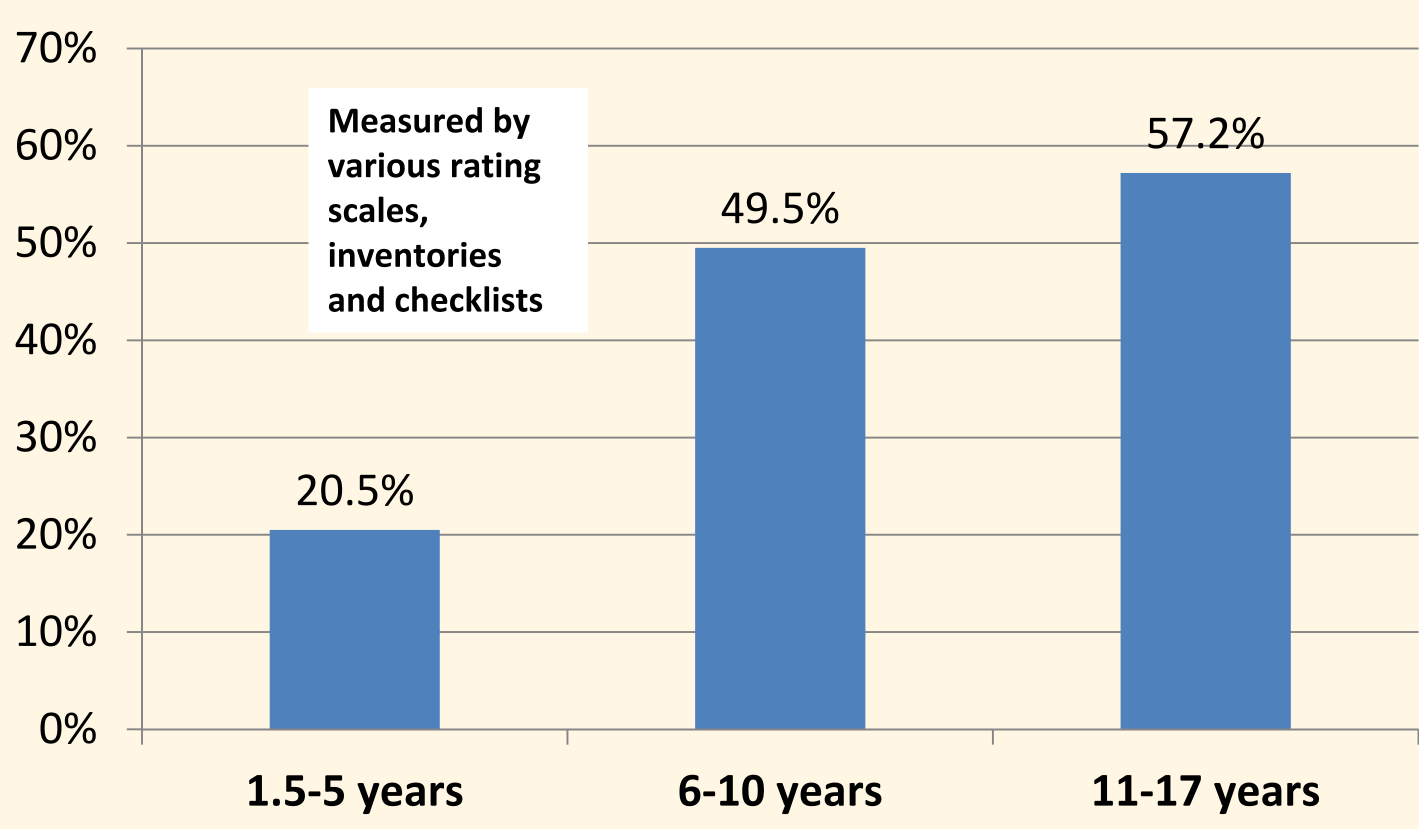
Ongoing Concerns Regarding Antipsychotic Use

- **More Toddlers, Young Children Given Antipsychotics, January 2010** HealthDay
- **Antipsychotics Tied to Kids' Weight Gain, October 2009** WebMD Better information. Better health.™
- **Study Finds Drug Risks With Newer Antipsychotics, January 2009** The New York Times
- **More Children on Antipsychotics, March 2006** AP Associated Press

Foster Children

- **Higher rates of psychiatric /behavioral disorders**
  - **> 50% of youth entering foster care**
  - **Up to 5x more likely**
  - **3x the rate of general population for ADHD, Conduct Disorder, PTSD**
  - **More developmental issues**
  - **More depression**
- **Prenatal**
  - **drug/alcohol exposure, poor prenatal care, poor nutrition**
- **Psychosocial**
  - **Poverty, abuse/neglect, impaired attachment, disruptions in home**

Risk of Social-Emotional Problems in Recipients of Child Welfare



ACF, ACYF-CB-IM-12-03, 04/11/2012 and NSCAW II

Foster Children

- Use more psychiatric / mental health services
  - ¼ more than Medicaid controls
  - Five times hospitalization rate
  - Make up 3% of Medicaid population, but receive 32% of behavioral health services

Foster Children

- Use more psychotropics
  - 2008 study of Medicaid recipients - psychotropic use 2.7x to 4.5x higher rate of use in foster vs. non-foster youth
  - 2011 GAO report - 21-39% of foster youth receive psychotropics vs. 5-10% of non-foster youth
  - 2011 studies in Medicaid recipients - foster youth receive psychotropics at rates 3x to 11x higher than non-foster youth
  - 41% of foster youth received 3 or more psychotropics within a single month
  - Males are 2-3x more likely to receive psychotropics
  - Those in more restrictive settings more likely to receive psychotropics

Federal Mandate

- **2008 Fostering Connections to Success and Increasing Adoptions Act**
  - **States must "develop a health oversight plan to identify and respond to the . . . mental health needs of children in foster care."**
  - **The plan must include "oversight of prescription medications."**
- **2011 Child and Family Services Improvement and Innovation Act**
  - **States must develop "protocols for the appropriate use and monitoring of psychotropic medications."**

Federal Mandate

- **2011 Child and Family Services Improvement and Innovation Act**
- **Subsequent recommendations for content of plans**
  - **Screening, assessment and treatment planning for children placed out of home**
  - **Mechanisms for informed consent for medication**
  - **Systems for monitoring medication (system & child levels)**
  - **Access to psychiatric consultation (system & child levels)**
  - **Access to and dissemination of information on evidence-based approaches (pharmacological and non-pharmacological)**

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

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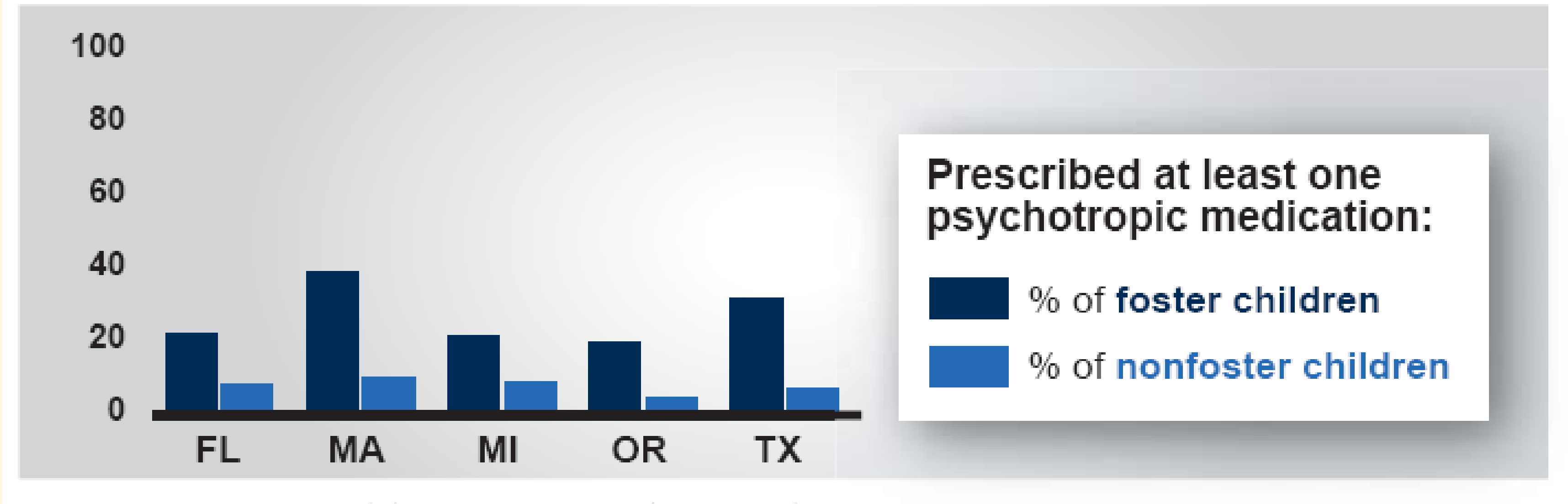
FOSTER CHILDREN

HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions

Psychotropic Prescription Rates for Foster and Nonfoster Children Age 0-17 in Medicaid Fee-for-Service in Five States



Source: GAO analysis of state Medicaid and foster care data.

Particular Concerns

- Use in very young children
- Off-label use
- Polypharmacy
- Excessive doses
- Inadequate monitoring
- Lack of non-pharmacologic treatment

Challenges

- Trauma
  - PTSD rate of ~14%
  - Direct relationship between trauma and increase in number of mental health symptoms
  - Non-pharmacologic trauma focused treatment may be difficult to access
- Who treats?
  - Providers change frequently
  - Primary care vs. specialists or both
  - Patients change residences /placements – lost to follow-up
  - Continuity of care suffers

Challenges

- Consent
- Assent
  - Usually around age 14
- Access to non-pharmacologic treatment
  - Geography
  - Trauma focused care
  - Behavior management
  - Autism services

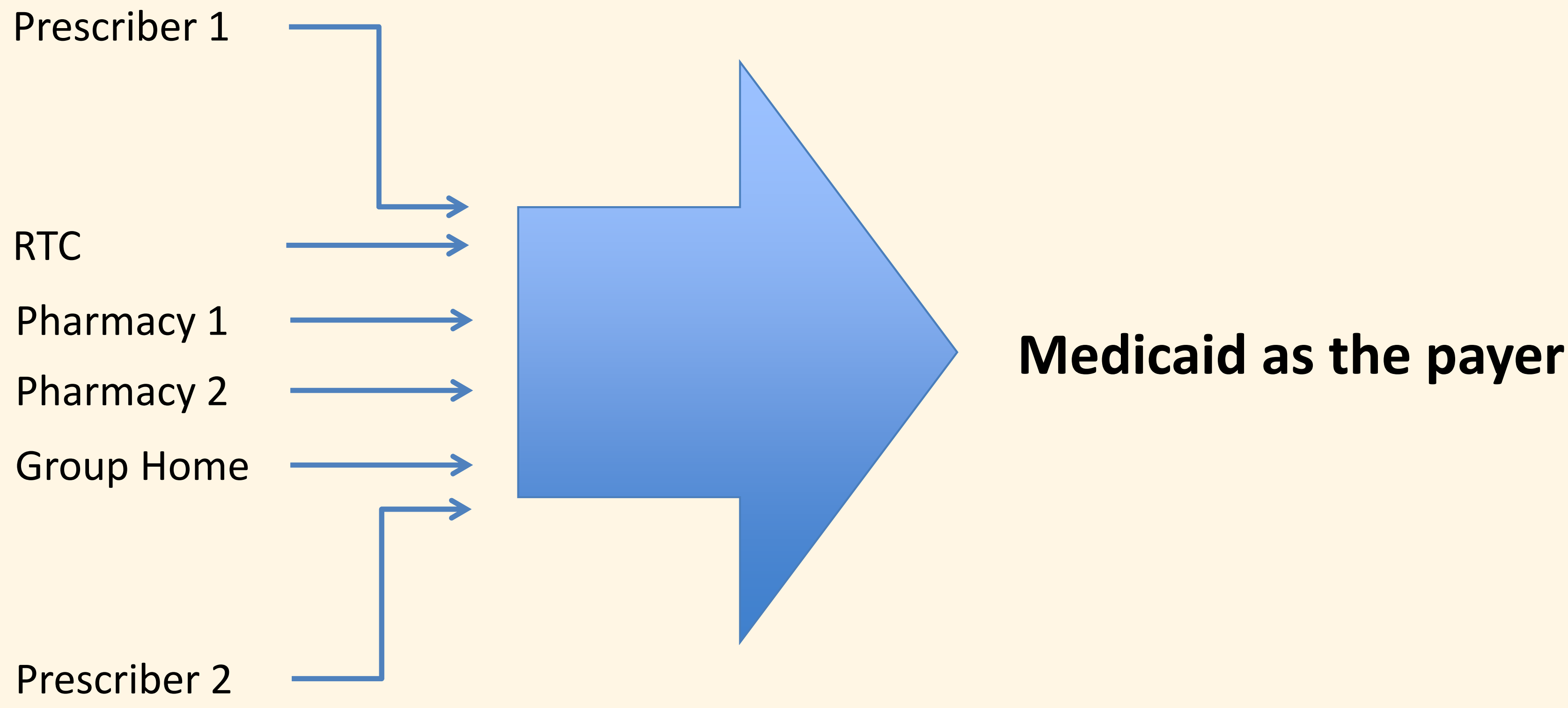
Challenges

- **Who's responsible?**
  - **Child welfare, juvenile justice, education system, mental health system**
  - **Where is the medical record located?**
  - **Who really knows the medication history?**
- **Who consents?**
  - **Child welfare, judges, medical consultants . . . Pharmacists?**
  - **Who even knows the patient is in foster care and that a consent is necessary?**

Consent

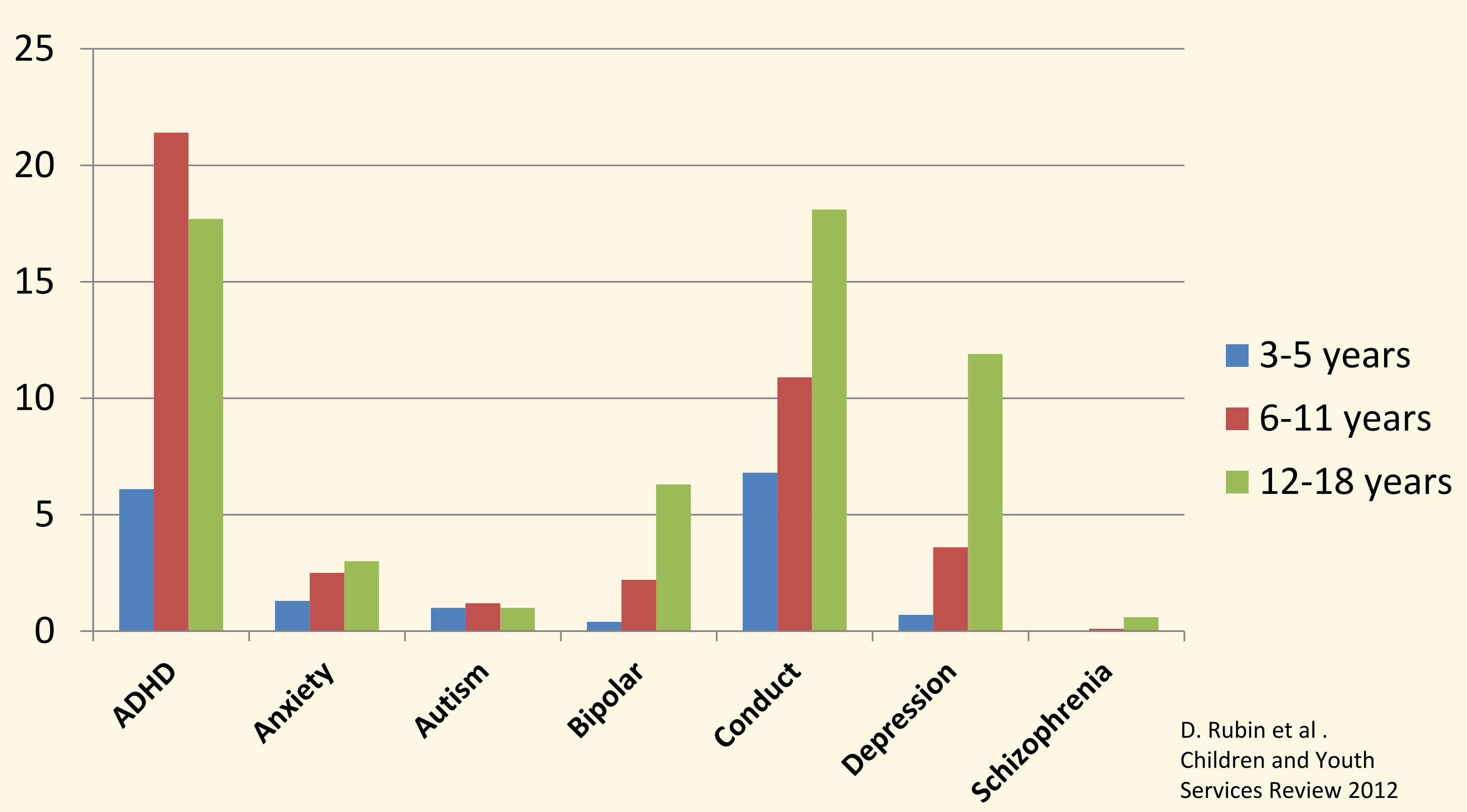
- Bring agencies together
  - Child welfare
  - Juvenile/legal justice
  - Education system
  - Mental health system
  - Medicaid
- Where is the repository of the information?
- Where is there a final common pathway?

Final Common Pathway



Diagnoses Change as Children Age

Medicaid Enrolled Foster Children 2007

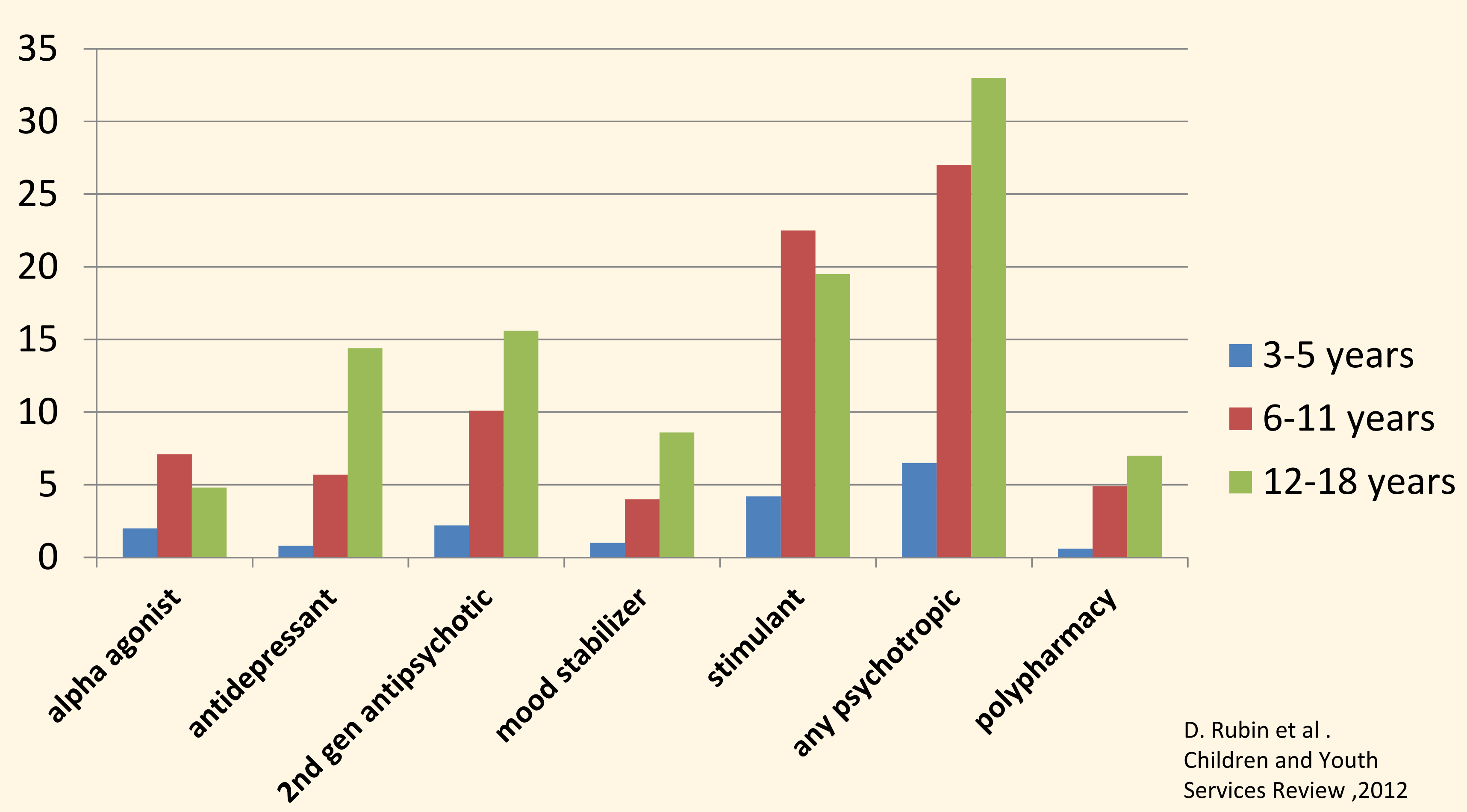


D. Rubin et al .
Children and Youth
Services Review 2012

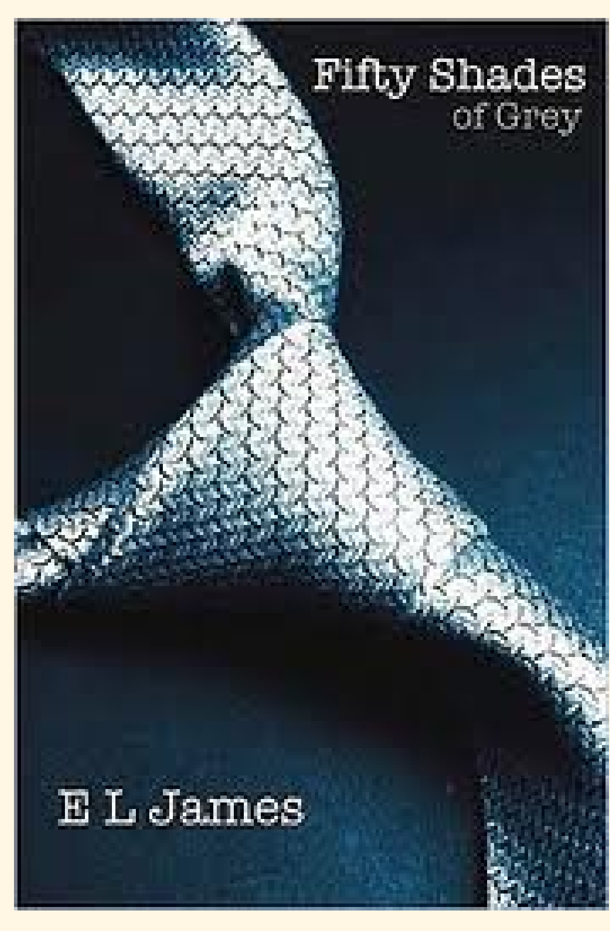
Adolescents vs. Children

- Assent
  - Greater role in determining choice of medication, dealing with adverse effects, adherence
- Diagnoses – bipolar, conduct disorder, depression
- Polypharmacy
- Age as a DSM criterion

Psychotropic Use by Age in Medicaid Enrolled Foster Children 2007



Off-label Use of Antipsychotics in Children and Adolescents



FDA Approved Indications for SGAs in Children and Adolescents

	Irritability due to Autism	Schizophrenia	Bipolar Disorder (mania or mixed)
Risperidone	age 5-16	age 13-17	age 10-17
Aripiprazole	age 6-17	age 13-17	age 10-17
Olanzapine	not approved	age 13-17	age 13-17
Quetiapine	not approved	age 13-17	age 10-17
Paliperidone	not approved	age 12-17	not approved

APA-ABIM 2013

Five Things Physicians and Patients Should Question

- **Don’t prescribe antipsychotic medications to patients for any indication without appropriate initial evaluation and appropriate ongoing monitoring.**
- **Don’t routinely prescribe two or more antipsychotic medications concurrently.**
- **Don’t use antipsychotics as first choice to treat behavioral and psychological symptoms of dementia.**
- **Don’t routinely prescribe antipsychotic medications as a first-line intervention for insomnia in adults.**
- **Don’t routinely prescribe antipsychotic medications as a first-line intervention for children and adolescents for any diagnosis other than psychotic disorders.**

www.choosingwisely.org accessed October 2013

Off-label Uses

- Most Common Conditions in Children
  - ADHD
  - Depression
  - Conduct disorder
  - Oppositional defiant disorder
  - Adjustment reactions
- >40% had no diagnosis supported by any publication

Pathak, Psychiatric Services, 2009

Antipsychotic Treatment of Disruptive Behaviors

- **Systematic review of RCT's for disruptive behavior disorders in youth**
- **All published trials funded by pharmaceutical companies**

8 trials (no participants <5 years old)

5 risperidone; subaverage-borderline IQ

1 risperidone; treatment resistant aggression ADHD-CD

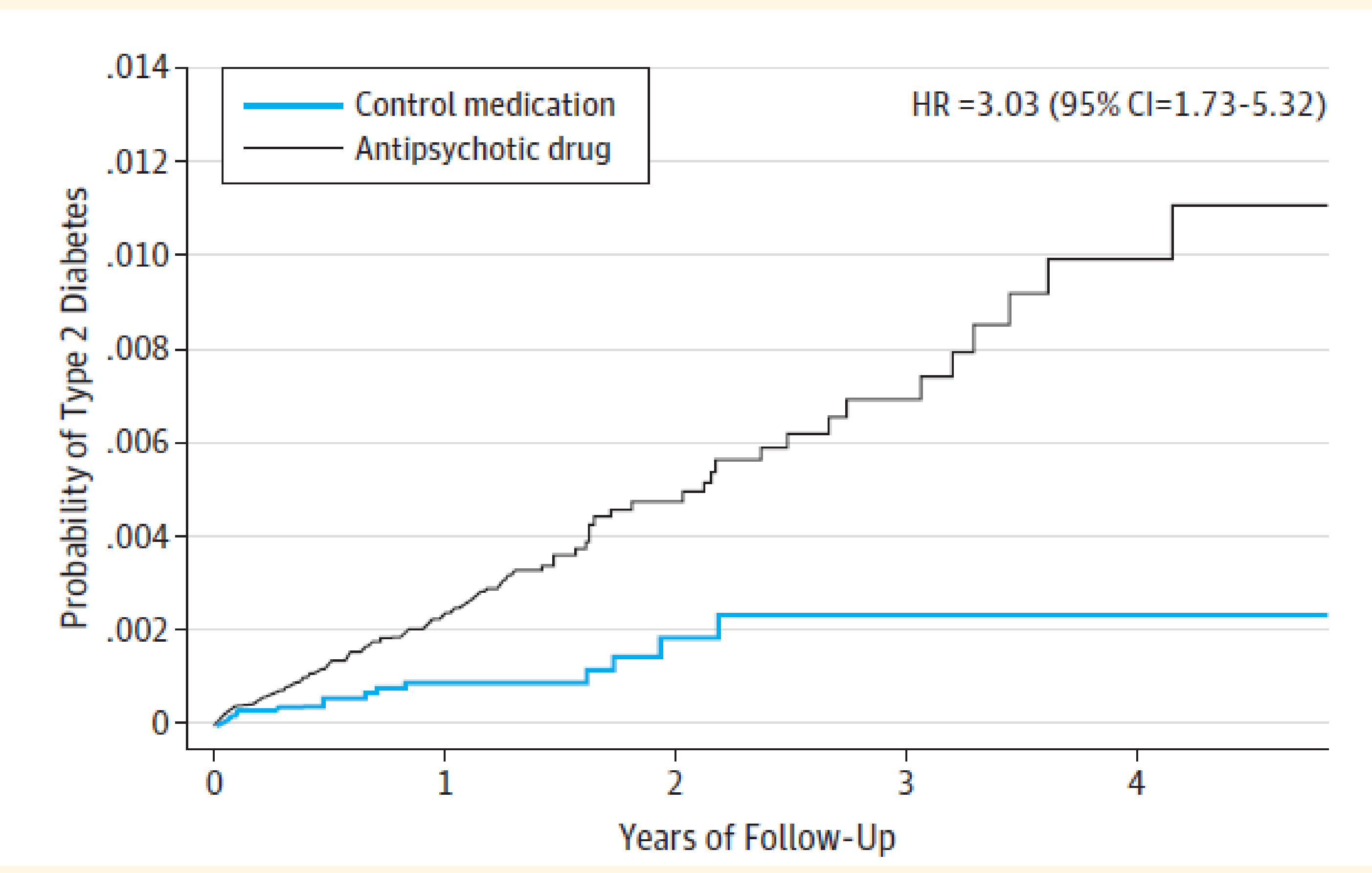
1 quetiapine for adolescent CD

Antipsychotics and the Risk of Type 2 Diabetes

- Tennessee Medicaid, published August 2013
- Youth 6 to 24 years
- Controls – users of other psychotropic drugs
- Antipsychotic users had 3 fold increase in risk
- Risk went up when only 6-17 years analyzed
- Risk increased with cumulative dose of antipsychotic
- Risk was significant in first year

Bobo et al. JAMA Psychiatry 2013

Antipsychotics and the Risk of Type 2 Diabetes



Bobo et al. JAMA Psychiatry 2013

APA/ADA Monitoring Schedule

		Follow-up in months					
	Base	1	2	3	6	9	12
Personal/Family History	X						X
Weight (BMI)	X	X	X	X	X	X	X
Waist Circumference	X			X			X
Blood Pressure	X			X			X
Fasting Glucose	X			X			X
Fasting Lipids	X			X			X

Evidence-Based Monitoring for Safety SGA's in Children and Youth

- Canadian Alliance for Monitoring Effectiveness and Safety of Antipsychotics in Children (CAMESA) included experts from Psychiatry, Neurology, Endocrinology, Cardiology, Epidemiology, Pediatrics, Nephrology
- Reviewed strength of evidence for risperidone, olanzapine, quetiapine, aripiprazole, clozapine, ziprasidone
- Developed drug specific recommendations, but noted drug specific recommendations cumbersome to implement & ignored ECG
- Developed "universal" SGA tool for 12 months, ending recommendations at one year due to lack of long term studies

Pringsheim et al. J Can Acad Child Adolesc Psychiatry, 2011

CAMESA Monitoring Schedule

		Follow-up in months					
	Base	1	2	3	6	9	12
Ht, Wt, BMI	X	X	X	X	X	X	X
Waist Circumference	X	X	X	X	X	X	X
Blood Pressure	X	X	X	X	X	X	X
Fasting Glucose, insulin	X			X	X		X
Fasting LDL, HDL, cholesterol, trigycerides	X			X	X		X
Neurological	X	X	X	X	X	X	X
AST, ALT	X				X		X
Prolactin	X						X
TSH for quetiapine	X						X

ECG Monitoring

- **American Academy of Child and Adolescent Psychiatry Practice Parameter**
- **General in tone and refers to ADA/APA Consensus Conference monitoring recommendations**
- **Recommendation 15.** ***Due to limited data surrounding the impact of AAAs on the cardiovascular system, regular monitoring of heart rate, blood pressure and EKG changes should be performed*** **.**

Pringsheim et al. J Can Acad Child Adolesc Psychiatry, 2011

ECG Monitoring (AACAP continued)

- **Family and patient history**
  - **sudden/unexplained death**
  - **syncope**
  - **palpitations**
  - **cardiovascular problems/abnormalities**
  - **Consider baseline and subsequent ECG monitoring when positive**
- **Consider alternative therapy if:**
  - **resting heart rate >130/min**
  - **PR interval >200 msec**
  - **QRS >120 msec**
  - **QTc is >460 msec**

AACAP Practice Parameter,
http://www.aacap.org/App_Themes/AACAP/docs/practice_parameters/Atypical_Antipsychotic_Medications_Web.pdf

Monitoring is a Problem

- Haupt et al, Am J Psychiatry. 2009;166:345-353.
  - Large managed care database
  - Baseline and 3 month monitoring lowest in children
  - Baseline glucose <25%
  - Baseline lipids ~10%
- Morrato et al, Arch Pediatr Adolesc Med. 2010;164:344-351
  - 3 state Medicaid programs
  - Baseline glucose ~30%
  - Baseline lipids <15%
  - Despite American Diabetes Association and American Psychiatric Association warnings, screening rates low

Safety Monitoring for SGAs in Children and Adolescents

	Baseline	3 months	every 6 months	annual	other
EPS Rating Scales	X	X		X	
Weight, BMI	X				each visit
BP, pulse	X	X	X		
Lipids (fasting)	X	X	X		
Glucose (fasting)	X	X	X		
Prolactin	X		X		if symptomatic
ECG	X				during titration

Monitoring is a Problem

- **Maryland 2011-2013**
  - **Maryland Medicaid Pharmacy Peer Review for Mental Health Drugs**
  - **First 59 patients, only one patient had baseline glucose and lipids**
  - **Pre-authorization ~75% have labs in first 90 days**

Conclusions

- Federal mandates regarding psychotropic medication use continue to challenge the states
- Prior authorization coupled with consultation and education can make a difference
- Systems that integrate prescriber and foster program education, consent and prior authorization have the potential to meet current many of these challenges
- Proper monitoring, particularly for antipsychotics is evolving and presents additional challenges

For More Information

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Questions

Second Generation Antipsychotics

Clozapine	Clozaril	Sandoz	1990
Risperidone	Risperdal	Janssen	1994
Olanzapine	Zyprexa	Lilly	1996
Quetiapine	Seroquel	AstraZeneca	1997
Ziprasidone	Geodon	Pfizer	2001
Aripiprazole	Abilify	BMS	2002
Paliperidone	Invega	Janssen	2007
Asenapine	Saphris	Merck	2009
Iloperidone	Fanapt	Vanda	2009
Lurasidone	Latuda	Sunovion	2010

Concerns

- Are drugs effective?
- Are non-pharmacologic treatments employed before resorting to psychopharmacotherapy?
- Co$t
- Extrapyramidal side effects/involuntary movements
  - Tardive dyskinesia, Dystonic reactions
- Obesity/metabolic effects
  - Lipid elevation, Glucose elevation
  - Diabetes mellitus, Weight gain
- Cardiovascular toxicity
  - QTc
- Hepatoxicity

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Additional Off-label Uses

- Attention deficit hyperactivity disorder
- Anxiety
- Sleep
- Bipolar disorder
- Mood disorder (not otherwise specified)
- Conduct disorder
- Oppositional defiant disorder
- Depression (some approved in adults)

Maryland Medicaid Statistics

Age Group	# of Prescriptions	# of Children
0 – 4 years	705	178
5 – 9 years	12,992	2,065
10 – 12 years	11,699	1,824
13 – 17 years	19,349	2,875

- **Review Period: 1/1/2010 – 12/31/2010**
- **48% of antipsychotic medications prescribed to children below the FDA approved ages were prescribed by providers who were not in the public mental health system (e.g., pediatricians and other primary care providers**

The Maryland Approach

- Early 2011 – Brainstorming
- Decision – Focus on Safety and Appropriate Use and gradual phase-in over for escalating age groups
- University of Maryland Schools of Pharmacy and Medicine to lead effort
- Summer 2011 – criteria development and involvement of additional stakeholders
- Fall 2011 – outreach
- October 2011 – implementation for children < 5 y.o.
- July 2012 – implementation for children < 10 y.o.
- July 2012 – implementation for ages < 18 y.o.

Pediatric Antipsychotic Peer Review Program

Child and Adolescent Psychiatry

Johns Hopkins

School of Medicine

Mental Health Program

University of Maryland

School of Pharmacy

Child and Adolescent Psychiatry

University of Maryland

School of Medicine

Medicaid Administration

Dept. of Health and Mental Hygiene

State of Maryland

Coalition of Pediatric Psychiatry Providers

Mental Hygiene Administration

Dept. of Health and Mental Hygiene

State of Maryland

Additional Partners and Outreach

- Major Psychiatric Hospitals
  - Sheppard Pratt Health System
- Major Outpatient Service Providers
  - Catholic Charities
- Advocacy
  - Maryland Coalition of Families for Children's Mental Health
- Professional Organizations
  - AACAP, AAP, AAFP, hospitals, health care systems . . .

The Peer to Peer Review Program

- Prior Authorization Plus
  - Education
  - Referrals
  - Consultation
- Call center staffed by psychiatric pharmacists
  - Educate prescribers
  - Make recommendations
  - Review criteria
  - Authorize real time through link to vendor system
- Child psychiatrists back up pharmacists
  - May override criteria
  - Often aid with psychosocial referrals
- Medicaid psychiatrist handles reviews, if requested
- Reauthorization in 90 days

The Peer to Peer Review Program

- Outreach to prescribers and pharmacists occurs before program initiated or expanded
- Outreach to existing prescribers with educational package
- Local pharmacist receives message to refer prescriber when submitting prescription for approval
- Physician faxes form to call center or calls
- Forms/data reviewed by psychiatric pharmacist
- Pharmacist approves or refers to child psychiatrist
- Pharmacist authorizes through Medicaid vendor system
- Call center proactively sends out renewal notices

The Data Collected

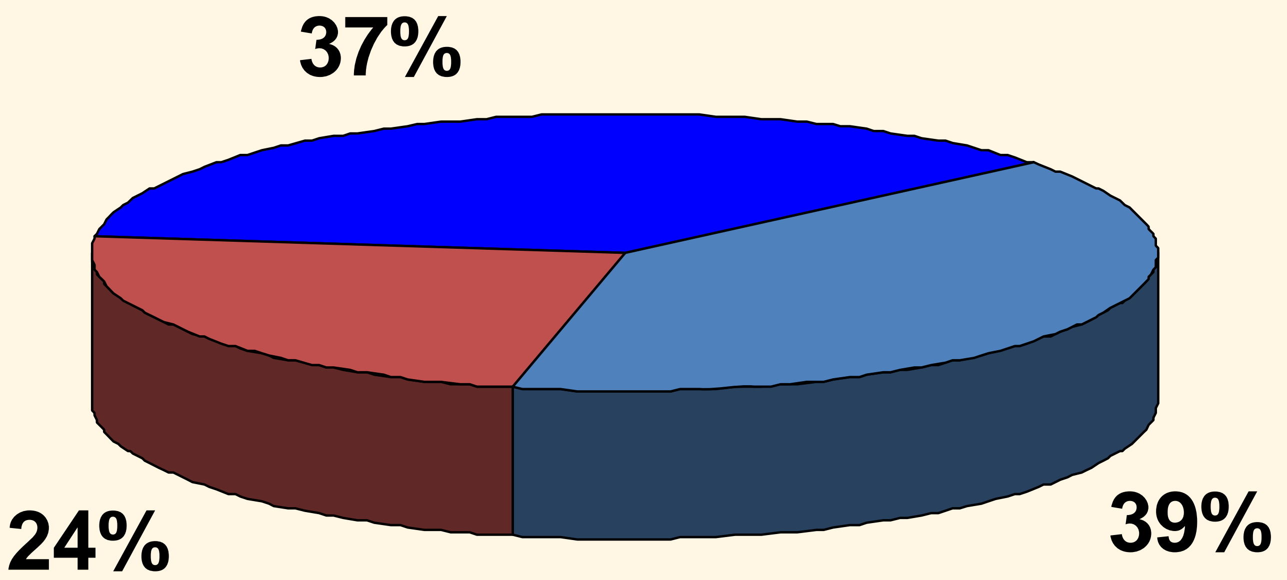
- Brief demographic information
- Foster care status
- Acuity of need
  - recent hospitalization, crisis intervention
- Diagnosis and indication for treatment
- Medications
  - Polypharmacy, dosing, regimens
- Psychosocial Services
- Weight, height, BMI
- Fasting labs
  - Glucose, lipids, LFTs
- ECG for ziprasidone or quetiapine

Criteria for Pharmacist Approval

- Mandatory Criteria
  - Age criteria
    - >3 or child psychiatrist reviews
  - Aggression, irritability, psychotic symptoms
  - Symptom severity
  - Dose, regimen appropriate
  - Baseline monitoring
- Selective Criteria
  - Acuity
  - Diagnosis
    - May include required concurrent psychosocial services

What's the Bottom Line?

Program Findings – The Diagnoses



Program Findings – The Prescribers

Approximately 1/3 of antipsychotics are prescribed by primary care providers

- **Pediatricians**
- **Family Practitioners**
- **Nurse Practitioners**
- **Psychiatrists**
- **Child Psychiatrists**
- **Psychiatric Nurse Practitioners**
- **Neurodevelopmental Pediatricians**
- **Behavioral Pediatricians**
- **Pediatric Neurologists**
- **Neurologists**

Program Findings

- Began October 2011 for children < 5 years of age
- About 60% of patients are approved
  - 65% of patients on medication at start of program were approved
  - Risperidone main agent employed
- Many prescribers unaware of psychosocial services
  - Many decide to no longer pursue antipsychotic treatment when other resources made available

More Findings

- Most prescribers do not adhere to recommended monitoring before contact with the program
  - Some prescribers think monitoring is not necessary
- Many prescribers elect to not pursue treatment once peer consultation/education occurs
- Need for medication in this age group not as acute as initially thought based on slowness of prescriber response

Prescriber Concerns

- Laboratory monitoring necessity
- Family resistance to laboratory monitoring
- Time/efficiency of process
- Concerns about who is prescribing
- Incorrect information from Medicaid during start up
- Availability of psychosocial services
- Need for psychosocial services

Other Initiatives - Adults

- Existing Dose Optimization Standards
- Review Exceptions
- Examine Outliers
  - Dose
  - Regimen
  - Polypharmacy
- Determine potential adherence problems
  - Some prescribers think monitoring is not necessary
- Consultation Panel