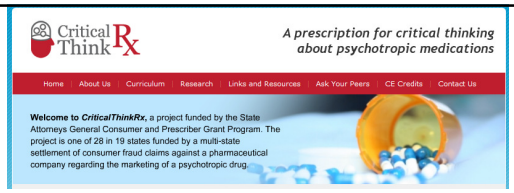


A Critical Curriculum on Psychotropic Medications

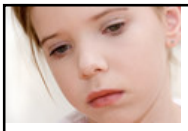
Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - **David Cohen, Ph.D.**
- **Research Coordinator:**
  - **Inge Sengelmann, M.S.W.**
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
www.CriticalThinkRx.org

CriticalThinkRx **was made possible by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®**



Module 1

Why a Critical Skills Curriculum on Psychotropic Medications?

Part A

Curriculum Rationale, Funding and Contents

Curriculum Rationale

Physicians write prescriptions, but other professionals often influence who gets prescribed and why

Training for these professionals is mostly haphazard and often influenced by the pharmaceutical industry

6

Curriculum Objectives

Help practitioners in mental health and child welfare sharpen *critical thinking skills* to deal with complex and evolving issues about psychotropic medication

7

Critical thinking

✓involves assessing beliefs, arguments and claims to arrive at well-reasoned judgments

✓uses standards such as clarity, accuracy, relevance, and completeness

8

Critical thinking

✓asks "who benefits?"

✓is sensitive to the influence of vested interests on information

✓emphasizes the ethical implications of treatment decisions

9

CriticalThinkRx

A prescription for critical thinking about psychotropic medications

10

Curriculum funding

- Received from the *Attorneys General Consumer & Prescriber Education Grant Program* (CPGP)
- CPGP is overseen by the Attorney General offices of Florida, New York, Ohio, Oregon, Texas and Vermont (plus two rotating states)

11

Funding source of CPGP

2003: Attorneys General of 50 states charged Warner Lambert, a subsidiary of Pfizer, Inc., with conducting an unlawful marketing campaign promoting the off-label uses of the anticonvulsant drug Neurontin

12

Neurontin settlements

2004: The company settled for $430 million

—$21 million was earmarked for research and education aimed at health professionals

13

CPGP awards grants

2006: CPGP funded 28 applications in 19 states

- *CriticalThinkRx*, funded at Florida International University, is the only project targeting non-medically trained professionals in child welfare and mental health

14

CPGP aims to improve prescribing practices by educating health professionals about

- ✓the drug development and approval process
- ✓pharmaceutical industry marketing
- ✓knowledge and skills to evaluate drug information critically

15

CPGP requires that

- ✓the curriculum be maintained in the public domain, freely accessible by anyone
- ✓the investigators and their consultants forego funding from the pharmaceutical industry for the duration of their grants

16

Selection of content

Systematic literature searches were conducted in 2006-2007 on databases in medicine, pharmacology, public health, social work, counseling, and psychology

- Materials were selected based on relevance and accuracy

17

Mainstream views

Researchers agree that clinical practice has far outpaced the empirical evidence, yet…

- Mainstream mental health practice subscribes to a "medical" model supporting medication of children with little evidence of safety or efficacy

18

Content bias

CriticalThinkRx offers alternative views based on empirical evidence to stimulate critical thinking and a more balanced evaluation based on ethical codes of practice

19

Content orientation

CriticalThinkRx emphasizes the ethical dictate: **"First, do no harm"**

CriticalThinkRx tries to close gaps between research and practice to maximize opportunities to help clients and avoid harm

20

Curriculum design

Modules designed by experienced researcher/clinician with input from independent consultants in counseling, psychology, psychiatry, social work, and law

21

Principal Investigator

David Cohen, Ph.D., L.C.S.W.

- Professor of Social Work, Florida International University, Miami, and a private practitioner
- Author of numerous publications on psychiatric drugs, medicalization, and law and psychiatry
- His latest books are *Your Drug May Be Your Problem* (2nd rev. ed, 2007) and *Critical New Perspectives on ADHD* (2006)

22

Research Coordinator

Inge Sengelmann, M.S.W.

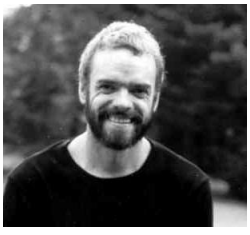
- M.S.W. with a background in journalism and corporate communication
- Clinician focused on holistic approaches to the treatment of trauma-related mood and behavioral problems

23

Consultant: Counseling

R. Elliott Ingersoll, Ph.D.

- Professor of Counseling, College of Education and Human Services, Cleveland State University
- A licensed psychologist and clinical counselor in Ohio, he has authored books, book chapters, and articles on psychopharmacology, spiritual approaches to counseling, and Integral theory in mental health
- Author, *Psychopharmacology for Helping Professionals: An Integral Exploration* (2006)



24

Consultant: Social Work

Kia J. Bentley, Ph.D., L.C.S.W.

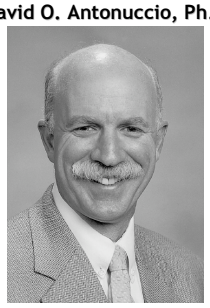
- Professor, Director of the Ph.D. Program, and Associate Dean for Strategic Initiatives in Social Work at Virginia Commonwealth University, where she has taught since 1989
- Author, *The Social Worker & Psychotropic Medication* (3rd ed., 2006) (with Joseph Walsh)
- Editor, *Psychiatric Medication Issues for Social Workers, Counselors and Psychologists* (2003)

25

Consultant: Psychology

- Professor, Department of Psychiatry, University of Nevada School of Medicine
- Fellow, American Psychological Association; Diplomate, clinical psychology, American Board of Professional Psychology
- His articles on the comparative effects of psychotherapy and pharmacotherapy have received extensive national coverage and are models of careful scholarship
- Has received many prestigious awards for his outstanding contributions to clinical science and research

David O. Antonuccio, Ph.D.



26

Consultant: Psychiatry

Stefan P. Kruszewski, M.D.

- Harvard Medical School graduate and board-certified in adolescent psychiatry
- Pensylvannia-based clinician and scientist working with U.S. and international judicial, legislative, and regulatory bodies
- His publications appear in *American Journal of Psychiatry* and *BMJ*

27

Consultant: Law

Robert E. Rosen, J.D., Ph.D.

- Professor of Law, University of Miami, Coral Gables, FL
- Has taught courses in children and the law, professional responsibility, and sociology and the law
- Has served as member of Miami-Dade's Community-Based Care Alliance, and is a reviewer for Foster Care Review
- Holds a J.D. from Harvard Law School, and a Ph.D. in sociology from the University of California at Berkeley
- Former fellow, Harvard's Program in Ethics and the Professions

Use of drug names

Most prescription drugs have a generic and a brand name (e.g., fluoxetine/Prozac)

In this course, charts show both names, but discussions use brand names because they are more familiar to laypersons

29

30

A recent tragic case raises questions about the use of psychiatric medications in young children

31

Case 1: Rebecca Riley

(April 11, 2002 - Dec.13, 2006)

What went wrong?

Concerns raised before death of 4-year-old girl

Teachers, a social worker, a nurse and a therapist had noticed something wasn't right about Rebecca Riley. A

32

CBS NEWS Oct. 1, 2007 12:10pm

CBS EVENING NEWS | THE EARLY SHOW | 48 HOURS MYSTERY | 60 MINUTES

60 MINUTES

What Killed Rebecca Riley?

Katie Couric Reports On The Diagnosis Of Bipolar Disorder In Kids

Sept. 30, 2007

Girl's death stirs debate over psychiatric meds

Parents of 4-year-old accused of intentionally overmedicating daughter

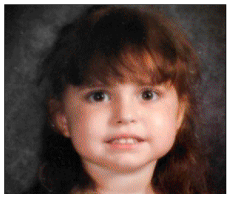
AP Associated Press

Updated: 3:11 p.m. ET March 23, 2007

HULL, Mass. – In the final months of Rebecca Riley's life, a school nurse said the little girl was so weak she was like a "floppy doll."

The preschool principal had to help Rebecca off the bus because the 4-year-old was shaking so badly.

And a pharmacist complained that Rebecca's mother kept coming up with excuses for why her daughter needed more and more medication.



33

Some salient facts

In 2002, then again in 2005-2006, Massachusetts' DSS investigated complaints that the three Riley children might be sexually or physically abused and neglected by their parents

DSS ruled complaints unfounded

34

By 2006, all three Riley children were diagnosed with Bipolar I Disorder and prescribed psychotropic drug cocktails by same child psychiatrist from Tufts Medical Center

- Parents were also diagnosed and mother received Paxil
- As discussed in next modules, diagnosing children with Bipolar Disorder I is a questionable and controversial practice

35

Rebecca, the youngest child, was first medicated at age 2

- By age 4, she was taking Seroquel (antipsychotic), Depakote (anticonvulsant), and clonidine (antihypertensive)
- She also took 2 over-the-counter cold medicines

36

Dec. 13, 2006: Rebecca Riley is found dead on her parents' bedroom floor

- Autopsy later indicated cause of death as **"intoxication due to the combined effects"** of clonidine, Depakote, and two cough medications
- *"The amount of clonidine alone in Rebecca's system was fatal."*

(Commonwealth of Massachusetts, Feb. 5, 2007)

37

Parents indicted …

Michael Riley, 34, and Carolyn Riley, 32, indicted in 2007 for the 1st degree murder of their daughter Rebecca (charge later reduced to 2nd degree murder)

- Parents charged with giving her "excessive amounts" of clonidine
- Child's doctor told mother Rebecca "was already on a high dose of clonidine" and a higher dose could kill the child

(Commonwealth of Massachusetts, Feb. 5, 2007)

38

Case leads to resignations…

GOODBYE TO DSS CHIEF

Agency has been under fire
since parents accused of killing Hull girl

By KEN MAGUIRE
Associated Press

BOSTON - The embattled head of the state's child welfare system is resigning five months after his agency was criticized for its action - or lack of action - in the death of a 4-year-old girl in Hull.

Lewis "Harry" Spence

Lewis "Harry" Spence, commissioner of the Department of Social Services since 2001, has been under fire for the agency's handling of the Hull case in which the parents of the dead girl are charged with killing her with an overdose of prescription drugs.

He also has been criticized for the department's handling of another high-profile child-abuse case involving a comatose child from Westfield.

Gov. Deval Patrick plans to replace Spence with Angelo McClain, a former DSS worker who now works for ValueOptions, a New Jersey-based health care company, according to a person with direct knowledge of the decision.

Patrick planned to announced Spence's departure today along with other changes in top positions, a source told The Associated Press.

Spence did not return calls to his cell phone seeking comment.

39

… puts careers on the line

February, 2007

Psychiatrist to suspend practice; denies wrongdoing

The Boston Globe

By Liz Kowalczyk, Globe Staff | February 8, 2007

Dr. Kayoko Kifuji, the psychiatrist who treated Rebecca Riley in the months before the Hull girl died from an overdose of prescription drugs, agreed yesterday to immediately stop treating patients while the state investigates her role in the case.

April, 2008

HOME / NEWS / LOCAL

Doctor is sued in death of girl, 4

The Boston Globe

Her psychiatrist treated her with powerful drugs

By Shelley Murphy
Globe Staff / April 4, 2008

Email | Print | Single Page | Text size

40

CBS EVENING NEWS

March 10, 2007

(CBS) Rebecca Riley's death shocked the Boston community. Did her parents deliberately give her overdoses of psychiatric drugs as prosecutors suggest? Or are her doctors to blame — as defense lawyers argue — for prescribing powerful medications when she was just 2 years

41

Girl's pill numbers disputed: The prescriptions Carolyn Riley gave 4-year-old were very close to allowed amount, defense says

By JULIE JETTE
The Patriot Ledger

The Patriot Ledger

March 10, 2007

42

Case shines light on therapists' roles…

An LCSW made 12 home visits in summer 2006, working with Rebecca and her 6-year-old sister

- Therapist was "initially concerned" about the medication regimen, since she "did not observe any behavior consistent with the diagnoses"

(Commonwealth of Massachusetts, Feb. 5, 2007)

43

… and on school personnel

In her pre-school, Rebecca was observed to be very lethargic and have "a tremor in her hand"

Mother was observed to be "lethargic" and "fall asleep during interviews"

44

Case stirs heated debate among doctors over bipolar diagnoses

The Boston Globe

Backlash on bipolar diagnoses in children
MGH psychiatrist's work stirs debate

By Scott Allen, Globe Staff | June 17, 2007

45

Leads one doctor to hold another "morally culpable"

LAWRENCE DILLER
Misguided standards of care
The Boston Globe

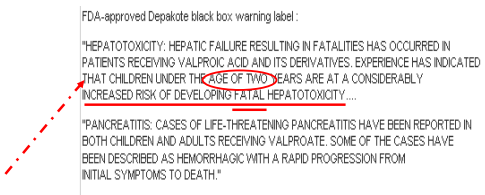
By Lawrence Diller | June 19, 2007

"… I felt compelled to name Joseph Biederman, head of the Massachusetts General Hospital's Pediatric Psychopharmacology clinic, as morally culpable in providing the 'science' that allowed Rebecca to die."

-- *Lawrence Diller, M.D.*

46

FDA "black box" warnings on Depakote ignored?



FDA-approved Depakote black box warning label :

"HEPATOTOXICITY: HEPATIC FAILURE RESULTING IN FATALITIES HAS OCCURRED IN PATIENTS RECEIVING VALPROIC ACID AND ITS DERIVATIVES. EXPERIENCE HAS INDICATED THAT CHILDREN UNDER THE AGE OF TWO YEARS ARE AT A CONSIDERABLY INCREASED RISK OF DEVELOPING FATAL HEPATOTOXICITY....

"PANCREATITIS: CASES OF LIFE-THREATENING PANCREATITIS HAVE BEEN REPORTED IN BOTH CHILDREN AND ADULTS RECEIVING VALPROATE. SOME OF THE CASES HAVE BEEN DESCRIBED AS HEMORRHAGIC WITH A RAPID PROGRESSION FROM INITIAL SYMPTOMS TO DEATH."

47

Case 2:
"Susan," 10 years old

Parents divorced 5 years ago, custody awarded to mother

Father seeking shared custody—only sees Susan a few times a year

Susan presented behavior problems since the age of 3

48

Loss and instabililty

Susan's life filled with losses of friends, pets, homes, adopted-away brother

Since age 5, Susan moved 10 times, attended 7 schools, was assessed by 20 physicians and therapists

49

Multiple diagnoses

Diagnosed with ADHD, OCD, bipolar disorder

Lives in a residential treatment center

Her file describes many behavioral outbursts, attributed to "bipolar disorder"

50

Since age 5, Susan has taken:

- ✓5 antipsychotics
- ✓4 anticonvulsants
- ✓3 stimulants
- ✓3 antidepressants
- ✓2 benzodiazepines
- ✓2 other sedatives (incl. antihypertensive)
- ✓lithium

51

Susan now takes:

- ✓2 anticonvulsants
- ✓1 antipsychotic
- ✓1 stimulant, and
- ✓1 antihypertensive

No evaluations of medication…

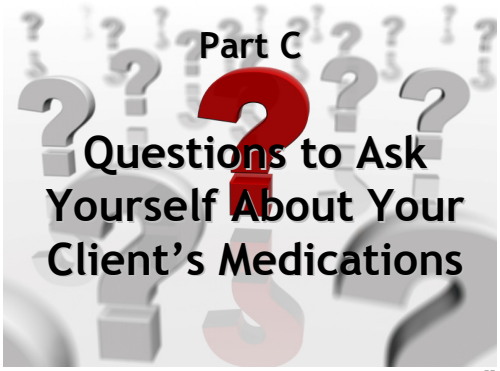
A psychologist and a social worker conducted separate assessments of Susan's situation for the Court

Neither commented on Susan's drug treatment or suggested any connections between the medications and her behavioral outbursts

53

No one expressed any concern about giving 5 psychiatric drugs (including 4 central nervous system depressants) to a 10-year-old

54



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56

- What are the client's symptoms or observed behaviors of concern, who has observed them?
- Has the client experienced any recent or chronic life events or stressors that may contribute to the problems?

57

- Could any of client's problems be caused by current medication?

- Does the client's psychiatric diagnosis truly reflect the client's problems? Is the diagnosis useful to plan for interventions with this client?
- What interventions have been tried to address client's problems? By whom, and with what results?
- Are alternative interventions available to address client's problems? Why have they not yet been tried?

59

- Why is medication being prescribed for this client? What other medication has been prescribed currently or in the past?
- How long before we see improvements? How will the improvements be measured?
- How long will the patient be on the medication? How will a decision to stop be made?

60

- If client is a minor, is the medication designed to benefit the child, or the child's caregivers?

61

62

- Why is this particular medication prescribed for this client?
- How long has it been on the market? Is it FDA-approved for use in children? Are there any FDA "black box" warnings about this medication?
- What is the recommended dosage? How often will the medication be taken? Who will administer it?

63

- Have any studies been evaluated by professionals working with this child?
- How much scientific support is there for its helpfulness with other children with similar conditions?
- How much scientific evidence exists to support safety and efficacy of this drug in children, alone or in combination with other psychotropic medications?

64

- Has this medication been shown to induce tolerance and/or dependence? What withdrawal effects may be expected when it is discontinued?

65

- Do any laboratory tests need to be done before, during, after use of this medication?
- Are there other medications or foods the child should avoid while on this medication?
- What are all the potential positive and adverse effects of this medication?

66

- How will the effects of the medication be monitored? By whom? Where will they be documented? What should be done if a problem develops?
- How will the use of medication impact other interventions being provided?

67

- How much does this medication cost and who is paying for it?
- Are there cheaper, generic versions of this medication?

68

69

- What is the experience of the physician prescribing the medication?
- Would you consider the physician's prescribing habits as cautious and conservative?
- Does this physician have any financial relationships with pharmaceutical companies? Have these been disclosed to patients?

70

- Have all the risks and benefits of this medication, and those of alternate interventions, been evaluated and discussed by the physician with the client or the client's family?
- Is there an adequate monitoring schedule and follow-up?

71

- Do I or my client/client's family have the opportunity to speak regularly with the physician and other healthcare providers about the medication's effects? Should my feedback be expressed in writing?

72

- Has a comprehensive assessment (e.g., biopsychosocial, holistic, integral) been conducted? Does it offer plausible reasons for the client's problems?
- Are there other explanations for the child's behavior?

74

- If necessary, do I have access to supervision to help me think through the medication issues?
- How knowledgeable is my supervisor about psychotropic medications?

75

- Am I familiar with all the risks and benefits of this medication, as well as those of alternate interventions? Have I discussed them with the client/client's family?
- Do I know how the client/client's family feel about the use of medication?

76

- What is my role and has it been clearly delineated with all other providers?
- Has the client/client's family been provided with all the information necessary to provide informed consent? Do they understand their choices?

77

- Do I feel confident that I can recognize the effects, adverse or otherwise, of this medication on my client? How should I record my observations?
- Will I be able to educate my client about these effects so he/she can raise concerns with the prescribing physician?

78

- What alternative services/interventions does this family need or want?
- Can I provide these or help them obtain access?

79

This course, in the remaining modules, is intended to help you answer the preceding questions

80

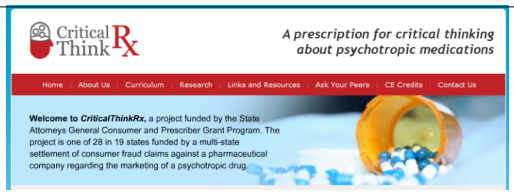
A Critical Curriculum
on Psychotropic Medications

Module 1

The End

www.CriticalThinkRx.org

81



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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)

6

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)

7

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)

8

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)

9

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)

10

Off-Label Uses and Polypharmacy

The New York Times

November 23, 2006

Proof Is Scant on Psychiatric Drug Mix for Young

11

"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)

12

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

(Vitiello, 2001; Zito et al. 2003)

13

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)

14

Polypharmacy common

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

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

15

Polypharmacy: *concomitant* or *multiple* psychotropic medication use

16

Concomitant = ≥ 2 drugs taken on the same day

Multiple = ≥ 2 drugs taken during a given period

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)

18

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)

19

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)

20

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
Sallee 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)	Amitriptyline, fluoxetine, [illegible]	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)

21

Medicating Preschoolers

22

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)

23

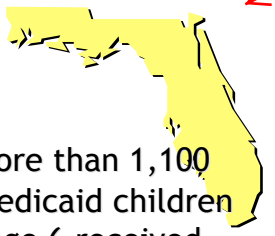
Newer drugs top the list

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

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

24

Incorporated to here



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

(*St. Petersburg Times*, 2007)

25

Concerns

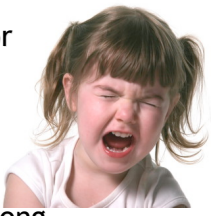
Treatment of preschoolers with psychiatric drugs has barely been studied

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

26

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)

27

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

28

Youths in Foster Care

More likely to be medicated

29

CBS EVENING NEWS

Are Drugs Being Misused On Foster Kids?

There'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 5/2/2006 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)

31

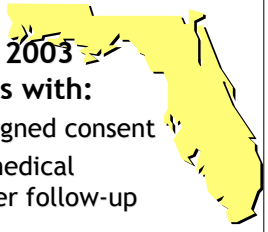
Group homes

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)

32

Concerns in Florida



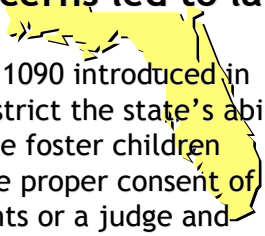
Reports in 2001 and 2003 highlighted problems with:

- 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)

33

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

34

"No List of Kids on Mood Drugs"

The Miami Herald / el Nuevo Herald (September, 2006)

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

35

Part B

Public Health Concerns

36

37

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)

38

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 GARDINER HARRIS

39

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

40

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"

41

CBS NEWS June 6, 2007 2:16pm FDA Orders Antidepressant Warning
All Antidepressants Must Carry 'Black Box' Caution

msnbc Home » Health » Mental Health
A Fuller Spectrum of News
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

42

Antipsychotics

Skyrocketing numbers despite safety concerns

43

44

45

Antipsychotics = Fastest rise

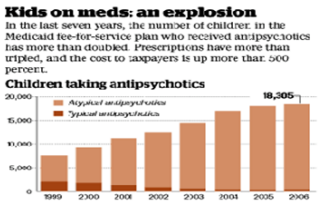
Number of non-institutionalized 6-18 year-olds on antipsychotics:

1993: 50,000
2002: 532,000

(Olfson et al. 2006)

St Petersburg Times (2007)

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



47

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

Most frequent diagnoses:

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

(Olfson et al. 2006)

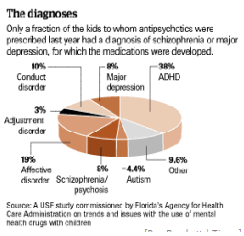
48

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

St Petersburg Times (2007)



49

Antipsychotics = polypharmacy

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

(Medco, 2006; Olfson et al. 2006)

50

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)

51

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)

52

medco

"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

53

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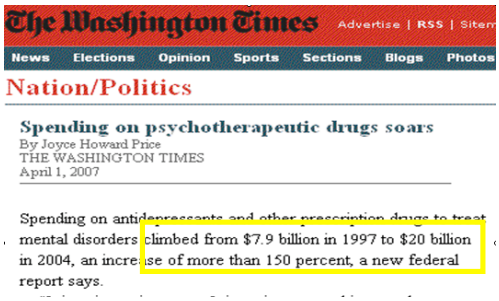
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Nation/Politics

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.

55

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)

57

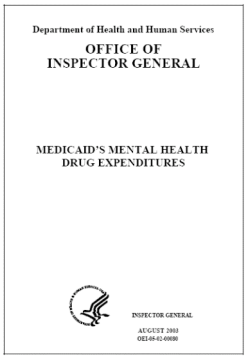
Use of newer antipsychotics grows faster

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)

58


Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID'S MENTAL HEALTH DRUG EXPENDITURES

INSPECTOR GENERAL

AUGUST 2003

OEI-03-02-00600

Medicaid pays more for psychotropic drugs than other Federal buyers…

59

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)

62

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

64

Usage is increasing

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

65

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

66

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

68

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

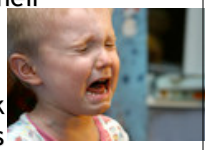
Soaring State Medicaid spending

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

72

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

73

Children in foster care

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

74

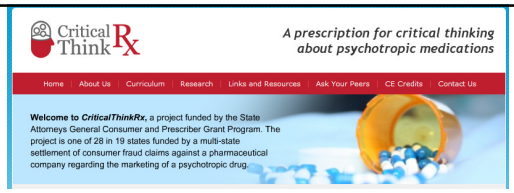
A Critical Curriculum on Psychotropic Medications

Module 2

The End

Critical Think Rx
www.CriticalThinkRx.org

75



A Critical Curriculum on Psychotropic Medications

A Critical Curriculum on Psychotropic Medications

Principal Investigator:
- David Cohen, Ph.D.

Research Coordinator:
- Inge Sengelmann, M.S.W.

Professional Consultants:
- David O. Antonuccio, Ph.D. (psychology)
- Kia J. Bentley, Ph.D. (social work)
- R. Elliott Ingersoll, Ph.D. (counseling & psychology)
- Stefan P. Kruszewski, M.D (psychiatry)
- Robert E. Rosen, J.D., Ph.D. (law)

Flash production and design:
- Sane Development, Inc., and Cooper Design, Inc.

Voice narration and Flash editing:
- Saul McClintock

www.CriticalThinkRx.org

CriticalThinkRx was made possible by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®

Module 3

The Drug Approval Process

All drugs intended for prescription in this country must be ***approved*** by the U.S. Food & Drug Administration (FDA)

There are huge financial and health stakes in drug approvals

7

The FDA was established by Congress in 1906 to enforce standards on purity of medicinal compounds

Today, the FDA's **Center for Drug Evaluation and Research (CDER)** oversees testing and approval of medications

8

The CDER conducts no drug tests of its own—drug firms (sponsors) pay for and conduct all tests

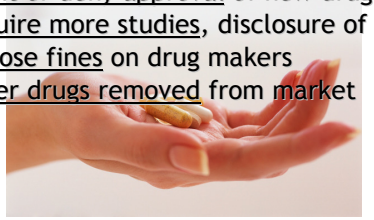
Based on data submitted by sponsors, CDER judges a drug's "efficacy" and "safety"

(Avorn, 2004)

9

Some FDA mandates

- ☑ grant permission to test drugs on humans
- ☑ review data on safety and efficacy
- ☑ set criteria for drug approval
- ☑ grant or deny approval of new drugs
- ☑ require more studies, disclosure of risks
- ☑ impose fines on drug makers
- ☑ order drugs removed from market



10

1938 Federal Food, Drug and Cosmetic Act:

Basis for FDA regulation of drugs

- Passed after 100 deaths in 1937 from a toxin in a batch of sulfa drugs

(Ballentine, no date)

11

FDA's drug testing rules tightened after **thalidomide**, prescribed to pregnant women in Europe in 1960, caused birth defects

12

As a result, 1962 amendments to *Food, Drug, & Cosmetic Act* of 1938 required sponsors to:

- ✓demonstrate efficacy in controlled trials
- ✓report serious adverse effects to FDA
- ✓list all known risks (on drug label and in drug ads to doctors)

13

More recent FDA laws have been controversial

Some scientists, advocacy groups, and legislators often accuse the FDA of treating industry, not the public, as its client

(Hawthorne, 2005; Sharav, 2007)

14

Prescription Drug User Fee Act, 1992

To speed up approval times, FDA collects fees from sponsors

User fees now make up over 50% of CDER's budget

(Avorn, 2007)

Impact of user fees

Since 1992 and the birth of user fees, the FDA has slashed its own testing laboratories and network of independent drug safety experts in favor of hiring more people to approve drugs for the pharmaceutical industry

(Harris, 2004)

16

"User fees have undoubtedly constrained the FDA's independence and influenced its decisions."

Marcia Angell, former editor, *New England Journal of Medicine*

FDA's User-Fee Habit

washingtonpost.com

By Cindy Skrzycki

Tuesday, April 3, 2007; D01

17

Draft Guidance on Direct-to-Consumer Advertising, 1997

After 15 years of industry pressure, the FDA allowed sponsors to advertise prescription drugs directly to consumers

- *DTCA is praised for providing drug information to consumers*
- *DTCA is criticized for increasing drug costs and promoting least effective drugs*

(Gellad & Lyles, 2007; Hollon, 1999)

18

Pediatric Research Equity Act, 2003 & *Pediatric Exclusivity Act*, 2004

FDA can request studies to be conducted on children, giving sponsors an extra 6 months of exclusive marketing for every drug studied

- *Acts are praised for stimulating research on drug effects and indications in children*
- *Acts are criticized for griving drug firms unneeded profits and using kids as guinea pigs for unnecessary drug testing*

19

Part B

FDA's Drug Approval Process

20

Few drugs make it to market

5,000 molecules screened in the lab = 1 obtains FDA approval as a medication

From start to finish, sponsor will spend $100 - $400 million to obtain FDA approval

(Goozner, 2004; Ng, 2004)

21

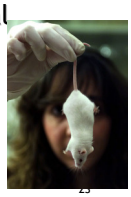
FDA requires that drugs intended for prescription undergo pre-clinical and clinical testing

22

Pre-clinical testing: 2-4 years

A promising molecule is tested in laboratory and on animals

- to establish its main biological activity and
- to rule out that it causes cancer, mutations, and birth defects



23

If drug remains promising after pre-clinical testing, sponsor may apply to start clinical trials on humans

Phase I trials: 1-2 years

Drug is given to 20-80 healthy volunteers to establish safe dosage levels, main adverse effects, "abuse potential"

25

Phase II trials: 2-3 years

Drug is given to 300-500 people with the illness for which the drug is supposed to be marketed

- The goal is to show promising therapeutic effects in order to justify the next phase of trials

26

Phase III trials: 2-4 years

In *randomized controlled trials* (RCTs), 1000-3000 diagnosed patients from many sites are *randomly* assigned to receive either the drug or a placebo

- Neither investigators nor patients are supposed to know who is receiving what ("double-blind")

27

FDA approval requires only 2 positive Phase III trials, even if more trials are negative

Positive trial: on a symptom rating scale, drug-treated group shows *statistically significant* advantage over placebo-treated group

(FDA, 1998)

A drug showing "efficacy"

✓has shown <5% chance of being worse than placebo

✓has *not* shown that it helps patient's condition to remit, or that it works better than another drug

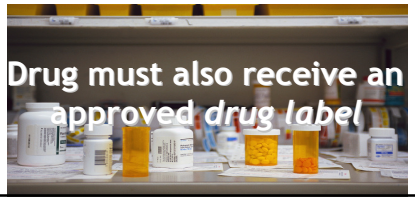
(Avorn, 2004)

29

With 2 positive Phase III trials, sponsor can make a **New Drug Application (NDA)**, requesting FDA approval to market drug for a specific indication and age group covered in the trials

30

FDA reviews pre-clinical and clinical studies and decides whether the drug's benefits outweigh its risks



31

Drug label

- Label summarizes information from pre-clinical and clinical trials
- Exact contents are negotiated in private by FDA and sponsor
- A shortened form must appear in all drug packaging and advertising, except broadcast
- Label is considered the authoritative drug information

32

Phase IV trials: Post-marketing surveillance

- As a condition for approval, FDA usually requests sponsor to conduct post-marketing trials
- These trials evaluate the drug under ordinary conditions, with ordinary patients
- Phase IV trials give more realistic view of drug's harms and benefits

33

Part C

Limitations of Clinical Trials

34

To discover new drugs for physical diseases

Researchers start with a *target* of drug action identified by understanding how a disease affects the body at the cellular/molecular levels

35

Not the same process for mental disorders…

- Cellular/molecular biology of mental disorders is *unknown*—drugs tested for these problems don't target known biological anomalies
- These drugs are selected based on their *effects on animal behavior* and *expected effects on people's complaints and behavior*

(Moncrieff & Cohen, 2005)

36

No biological markers exist

To repeat – mental and emotional problems ***are not*** equivalent to physical diseases

No cause has been shown to be exclusively biological

There is ***no biological marker*** for any DSM "primary mental disorder," including schizophrenia

(Charney et al., 2002)

37

Flaws in clinical trials

Analysts and critics have revealed many problems with the design and conduct of clinical trials of psychotropic drugs

Overall conclusion:

Clinical trials do not provide definite basis to determine benefits or risks of drugs

(Cohen, 2002; Safer, 2002)

38

If this or any other citation is to a book, PsychRights will probably purchase it. Just let me know.

Trials at all phases neglect most psychoactive effects

Practice: Trials focus on measuring narrowly selected complaints and behavior

Problem: Main psychological alterations produced by drugs remain unknown

(Jacobs & Cohen, 1999; Cohen & Jacobs, 2007)

39

Phase II & III trials are very short

Practice: Most last only 3-8 weeks, and up to 70% of subjects drop out before trial's end

Problem: Only some acute effects are detected—not those emerging over a longer time

(Cohen & Jacobs, 2007)

40

Subjects are wrongly assumed to have the "same" disorder

Practice: In a depression drug trial, a subject meeting DSM criteria for depression is eligible

Problem: 200 distinct symptom combinations = DSM diagnosis of depression

Also, subjects usually meet DSM criteria for *several* diagnoses

The "sameness" of subjects' problems—needed for a valid comparison of treatments—is not established

(Beutler & Malik, 2002; Cohen & Jacobs, 2007; Emslie et al. 2002)

41

Inert pills are used as comparisons

Practice: Drugs with psychoactive effects are compared to inert sugar pills

Problem: Placebos can be active (causing physical sensations) or inert (no sensations)

Because they are more powerful, active placebos are almost never used

Also, sponsors routinely screen and exclude placebo responders from clinical trials

(Abboud, 2004; Fisher & Greenberg, 2003)

42

The "blind" is often broken

Practice: It's assumed that patients and investigators are "blind" to treatment status

Problem: Obvious side effects in drug-treated subjects cue everyone about which treatment they're getting. This breaks the "blind"—making objective studies impossible

(Fisher & Greenberg, 1993)

43

pretty sure already have.

High doses of comparison drugs are used

Practice: When comparing a new drug to an older drug, very high doses of the older drug are used

Problem: The older drug produces more side effects, making the newer drug appear safer

(Geddes et al., 2000)

44

Outcomes are researcher-rated rather than patient-rated

Practice: Main outcome measures are rated by *researchers*

Problem: In all Phase III pediatric trials of antidepressants, *not one of 10* parent- or child-rated scales showed advantage for the drug

(Jureidini et al., 2004)

45

Adverse effects are carelessly investigated

Practice: Most trials elicit side effects by asking subjects general questions once a week, or waiting for subjects to report them *spontaneously*

Problem: This *underestimates* rates of side effects, especially psychological and behavioral ones, giving false impression of drug's safety

(Greenhill et al., 2003)

46

Adverse effects are mis-coded

Practice: Sponsor decides which effects qualify as "adverse drug events" and how to name them

Problem: Many adverse events are coded as something else, giving false impression of drug's safety

(Breggin, 2002)

47

Strattera pediatric trial:

Mis-coding why patients dropped out

What the researcher wrote	How the sponsor coded it	How it was re-coded after FDA reanalysis
"Parents felt 'too many side effects'; stopped drug early; Abdominal pain, nausea, anxiety"	*Protocol Violation*	*Adverse Event*
"Increasing behavior problems, worsening oppositional behavior; depression"	*Physician Decision*	*Adverse Event*

(Lillytrials.com, 2007)

48

Post-treatment ratings unreported

Practice: Sponsor gathers data for weeks *after* subjects stop treatment, but does not submit them to FDA

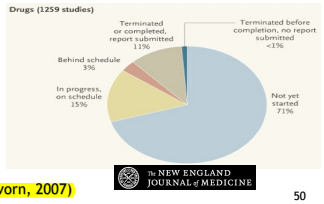
Problem: How subjects rate their treatment *once they're off drugs* may contradict their ratings while *on* drugs. This discrepancy is rarely discussed or explored

(Healy & Farqhar, 1998)

49

Post-marketing trials rarely conducted

As of late 2006, more than 70% of promised Phase IV trials had not yet started…



(Avorn, 2007)

50

The preceding limitations of clinical trials give clinicians and policymakers false ideas about how medications can help and how they can harm people

- FDA approval by itself does not guarantee that a drug is either *safe* or *efficacious* for its intended uses

(Strom, 2006)

51

The increasing involvement of industry in clinical trials has further muddled this worrisome situation

52

Part D

Blurring Science and Marketing

53

Huge payoffs can follow an FDA drug approval

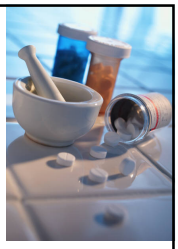
Zyprexa sales since 1996: ***$20 billion***

These create enormous incentives to turn clinical trials into marketing tools

(Smith, 2005)

For the FDA, a clinical trial is a limited test of the efficacy of a product

For the sponsor, it's a ticket to get its product past the FDA hurdle—and possibly to blockbuster status



(Smith, 2003)

55

How sponsors turn trials into marketing tools

- ☑ design studies solely to get positive results
- ☑ suppress and twist negative results
- ☑ publish positive results multiple times

(Quick, 2001)

56

The NEW ENGLAND JOURNAL of MEDICINE (2008)

Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

"According to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis showed that 51% were positive."

57

Contract Research Organizations (CROs)

To get drugs approved by the FDA, sponsors outsource clinical trials to CROs, a $15 billion/year business

These private firms make it easier to:

- Enroll thousands of subjects
- Conduct more multi-site trials
- Shield trials from public scrutiny

(Hunley, 2007)

58

Conflicts in research

"It's a house of cards built on a fundamental conflict of interest. The problem is that drug companies have inordinate influence over the evaluation of their own products. That, on the face of it, doesn't make sense."

- **Marcia Angell**, former editor, *New England Journal of Medicine*, author, *The Truth About the Drug Companies*

59

I have this book (if it can be found)

Funder's drugs come out ahead

In 90% of studies pitting one newer antipsychotic against another, the best drug was the study sponsor's drug

THE AMERICAN JOURNAL OF PSYCHIATRY

(Heres et al., 2006)

60

Independent studies don't favor newer drugs

NIMH's (CATIE) study compared 5 antipsychotics in largest schizophrenia trial. Older, cheaper drug worked as well (or as poorly)

- Regardless of drug, ¾ of patients stopped treatment because they did not improve or had intolerable side effects

The NEW ENGLAND JOURNAL of MEDICINE

(Lieberman et al., 2005)

61

The New York Times

November 22, 2002

Madison Ave. Has Growing Role In the Business of Drug Research

By MELODY PETERSEN

"You cannnot separate advertising and marketing from the science anymore."

- **Arnold S. Relman, MD**, Professor Emeritus, Harvard Medical School, and former editor, *New England Journal of Medicine*

THE WEEK

The Best of the U.S. and International Media

The Corruption of Medicine

Several top medical journals recently admitted that studies they published on new medications have been tainted by undisclosed financial ties between researchers and drug companies. Does Big Pharma have too much influence over drug research?

9/22/2006

63

Part E

Problems in Drug Safety After Marketing

64

Because of the limitations of clinical trials, detecting adverse effects from drugs falls to **post-marketing surveillance**, when drugs are commonly prescribed, and used for longer periods, in more natural conditions, by more varied patients

(Strom, 2006)

This is when most adverse effects, and a more accurate portrait of the drug's risk-benefit ratio, emerge

Yet such post-marketing monitoring also appears spotty

(Lasser et al., 2002)

66

Newer drugs more likely to have hidden risks

50% of warnings occur within 7 years of a drug's introduction

Half of the withdrawals occur within 2 years

(Lasser et al., 2002)

67

Black Box Warnings

If the adverse drug reaction is serious enough to require extraordinary monitoring or special screening, the FDA will ask the drug sponsor to insert a "*black box warning*" in all marketing and product information to alert clinicians and consumers of the nature of the risk

68

Safety questions are "answered" post-marketing

51% of drugs get label changes

20% of drugs get new black box warnings

3-4% of drugs are withdrawn

(Strom, 2006)

69

Former and current FDA officials, outside scientists, and advocates for patients say the FDA's efforts to monitor the ill effects of drugs on the market are insufficient

70

USA TODAY

Report: FDA so underfunded, consumers are put at risk

(December 3, 2007; http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm)

abc NEWS

FDA Is Broken, Endangers American Lives

Report Blames Congress for Cutting FDA's Budget

December 6, 2004

The New York Times

At F.D.A., Strong Drug Ties and Less Monitoring

Example: Prozac, 2004

Prozac was on the market for 17 years before FDA warned of increased suicidality

Sponsors of several SSRIs have been accused of not disclosing all the data from clinical trials

72

Example: Vioxx, 2004

Vioxx was taken by 20 million Americans before Merck withdrew it after links to heart attacks and strokes

Merck accused of not disclosing all the data from clinical trials

FDA Public Health Advisory: Safety of Vioxx

73

Serious Adverse Events (SAEs)

- Fatal or life-threatening, cause disability or require hospital stay

Only 1% to 10% of all drug-related SAEs are actually reported to the FDA through MedWatch

Medwatch The FDA Safety Information and Adverse Event Reporting Program

(Moore, Cohen & Furberg, 2007)

74

Thousands die annually

Reports to Medwatch of fatal drug reactions tripled between 1998-2005

- Over **80,000** deaths suspected from medications were reported by health professionals and others during that 7-year period

(Moore, Cohen & Furberg, 2007)

75

26,000 deaths suspected to be linked to 15 drugs, including:

3 antipsychotics and

1 antidepressant

Clozaril, Risperdal, Zyprexa, Paxil

(Moore, Cohen & Furberg, 2007)

76

Table 4. Most Frequent Suspect Drugs in Death and Serious Nonfatal Outcomes, 1998-2005

Drug Name	Rank/Deaths	Drug Class
Death outcome		
Oxycodone	1/5548	Opioid analgesic
Fentanyl	2/3545	Opioid analgesic
Clozapine	3/3277	Antipsychotic
Morphine	4/1616	Opioid analgesic
Acetaminophen	5/1393	Analgesic
Methadone	6/1258	Opioid analgesic
Infliximab	7/1228	DMARD
Interferon beta	8/1178	Immunomodulator
Risperidone	9/1093	Antipsychotic
Etanercept	10/1034	DMARD
Paclitaxel	11/1033	Antineoplastic
Acetaminophen-hydrocodone	12/1032	Combination analgesic
Olanzapine	13/1005	Antipsychotic
Rofecoxib	14/932	NSAID
Paroxetine	15/850	Antidepressant

77

(Moore, Cohen & Furberg, 2007)

Part F

Conclusions and Recommendations

78

FDA's independence in question

As a result of inordinately close ties to drugmakers, the FDA appears to have compromised its independence and its mandate to protect the public from dangerous products

79

Clinical trials provide skewed portrait of drug risks and benefits

Predictable limitations of trials suggest that their positive findings cannot generalize to real-life clinical conditions

Trials are especially poor at detecting adverse effects

80

Most psychological alterations produced by drugs are unstudied

Drugs' main psychological and behavioral effects can remain unknown even years after their approval by FDA and use by millions of people

Clinical trials ≠ objective evaluations of drug effects

Excessive involvement of sponsors in testing drugs may have tainted the research process, turning many clinical trials into "infomercials"

82

Conflicts of interest = suppression of negative trial findings

"Selective reporting of clinical trial results may have adverse consequences for researchers, study participants, health care professionals, and patients."

(Turner et al. 2008)

83

Need for skepticism and vigilance

Professionals should view announcements of clinical trial findings with skepticism and review them critically

84

Use new drugs cautiously

The first users of a newly marketed FDA-approved drug are the true research subjects

Public Citizen recommends waiting 7 years after marketing to use new drugs

"The public misunderstands drug safety, believing that a drug is safe at the time of marketing."

(Strom, 2006)

85

Your role in post-marketing surveillance?

Non-medical professionals and consumers can play an important role in *observing* and *reporting* adverse drug reactions to FDA, thus helping to create a more accurate portrait of medications and their impact on people's lives

86

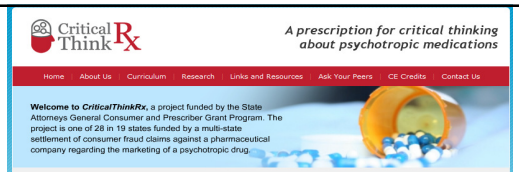
A Critical Curriculum on Psychotropic Medications

Module 3

The End

www.CriticalThinkRx.org

87



A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - David Cohen, Ph.D.
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
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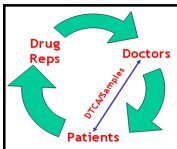
CriticalThinkRx **was made possible by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®**



Module 4

Pharmaceutical Industry Influences on Prescribing

Part A

Expanding Drug Markets

5

Pharmaceutical drugs = Big business

World sales:

$643 billion in 2006

$685 billion projected for 2008

(IMS Health, 2006, 2007; *Pharmaceutical Executive*, 2007; *Los Angeles Times*, 2007) 6

Brand-name drugs

Manufacturer holds an exclusive patent to market them for about 15 years
- 40% of prescription volume
- 90% of revenues

(IMS Health, 2007; *Pharmaceutical Executive*, 2007) 7

Generic drugs

Once patent on marketing a brand-name drug expires, drug becomes a "generic," and sells for much less, as other manufacturers may apply to market it

(IMS Health, 2007; *Pharmaceutical Executive*, 2007) 8

"Blockbuster" drugs

Generate more than $1 billion of revenue each year

Are heavily marketed, so their manufacturer can make profits during the marketing exclusivity period

7 of the top 10 companies have 1 psychotropic drug among their top 3 blockbusters

(*Pharmaceutical Marketing*, 2006) 9

Antidepressants, antipsychotics, anticonvulsants: among top 6 drug classes sold in U.S.

(*Pharmaceutical Executive*, 2007; IMS Health, 2006)

Growing consensus:

Psychotropics are not popular because they are particularly effective

…"medicalization" and "disease mongering" also stimulate drug use

11

"Medicalization"

- Defining or treating a problem as a ***medical*** disease, requiring ***medical*** treatments

(Conrad & Leiter, 2004; Mintzes, 2002) 12

"Disease mongering"

- Turning ordinary ailments into diseases
- Framing conditions as being severe and widespread
- Seeing mild symptoms as serious
- Seeing risks as diseases

(Moynihan, Health, & Henry, 2002; Moynihan, 2002)

13

Disorders Made to Order

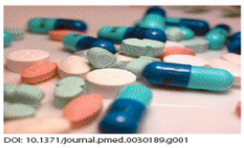
Pharmaceutical companies have come up with a new strategy to market their drugs: First go out and find a new mental illness, then push the pills to cure it.

Brendan I. Koerner
July/August 2002 Issue

MotherJones

Disease awareness campaigns turn healthy people into patients

Owen Dyer *London*



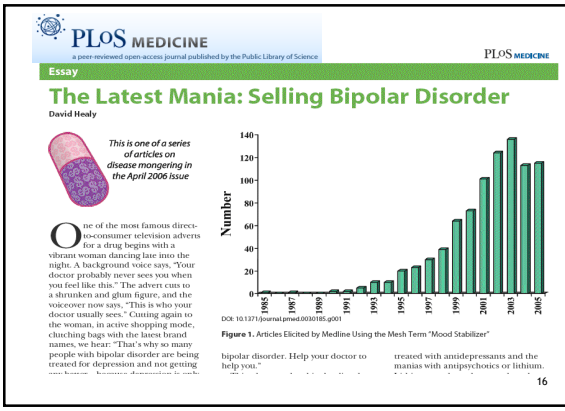
DOI: 10.1371/journal.pmed.0030189.g001

Pills are often marketed as a solution to human anxieties and dissatisfactions

14

Psychiatry by Prescription

Do psychotropic drugs blur the boundaries between illness and health?



16

Part B

Marketing Expands Drug Markets

17

Cost of marketing and promoting drugs in U.S.

Industry estimates: $29.9B

Independent estimates: $57.5B

The NEW ENGLAND JOURNAL of MEDICINE

(Donohue, Cevasco & Rosenthal, 2007)

PLoS MEDICINE

(Gagnon & Lexchin, 2008)

18

Drug company marketing targets *all players* in the health care system

19

It influences physicians to prescribe through:

Gifts:

- *free lunches*
- *drug samples*
- *continuing medical education*
- *payments* for lecturing, consulting and research

20

It influences physicians to prescribe by:

- ✓funding countless activities of professional organizations
- ✓drug advertising in professional journals
- ✓paying doctors to serve on "expert committees" that create and promote guidelines for drug treatments used by other doctors

21

It influences consumers to seek drugs through:

- ✓direct-to-consumer-advertising (DTCA)
- ✓"disease awareness" campaigns
- ✓funding "patient advocacy" groups
- ✓online medical information and promotions

22

It influences legislators and government agencies to approve drugs and create favorable conditions for drugmakers through:

- ✓lobbying at all levels of government
- ✓large donations to political parties
- ✓payment of "user fees" to the FDA

23

It influences experts to evaluate drugs positively by:

- ✓paying researchers to run clinical trials and develop treatment guidelines
- ✓signing "secrecy agreements" with researchers to conceal negative drug information
- ✓paying academics and researchers to lend their names to articles they have not written ("ghostwriting")

24

Drug Reps

25

100,000 drug reps in the United States

~ 1 for every 6 doctors

(Oldani, 2004; Greene, 2004; Fugh-Berman & Ahari, 2007)

26

Doctors who meet frequently with reps:

- ✓increase prescribing of newer, costlier drugs
- ✓reduce prescribing of generics
- ✓increase nonrational prescribing
- ✓use rep as main information source

(Dana & Loewenstein, 2003; Reist & VandeCreek, 2004, Schwartz et al. 2001; Wazana, 2000)

27

Reps know just which doctors to target and how

Health Information Organizations combine purchased pharmacy data, AMA physician data, and patient data to determine which drugs individual physicians prefer for which diagnoses and which patient groups

This *prescription tracking* is used to tailor marketing to physicians and evaluate effects of promotions on their prescribing behavior

(Fugh-Berman, 2008)

28

Gift-giving

Very effective, *even when doctors don't think so*

29

The Boston Globe

Does a drug firm's free lunch influence doctors?

By Scott Lassman | May 18, 2007

Physicians and the Pharmaceutical Industry

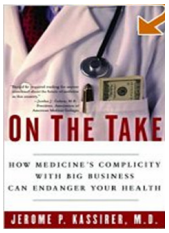
Is a Gift Ever Just a Gift?

JAMA

The Journal of the American Medical Association

30

Are doctors "on the take"?



31

The NEW ENGLAND JOURNAL of MEDICINE

A National Survey of Physician–Industry Relationships

Among a sample of 3,200 physicians:

- 83% received food at work
- 78% received drug samples
- 35% were reimbursed for CME
- 28% were paid to give lectures or recruit patients in trials

(Campbell et al., 2007)

32

The New York Times

Psychiatrists Top List in Drug Maker Gifts

By GARDINER HARRIS
Published: June 27, 2007

1997- 2005: drug companies paid Minnesota doctors $57 million

- **psychiatrists received $6.7 million**

(Ross et al., 2007; *The New York Times*, 2007)

33

1 in 3 Minnesota psychiatrists received money from drugmakers

"One in three Minnesota psychiatrists has received funding from drug manufacturers in the past five years, including seven past presidents of the Minnesota Psychiatric Society, two state drug policy advisers and 17 faculty psychiatrists at the University of Minnesota."

(Olson, 2007)

34

The New York Times
May 10, 2007

Psychiatrists, Children and Drug Industry's Role

By GARDINER HARRIS, BENEDICT CAREY and JANET ROBERTS

Psychiatrists receiving money from drug companies more likely to prescribe "off-label" antipsychotics to children

"Free" samples…

- ✓introduce drug into doctor's office
- ✓generate sales, influence brand choice
- ✓Mostly go to wealthy/insured patients
- ✓63% of total promotional spending

Return-on-investment:

$10 in sales for every $1 spent

(Adair & Holmgren, 2005; Backer et al. 2000; Chew et al. 2000; Cutrona et al. 2008; ugh-Berman & Ahari, 2007)

36

Small gifts are powerful

Studies suggest that ***the most powerful form of influence might be small gifts***

The more gifts a doctor received, the more he/she believed that they had no influence on prescribing

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 37

The "gift cycle"

A three-way exchange of gifts between doctors, drug reps, and patients

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 38

"Ask your doctor…"

39

1997: FDA allows full-scale, direct-to-consumer advertising (DTCA) of prescription drugs

- DTCA only allowed in the U. S. and New Zealand

(Gellad et al. 2007) 40

DTCA increases drug use by

- ✓encouraging people to visit doctor
- ✓encouraging patients to request advertised drugs
- ✓influencing doctor's behavior through patient requests

(Gellad et al., 2007; Donohue & Bernd, 2004; Wolfe, 2002; *Consumer Reports*, 2007) 41

DTCA increases spending by

stimulating sales of newer, costlier drugs above older generics

(Gellad et al., 2007; Donohue & Bernd, 2004) 42

Accuracy of DTC ads questioned

1995 to 2004: FDA sent 1,359 warning letters to drug companies for false or misleading advertising

Only 4 FDA staffers review thousands of ads

(Donohue et al., 2007; Zalesky, 2006)

43

Example: 2007 Geodon ad "false and misleading"

2007 FDA letter: maker exaggerated claims of efficacy and did not mention risks of neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes

GEODON "exaggerated claims, downplayed risks"

44

Industry funds "patient advocacy" groups

2005-2006: $29 million to 6 groups
- 7%-91% of the groups' budgets

Groups rarely disclose funding

Funds decline when drugmakers don't benefit

(*Philadelphia Inquirer*, 2006; *Los Angeles Times*, 2007)

45

- ***National Alliance on Mental Illness*** received $11.7 million from 18 drugs firms in three years
- ***Children and Adults with Attention Deficit/Hyperactivity Disorder*** is funded by Shire PLC, the #1 ADHD drugmaker
- ***Depression and Bipolar Support Alliance*** receives more than half its funding from drug firms

(*Philadelphia Inquirer*, 2006; *Los Angeles Times*, 2007)

46

NAMI, CHADD, and DPSA, among "patient advocacy" groups receiving most industry funding, promote view of distress as *chronic brain disease*, requiring latest drugs and neurobiological research

47

Continuing Medical Education

"Educating" to expand markets?

48

Medical Education Communication Companies (MECCs)

earned over $1 billion in 2004 to deliver industry-sponsored continuing medical education (CME)

(Relman, 2001; Elliott, 2004; Wazana, 2000)

49

Industry-sponsored CME highlights sponsor's drugs and is associated with increased prescriptions of those drugs

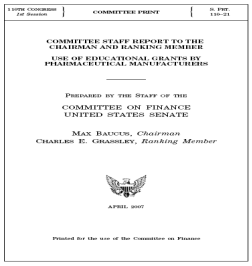
(Relman, 2001; Elliott, 2004; Wazana, 2000)

50

Concerns in U.S. Senate

APRIL 2007

Concern over drug firms' influence on CME, and its impact on off-label drug use



COMMITTEE STAFF REPORT TO THE CHAIRMAN AND RANKING MEMBER

USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS

PREPARED BY THE STAFF OF THE COMMITTEE ON FINANCE UNITED STATES SENATE

MAX BAUCUS, *Chairman*
CHARLES E. GRASSLEY, *Ranking Member*

APRIL 2007

(Report to Committee on Finance, US Senate, April 2007)

51

"Ghost" Marketing

Industry marketers and scientific journals

52

"Ghostwriting"

Pharmaceutical firms hire MECCs to write academic papers favorable to their products

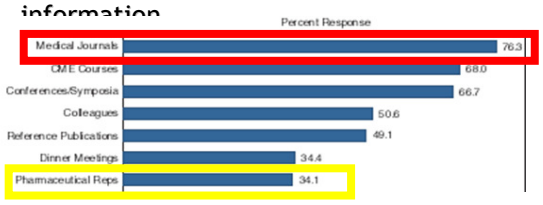
MECCs then hire academics to publish the articles under their name without disclosure about the true source

(Moffat & Elliott, 2007)

53

"Ghostwriting" works because…

~ 76% of doctors consider medical journals their most important source of information



(Source: www.RxPromoROI.org; Fugh-Berman et al. 2006)

54

Even without ghost-writing…

A drug firm may pay a journal $1 million for reprints, creating enormous incentive for the journal to publish a favorable article

- A former editor of *British Medical Journal* called journals "extensions of marketing arms" of drug firms and urged journals to *stop publishing all clinical trials*, and only evaluate them critically

(Moffat & Elliot, 2007; Smith, 2004; *The New York Times*, 2002)

55

56

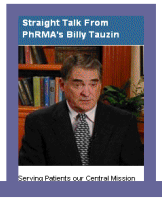
Pharmaceutical Researchers and Manufacturers of America (PhRMA) represents pharmaceutical and biotechnology companies in the U.S.

PhRMA
New Medicines. New Hope.

57

PhRMA hired hundreds of lobbyists to help pass the Medicare Part D bill in 2004

Originally estimated to cost taxpayers $534 billion, Medicare Part D forbids the government from negotiating drug prices



PhRMA head is Billy Tauzin, former Republican congressman from Louisiana

Drug industry lobbyists outnumber Congressmen 2:1

2006: Drug interests employed about **1,100** lobbyists, including **40** former members of Congress

CBS NEWS
Under The Influence
NEW YORK, April 1, 2007

(Center for Public Integrity, 2007; *CBS News/60 Minutes*, 2007)

59

Large investments in lobbying

2005 - 2006: $182 million spent on federal lobbying

2005 - 2006: $100 million spent on campaign contributions

Sales of top 20 lobbying spenders = 77% of the US drug market

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

60

Defending industry interests

Main goal in 2007:

- Oppose laws that would strengthen FDA's ability to monitor drug safety
- Fight bills that would allow Medicare to negotiate drug prices, which could reduce government drug spending by 60%

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

61

Part C

Conclusions and Recommendations

62

Conclusions

Industry promotion of expensive drugs permeates all phases of the life-cycle of drugs

Deceptive drug marketing is "pervasive, dangerous and primarily aimed at doctors"

63

Skepticism of industry grows

Previously "hidden" practices are increasingly exposed and scrutinized

Government hearings and legislative efforts highlight concerns over public health and public spending

64

Some doctors call for limits

Asking for stringent regulation to eliminate conflicts of interest:

- no gifts, no speaking at industry-sponsored CME, no ghostwriting, disclose research and consulting contracts, replace free samples with vo[illegible] patients

(Troyen et al., 2006; *Washington Post*, 2006)

Medical students take action

More Med Schools Show Pharma The Door

July 2nd, 2007 8:56 am By Ed Silverman

Last month, the American Medical Student Association ranked med schools based on their freebie policies, using a PharmFree scorecard. Since then, several schools reacted with embarrassment over their rankings.

- **Only 5 of 116 medical schools got an "A" for having a policy restricting drug industry access to students and faculty**

66

But medical schools lag behind

- The International Committee of Medical Journal Editors (ICMJE) requires full disclosure of drug companies' role in research
- But even major journals still can't ensure transparency
- A study of 108 medical schools' agreements to conduct research for drug firms found that ICMJE guidelines were rarely followed
- Researchers have little access to data or power over publishing

(Rivera & Cummings, 2002) (Schulman et al., 2002) 67

States attempt legislation and sue drug firms

Most states have introduced bills or resolutions aimed at marketing

Several states are suing drugmakers for off-label promotion of antipsychotics and for hiding drug risks (see Module 5)

(Reist & VandeCreek, 2004; Zalesky, 2006) 68

9 in 10 Americans favor reforms

Consumer Reports **survey finds strong backing for drug reforms**

As Congress prepares to vote on the most significant prescription drug safety legislation in 45 years, a new *Consumer Reports* poll finds that the American public strongly backs a number of reforms. Safety issues rose to the top, with 9 of every 10 Americans supporting reforms that would require warning labels and follow-up studies on drugs with safety problems, and public disclosure of all clinical drug trials. c

ConsumerReports (2007)

69

Recommended reforms to research

Create a public registry of all clinical trials

Fund clinical trials publicly, and cease drugmakers' ties to clinical research

Make *raw* clinical trial data accessible for independent analyses

(Antonuccio & Healy, 2008; NJPIRG Law & Policy Center, 2006) 70

Researchers' commitment?

Because research participants expose themselves to risk, information derived from them should not be misused, suppressed, or distorted

Researchers should promise to make *all raw research data available publicly*, or forego approval from Institutional Review Boards

(Antonuccio & Healy, 2008) 71

Teach prescribers, academics and consumers to:

✓critically evaluate drug marketing

✓rely on independent sources of information

✓implement best practices to minimize industry influence in schools, professional organizations, and mental health providers

(NJPIRG Law & Policy Center, 2006) 72

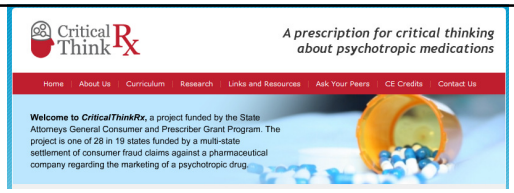
A Critical Curriculum
on Psychotropic Medications

Module 4

The End

www.CriticalThinkRx.org

73



A Critical Curriculum on Psychotropic Medications

Critical Think Rx

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Critical Think Rx
www.CriticalThinkRx.org

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Module 5

Specific Drug Classes: Use, Efficacy, Safety

4

Part A

Overview: Psychotropic Drugs Used with Children and Adolescents

5

"Psychotropic" or "psychoactive" drugs

affect the central nervous system and alter feeling, thinking, and behaving

6

"Approved use" means…

FDA has reviewed limited data on safety and efficacy for one indication, usually in one population

A "label" for the drug is established to guide dosage and describe observed side effects

FDA Drug Approvals List

7

Fewer than 10% of psychotropic drugs are FDA-approved for any psychiatric use in children

8

Focus: Stimulants

9

Stimulants approved by FDA for pediatric use

Brand Name	Generic Name	Psychiatric Indication	Age group
Adderall, Adderall XR, Dexedrine, Dextrostat	amphetamine, dextroamphetamine	ADHD, narcolepsy	3 +
Concerta, Ritalin, Daytrana, Metadate Focalin, Focalin XR	methylphenidate, dexamethylphenidate	ADHD	6 +
Vyvanse	lisdextroamphetamine		
Strattera (*not considered a stimulant*)	atomoxetine		

10

Stimulants act quickly

Stimulants change behavior *within one hour* in 60-70% of children who take them

11

Long-term evidence of benefits doubtful

APA Report noted lack of data supporting long-term efficacy or safety

- Stimulants show minimal efficacy in general life domains of the child, including social and academic success

(APA Working Group on Psychoactive Medications for Children and Adolescents, 2006; MTA Cooperative Group, 2004)

12

Short-term desirable effects of stimulants at usual doses

- ✓Increase alertness and wakefulness
- ✓Induce sense of well-being (euphoria)
- ✓Improve accuracy on brief physical and mental tasks

(Bezchlibnyk-Butler & Jeffries, 2005)

Effects misconstrued as therapeutic in children

- ✓Increased repetitive, persistent behavior
- ✓Decreased exploration and social behavior
- ✓Increased compliance

(Breggin, 1998)

14

In Module 5 references, but couldn't find in big one

Undesirable *behavioral* effects of stimulants

- Nervousness, restlessness
- Insomnia
- Agitation
- Depression, "zombie" look
- Irritability, Aggression
- Psychological dependence
- Mania, Psychosis

(Bezchlibnyk-Butler & Jeffries, 2005)

15

Undesirable *physical* effects of stimulants

- Increased blood pressure
- Dizziness, headaches
- Palpitations
- Stomach cramps, nausea
- Apetite/weight loss
- Stunted growth
- Cardiac arrest

(Bezchlibnyk-Butler & Jeffries, 2005)

16

Stunted growth

Decreases in growth averaging ¾" and 6 lbs. without evidence of rebound 3 years after stopping treatment

(Swanson et al., 2007)

17

Emergency room visits

2,500 children visited ERs in 2004 after taking stimulants for ADHD, most due to accidental overdoses

- 1 in 4 children had heart or blood pressure symptoms including palpitations, chest pain or fainting

CDC

(Waters, 2007)

18

2006: FDA warning on stimulants

- ✓increased risk of sudden death in patients with heart problems
- ✓increased aggression, mania and/or psychotic symptoms (including hallucinations)

The New York Times

August 22, 2006

F.D.A. Strengthens Warnings on Stimulants

19

Definite risk of tolerance and dependence

Stimulants prescribed to children are Drug Enforcement Administration (DEA) "Schedule II Drugs," indicating a high risk of tolerance and dependence

RITALIN LA® is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep RITALIN LA® in a safe place to prevent misuse and abuse. Selling or giving away RITALIN LA® may harm others, and is against the law.

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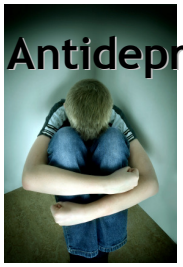
Focus: Antidepressants



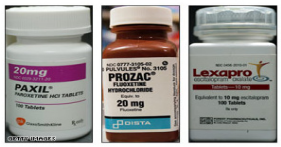
21

FDA-approved antidepressants for pediatric use

Brand Name	Generic Name	Psychiatric Indication	Age group
Sinequan	doxepin	OCD	12+
Anafranil	clomipramine		10+
Luvox	fluvoxamine		8 +
Zoloft	sertraline		6 +
Tofranil	imipramine		
Prozac	fluoxetine	Depression, OCD	7 +

22

CDC: Antidepressants most prescribed drugs in U.S.



Antidepressants such as Paxil, Prozac and Lexapro are among America's most-prescribed drugs.

CNN.com /health 2007

23

But are they effective?

Meta-analyses of drug vs. placebo studies show 75-82% of the response was duplicated by placebo

- 57% of studies submitted to FDA failed to show a difference between drug and placebo

(Moncrieff et al., 2004; Kirsch et al., 2002; Kirsch & Sapirstein, 1998)

24

Unimpressive evidence from FDA's complete adult database

"[I]n 189 trials of 53,048 adult subjects with psychiatric disorders … Approximately 50% of subjects who received active drug and 40% of subjects who received placebo were designated as responders."

(Stone & Jones, 2006)

The entire scientific case for antidepressants rests on this 10% difference—which may result from biases in the conduct of clinical trials

25

FDA analysis of pediatric trials concurs

Only 3 of 15 published and unpublished randomized controlled trials show SSRIs as more effective than placebo in depressed children

None of the studies found drugs better on client- or parent- rated measures

(Laughren, 2004)

26

No evidence that older antidepressants (tricyclics or MAO inhibitors) have any efficacy with depressed youths

(Somers-Flanagan & Somers-Flanagan, 1996)

27

Short-term desirable effects at usual doses

- ✓Increased physical activity
- ✓Elevated mood
- ✓Decreased expressions of distress such as crying, hopelessness
- ✓Improved sleep and appetite

(Bezchlibnyk-Butler & Jeffries, 2005)

28

Undesirable *behavioral* effects of antidepressants

- Anxiety, nervousness
- Agitation, irritability
- Mood swings, mania
- Aggressiveness
- Thoughts of suicide
- Attempted or actual suicide

(Antonuccio et al., 1999; Preda et al., 2001; Healy, 2003)

29

Undesirable *physical* effects of antidepressants

- Gastrointestinal distress (nausea, vomiting, stomach pain, constipation, diarrhea)
- Sexual problems (loss of libido, anorgasmia, erectile dysfunction)
- Sleep disruption (insomnia, hypersomnia)
- Urinary retention
- Blurred vision
- Weight gain
- Headaches, dizziness

(Antonuccio et al., 1999; Preda et al., 2001; Healy, 2003)

30

Six clusters of withdrawal effects likely upon abrupt discontinuation of SSRI antidepressants

1. Neurosensory (vertigo, tingling & burning)
2. Neuromotor (tremor, spasms, visual changes)
3. Gastrointestinal (nausea, vomiting, diarrhea, weight loss)
4. Neuropsychiatric (anxiety, depression, crying spells, irritability, suicidal thinking)
5. Vasomotor (heavy sweating, flushing)
6. Other (insomnia, vivid dreaming, fatigue)

(Schatzberg et al., 2006)

31

Antidepressants double risk of suicidality

U.S. Food and Drug Administration

2005: FDA issues "black box" warning of "Suicidality in Children and Adolescents":

- *"Antidepressants increase the risk of suicidal thinking and behavior (suicidality)"*
- *(22 RCTs testing 9 antidepressants: **2.3%** rate of serious suicidal events among drug-treated children, vs. **1.2%** among placebo treated—no completed suicides)*

32

"Activation" syndrome: A more common risk

FDA also warns of ***increased agitation, irritability, aggression, worsening anxiety, severe restlessness, and other unusual behaviors*** in youth treated with antidepressants

(Breggin, 2006)

33

Concern over "prescription cascade"

Continued exposure to the drug can lead to effects misinterpreted as psychiatric symptoms (such as mania), leading to increases in dosage or additional drugs—when reducing or stopping the drug would relieve the patient's discomfort

(Breggin, 2006)

34

Focus: Anticonvulsant Drugs

35

Anticonvulsants on U.S. market (antiepileptics, antiseizure drugs)

Brand Name	Generic Name	Yr of intro
Tegretol, Equetro	carbamazepine	1968, 2004
Neurontin	gabapentin	1993
Lamictal	lamotrigine	1994
Depakene, Depakote	valproate	1995
Topamax	topiramate	1997
Trileptal	oxcarbazepine	2000

36

Anticonvulsants FDA-approved for pediatric seizure disorders

Brand Name	Generic Name	Approved Indications	Age
Tegretol, Equetro	carbamazepine	NO PSYCHIATRIC INDICATIONS	Any
Gabitril	iagabine		12 +
Depakote Depakene	divalproex sodium, valproate		10 +
Topamax	topiramate		
Neurontin	gabapentin		3 +
Lamictal	lamotrigine		2 +
Trileptal	oxcarbazepine		

37

Anticonvulsants widely promoted as "mood stabilizers"

Use started in 1980s-1990s due to dissatisfaction with lithium and antipsychotics in treatment of Bipolar Disorder

Use spread rapidly with the promotion of "mood stabilizer" expression and of Bipolar Disorder diagnosis in children

(Healy, 2006)

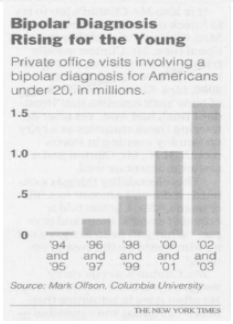
38

39

The New York Times

Bipolar Illness Soars as a Diagnosis for the Young

40-fold increase in less than a decade



(Moreno et al., 2007)

40

Polypharmacy without psychotherapy

More than 90% of children diagnosed with Bipolar Disorder received more than 1 psychoactive drug

Less than 40% received psychotherapy

(Moreno et al., 2007)

41

Scant empirical support

No studies confirm the efficacy and safety of anticonvulsants to treat Bipolar Disorder in children and adolescents

*"Despite the frequent use of antiepileptic drugs in the treatment of **juvenile bipolar disorder**, migraine, and neuropathic pain, the data are insufficient to make recommendations regarding the efficacy of antiepileptics in these conditions in children and adolescents."* *(Golden et al., 2006)*

(Kowatch et al., 2000, 2005; National Institute of Mental Health, 2000; Ryan, Bhatara & Perel, 1999)

42

Most trials are open, small, and show limited response in youth

Half of all participants in an open trial of lithium, divalproex, or carbamezepine did not respond to treatment

- 58% received *at least one* mood stabilizer *plus* a stimulant, an atypical antipsychotic, or an antidepressant

(Lopez-Larson & Frazier, 2006)

43

Desired behavioral effects of anticonvulsants

✓Reduce aggression and impulsivity

✓Calm restlessness and excitability

(Bezchlibnyk-Butler & Jeffries, 2005)

44

U.S. Food and Drug Administration

2008: FDA warns anticonvulsants *double risk* of suicidal behavior or ideation

Risk is highest in treatment of epilepsy—which rules out psychiatric status as confounding variable

45

Undesired *behavioral* effects of anticonvulsants

- Depression, sedation
- Hostility and irritability
- Anxiety, nervousness
- Hyperactivity
- Abnormal thinking
- Confusion and amnesia
- Slurred speech
- Sedation, sleepiness

(Bezchlibnyk-Butler & Jeffries, 2005)

46

Undesired *physical* effects of anticonvulsants

- Nausea and dizziness
- Vomiting and abdominal pain
- Headaches and tremors
- Fatal skin rashes
- Hypothyroid
- Blood disorders
- Pancreatitis, liver disease
- Birth defects and menstrual irregularities
- Withdrawal seizures

(Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al., 2003)

47

Birth defects of concern given new patient profiles

Anticonvulsants cross placenta and increase the risk of fetal malformations and cognitive impairments in children exposed in utero

- *Highest rates for valproate and carbamazepine*

(Adab et al., 2006)

FDA black-box warnings

Depakote	Liver toxicity (particularly for under 2 yrs of age); birth defects; pancreatitis
Tegretol	Aplastic anemia and agranulycytosis (severe reduction in white blood cells)
Lamictal	Serious rash requiring hospitalization; Stevens-Johnson Syndrome for under 16 yrs of age (fatal sores on mucuous membranes of mouth, nose, eyes and genitals)
All anticonvulsants	Suicidal ideation and behavior

49

50

"Atypical" (newer, 2nd generation) antipsychotics on U.S. market

Brand Name	Generic Name	Yr of intro
Clozaril	clozapine	1989
Risperdal	risperidone	1994
Zyprexa	olanzapine	1996
Seroquel	quetiapine	1997
Geodon	ziprasidone	2001
Abilify	aripriprazole	2002
Invega	paliperidone	2007

51

FDA-approved psychiatric indications of atypicals

Risperdal	Autism, bipolar mania, schizophrenia	5 +
Abilify	Schizophrenia	10+
Clozaril	Treatment resistant schizophrenia	Adults only
Zyprexa	Bipolar mania, schizophrenia	
Seroquel		
Geodon		
Symbyax		
Invega		

52

FDA-approved psychiatric indications of typicals for children

Brand Name	Generic Name	Psychiatric Indication	Age
Orap	pimozide	Tourette's Disorder (for Haldol non-responders)	12 +
Haldol	haloperidol	Schizophrenia, Tourette's Disorder	3 +
Mellaril	thioridazine	Schizophrenia	2 +

Typicals make up less than 5% of FL Medicaid prescriptions of antipsychotics

53

"Typical" & "Atypical" antipsychotics

Since 1950s, antipsychotics were used to treat psychoses, despite high toxicity and limited effectiveness

Newer, expensive "atypical" antipsychotics were heavily promoted in the 1990s as safer and more effective

54

Yet, newer no better than older…

The NEW ENGLAND JOURNAL of MEDICINE

2005: largest-ever schizophrenia treatment study finds atypicals neither more effective *nor* better tolerated than older drug

- 75% of patients quit either drugs within 18 months due to inefficacy or intolerable side effects

(Lieberman et al., 2005)

55

Non-psychotic diagnoses in children treated with atypicals

Diagnosis	% of Florida Medicaid children on antipsychotics (2006)
ADHD / Conduct Disorder	48
Nonpsychiatric, Anxiety, Other Psychiatric	27
Bipolar / Depression	13
Schizophrenia / Psychosis	8
Austism / Mental Retardation	4

St. Petersburg Times (2007)

56

Assuming this is the CATIE study, I have it.

"Aggression" said to account for most of the antipsychotic prescribing in children and adolescents

(Patel et al., 2005)

57

But do antipsychotics effectively control aggression?

The latest randomized-controlled trial found ***placebo more effective*** than either a typical (haloperidol) or atypical (risperidone) antipsychotic to reduce aggression in patients with intellectual disability

Trial had no drug company sponsorship

(Tyrer et al., 2008)

58

"Antipsychotic drugs should no longer be regarded as acceptable routine treatment for aggressive behavior in people with intellectual disability."

(Tyrer et al., 2008)

59

Few pediatric clinical trials of atypicals for *any* indication

As of 2006, only a few studies of direct AAP comparisons with placebo

Most studies are short-term (3-6 weeks) and results favor the funder's drugs

(McDonagh et al., 2006)

60

"There are no studies that have shown (atypicals) are safe, or for that matter, that they are effective for children…The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness."

Ronald Brown, Chair,
2006 American Psychological Association
Task Force on Psychotropic Drug Use in Children

St Petersburg Times (2007)

61

Dopamine-blocking action of all antipsychotics explains

- ✓indifference, sedation, drowsiness, apathy
- ✓reduced spontaneity and affect
- ✓reduced ability to monitor one's state
- ✓increased abnormal movements
- ✓cognitive and motor impairments
- ✓confusion and memory problems
- ✓depression, mood swings, agitation

(Bezchlibnyk-Butler & Jeffries, 2005)

62

Desirable effects of antipsychotics at usual doses

- ✓suppress psychotic symptoms (delusions, hallucinations, agitation)
- ✓suppress manic symptoms (euphoria, expansiveness, irritability)

(Bezchlibnyk-Butler & Jeffries, 2005)

63

Effects misconstrued as therapeutic

- ✓increased indifference
- ✓reduced spontaneity and affect
- ✓reduced ability to monitor one's state
- ✓increased compliance with social norms

(Bezchlibnyk-Butler & Jeffries, 2005)

64

Undesirable *behavioral* effects of antipsychotics

- Cognitive and motor impairments
- Sedation, drowsiness
- Confusion and memory problems
- Anxiety
- Depression, mood swings
- Abnormal thinking
- Hostility, aggression

(Bezchlibnyk-Butler & Jeffries, 2005)

65

Undesirable *physical* effects of antipsychotics

- Weight gain, high blood sugar
- Abnormal movements (all body parts)
- Diabetes
- Cardiac problems
- Liver problems, jaundice
- Neuroleptic malignant syndrome
- Death

(Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al., 2003; Meyer, 2001)

66

Hormonal dysfunctions

Elevated prolactin levels cause:

- ✓sexual and menstrual disturbances
- ✓infertility
- ✓decreased bone density

(Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006; Patel et al., 2005)

67

Extrapyramidal symptoms (abnormal movements)

Akathisia: inner distress, rocking, pacing, agitation

Dystonia: sudden, bizarre muscle spasms

Dyskinesia: rhythmic movements of face, mouth and tongue, sometimes of hands and feet

Parkinsonism: rigid muscles, loss of facial expression, unsteady gait, drooling

(Campbell, Rapaport & Simpson, 1999)

68

Tardive dyskinesia risk highest for typical antipsychotics

Long-lasting abnormal movements affect 12% to 35% of children who receive typical antipsychotics for more than 3 months

(Campbell, Rapaport & Simpson, 1999)

69

Weight gain and diabetes

50% of patients on antipsychotics gain 20% of their weight (primarily as fat)

Weight gain linked to "metabolic syndrome"

3 Schizophrenia Drugs May Raise Diabetes Risk, Study Says

By ERICA GOODE
Published: August 25, 2003

The New York Times

(Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006; Patel et al., 2005)

70

Neuroleptic malignant syndrome

Can occur with any antipsychotic agent, at any dose, at any time

Symptoms: extreme muscular rigidity, high fever, & altered consciousness

1-2% rate per year

Fatal if untreated

(Bezchlibnyk-Butler & Jeffries, 2005; Silva et al., 1999)

71

3 atypicals suspected in nearly 4,500 deaths reported to FDA, 1998-2005

Clozaril:	3,277 deaths
Risperdal:	1,093 deaths
Zyprexa:	1,005 deaths

(Moore, Cohen & Furberg, 2007)

72

FDA "black-box" warnings

All atypicals	Increased mortality in frail elderly
Clozaril	Serious risk of agranulocytosis (severe drop in white blood cells), seizures, myocarditis, and other cardiovascular and respiratory effects
Seroquel	Risk of suicidality in children and adolescents

73

"For many adults, and a small number of children, these agents can be an important component of treatment. However, it's so rare to find an example where evidence-based alternatives were exhausted prior to starting an atypical antipsychotic in a child that I have not found one yet in three years of searching."

Mark E. Helm, MD, MBA
Medical Director, Evidence-Based Prescription Drug Program
University of Arkansas Medical Sciences
College of Pharmacy, 2007

74

Part B

Lawsuits against drug makers shed light on illegal promotion and serious risks

The New York Times
December 18, 2006

Drug Files Show Maker Promoted Unapproved Use

By ALEX BERENSON

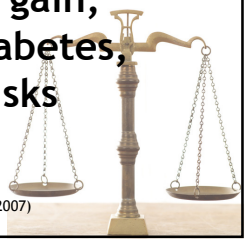
75

States sue drug makers for illegal marketing of unapproved uses

to recover money states paid to purchase atypical antipsychotics and the costs of medical care for the people injured by these drugs

(Pringle, 2007; Kesselheim & Avorn, 2007)

Patients sue, charging that drug makers did not adequately warn about severe weight gain, pancreatitis, diabetes, and other risks



(Pringle, 2007; Kesselheim & Avorn, 2007)

The New York Times

January 5, 2007

Lilly Settles With 18,000 Over Zyprexa

By ALEX BERENSON

78

Zyprexa lawsuits

2007: Several states sue Eli Lilly for downplaying or hiding data linking use of the drug to weight gain and hyperglycemia

- *Most of those states' Medicaid spending on antipsychotics is for Zyprexa*

79

2007: Zyprexa settlements top $1.2 billion, *so far*

Eli Lilly has paid more than **$1.2 billion** to settle 30,000+ Zyprexa lawsuits

- The settlements required data on rates of adverse effects be kept *secret*

(Berenson, 2008)

80

2008: Feds, Eli Lilly negotiate $1 billion Zyprexa fine

If a deal is reached, it would be the largest fine ever paid by a drug company for breaking the federal laws governing how drugmakers can promote their medicines

The New York Times
Thursday, February 7, 2008

Lilly Considers $1 Billion Fine To Settle Case

81

Department of Justice

FOR IMMEDIATE RELEASE
FRIDAY, SEPTEMBER 28, 2007
WWW.USDOJ.GOV

2007: Bristol-Myers Squibb pays $515 million over illegal marketing and pricing of Abilify, Serzone, other drugs

82

Litigation has

- ☑ exposed shady practices of pharmaceutical manufacturers
- ☑ uncovered previously hidden data about adverse events
- ☑ helped doctors reassess risks and benefits of some drugs and think critically about the available "evidence"

(Kesselheim & Avorn, 2007)

83

Part C

Conclusions and Recommendations

84

Evidence "poor" for the use of psychotropics in children

- *Little or no evidence of efficacy and safety* of long-term use of these drugs in children
- *Clear evidence of harm* and risk of serious adverse events, including death
- *Risk-benefit ratio especially poor* for antidepressants, anticonvulsants, and antipsychotics

85

Need to rethink risk-benefit ratio

Risks for adverse events, including death, increase with the number of concomitant drugs administered

Risks for adverse events are higher in children, who are receiving adjusted adult dosages of drugs rarely studied in children

(Brown & Sammons, 2002; Riddle, Kastelic & Frosch, 2001; Vitiello, 2001) 86

Side effects leading to multiple medications?

After initial medication, side effects may be viewed as mental disorders and drugged, in a "prescribing cascade" of polypharmacy that keeps children at risk with no sign of behavioral improvement

87

Available evidence does not justify use of psychotropic drugs as **first-line** treatments for children and adolescents

Reassess all cases?

Given known risks and dearth of valid studies showing benefits, cases of children receiving psychiatric medications should be reassessed

Children are involuntary patients. To support continuing psychotropic drug treatment, ***rock-solid*** rationale should be provided in every single case

89

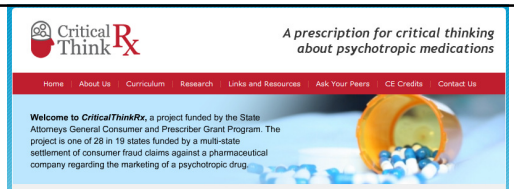
A Critical Curriculum on Psychotropic Medications

Module 5

The End

www.CriticalThinkRx.org

90



A Critical Curriculum on Psychotropic Medications

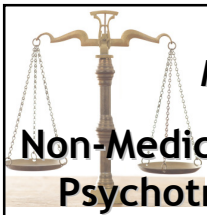
Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - David Cohen, Ph.D.
- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
www.CriticalThinkRx.org

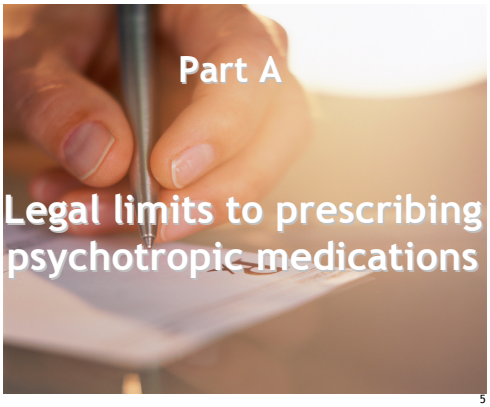
CriticalThinkRx was made possible by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin®



Module 6

Non-Medical Professionals and Psychotropic Medications:

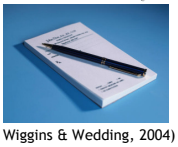
Legal, Ethical and Training Issues



5

Who can prescribe?

Most states grant full or partial prescriptive authority to licensed **physicians, dentists, advanced nurse practitioners, pharmacists, podiatrists,** and **optometrists**



(NASW, 2005;Norfleet, 2002; Wiggins & Wedding, 2004)

6

Who cannot prescribe?

Social workers, mental health counselors, and most psychologists are not authorized to **prescribe, dispense, or administer** any medication

(NASW, 2005;Norfleet, 2002; Wiggins & Wedding, 2004)

7

Discussing *any and all* medication issues with clients is *OK*

For example, Florida and California *do not* prohibit non-medical professionals to discuss any medication issue with clients

A review of case law indicates that this could not be construed as practicing medicine without a license

(Cohen, 2007; Ingersoll, Bauer, & Burns, 2004; Littrell, 2003; Litrell & Ashford,[8]1995)

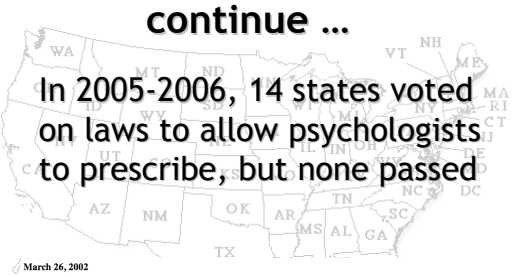
Psychologists have gained limited authority to prescribe in 2 states and 1 U.S. territory

New Mexico (2002)
Louisiana (2004)
Guam (1998)

Specially-trained Department of Defense psychologists also may prescribe

9

Psychologists' efforts continue …



In 2005-2006, 14 states voted on laws to allow psychologists to prescribe, but none passed

March 26, 2002

Psychologists Get Prescription Pads And Furor Erupts

The New York Times

(Goode, 2002; Long, 2005; McGrath et al., 2004; Norfleet, 2002)

Issue is debated…

- Who needs psychologists to prescribe?
- What special training is needed?
- Is it simply about more money?
- Is psychology selling its soul for a mess of (pharmaceutical) pottage?

but the discussion has shifted from"Should psychologists prescribe?" to "When will they prescribe and how should they prepare?"

(Heiby, 2002; Kenkel, 2006; Sanua, 2003)

11

Are counselors next?

Among members of the American Mental Health Counselors Association,

- 41% would like to pursue independent prescription privileges
- 64% would like to obtain dependent privileges
- > 90% want psychopharmacology training in their curriculum

(Scovel, Christensen, & England, 2002)

How about social workers?

Survey of a national sample of 176 practitioners in late 1990s

- 52% opposed to obtaining prescription privileges
- 19% in favor
- the rest said "maybe" or did not respond

(Piotrowski & Doelker, 2001)

Professional associations' stances

American Psychological Association supports psychologists' efforts to gain prescriptive authority

National Association of Social Workers views prescription as beyond the scope of the profession

American Psychiatric Association actively opposes all such initiatives from non MDs

Part B

Ethical and Legal Issues:

Competence and Training
Informed Consent
Confidentiality

15

Professional *competence* is a core principle in the codes of ethics and standards for practice of various helping professions

(ACA, AMHCA, APA, NASW)

16

To maintain competence, professional codes recommend

Education and training
Consultation
Supervision
Continuing education

(ACA, AMHCA, APA, NASW)

17

Competence requires

✓knowledge of valid information relevant to practice
✓regular critical review of literature and emerging information
✓participation in relevant and unbiased CE

(ACA, AMHCA, APA, NASW)

18

No specific standards address working with clients and others around medication-related issues

In the absence of standards, Codes advise exercising careful judgment and taking responsible steps to ensure competence and protect clients from harm

(ACA, AMHCA, APA, NASW)

19

Knowledge = Competence
Training = Knowledge

Without knowledge about drugs, counselors, psychologists and social workers are ill-prepared to meet their clients' needs

Psychopharmacology should be part of training for non-medical practitioners

(Barnett & Neel, 2000; Bauer, Ingersoll & Burns, 2004; Bentley, 2005; Carlson, Thaler & Hirsch, 2005; Dziegielewski & Leon, 1998; Farmer, Walsh & Dziegielewski, 1998; Ingersoll, 2000)

20

Knowledge increases confidence and empowers non-medical professionals to participate fully in multidisciplinary environments

(Farmer, Walsh & Bentley, 2006; Dziegelewski, 1998; Littrell, 2003)

Education vs. indoctrination

Students & practitioners must be *educated* rather than *indoctrinated*, and should be exposed to controversies, uncertainties in knowledge, and well-argued alternatives to popular views

(Dziegelewski, 1998; Gomory & Lacasse, 2001; Litrell, 2003)

22

Special guidelines needed

Use of polypharmacy

Integrating psychosocial and biological therapies

Specific groups, such as children, older persons, pregnant women

Ethical and critical thinking skills in the age of "Big Pharma"

(Buelow & Chafetz, 1996; Chafetz & Buelow, 1994; Dunivin & Southwell, 2000; Freimuth, 1996; Levant & Shapiro, 2002; Smyer et al., 1993)

23

24

Why obtain informed consent?

Informed consent is the bedrock of professional practice in a free society

- It promotes the **right to self determination, prevents harm** and provides for the **client's best interest**

(Cohen & Jacobs, 2000; Strom-Gottfried, 1998; Littrell & Ashford, 1995; Littrell, 2003)

25

What is informed consent?

A systematic ***process*** intended to guarantee the client's right to choose, to privacy and to safety

(Dell et al 2008; Littrell & Ashford, 1995; Litrell, 2003; Strom-Gottfried, 1998)

What is *not* informed consent?

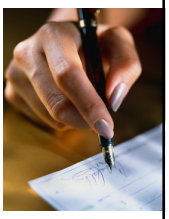
Having a client sign-off on services without a clear understanding of the information, including uncertainties about the treatment

(Cohen & Jacobs, 2000; Littrell & Ashford, 1995; Reamer, 2003) 27

Validity of consent forms

Blanket consent forms lack specificity and have been challenged in court

Signing a blank consent form to be completed later *is not* valid consent



(Littrell & Ashford, 1995; Reamer, 2003; Strom-Gottfried, 1998) 28

Standards for valid consent

1. Avoid coercion and undue influence
2. Assess client competence to consent
3. Specify procedures or actions in the form
4. Inform clients of the right to refuse or withdraw consent
5. Provide adequate information on risks, benefits **and** alternatives to treatment

(Reamer, 2003) 29

Coercion or undue influence

Practitioners who *want* clients to agree to treatments or procedures may be exercising undue influence and will jeopardize validity of their consent

(Dell et al 2008; Littrell & Ashford, 1995; Reamer, 2003; Strom-Gottfried, 1998) 30

"Adequate" information

- ✓Critical findings on usefulness, ineffectiveness and **reported information on harm**
- ✓Description of the hoped-for benefits and **how success will be evaluated**
- ✓**Alternatives** to treatment being proposed
- ✓Costs of treatment

(Littrell, 2003; Littrell & Ashford, 1995; Strom-Gottfried, 1998) 31

Knowledge of alternatives

Lack of knowledge about the alternatives to proposed treatment **invalidates** informed consent

*Competence by providers in a variety of treatment methods is **essential** to informed consent*

(Littrell, 2003; Littrell & Ashford, 1995; Strom-Gottfried, 1998) 32

Encourage questions

Informed consent should serve to empower clients to make intelligent decisions about their care, not protect practitioners from liability

*Practitioners must ensure the persons receiving the information understand it, and should **encourage questions***

(Littrell, 2003; Cohen & Jacobs, 2000; Strom-Gottfried, 1998; Tan et al., 2007) 33

Competence to consent

"The capacity to act on one's own behalf, to understand and weigh potential outcomes, to anticipate future consequences of a decision."

(Tan et al., 2007) 34

Assessing competence to consent

In youths, assessment considers intelligence and cognitive functioning, maturity, impact of any distress, seriousness and urgency of situation, and impact of youth's relationships

Refusing to consent does not mean incompetence

(Dell et al 2008; Tan et al 2007)

Cognitive capacity of children

By about age 9, children reach the same conclusions as adults, but by different strategies

By about age 14, minors show the same risk-benefit reasoning as adults and can participate in the consent process

(Dell et al 2008; Spetie & Arnold, 2007)

36

Respect for autonomy

Older children and adolescents should participate in the consent process in order to protect them from being subjected to treatment procedures against their will, and to respect their developing autonomy and personhood

(Dell et al 2008; Spetie & Arnold, 2007)

37

Third-party representation

Those who cannot give consent require a third party to act "in their best interests"

There are many views on just what this means…

(Spetie & Arnold, 2007)

38

What about preschoolers?

Are parents fully able to carry out their advocacy role?

Their capacity to act in their young child's best interest warrants careful evaluation

(Dell et al 2008; Spetie & Arnold, 2007)

39

"The clinician must be watchful for caregivers who may have ulterior motives and want a child to be medicated for their own convenience, or because pharmacotherapy may simply be 'easier' than behavioral therapy, or as is more often the case, caregivers who have <u>unrealistic expectations</u> about what benefits a treatment may potentially hold for the child."

(Dell et al., 2008, p. 105)

Constitutional right to refuse or withdraw consent

Clients have the right to refuse or withdraw consent at any time and must be informed of this right

State and federal courts have consistently ruled that it is unfair to allow forced medication without "adequate" procedural guidelines

(Bentley, 1993)

41

Forced treatment remains a most controversial issue

Although a fixture of mental health interventions, involuntary treatment must be ***<u>literally</u>*** **"option of last resort"**

Opponents of forced treatment assert that it violates one's fundamental human rights, creates distrust of helpers, and undermines the foundation for recovery

(Bassman, 2005)

42

Taking psychotropic medications, having a psychiatric diagnosis, or experiencing major distress, does not by itself provide grounds for being denied the right to refuse or withdraw consent

(Bentley, 1993)

43

Confidentiality

44

Confidentiality vs. privacy

U.S. Constitution guarantees **privacy** rights, not confidentiality, to the individual

Confidentiality is essential to develop trust between client and professional

(Corcoran, Gorin & Moniz, 2005; Hanson & Sheridan, 1997; Millstein, 2000)

45

"Duty to protect"

However, the state can breach confidentiality if it has a rationale for seeing the information, such as the "duty to protect" client or others from harm

(Corcoran, Gorin & Moniz, 2005; Millstein, 2000)

46

Relinquishing confidentiality

Managed care organizations and publicly-funded payers require information from providers about clients'

- psychiatric diagnoses
- treatment procedures
- progress and outcomes

(Bilynsky & Vernaglia, 1998;
Corcoran, Gorin & Moniz, 2005; Millstein, 2000)

47

Ethical mandates

Clients must be informed of, ***and authorize***, all disclosures made to insurers and advised of the potential risks of such disclosure ***before*** disclosure is made

(Reamer, 2001; Millstein, 2000)

48

Part C

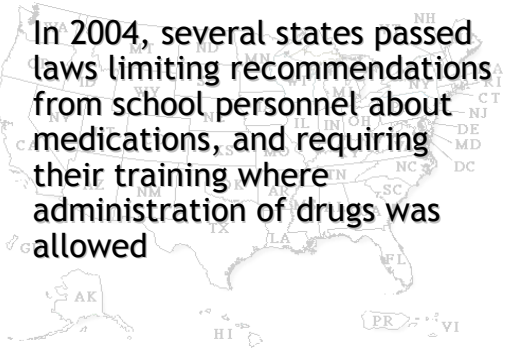
Emerging Legislative Issues

Concerns over medicating children lead to new laws

49

States respond to concerns

In 2004, several states passed laws limiting recommendations from school personnel about medications, and requiring their training where administration of drugs was allowed



2005: U.S. House of Representatives passes *Child Medication Safety Act* (H.R. 1790)

- Bill seeks to *protect children from being forced to take psychotropic drugs as a pre-condition for* attending public school, and intends to restore parental authority over decisions about their children's health

51

Florida limits school's roles F.S. 1006.0625

Public schools cannot require students to receive psychotropic medication as a condition for attending school

"Any medical decision made to address a student's need is a matter between the student, the student's parent, and a competent health care professional chosen by the parent."

52

F.S. 39.407 places limits on medicating children in state custody

Children under state care can be medicated **only** after obtaining ***express and informed consent*** from the parent, or, if parental rights have been terminated, receiving authorization from a judge

Florida and other states now require state agencies to keep list of foster care children on meds—but no register in U.S. tracks health effects of prescriptions on kids

53

Mental health screening debate

Joining the list of issues hotly debated is a 2003 Presidential task force recommendation to screen all school-aged children for mental health problems

(President's New Freedom Commission Report on Mental Health, 2003)

Early detection or pharmaceutical ploy?

Pros: early detection and treatment of disorders

Cons: invalid diagnoses and screening instruments; drug companies attempt to increase market share for psychiatric drugs

55

Part D

Psychotropic Medications and Children:

"First Do No Harm"

56

"Children and adolescents are deemed vulnerable populations, at risk of being harmed by unethical or suboptimal practice and research and are in need of protection."

(Spetie & Arnold, 2007, p. 15)

57

Medications have socio-cultural implications and impact children's identities

(Dell et al, 2008; Floersch, 2003)

58

How do children interpret their taking drugs?

To make sense of everyday medication treatment, children develop "illness narratives"

They may learn to see themselves as "defective" and unable to control their actions

(Dell et al 2008; Floersch, 2003)

59

Medication "messages"

"Better living through chemistry":

Children learn to use drugs to deal with behavioral, emotional, academic and social difficulties

(Dell et al 2008; Floersch, 2003; Jacobs, 2006)

60

Competent practice involves listening and responding to how youths make sense of their medication experience

This requires therapeutic and personal interpretation

(Dell et al 2008; Floersch, 2003; Rappaport & Chubinsky, 2000)

61

In child and adolescent psychiatry, medication decisions are infrequently guided by scientific knowledge, as data on safety and efficacy for most psychotropics in youths remains limited

(Jensen et al., 1999: Matsui et al. 2003; Spetie & Arnold, 2007; Vitiello, 2003)

62

"The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness"

Ronald Brown, Chair,
2006 American Psychological Association (APA)
Working Group on Psychoactive Medications for Children and Adolescents

St Petersburg Times (2007)

63

"Whether one subscribes to the Hippocratic dictum 'first, do no harm' or takes a risk-benefit approach to treatment, it is impossible to discount possible unwanted treatment effects."

(APA Working Group on Psychoactive Medications for Children and Adolescents, 2006, p. 27)

64

Part E

Conclusions and Recommendations

65

Non-medical professionals may neither prescribe, dispense, or administer drugs, but they may *discuss* any medication-related issue with their clients, including how their clients can attain their goals with the use or non-use of medications

66

Legal implications

Even professionals who do not prescribe are being called to testify in court about matters that directly concern treatment of clients with psychotropic medications

67

Training for competence

To remain competent in this emerging field requires basic education and training, including critical perspectives on drug use and marketing

68

Professionals working with children receiving psychotropic drugs must take responsibility for their education, and be accountable to clients and society for *their own decisions* about medication-related issues

69

Ethical standards

A practitioner's involvement in referring children for medication, encouraging medication compliance, and monitoring effects, must rest on the *highest* ethical standards

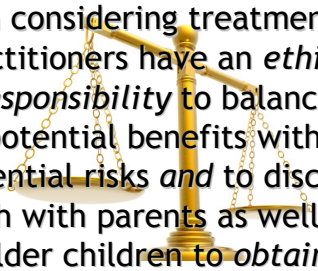
70

Can anyone ethically reassure clients about the safety of psychiatric drugs for children when information is not yet available?

(Littrell, 2003)

71

Balancing risks and benefits



When considering treatments, practitioners have an *ethical responsibility* to balance potential benefits with potential risks *and* to discuss both with parents as well as older children to *obtain informed consent from both*

72

"The potential for benefit from these medications must be balanced against the risks of not only the physical side effects, but also the social stigma, cost, inconvenience, and even family disapproval that can accompany even the most seemingly clear-cut, evidence-based treatment recommendation."

(Dell et al., 2008, p. 99)

Given all the known risks associated with psychotropic drugs, attempting psychosocial therapies to treat problems in children ***prior to considering medication*** is an ***ethical priority***

74

"First do no harm"

Use of psychotropic medications that have been *reported to have serious adverse effects in children—**including death**—should be halted* until research demonstrates that both short- and long-term benefits outweigh the already known risks

Avoid psychotropic drug use in young children until

- ✓evidence-based psychosocial interventions have been exhausted
- ✓rationally-anticipated benefits outweigh the likelihood of risks
- ✓parents/guardians are fully informed
- ✓close monitoring is in place

(Vitiello, 2001)

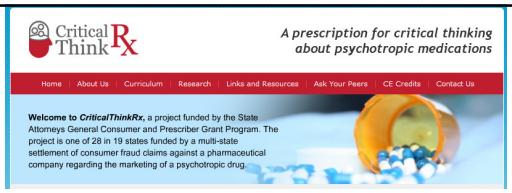
76

A Critical Curriculum on Psychotropic Medications

Module 6

The End

www.CriticalThinkRx.org



A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - **David Cohen, Ph.D.**
- **Research Coordinator:**
  - **Inge Sengelmann, M.S.W.**
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
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- **Voice narration and Flash editing:**
  - Saul McClintock

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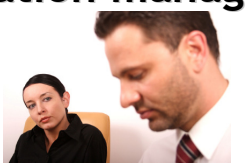
Module 7

Medication Management: *Professional Roles and Best Practices*

Part A

Non-medical roles and medication management



Historical roles of non-medical helpers

To serve as resources for physicians and allied professionals:

- First, giving clients information about their medications;
- Then, identifying obstacles to compliance;
- Later, advocating for clients

(Bentley, Walsh, & Farmer, 2005)

6

A 2001 national survey of clinical and mental health social workers identified 31 possible tasks and activities related to medication

(Bentley, Walsh, & Farmer, 2005)

Survey found some tasks "frequently" performed with clients

- ✓Discussing clients' feelings about taking medications
- ✓Making referrals to physicians
- ✓Discussing how medications may work with other interventions

(Bentley, Walsh, & Farmer, 2005)

8

Tasks "often" performed with clients

- ✓Helping weigh pros and cons of taking medication
- ✓Monitoring clients' compliance with medication
- ✓Discussing medication problems

(Bentley, Walsh, & Farmer, 2005)

9

Tasks "rarely" performed

- ✓Assessing and documenting adverse effects
- ✓Educating about medications
- ✓Suggesting changes in medications to physicians

(Bentley, Walsh, & Farmer, 2005)

10

Assuming roles is complicated by:

- ✓ priority of some professional values and ethics, such as client's right to self-determination
- ✓ questions about validity of medical model for explaining human distress
- ✓ gaps and uncertainties in evidence about medications
- ✓ influence of pharmaceutical companies on the entire mental health system

(Walsh, Farmer, Taylor & Bentley, 2003)

11

Increasing demands to regulate medicated clients clash with professional values, creating a "professional dissonance"

(Taylor & Bentley, 2005)

12

Public and professional attitudes

Overall, the public does not embrace psychiatric medications as a solution to children's problems

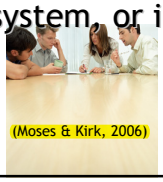
- *70% of adult Americans refuse to use medication for children labeled "oppositional" or "hyperactive"*
- *Only 10% see medication as the most effective component of treatment, and 66% believe it is used as a substitute for other interventions*

(McLeod, et al. 2004)

Practitioners divided

Some find drug treatment of youth helpful or essential

Others find drugs used as a form of social control, misused as a remedy for frustrated parents or overtaxed system, or ineffective



(Moses & Kirk, 2006)

15

Helping parents find solutions

When faced with a distressed child, parents may perceive few options in a world where insurers, medical providers and schools pressure them to medicate their children

(McLeod et al., 2004)

16

Unbiased sources of information

Non-medical professionals should serve as "unbiased sources of information" to help parents find the right solutions for their children and to promote alternatives based on critically-evaluated evidence

(Bradley, 2003; Buccino, 2006; McLeod et al., 2004)

17

"Vigilant and critically minded"

Non-medical professionals are urged to maintain an ***"informed but critical"*** stance by developing adequate knowledge about the benefits and adverse effects of psychotropic drugs, and remain ***"vigilant, and critically minded"***

(Moses & Kirk, 2006, pp. 220-221)

18

Yet be familiar with basic psychopharmacology

including uses, side effects, dosages, and drug interactions in order to be effective in this complex environment

(Bradley, 2003; Buccino, 2006)

19

Part B

Evolving roles in medication management

In today's *collaborative*, *multi-disciplinary environment*, non-medical practitioners are called upon to play many roles on behalf of clients taking medication

21

Physician's Assistant

Traditionally the most common role for professionals legally limited in their scope of work with medications, they

- Help clients follow doctor's recommendations
- Not expected to give advice about decisions involving the prescription

(Bentley & Walsh, 2006)

Consultant

Evaluates client to assess for referral to physicians

Prepares clients to talk with the prescribing physician

Monitors client's subjective experience of medication

Assesses client's ability to pay for expensive drugs

(Bentley & Walsh, 2006)

23

Counselor

Coaches and teaches by providing information and advice about medications

Teaches problem solving, helps identify alternatives, assists in making decisions

(Bentley & Walsh, 2006)

24

Monitor

- Helps client observe positive and negative effects of medication
- Evaluates client's medication responses, in psychological, interpersonal, and social realms, and effects on self-image and identity
- Discusses the monitoring process with clients, families and physicians

(Bentley & Walsh, 2006)

25

Advocate

- Presents client's expressed wishes to those in the medical or mental health system
- Ideally, has a peer relationship with the physician and participates in all phases of medication decision-making

- Possesses knowledge of psychopathology, medications, and related laws and regulations

(Bentley & Walsh, 2006)

26

Teacher

Provides educational materials and other information to clients about:

- The purposes, actions and effects of medications
- Problem-solving regarding medication issues and adverse effects
- Practical suggestions to help clients take medication appropriately

(Bentley & Walsh, 2006)

27

Researcher

Conducts and publishes research in medical and non-medical literature about the full range of psychotropic medication issues

(Bentley & Walsh, 2006)

28

An emerging clinical role: *easing clients off meds*

- Helping clients withdraw from psychiatric drugs or helping simplify medication regimen
- Contingent on practitioner competence and a "rational, person-centered" approach
- Guidelines exist for non-medical practitioners to recognize and address discontinuation effects

(Cohen, 2007; Meyers, 2007; Rivas-Vasquez et al., 1999)

29

Effective collaboration with clients, physicians and other providers of care

Traditional

Reflects dominance of medical profession

Characterized by limited, unclear or subservient roles of non-medical professionals

(Bentley & Walsh, 2006, Bronstein, 2003)

Interdisciplinary

Improves services to the client and work satisfaction for professionals

- May not translate in all environments and training in effective models is needed

(Bentley & Walsh, 2006; Bronstein, 2003)

32

Transformational

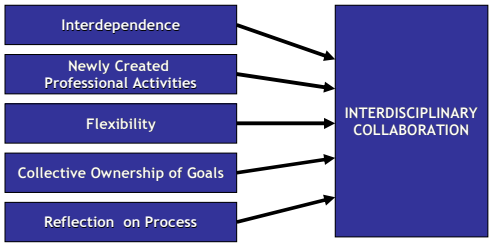
Enhances the contributions of all members of a team

Assumes non-hierarchical relationships where physicians integrate psychosocial aspects of care and involve non-medical professionals in decision-making

(Bentley & Walsh, 2006; Bronstein, 2003)

33

Components of an Interdisciplinary Model



(Bronstein, 2003)

34

Elusive qualities of successful collaboration?

- A favorable political and economic climate
- Shared vision, attainable goals
- Open and frequent communication
- Trust, adaptability, respect
- Clear roles but flexibility in assuming them
- Competent, well-trained practitioners
- A leader with strong interpersonal skills

Unfortunately, these qualities may be absent in interdisciplinary settings

(Bentley & Walsh, 2006; Bronstein, 2003)

35

Collaboration to enhance client's self-determination

Collaboration between clients, families and professionals as ***partners*** in the helping process is key to respecting the client's right to self-determination

When partnership with other professionals is difficult, focus should be on empowering clients with information so that they make choices in collaboration with prescribers

(Bentley & Walsh, 2006; Cohen, 2007; Slavin, 2004; Weene, 2002)

36

Needed—but difficult to accomplish: A balance between…

- ✓the rights of individuals, families and society
- ✓the costs and benefits of using psychotropic medication
- ✓the non-medical practitioner's role in medication management and the legitimacy and uniqueness of other helping professions

(Bentley & Walsh, 2006)

37

Integrating drugs and psychosocial treatment introduces complex dynamics that require attention and management

Managing parallel treatment requires navigating

- ✓the relationships among client, prescriber and therapist
- ✓competing ideologies held by providers

(Bentley & Walsh, 2006; Bradley, 2003)

39

Dimensions of partnership in medication management

Dimension	Traditional model	Partnership model
Goals of medication	Reduce symptoms	Improve quality of life; emphasis on client priorities
Who selects medication	Physician provider	Client collaboration to help define options
Education focus	Increasing compliance	Improving client's ability to manage recovery
Monitoring and evaluating	Physician evaluates clinical status and compliance	Client and providers evaluate range of outcomes and options
Self-care by client	Largely ignored in mental health	Integrated into consultations with client and family
Control and status	Providers control processes and hold status positions	Emphasis on client control, and client's experiences valued
Refusal and reluctance	Seen as related to denial and paranoia	Seen as a right to be respected in all but emergency situations

(Bentley & Walsh, 2006, p. 223)

40

Part C

Tools for Competence

Assessments, Referrals, Court Affidavits and Medication Monitoring

Comprehensive assessments

Understanding the person in the context of their experiences

Working Definition

An ongoing, systematic data collection about a client's functioning

A process of problem selection and specification guided by a person-in-environment, systems orientation

(Jordan & Franklin, 2003)

43

An individualized process

views the whole person in context, including all factors contributing to their distress and strengths, and changes required to improve coping and mastery

- the person's own perspective is key to understand their situation

(Austrian, 2005; Jordan & Franklin, 2003)

44

Elements of assessment

1. ***Exploration*** of client's unique story and facts
2. ***Inferential thinking*** to evaluate meaning of the facts of their story
3. ***Evaluation*** to assess client functioning, strengths and weaknesses in context
4. ***Problem definition*** based on the first three steps and in collaboration with client
5. ***Intervention planning*** based on preceding four steps and in context of environment

(Austrian, 2005; Jordan & Franklin, 2003)

45

Mental status examination

☑Appearance, speech, attitude, motor behavior

☑Mood, range and appropriateness of affect

☑Hallucinations, depersonalization, derealization

☑Remote, recent, and immediate memory

☑Level of consciousness, orientation

☑Impulse control

☑Judgment and insight

(Austrian, 2005; Jordan & Franklin, 2003)

46

"Integral" assessment approach requires knowledge of

- the client's experience (the individual viewed subjectively/from within)
- the client's behavior (the client viewed objectively/from without)
- the client's culture (the client's system viewed subjectively/from within)
- the client's social system (the client's system viewed objectively/from without)

(Marquis, 2008; Ingersoll, 2002)

47

Referrals

Best practices in referring clients for psychiatric evaluation

Few empirical evaluations

Few researchers have investigated effective referral practices, despite frequency of this activity

Tentative guidelines are offered

(Bentley, Walsh & Farmer, 2005)

49

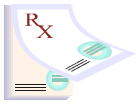
Quality referrals

1. Establish and maintain collaborative relationships with prescribers
2. Share ***up-to-date*** information about medications with clients and families
3. Help clients and families articulate and manage the meaning of medication
4. Prepare clients and families for the medication evaluation
5. Follow up on the referral
6. Manage legal and ethical concerns

(Bentley, Walsh & Farmer, 2005)

50

- Prescription
- Reason for the prescription
- Expectations of benefit
- Probability of benefits
- Alternative treatments available
- Risks of the medication
- Expenses involved (direct/indirect)
- Decision



(Chewning & Sleath, 1996, in Bentley & Walsh, 2006)

51

A medication evaluation should be requested only if the child's symptoms do not improve or worsen significantly after good psychosocial interventions have been attempted

52

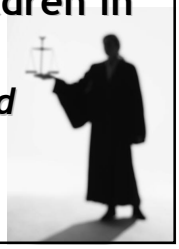
If drugs are considered, all practitioners should evaluate if there is clear evidence of favorable benefit-to-risk ratio

Drugs unapproved for that age group cannot be recommended without special consideration

53

Affidavits to judges regarding medication suggestions for children in state care

A recommended checklist



Psychosocial situation and stressors

1. Describe the observed behaviors of concern & who has observed them, when and where
2. Describe past, recent, or chronic stressors in the child's life that may be contributing to any of the observed behaviors

55

Psychosocial assessment

3. Summarize the results of your own assessment of this child's situation: what, in your judgment, could explain how this child is now acting?
4. If the child has been on medication, could the symptoms be adverse effects of the medication? List sources to justify your conclusion

56

Assessment of interventions

5. Describe any previous interventions to address the problems identified in your assessment
6. Describe how these interventions have been evaluated, and their results
7. What other interventions might address this child's problems? To what extent are they available for this child? Why or why not?

57

Medication history

8. List medications (names, dosages, times per day) the child takes now and over the past 2 years
9. Have you participated in evaluating the child's progress on medication? What specific goals have been expected, how has their attainment been evaluated?

58

Medication monitoring, evaluation

10. Have you evaluated for adverse effects, behavioral or other? Have you used any rating scales? How well, <u>in your ***own*** careful, overall judgment</u>, is this child tolerating his or her medication?

59

Informed consent

11. Do you have any information on this child's attitude to the medication?
12. How have the risks and benefits of the medication, as well as those of alternate interventions, been assessed and discussed with parents or caregivers?

60

Future monitoring

13. If the child is placed on medication, describe your specific role in monitoring its effects.
14. What reasons do you have to expect that the proposed medication will be beneficial to this child?

61

Medication monitoring

Attending to anticipated and unanticipated effects

Monitoring helps clients and families

- Keep track of medication effects
- Cope with bothersome effects
- Solve medication-related issues
- Make decisions about treatment using critically-evaluated information
- Prevent medication errors

(Shojania, 2006)

63

Clients may not know

Clients typically fail to link behavioral drug effects to their drug, and may incorrectly believe they are suffering from additional unrelated physiological or psychological symptoms

Do not dismiss unusual effects, watch out for amplified usual effects, and educate clients about risk of "prescribing cascade"

(Otis & King, 2006)

64

Formal monitoring essential

Without formal monitoring, only a fraction of drug problems are recognized

Structured medication reviews have been shown to be more valid and improve client's quality of life

(Otis & King, 2006; Greenhill et al, 2004; Jordan et al., 2004; Kalachnik, 1999)

65

Tools for monitoring

Drug effect checklists – existing or individualized for client's situation *(see checklist handout in website)*

- Use before starting the medication
- Use after starting the medication

(Jordan et al., 2004)

66

Adapted from: Kalachnik JE. Measuring side effects of psychopharmacologic medication. *Mental Retardation & Developm. Disability Research Review* 1999; 4, 349-359; 2) Rosenbaum et al. SSRI discontinuation syndrome, *Biological Psychiatry* 1998; 44, 77-87. (3) Baschilnyk-Butler & Jeffries, 2005, *Clinical handbook of psychotropic drugs* (15th rev. ed). Seattle: Hogrefe.

MEDICATION MONITORING—ADVERSE EVENT CHECKLIST

Client's name: _____ Date of assessment: ___/___/___ Assessor ____

Drug(s) and dosage:

_____

_____

Instructions: *Fill out once a month or more, before, during, and for 3 months after medication use. Inquire about the presence of each event over the past 7 days. If present, score as* ***1*** *(mild),* ***2*** *(moderate), or* ***3*** *(severe). If not present, leave blank. For items listing different or opposite events (e.g., "increased" or "decreased" appetite, circle the appropriate one.)*

Psychological	1, 2, 3	Gastrointestinal	1, 2, 3
1. Agitation (restless, nervous, hyperactive)		43. Increased or Decreased appetite	
2. Confusion, cognitive difficulties		44. Weight Gain or Loss	
3. Memory problems, forgetfulness		45. Abdominal pain or cramps, Stomach bloating	
4. Irritability (easily upset, angry)		46. Increased thirst	
5. Impulsivity		47. Nausea, vomiting	
6. Trouble concentrating or paying attention		48. Diarrhea	
7. Insomnia, trouble falling or staying asleep		49. Constipation	
8. Hypersomnia, trouble waking up		50. High blood sugar	
9. Crying spells, sadness		51. Other:	
10. Anxiety, tension, Panic (racing heart, breathless)		**Musculoskeletal/Neurological**	
11. Lethargy, apathy, drowsiness, sedation		52. Disequilibrium, unsteady gait, poor coordination	
12. Nightmares, intense dreaming		53. Spinning, swaying, lightheaded	
13. Feeling detached or unreal		54. Weakness, fatigue	
		55. Numbness, burning or tingling sensations	
		56. Slowed movements, muscle rigidity	
		57. Muscle cramps, stiffness, twitches, jerks	
		58. Restlessness, pacing, rocking, can't sit still	
		59. Tremor (slight shaking/trembling of limbs or muscles)	
		60. Any abnormal involuntary movements	
		61. Other:	
		Skin	
		62. Increased or Reduced sweating	
		63. Increased sensitivity to sun	
		64. Chills or Feelings of warmth	
		65. Rash, hives / Dry skin, crusty	
		66. Acne	
		67. Easy bruising	
		68. Pale, yellowing skin	
		69. Hair loss or Abnormal hair growth	
		70. Other:	
		Genito-Urinary	
		71. Menstrual disturbances (absent or irregular periods)	
		72. Difficulty urinating / Increased urination	
		73. Enuresis, night bedwetting	
		74. Difficulties with orgasm	
		75. Erectile dysfunction	
		76. High or Low sexual desire / activity	
		77. Other:	
		Cardiovascular	
37. Flu-like aches and pains		78. High blood pressure	
38. Sore throat/Difficulty swallowing		79. Arythmia (irregular heartbeat)	
39. Labored breathing		80. Tachychardia (abnormally fast hearbeat)	
40. Chest pain			

Systematic monitoring must be carried out to evaluate the wide-ranging effects of medications on behavior, mood, as well as physical and emotional development

68

Children should be evaluated for

Emotional development (to examine whether the drug induces or worsens certain problems)

Cognitive development

Physical growth (i.e., weight and height)

Pubertal development (to examine drug effects on course of puberty)

(Greenhill et al., 2003)

69

Medication guidelines for child welfare

Medication should only be used as part of a comprehensive treatment plan integrating behavioral interventions

- not used in lieu of other treatments or supports
- based on adequate information, including full biopsychosocial and medical assessment
- resting on informed consent

(Bellonci & Henwood, 2006)

70

With children (*after rock-solid justification for medication has been provided*)

✓adjust doses to a minimum to minimize side effects

✓periodically attempt to take child off medication

✓avoid polypharmacy

✓continually reassess risk-to-benefit ratio

(Bellonci & Henwood, 2006)

71

Medical monitoring schedule

Children on psychotropic medications should be seen no less than every three months *at a bare minimum*

FDA guidelines for antidepressants require more frequent monitoring due to risks

(Bellonci & Henwood, 2006)

72

Red flags: Additional monitoring concerns

- ☑Children under five years of age
- ☑Children on 2 or more medications
- ☑Children in state custody

(Bellonci & Henwood, 2006)

73

"Psychotropic medications for young children should be used only when anticipated benefits outweigh risks. Parents should be fully informed and decisions made only after carefully weighing these factors. Children and adolescents must be carefully monitored and frequently evaluated as the side effects common to some medications are particularly difficult for children."

National Alliance for Mental Illness (NAMI) Policy Research Institute, 2004

Part D

Conclusions and Recommendations

Beyond biology…

…medications affect the psychological and social concerns of clients, leading non-medical providers to be increasingly involved in medication issues

76

What is needed?

Education and training about psychiatric medications for non-medical professionals

Guidelines regarding responsibilities with respect to medication, including dealing with ethical and legal issues such as obligations to report adverse effects

Improved collaboration with *clients as partners* and with medical providers as part of interdisciplinary teams—though key concern remains empowering clients to make their own decisions

77

Training on

- ☑ the impact of meanings of medication-taking
- ☑ monitoring clients for adverse effects
- ☑skills in educating clients about risks and benefits of psychotropic medications
- ☑ finding and critically evaluating research on specific medications
- ☑ understanding the strong ideological, economic and political influences on prescription writing in the U.S.

78

Research on

- ☑ how medications and psychosocial interventions interact
- ☑ how medications affect child's self-control, self-image, and personal responsibility (autonomy)
- ☑ how medications affect therapeutic relationships

79

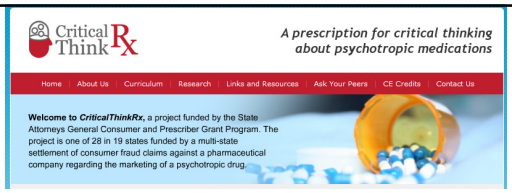
A Critical Curriculum
on Psychotropic Medications

Module 7

The End

www.CriticalThinkRx.org

80



A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

Principal Investigator:
- David Cohen, Ph.D.

Professional Consultants:
- David O. Antonuccio, Ph.D. (psychology)
- Kia J. Bentley, Ph.D. (social work)
- R. Elliott Ingersoll, Ph.D. (counseling & psychology)
- Stefan P. Kruszewski, M.D (psychiatry)
- Robert E. Rosen, J.D., Ph.D. (law)

Research Coordinator:
- Inge Sengelmann, M.S.W.

Flash production and design:
- Sane Development, Inc., and Cooper Design, Inc.

Voice narration and Flash editing:
- Saul McClintock

Critical Think Rx
www.CriticalThinkRx.org

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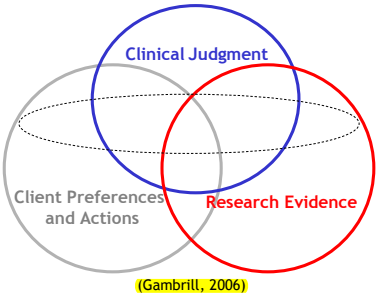
Module 8

Alternatives to Medication: *Evidence-Based Psychosocial Interventions*

Part A

What is Evidence-Based Practice?

The integration of *best research evidence* with *clinical judgment* and *client values*



(Gambrill, 2006)

6

A philosophy *and* a process designed to unite research and practice in order to

maximize chances to help clients

minimize harm to clients (in the name of helping)

(Gambrill, 2006)

Deeply participatory

EBP is "anti-authoritarian"—it urges all involved to question claims about what is known *and unknown* about treatments

(Gambrill, 2006)

8

EBP difficulties

- ☑ Threats to business-as-usual
- ☑ Limited training and supervision
- ☑ Concerns about cultural sensitivity
- ☑ Worries that "cook book" methods mask real-world complexity

(Barratt, 2003; Chorpita et al. 2007; Duncan & Miller, 2006)

9

An intervention should have *at least some* unbiased observations or tests supporting its usefulness with particular problems and clients

10

Some criteria for judging an intervention

- ☑ Sound theoretical basis
- ☑ Low risk for harm
- ☑ *Unbiased* research exists
- ☑ Therapist and client concur

11

Available "evidence" no guarantee of usefulness

Published evidence is influenced by funding sources, researcher biases, and conventional wisdom

Statistically significant differences between treatment groups means simply that more clients in one group had some type of response (partial to complete)

(Hoagwood et al. 2001; Ingersoll & Rak, 2006)

12

However, on average, *all major therapies produce equivalent results.*

Clients' improvement may result from *factors common to every therapy*

(Elkins, 2007; Hubble, Duncan, & Miller, 1999)

13

Most improvement has little to do with therapy or technique

Factor	% improvement explained
Client + outside therapy factors	87
Client-therapist alliance	8
Therapist allegiance to model	4
Therapist technique	1

(Hubble, Duncan, & Miller, 1999; Wampold, 2001)

14

Healthy skepticism

"We would do well … to remain optimistically humble on the matter of evidence-based practices in mental health" by accepting that all assumptions are "provisional and reversible"

(Norcross, Beutler & Levant, 2006, p. 11)

15

A clinician's "rubric" for EBP

"Adhere when possible, adapt when necessary, assess along the way"

(Amaya-Jackson & DeRosa, 2007, p. 388)

16

Choosing proper interventions rests on

- ☑ a clear understanding of the problem from a person-in-situation perspective
- ☑ addressing the complexity of the problem
- ☑ a policy of **"First, do no harm"**

Part B

Deconstructing the Diagnosis:

What is this child's problem in behavioral terms?

Bio-psycho-social or bio-bio-bio?

- ✓Complex problems in living reduced to "brain disorders"
- ✓Complex life events reduced to "triggers"
- ✓Medicalization of distress and disability leading to false hopes of "quick fix" via pills

(Read, 2005)

19

We often ignore environmental influences on behavior

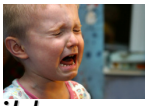
- ☑ Poor parenting, neglect, abuse
- ☑ Schools' failure to motivate children
- ☑ Poverty, lack of access to resources
- ☑ Violence in media, society, neighborhood
- ☑ Culture's emphasis on instant gratification
- ☑ Drug culture ("take," not "talk")
- ☑ Lack of tolerance for differences

(Bentley & Collins, 2006)

20

Children's distress:

"Disorders" or complex adaptations to distressing life experiences?



By seeing children as real persons with their own view of their situation, one ascribes a different ***meaning*** *to their behavior*

(Donovan & McIntyre, 1990)

21

"Understanding" rather than "diagnosing"

A developmental-contextual approach views actions as "communicative": attempts by individuals to cope, adapt, struggle with their life experiences

(Donovan & McIntyre, 1990)

22

Here's a list of feelings and behaviors from DSM-IV-TR criteria of "disorders" commonly diagnosed in children

Note the similarities…

"Attention-Deficit/ Hyperactivity Disorder (ADHD)"

Feels:

- Angry, irritable, frustrated

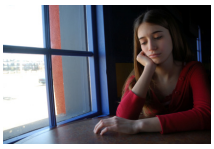
Acts:

- Fidgets, squirms
- Easily distracted, forgetful (difficulty thinking, concentrating)
- Interrupts others (acts impulsively)
- Acts aggressively

24

"Major Depressive Disorder"

Feels:
- Sad, empty
- Afraid, anxious
- Angry, irritable, frustrated



Acts:
- Eats, sleeps too little (or too much)
- Moves, speaks slowly
- Acts impulsively
- Acts aggressively
- Easily distracted (difficulty thinking, concentrating)

25

"Anxiety Disorder"

Feels:
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Cries, throws tantrums
- Freezes, clings
- Fidgets (psychomotor agitation)

26

"Conduct Disorder"

Feels:
- Angry, irritable, frustrated, hostile

Acts:
- Bullies and threatens
- Fights
- Steals, lies
- Runs away
- Destroys property

27

"Oppositional Defiant Disorder"

Feels:
- Angry, irritable, frustrated, hostile

Acts:
- Disobedient
- Loses temper
- Argues with adults
- Annoys people
- Refuses to follow rules

28

"Bipolar Disorder"

Feels:
- Alternating sad and euphoric
- Alternating fearful and reckless
- Angry, irritable, frustrated

Acts:
- Easily distracted (difficulty thinking, concentrating)
- Moves, speaks fast (agitation)
- Acts impulsively
- Acts aggressively
- Does not sleep well

29

"Psychotic Disorder"

Feels:
- Sad, empty
- Blunted feelings, expressionless
- Angry, irritable, frustrated
- Afraid, anxious

Acts:
- Apathetic
- Refuses to speak
- Dresses inappropriately
- Cries frequently
- Sees or hears things

30

"Post-Traumatic Stress Disorder"

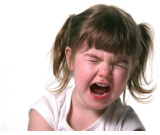
Feels:
- Sad
- Afraid, anxious
- Angry, irritable, frustrated
- Helpless, guilty, shameful

Acts:
- Agitated, impulsive, re-enacts trauma
- Hypervigilant: distrustful, withdraws
- Dissociated: forgets and can't focus

31

"Reactive Attachment Disorder"

Feels:
- Afraid, anxious
- Angry, irritable, frustrated



Acts:
- Watchful, frozen
- Avoids attachments
- Seeks approval or can't be comforted
- Disregards danger cues

32

The common elements

Experiencing negative emotions
(sadness, fear, anger, irritability)

Difficulty controlling oneself
(impulsivity, aggression, inattention)

Seeing self and world negatively
(hopelessness, helplessness, shame, withdrawal)

33

What are we medicating?

Negative emotions leading to disruptive actions—especially under stressful conditions that tax the child's adaptive capacities

(Schore, 1994, 2003)

34

Most commonly medicated

Impulsive aggression

"a key therapeutic target across multiple disorders"

(Jensen et al. 2007, p. 309)

35

DSM's scientific value seriously challenged in all disciplines

✓ internal inconsistency in the manual (rejects categorical approach in intro but then lists 300+ categories)

✓ overlap between categories leads to "co-morbidity"—with no increase in understanding

✓ persistent problems of unreliability, especially with children's diagnoses

✓ lack of fit between categories and empirically observed symptom clusters

(Caplan, 1995; Duncan et al. 2007; Maj, 2005; Kirk & Kutchins, 1992, 1994; Jacobs & Cohen, 2004; Mirowsky & Ross, 1990)

36

More recent DSM critiques…

- ✓ more behaviors now seen as "mental disorders" (from 106 in 1952 to 365 in 1994)
- ✓ political lobbying determines inclusion or exclusion of diagnoses
- ✓ all DSM task force members on mood and psychotic disorders tied to drug industry
- ✓ practitioners focus on diagnosis rather than client, losing client's actual story
- ✓ still no "gold standard" validity—no specific bio-marker linked to *any* disorder

(Andreasen, 2006; Tucker 1998; Charney et al. 2005; Kutchins & Kirk, 1998)

37

Critical list of DSM "accomplishments"

- ☑ increases people's interest to classify psychosocial problems as medical disorders
- ☑ Helps justify more studies to see how many people can fit how many DSM categories (which often change)
- ☑ led to modest increase in diagnostic reliability since 1980
- ☑ now used by most practitioners in main schools of thought—mostly to obtain third-party reimbursement?
- ☑ brings financial revenues to the American Psychiatric Association from sales of DSMs and training materials
- ☑ strengthened psychiatry's leadership in mental health system (as official definer of mental distress)

38

Part C

Empirically-supported psychosocial interventions for children and adolescents

Focus: Trauma, Resilience and Child Welfare

Trauma and early loss

For thousands of children every year, loss and trauma due to disrupted attachments to biological parents result in foster care placements

(Jones Harden, 2004; Racussin et al. 2005)

41

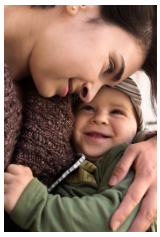
Additional, placement-related traumas

- ✓Emotional disruption of out-of-home placement
- ✓Adjusting to a foster care setting
- ✓Relative instability of foster care
- ✓High turnover of workers

(Jones Harden, 2004; Racussin et al. 2005)

42

Neurobiology of attachment



Brains develop in a *socially dependent manner*, through secure attachments and *consistent*, *competent* adults attuned to the needs of the child

(Schore, 1994, 2001, 2003; van der Kolk, 2003)

43

Child's "job": to form close, trusting attachments with caregivers

Adolescent's "job": to expand attachments using secure base with caregivers

(Gunnar et al. 2006; Mash & Barkeley, 2006; Moran, 2007; Wolfe & Mash, 2006)

44

Trauma, abuse, and neglect

- ☑ disrupt a child's ability to form secure attachments
- ☑ impair brain development and regulation
- ☑ make self-control difficult
- ☑ alter identity and sense of self

(Bowlby, 1988; Cook et al. 2005; Courtois, 2004; Creeden, 2004; Jones Harden, 2004; van der Kolk, 1994)

45

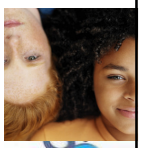
Resilience

The ability to function well despite living or having lived in adversity rests mainly on normal cognitive development and involvement from a caring, competent adult

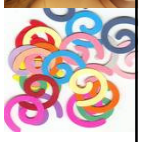
(Agaibi & Wilson, 2005, Masten et al. 1990; Schofield & Beek, 2005)

46

- ✓Risk and protective factors in the foster child, foster-families, agencies, and birth family interact to produce upward or downward spirals



- ✓Understanding resilience helps create interventions that produce positive turning points in children's lives



(Schofield & Beek, 2005)

47

Three key elements

1. Secure base: *is child strengthening sense of security and able to use foster-parents as a secure base?*
2. Sense of permanence: *is placement stable and foster-parents offering family membership?*
3. Social functioning: *is child functioning well in school, with peers?*

(Schofield & Beek, 2005)

48

Treatment goals

- ✓Enhance sense of personal control and self-efficacy
- ✓Maintain adequate level of functioning
- ✓Increase ability to master, rather than avoid, experiences that trigger intrusive re-experiencing, numbing, and hyper-arousal

(Ford et al. 2005; Kinniburgh et al. 2005)

49

What could help?

Activating child's internal reparative mechanisms through *dyadic interventions* and creating secure attachments

- dyadic therapy mobilizes the completion of interrupted biological and emotional developmental processes

(Amaya-Jackson & DeRosa, 2007; Courtois, 2004; Ford et al. 2005; Pearlman & Courtois, 2005)

50

A sensorimotor approach

Children's internal stimuli, can trigger dysregulated arousal, causing emotions to escalate

- Integration of cognitive, emotional and sensorimotor levels is crucial for recovery

(Ogden, 2006)

51

Why would this help?

Child develops the ability to take in, sort out, process, and interrelate information from the environment — leading to self-organization of internal states and self-control of behavior

(DeGangi, 2000; Kinniburgh et al. 2005; Schore, 2003; van der Kolk, 2006)

52

How would this help?

By enhancing children's:

- ✓social skills
- ✓ability to understand and express feelings
- ✓ability to cope with anger and distress
- ✓ability to problem-solve and think helpful thoughts
- ✓skills to self-direct and create goals

(Bloomquist, 1996; Kinniburgh et al. 2005)

53

Alternatives to medication

- ☑ Consistent, structured, supportive adult supervision
- ☑ Opportunities for self-expression and physical activity, to give children a sense of mastery over their minds and bodies

(DeGangi, 200; Faust & Katchen, 2004)

54

Helpful activities

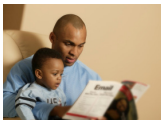
- ☑ Teaching problem-solving and pro-social skills
- ☑ Modeling appropriate behaviors
- ☑ Teaching self-management
- ☑ Helping children learn to comply and follow rules

(DeGangi, 2000; Faust & Katchen, 2004)

55

Helpful interactions

- ☑ Desensitizing hyper-reactivity
- ☑ Promoting self-calming and modulation of arousal states
- ☑ Organizing sustained attention
- ☑ Facilitating organized, purposeful activity



(DeGangi, 2000)

Expected outcomes

Children learn to develop appropriate responses, self-organization and control, which in turns leads to

MASTERY AND SELF-ESTEEM

(Kinniburgh et al. 2005)

57

Many treatment alternatives

Symptom-focused: Behavioral, cognitive-behavioral, and interpersonal therapies, attachment-based therapies, trauma-focused therapies

System-focused: Treatment foster care (TFC), Multi-dimensional treatment foster care (MTFC)

(Farmer et al. 2004; Racussin et al. 2005)

Focus: Dysregulated "moods"

"Depression" and "Anxiety"

60

The New York Times

Talk Therapy Pivotal for Depressed Youth

February 6, 2007

In Rigorous Test, Talk Therapy Works for Panic Disorder

By BENEDICT CAREY

61

Link to child maltreatment

Abuse leads to "hypervigilance" to threat, resulting in anxiety and hopelessness

Neglect results in dysregulated "moods"

(Greenwald, 2000; Lee & Hoaken, 2007)

62

"Traumatized children tend to communicate what has happened to them … by responding to the world as a dangerous place by activating neurobiologic systems geared for survival, even when objectively they are safe"

(van der Kolk, 2003, p. 309)

Therapy or no therapy?

Some 30-40% recover without intervention

Approximately 50% of treated patients improve within 8 weeks

A friendly sympathetic attitude and encouragement are key

(Roth & Fonagy, 1996)

64

Consensus strongly favors cognitive-behavioral therapy (CBT) as **first-line** treatment *above* medications

(APA Working Group, 2006; March, 1995; Roth & Fonagy, 1996; Velting et al. 2004)

65

Other effective interventions

1. Interpersonal psychotherapy
2. Psychodynamic psychotherapy
3. Exposure-based contingency management
4. Problem-solving and coping-skills training

(APA Working Group, 2006; Roth & Fonagy, 1996)

66

Patient preference

When given a choice, patients express a preference for psychosocial interventions over medications

(APA Working Group, 2006)

67

"Bipolar Disorder" and "Schizophrenia"

68

Very rare in children (~1%)

Diagnosis controversial:

- no laboratory "test"
- "symptoms" may be manifestations of ordinary developmental differences

(Birmaher, 2003; Birmaher & Axelson, 2006; Cepeda, 2007; Correll et al. 2005; Danielson et al. 2004; Irwin, 2004; Findling, Boorady & Sporn, 2007; Roth & Fonagy, 1996)

69

High risk of over-diagnosis

NIMH Review: 95% of 1500 children referred for high clinical suspicion of childhood-onset schizophrenia did not meet DSM criteria after careful inpatient observation *off all medications*

No evidence that they would have developed psychosis if left untreated

(Shaw & Rapoport, 2006)

70

Link to child maltreatment

Child abuse and neglect considered a causal factor for psychosis and "schizophrenia"

- Content and severity of psychotic symptoms related to severity of past abuse

(Cepeda, 2007; Morrison et al. 2005; Read & Ross, 2003; Read et al. 2004, 2005)

71

Many children improve when treated with family-based psychosocial interventions, *even without medications*

- High rates of "relapse" observed on medication

(Birmaher, 2003; Birmaher & Axelson, 2006; Cepeda, 2007; Correll et al. 2005; Danielson et al. 2004; Findling et al. 2007; Irwin, 2004; Roth & Fonagy, 1996)

72

Effective psychosocial treatments

Child- and Family-Focused CBT combined with interpersonal and "social rhythm" therapy to stabilize mood, activities and sleep

Community support and social acceptance through day programs and sports/cultural activities

(Findling et al. 2007)

73

Who recovers and why?

Psychiatric literature is mostly silent about the characteristics of people who fully recover from psychosis and how and why they do so

(Siebert, 2000)

74

Focus: Disruptive behaviors

Disruptive behaviors: the most frequent reason for referral of children to mental health services

(Brestan & Eyberg, 1998; Butler & Eyberg, 2006)

76

For disruptive behaviors and conduct "disorders"

☑ Family-based behavioral interventions

(APA Working Group, 2006; Brestan & Eyberg, 1998; Diamond & Josephson, 2005; Kazdin, 2005, 2000, 2000b; Kazdin & Weisz, 2003; Thomas, 2006)

The New York Times (2006, December 22)

TROUBLED CHILDREN

Parenting as Therapy for Child's Mental Disorders

Fabrizio Costantini for The New York Times

TJ Van de Walls attention deficit problems have improved in response to parenting techniques, his mother Dawn, right, said.

78

Effective parenting: the most powerful way to reduce child and adolescent problem behaviors

(Caspe & Lopez, 2006; Johnson et al. 2005; Kumpfer et al. 2003)

79

Strongest evidence base

1. Parent management training (PMT)
2. Problem-solving skills training (PSST)
3. Brief strategic family therapy (BSFT)
4. Functional family therapy (FFT)

(Brestan & Eyberg, 1998; Butler & Eyberg, 2006; Farley et al. 2005; Kazdin, 2003; Kazdin & Whitley, 2003; Springer 2006; Thomas, 2006)

80

Goals of parent training

- ☑ Promote parent competencies & strengthen parent-child bonds
- ☑ Increase consistency, predictability & fairness of parents
- ☑ Produce behavior change in children

(Kazdin, 2003; McCart et al. 2006; Webster-Stratton & Reid, 2003)

81

"Problem" children or "problem" adults?

Coercive parenting was the only factor linked to children's failure to improve their conduct after family treatment

(Webster-Stratton, Reid & Hammond, 2001)

82

Maltreatment consistently linked to aggressive behaviors

- ☑ History of trauma virtually *universal* in youth with conduct "disorders"

(Greenwald, 2000; Lee & Hoaken, 2007)

83

Children in foster care

- ✓ have socio-emotional problems ***3 to 10 times more often*** than other kids
- ✓ Coercive interactions only result in escalation of aggressive behaviors

(Nilsen, 2007)

84

Parent-training in child welfare

Promising programs exist to train biological and foster parents

Goal is to break the cycle of coercive parenting and child oppositional behavior

(Barth et al. 2005; Nilsen, 2007)

85

"ADHD"

Large evidence base exists for behavioral interventions, incl. parent training, social skills training, and school-based services

- Results equivalent to stimulant medications *without the health risks*

(APA Working Group; Chronis et al. 2004, 2006)

86

Focus: Mentoring

Children's development depends upon reciprocal activity with others with whom they have a strong and lasting bond

(Jones Harden, 2004; Rhodes et al. 2006)

Mentorship

A relatively long-term, non-expert relationship between a child and non-parental adult, based on acceptance and support, aiming to foster the child's potential, where change is a desired but not predetermined goal

(Dallos & Comley-Ross, 2005; Rhodes et al. 2006)

Significant effects

Meta-analysis of 55 studies found significant effects of mentoring programs

- Community-based programs more effective than school-based programs

(DuBois & Silverthorn, 2005)

90

Mentoring in foster care

Survey of 29 programs found mentoring provides a bridge to employment and higher education, helps with transitional problem-solving

(Mech, Pryde & Rycraft, 1995)

91

Common factors for success

- ☑ Frequent contacts
- ☑ Emotional closeness (attunement)
- ☑ Longer duration
- ☑ Structured activities
- ☑ Ongoing training for mentors

(DuBois & Silverthorn, 2005; Gilligan, 1999; Rhodes et al. 2006)

92

Mentors enhance resilience

Sensitive mentoring increased self-esteem and well-being, reduced aggression and opened new relationships beyond care system

- *prevents negative outcomes as youth leave foster care*

(DuBois & Silverthorn, 2005; Gilligan, 1999; Lemon et al. 2006; Legault et al. 2005; Rhodes et al. 1999, 2006; Schofield & Beek, 2005)

93

Reduces violence

"Having someone to count on when needed" softened the impact of trauma and reduced likelihood of youth engaging in violent offenses

(Maschi, 2006)

94

Part D

Conclusions and Recommendations

Medicalized approach to distress and disability pathologizes children's behaviors and ignores the context of their experiences

- "Understanding" rather than "diagnosing" changes the meaning of those behaviors and can lead to more helpful interventions

96

Abuse, neglect and trauma disrupt secure attachment and impair the child's ability to self-regulate

- "Repair" occurs through the formation of secure attachments, rather than by medication

Irritability, impulsivity and aggression appear in criteria for most DSM diagnostic labels used on children

- We are medicating children's negative emotions and immature self-control

98

Growing consensus

Just Say 'No' to Drugs as a First Treatment for Child Problems

(Duncan, Sparks, Murphy, & Miller, 2007)

99

Attempt psychosocial interventions *before* initiating medication

Ample evidence supports their use as effective first-line options for children's behavioral problems, *with no apparent risk of medical harm*

100

Fundamental issues of efficacy and safety of psychotropic medications in children remain unresolved

Therefore, medicating children should be avoided

101

A Critical Curriculum on Psychotropic Medications

Module 8

The End

Critical Think Rx
www.CriticalThinkRx.org

102