

A Critical Curriculum on Psychotropic Medications

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Module 2

Increasing Use of Psychotropics

Public Health Concerns

Part A

Medicating Youth

Surveys and insurance databases show increasing use

5-8 million children in the U.S. (8-11% of all children) receive prescriptions for psychotropic medications

(Medco, 2006; St. Luke's Health Initiatives, 2006)

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Prescriptions of psychotropics to youths tripled in the 1990s and are still rising in this decade

In some drug classes, rates in children rival adult rates



(Olfson et al. 2002, 2006; Thomas et al. 2006; Zito et al. 2000, 2002, 2003)

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Drug treatment without any other form of therapy is becoming the norm



(Olfson et al. 2002, 2006; Thomas et al. 2006; Zito et al. 2000, 2002, 2003)

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A worldwide phenomenon...



...but the proportion of children prescribed psychiatric drugs remains 2 to 20 times higher in the U.S., Canada, and Australia than in other developed nations

(Wong et al. 2004)

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In the U.S., “cultural” differences remain



White children are twice as likely as Black and Latino children to receive prescriptions

- Difference appears unrelated to socio-demographic, access, or clinical factors, and may relate to parental attitudes

(Cooper et al. 2006; Dos Reis et al. 2005; Leslie et al. 2003)

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Off-Label Uses and Polypharmacy



The New York Times

November 23, 2006

Proof Is Scant on Psychiatric Drug Mix for Young

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“Off-label” use common

The practice of administering medications for indications or age groups not approved by the FDA, as indicated on the drug’s “label”



(Vitiello, 2001; Zito et al. 2003)

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75% of all medication use in children is off-label



(Vitiello, 2001; Zito et al. 2003)

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Concerns about off-label use


“Bearing in mind that some off-label use is perfectly justifiable, it is fair to say that much of it is not justifiable. If there is not evidence presented to the FDA about a given indication, it is certainly a user-beware situation.”



- Jerry Avorn, M.D., Professor of Pharmacology, Harvard Medical School, and author, *Powerful Medicines* (2005)

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Polypharmacy common




40% or more of all psychiatric drug treatments today involve polypharmacy

(Bhatara et al. 2004; Olsson et al. 2002; Safer et al. 2003)

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Polypharmacy: concomitant or multiple psychotropic medication use



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Concomitant = ≥ 2 drugs taken on the same day

Multiple = ≥ 2 drugs taken during a given period



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Concerns about polypharmacy

Basic empirical support of efficacy in children is lacking for *most individual* medication classes

No studies have established the safety and efficacy of combination treatments in children

(Bhatara et al. 2004; Jensen et al. 1999; Martin et al. 2002; Vitiello, 2001)

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Increases behavioral toxicity

Behavioral toxicity = drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis

(Safer, Zito & dosReis, 2003)

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The “prescribing cascade”

Adverse effects are often confused with symptoms of disorders, leading to co-morbid diagnoses, and even more complex drug regimens



(Safer, Zito & dosReis, 2003)

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Examples of behavioral toxicity

TABLE 4. Single Case Reports of Adverse Drug Events Associated With Use of Concomitant Psychotropic Medication for Youths

Study	Medications	Diagnosis	Age	Gender	Adverse Drug Events
Salice et al. (89)	Fluoxetine, promethazine, methylphenidate, clonidine	ADHD, conduct disorder, and Tourette's syndrome	9	Male	Death
Preda et al. (90)	Perphenazine, carbamazepine, valproic acid, lorazepam, thioridazine	Bipolar I disorder and adjustment disorder	10	Female	Psychosis
Budman et al. (91)	Pemoline, paroxetine, haloperidol	OCD, ADHD, and Tourette's syndrome	12	Male	Acute dystonia
Levy et al. (92)	Amiripryline, fluoxetine, clonidine	ADHD and conduct disorder	7	Male	Serotonin syndrome
Fisman et al. (93)	Risperidone, clomipramine, erythromycin	ADHD, OCD, and Tourette's syndrome	15	Male	Deteriorated mental state

(Safer, Zito & dosReis, 2003)

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Medicating Preschoolers



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Similar patterns in preschoolers

Use of most classes of psychotropics among 2-4 year-olds continues to increase

- Almost half of those receiving prescriptions received two or more medications



(Coyle, 2000; Rappley, 2006; Zito et al. 2000)

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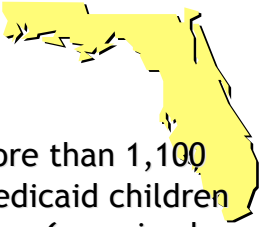
Newer drugs top the list

Fastest increases have been in newer drugs without established efficacy or safety profiles



(Pathak et al. 2004; Rappley, 2006; Zito et al. 2000)

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2006: more than 1,100 Florida Medicaid children under age 6 received atypical antipsychotics

(St. Petersburg Times, 2007)

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Concerns

Treatment of preschoolers with psychiatric drugs has barely been studied



(Rappley, 2006 ; Vitiello, 2001; Waller et al. 2005; Zito et al. 2000)

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Insufficient evidence to...

- Provide guidelines for treatment
- Establish efficacy of treatment
- Guarantee safe use
- Evaluate short- and long-term consequences on development



(Rappley, 2006 ; Vitiello, 2001; Waller, Lewellen & Bresson, 2005; Zito et al. 2000)

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SCIENTIFIC AMERICAN

May 30, 2007

Kids on Meds -- Trouble Ahead

Antidepressants, designed for adults, may be altering the brains of kids who take them

By Paul Raeburn

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Youths in Foster Care

More likely to be medicated



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CBS EVENING NEWS

Are Drugs Being Misused On Foster Kids?
Three's Growing Concern: That Anti-Psychotic Drugs Are Being Misused On Children In Foster Care

msnbc

States wrestle with medicating foster kids
 Critics worry psychiatric drugs flow too freely to forgotten children

USA TODAY

Home News Travel Money Sports Life Tech

Health and Behavior Inside News

For foster kids, oversight of prescriptions is scarce

Updated 5/2/2008 12:21 AM ET

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National foster care

Children in child welfare settings are **2 and 3 times more likely** to be medicated than children in the general community



(Breland-Noble et al. 2004; Raghavan et al. 2005)

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Group homes

After controlling for demographic *and* clinical factors, youths in group homes still **twice as likely** to be medicated than youths in therapeutic foster care

(Breland-Noble et al. 2004; Raghavan et al. 2005)

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Concerns in Florida

Reports in 2001 and 2003 highlighted problems with:

- Medication without signed consent
- Medication without medical evaluations and proper follow-up monitoring
- High rates of polypharmacy

(Green, Hawkins & Hawkins, 2005; Florida Statewide Advocacy Council, 2003)

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Florida concerns led to law

Senate Bill 1090 introduced in 2005 to restrict the state's ability to medicate foster children without the proper consent of their parents or a judge and required improved tracking of these children

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"No List of Kids on Mood Drugs"

The Miami Herald  (September, 2006)
 el Nuevo Herald

Child welfare officials acknowledged lacking an accurate list of children in state care receiving psychiatric drugs

- Advocates called use of these drugs in children "chemical restraints" used to control behavior

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Part B

Public Health Concerns



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Numbers of American children on psychotropics: 2006

Stimulants: 3.6 million
 Antidepressants: 2 million
 Anticonvulsants: 900,000
 Antipsychotics: 540,000

The New York Times
 (Medco Health Solutions, 2006)

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FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2006 FDA warning on cardiovascular effects also alerts doctors to stimulant-induced psychosis and hallucinations

The New York Times

August 22, 2006
 F.D.A. Strengthens Warnings on Stimulants
 By GARDNER HARRIS

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FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2004: FDA issued a “Public Health Advisory” about all antidepressants, warning of drug-induced:

- Anxiety and panic attacks
- Agitation and insomnia
- Irritability and hostility
- Impulsivity and severe restlessness
- Mania and hypomania

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FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

FDA “black box” warns:

“Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder and other psychiatric disorders”

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CBS NEWS June 6, 2007 2:16pm FDA Orders Antidepressant Warning

msnbc Home Health Mental Health

Health FDA urges new warnings on antidepressants

2005: FDA extends “black box” warnings to children and adolescents

2007: FDA extends “black box” warnings to young adults 18-24

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Antipsychotics

Skyrocketing numbers despite safety concerns

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The New York Times
 June 6, 2006
A rush to overprescribe?
 Updated 5/22/06 12:19 AM ET
Use of Antipsychotics by the Young Rose Fivefold
 By **BENEDICT CAREY**

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USA TODAY
 Health and Behavior | Inside News
New antipsychotic drugs carry risks for children
 Updated 5/22/06 10:09 AM ET

USA TODAY
 Health and Behavior | Inside News
Adult antipsychotics can worsen troubles
 Updated 5/22/06 10:09 AM ET

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Antipsychotics = Fastest rise

Number of non-institutionalized 6-18 year-olds on antipsychotics:

1993:	50,000
2002:	532,000

(Olfsen et al. 2006)

St. Petersburg Times (2007)

More than 18,000 kids on Florida Medicaid prescribed atypical antipsychotics in 2006

Kids on meds: an explosion
 In the last seven years, the number of children in the Medicaid fee-for-service plan who received antipsychotics has more than doubled. Prescriptions have more than tripled, and the cost to taxpayers is up more than 500 percent.

Children taking antipsychotics

Year	Atypical antipsychotics	Typical antipsychotics
1999	~5,000	~1,000
2000	~6,000	~1,000
2001	~7,000	~1,000
2002	~8,000	~1,000
2003	~9,000	~1,000
2004	~10,000	~1,000
2005	~11,000	~1,000
2006	18,005	~1,000

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Nationwide, antipsychotics typically prescribed to children for non-psychotic conditions

Most frequent diagnoses:

- disruptive behavior disorders, including ADHD (38%), and mood disorders (32%)

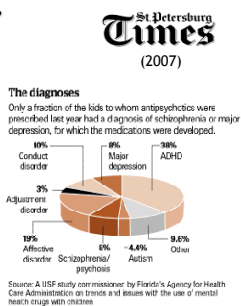
(Olfsen et al. 2006)

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In Florida too...

2006: Only 8% of Florida Medicaid children receiving antipsychotics had a diagnosis of psychosis

- Half were diagnosed with attention or conduct disorders



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Antipsychotics = polypharmacy

77% to 86% of youths taking antipsychotics do so with other drugs



(Medco, 2006; Olfson et al. 2006)

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Safety and efficacy unknown

"We don't know the first thing about safety and efficacy of these drugs even by themselves in these young ages, let alone when they are mixed together."

Dr. Steven Hyman, former NIMH director, Harvard University provost

The Boston Globe (2006)

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Adverse effects of "atypicals"

	Clozaril	Risperdal	Zyprexa	Seroquel	Geodon	Abilify
Clinical name	Clozapine	Risperidone	Olanzapine	Quetiapine	Ziprasidone	Aripiprazole
Major symptoms reported						
Diabetes	Severe	Mild	Severe	Moderate	Minimal	Minimal
Weight gain	Severe	Moderate	Severe	Moderate	Mild	Mild
Sedation	Severe	Mild	Moderate	Moderate*	Minimal	Minimal
Tardive dyskinesia	None	Minimal	Minimal	Minimal	Minimal	Minimal

(Correll, 2006; USA Today, 2006)

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"Doctors need to be judicious when prescribing antipsychotic drugs to children. The use of these drugs can have the pediatric patient trading a behavioral condition for a lifelong metabolic condition that can lead to significant health complications"

—Robert Epstein, M.D., chief medical officer, Medco

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 Nation/Politics
Spending on psychotherapeutic drugs soars
 By Joyce Howard Price
 THE WASHINGTON TIMES
 April 1, 2007

Spending on antidepressants and other prescription drugs to treat mental disorders climbed from \$7.9 billion in 1997 to \$20 billion in 2004, an increase of more than 150 percent, a new federal report says.

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2004: 17% of total drug spending for children was for psychotropics

- *greater than cost of antibiotics and asthma drugs*

medco (2004)

State insurance increases likelihood of medication

Medicaid-enrolled children are more likely to:

- Receive psychotropics
- Be treated with multiple medications
- Receive medications as sole treatment

(Goodwin et al. 2001; Martin et al. 2002, 2003)

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Use of newer antipsychotics grows faster

1996-2001: increased most dramatically in these Medicaid populations:

- Preschool children (61%)
- Ages 6-12 (93%)
- Ages 13-18 (116%)

(Cooper et al. 2004; Olfson et al. 2006; Patel et al. 2005)

Department of Health and Human Services
 OFFICE OF INSPECTOR GENERAL
 MEDICAID'S MENTAL HEALTH DRUG EXPENDITURES
 INSPECTOR GENERAL
 AUGUST 2003
 OIG-04-02-0099

Medicaid pays more for psychotropic drugs than other Federal buyers...

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Medicaid programs struggle to contain costs

1997 - 2004: Tripling of Medicaid spending on psychotropics attributed to the expanding use of expensive atypical antipsychotics

(Duggan, 2005; Stagnitti, 2007; OIG, 2003)

Antipsychotics top Medicaid spending on psychiatric drugs

10 state Medicaid programs paid \$562 million on 25 psychotropic drugs
- 67% of this total spent on nine antipsychotics

(Duggan, 2005; OIG, 2003; Stagnitti, 2007)



Average prescription price for top 2 antipsychotics, 1993 vs. 2001

1993: Haldol, Mellaril = \$29

2001: Zyprexa, Risperdal = \$286

(Duggan, 2005)

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Florida Medicaid (fee-for-service) spending on atypical antipsychotic drugs, 2002-2007

\$1.1 billion

(Farley, R., *St. Petersburg Times*, April 12, 2008)



Part D

Conclusions and Recommendations

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Usage is increasing

Usage of all psychiatric drug classes has skyrocketed during past decade in all age groups, all ethnic/racial groups, all settings



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Ongoing debate

Debate persists on whether disorders are under- or over-diagnosed, and under- or over-treated, with heated arguments from supporters and critics in professional and public discourse



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Supporters argue...

- Up to 1/5 of youth have a “DSM-diagnosable disorder”
- Popularly-accepted causes of disorders are neurobiological
- Medications remove “blame”
- Stimulants greatly impact ADHD-like behavior



Critics reply...

- Medication use outpaces research evidence
- Growing use leads to increase in pediatric adverse effects
- Medicating the developing brain may lead to long-term negative changes in functioning
- No pathophysiological variable is associated with any DSM disorder



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Fastest rise: Antipsychotics

Antipsychotics with serious adverse effects growing faster than any other drug class

- More frequently used in polypharmacy and for non-psychotic disorders, with no research evidence



Racial issues

Black children: fastest-growing group being prescribed antipsychotics

- Increase related to enormous rise in the diagnosis of bipolar disorder in this population



Soaring State Medicaid spending

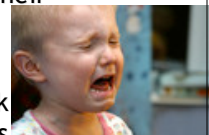
Largest spending increases on antipsychotics

- Until now, states appear unable to contain such fast-rising drug costs



Young children

Children are particularly vulnerable to harm by psychiatric drugs because their brains are still developing



Research is needed to track subtle changes in children’s developing personality resulting from drug’s impact on brain

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Children in foster care

Little empirical evidence exists to support the use of drug interventions in traumatized children

- Clinicians need to consider risk/benefit analysis of drugs vs. evidence of effective psychosocial interventions

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Children in foster care

Experts recommend antipsychotics should not be considered first-line treatment for childhood trauma because of their serious adverse effects



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A Critical Curriculum on Psychotropic Medications

Module 2

The End



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