The Society for Clinical Child and Adolescent Psychology (SCCAP): Initiative for Dissemination of Evidence-based Treatments for Childhood and Adolescent Mental Health Problems

With additional support from Florida International University and The Children's Trust.

SOCIETY OF CLINICAL CHILD & ADOLESCENT PSYCHOLOGY

practice into science into practice

DIVISION 53

American Psychological Association

The Children's Trust

FIU Center for Children and Families

Workshop

Multimodal Treatment for Externalizing Disorders

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Part 1 of 2

Disclosures

Past Consultant, scientific advisor, speaker, grant recipient:

McNeil/Alza/Janssen (Concerta)

Abbott (Cylert)

Shire (Adderall, Adderall XR, guanfacine)

Noven (Daytrana)

Lilly (Strattera)

Cephalon (Sparlon)

Current consultant: Noven

ADHD: Importance to Professionals

Prevalence: 2-9% of population in the U.S.--higher in boys—similar prevalence across many countries

Children dealt with by:

- Health Care Professionals
- Mental Health Professionals
- Allied Health Professionals
- Educators

Most common behavioral referral to health care professionals

Most common referral/diagnosis in special education

Most common behavior problem in regular education classrooms

Most common diagnosis in child mental health facilities

(Barkley, 2006; CDC, 2010; Pelham, Fabiano & Massetti, 2005)

“All of the ‘experts’ at Jerome Horwitz Elementary School had their opinions about George and Harold. Their guidance counselor, Mr. Rected, thought the boys suffered from A.D.D. The school psychologist, Miss Labler, diagnosed them with A.D.H.D. And their mean old principal, Mr. Krupp, thought they were just plain old ***B.A.D.***!”

ADHD: Core Symptoms--Same Over Past 50 Years

Inattention

Impulsivity

Hyperactivity

A Variety of Names—Same Disorder—Same Children

(Barkley, 2006)

- Brain Damage (BD)
- Minimal Brain Damage (MBD)
- Minimal Brain Dysfunction (MBD)
- Hyperkinetic-Impulse Disorder
- Hyperkinetic Reaction of Childhood/Hyperkinesis/Hyperactivity—DSM II
- Attention Deficit Disorder (with and without hyperactivity)—DSM III
- Attention Deficit-Hyperactivity Disorder—DSM III-R, DSM-IV, DSM V

DSM-IV Definition of ADHD

A. Six Symptoms of either Inatt. or Hyp/Impuls.

(1) Inattention:

- often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities
- often has difficulty sustaining attention in tasks or play activities
- often does not seem to listen to what is being said to him or her
- often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace
- often has difficulties organizing tasks and activities
- often avoids or has difficulties engaging in tasks that require standard mental effort
- often loses things necessary for tasks or activities
- is often easily distracted by extraneous stimuli
- often forgetful in daily activities

DSM-IV Definition of ADHD

(2) Hyperactivity-Impulsivity:

- often has difficulty playing or engaging in leisure activities quietly
- is always "on the go" or acts as if "driven by a motor”
- often talks excessively
- often blurts out answers to questions before the questions have been completed
- often has difficulty waiting in lines or awaiting turn in games or group situations
- often interrupts or intrudes on others (e.g. butts into other's conversations or games)
- often runs about or climbs inappropriately
- often fidgets with hands or feet or squirms in seat
- leaves seat in classroom or in other situations in which remaining seated is expected

DSM-IV Definition of ADHD

- **Predominantly Inattentive Type**: Criterion (1) is met but not criterion (2) for the past six months
- **Predominantly Hyperactive-Impulsive Type**: Criterion (2) is met but no criterion (1) for the past six months
- **Combined Type**: Both criteria (1) and (2) are met for the past six months
- Not Otherwise Specified: This category is for disorders with prominent symptoms of attention-deficit or hyperactivity-impulsivity that do not meet criteria for Attention Deficit/Hyperactivity Disorder.

DSM-IV Definition of ADHD

B. Some symptoms that caused impairment were present before age seven.

C. Some symptoms that cause impairment are present in two or more settings (e.g. at school, work, and at home).

D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.

E. Does not occur exclusively during the course of Pervasive Developmental Disorder, Schizophrenia or other Psychotic Disorder, and is not better accounted for by a Mood Disorder, Anxiety Disorder, Dissociative Disorder, or a Personality Disorder.

Domains of Functional Impairment in ADHD Children

- Relationships with parents, teachers, and other adults
- Relationships with peers and siblings
- Academic achievement
- Behavioral functioning at school
- Family functioning at home
- Leisure activities

(Barkley, 2006; Fabiano & Pelham, in press)

Central Role of Functional Impairment in Treatment

- **Impairment--that is, problems in daily life functioning that result from symptoms and deficits in adaptive skills is**
  - (1) why children are referred,
  - (2) what mediates long-term outcome, and therefore
  - (3) what should be targeted in treatment.
- **Key domains are peer relationships, parenting/family, and academic achievement**
- **Assessment of impairment in daily life functioning and adaptive skills is the most fundamental aspect of**
  - initial evaluation to determine targets of treatment
  - Ongoing assessment to evaluate treatment response.
- **Normalization or minimization of impairment in daily life functioning and maximization of adaptive skills is the goal of treatment--not elimination of symptoms**

(Pelham, Fabiano, & Massetti, 2005; Pelham & Fabiano, 2008)

Why Is it Important to Treat ADHD in Childhood?

Prognosis for ADHD Children

Chronic disorder (AAP, 2000, 2011) extending into adolescence and adulthood

One-third: **Tolerable outcome**; appear to have mild problems but must constantly work to adapt to their difficulties

One-third: **Moderately poor outcome**; continue to have a variety of moderate to serious problems, including school difficulties (adolescents) or vocational adjustment difficulties (adults), interpersonal problems, general underachievement, problems with alcohol, etc.

One-third: **Bad outcome**; severe dysfunction and/or psychopathology, including sociopathy, repeated criminal activity and resulting incarceration, alcoholism, drug use disorders

Annual Societal Costs of Childhood/Adolescent ADHD in North America

Health and Mental Health	**$7.9 billion**
Education	**$13.6 billion**
Crime and Delinquency	**$21.1 billion**
Parental work loss	**?**
Total (low estimate based on incomplete data)	**$42.5 billion**
Range (lower to upper bounds based on currently available data)	**$36--$52.4 billion**

***Using 5% prevalence estimate and US 2000 Census data**

(Pelham, Robb & Foster, Ambulatory Pediatrics, 2007; Robb et al, 2011)

Annual Societal Cost of Several Public Health Problems in U.S.

Depression (adults):	**$44 billion**
Stroke:	**$53.6 billion**
ADHD (child, adolescent)	**$50-60 billion**
ADHD (adult)	**$30 billion**
Alzheimer's	**$100 billion**
Alcohol abuse/dep.	**$180**

(Pelham, Foster & Robb, 2007)

What is Effective, Evidence-based Treatment for ADHD in Children?

Common but Not Evidence-Based Treatments

(1) Traditional one-to-one therapy or counseling
(2) Cognitive therapy
(3) Office based "Play therapy”
(4) Elimination diets
(5) Biofeedback/neural therapy/attention (EEG) training
(6) Allergy treatments
(7) Chiropractics
(8) Perceptual or motor training/sensory integration training
(9) Treatment for balance problems
(10) Pet therapy
(11) Dietary supplements (megavitamins, blue-green algae)
(12) Duct tape

(AAP, 2001, 2011; Pelham & Fabiano, 2008)

Evidence-Based Short-term Treatments for ADHD

(1) Behavior modification

-175 studies

(2) CNS stimulant medication

>300 studies

(3) The combination of (1) and (2).

>25 studies

Moderate to large effect sizes across treatments

(AAP, 2001, 2011; Fabiano et al, 2009; Greenhill & Ford, 2002; Hinshaw et al, 2002; Pelham & Fabiano, 2008; Swanson et al, 1995)

AAP Clinical Practice Guideline: Treatment of the School-Aged Child with Attention-Deficit/Hyperactivity Disorder

(Pediatrics, 2001, 2011)

- For elementary-aged children, the primary care clinician should recommend FDA-approved medication and/or behavior therapy, preferably both, to improve target outcomes in children with ADHD.

- For children under 6, behavior therapy should be the first line treatment, with medication perhaps as ancillary.

- For adolescents, medication should be prescribed with behavior therapy as ancillary.

Given that Two Modalities of Treatment Work (Medication, and Behavioral Treatment), Which Should be Used as First Line Treatment?

Components of Effective, Comprehensive Treatment for ADHD

- **Behavioral Intervention**
  - Behavioral Parent Training
  - Behavioral School Intervention
  - Behavioral Child Intervention (not automatic—if indicated)
- **Medication as adjunct**

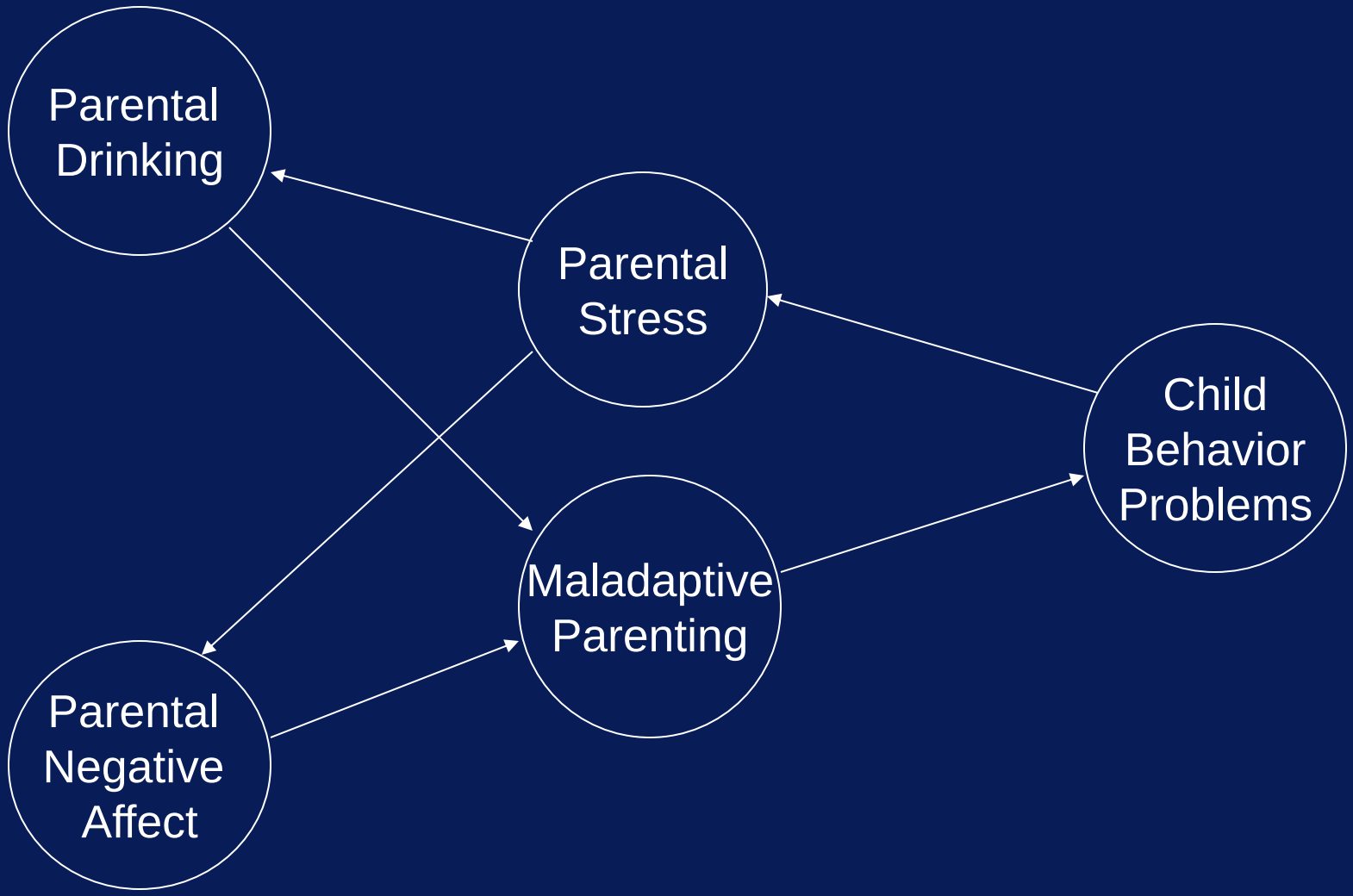
(Pelham & Fabiano, 2008; Fabiano et al, 2009)

Why is it Important to Include Parent Training in ADHD Treatment?

- **No one is taught how to be a parent**
- **Parents of ADHD children have significant stress, psychopathology, and poor parenting skills**
- **ADHD children contribute greatly to parental stress and disturbed parent-child relationships**
- **Parenting styles characteristic of ADHD parents predict and mediate long term negative outcomes for children**

(Johnston & Mash, 2001)

Do Your Children Cause You Stress?


Parental Drinking
Parental Stress
Child Behavior Problems
Maladaptive Parenting
Parental Negative Affect

Components of Evidence-based Treatment for ADHD

Parent Training

- Behavioral approach
- Focus on parenting skills, child's behavior, and family relationships
- Parents learn skills and implement treatment with child, modifying interventions as necessary using ongoing functional analysis
- Group-based or individual weekly sessions with therapist initially (8-16 sessions), then contact faded
- Don't expect instant changes in child--improvement (learning) often gradual
- Continued support and contact as long as necessary (e.g., 2 or 3 years and/or when deterioration occurs)
- Program for maintenance and relapse prevention (e.g., develop plans for dealing with concurrent cyclic parental problems, such as maternal depression, parental substance abuse, and divorce; make programs palatable and feasible)
- Reestablish contact for major developmental transitions (e.g., adolescence)
- Can be offered in MH, primary care, schools, churches, community centers by individuals with wide variety of training--very cost effective
- Many studies documenting benefits of behavioral parent training

(Pelham & Burrows-MacLean, 2004)

Evidence-Based Parent Training Programs

- Triple P (Sanders-Australia)
- PMT (Patterson & Forgatch-Oregon)
- Incredible Years (Webster-Stratton-Washington)
- Helping the Noncompliant Child (Forehand and McMahon)
- PCIT (Eyberg-Florida)
- Parent Management Training (Barkley)
- COPE (Cunningham-McMaster)
- Many generic versions—some free—key question for evaluation is do they have the common effective elements
- Different formats—individual, group, self directed, top-down or bottom up, web/phone based

Common Elements of Behavioral Parent Training

1. Rules for the home
2. Ignore mild inappropriate behaviors and praise appropriate behaviors (choose your battles)
3. Appropriate commands:
   - Obtain the child's attention: say the child's name
   - Use command not question language
   - Be specific
   - Command is brief and appropriate to the child's developmental level
   - State consequences and follow through
4. Daily charts (e.g., School, Home Daily Report Cards)
5. Premack contingencies (e.g., watch TV or phone time contingent upon homework completion)
6. Time out from positive reinforcement/work chores
7. Point/token system with both reward and cost components
8. Level system
9. Homework hour
10. Contracting/negotiating with adolescents

Why is it also important to use behavioral treatments for ADHD in school settings?

Academic Functioning

- 33% of ADHD children/teens have academic problems (special ed., academic probation, dropped out, or held back) every year of school, vs. 2% of controls
- 29% of ADHD children have a school discipline problem monthly vs 1% of other children
- 48% of ADHD children have at least one year of special education placement vs. 3% of controls (bulk of cost)
- 12% of ADHD vs. 5% of controls have been held back a grade
- 9% of ADHD adolescents drop out of school vs. 1% of controls
- ADHD adolescents a full letter grade lower than controls, with twice the rate of absences

(Dupaul & Stoner, 2003; Kent et al, 2011; Loe & Feldman, 2007; Molina et al, 2009; Robb et al, 2011)

Classroom Behavioral Interventions

- Techniques are similar to those that have been employed in the classroom management literature for some time.
- Many widely-available handbooks, texts, or web-based training materials.
- Most of these programs are designed to be implemented by classroom teachers with training and guidance from school support staff or outside consultants.
- Hundreds of studies documenting effectiveness

Components of Evidence-based, Treatment for ADHD

School Intervention

- Behavioral approach--teachers are trained and implement treatment with the child, modifying interventions as necessary using ongoing functional analysis
- Focus on classroom behavior, academic performance, and peer relationships
- Widely available in schools
- Teacher training: (1) in service training and follow up or (2) consultant model—initial weekly sessions as needed, then contact faded—Daily Report Card
- Don't expect instant changes in child--improvement (learning) often gradual
- Continued support and contact for as long as necessary--typically multiple school years and/or if deterioration
- Program for maintenance and relapse prevention (e.g., school-wide programs, train all school staff, including administrators; train parent to implement and monitor)
- Reestablish contact for major developmental transitions (e.g., adolescence

(Pelham & Burrows-MacLean, 2004)

Classroom Behavioral Interventions

1. Classroom rules and structure
    - Be respectful of others
    - Obey adults
    - Work quietly
    - Stay in assigned seat/area
    - Use materials appropriately
    - Raise hand to speak or ask for help
    - Stay on task/complete assignments
2. Ignore mild inappropriate behaviors that are not reinforced by peer attention and praise appropriate behaviors
    - Praises should outnumber reprimands and/or commands - at least 3 to 1 ratio.
    - Use commands/reprimands to cue positive comments for children who are behaving appropriately - that is, find two or more children who can be praised each time a reprimand or command is given to a child who is misbehaving.
    - Shape appropriate behavior by working within the child's ability/skill level.
    - Use praise and ignore *consistently*.

Classroom Behavioral Interventions

3. Appropriate commands (clear, specific, manageable) and private reprimands (at child's desk as much as possible).
   - Obtain the child's attention
   - Use command not question language
   - Be specific
   - Command is brief and appropriate to the child's developmental level
   - State consequences and follow through
   - Firm but neutral tone of voice
   - Neutral affect
   - Reward compliance
   - Use prearranged silent cues for individual or class
   - Possibly use choices with oppositional children
   - Give reprimands at child's desk and privately if possible (avoids acting out as a result of embarrassment)

Classroom Behavioral Interventions

4. Rules and structure for individual child (e.g., desk placement, task sheet)

5. The One Necessary (though not always sufficient) Component of Behavior Modification in Schools:

Daily Report Card from School to Home

Daily Report Card
(Downloadable at our website ccf.FIU.edu)

- An integral part of all of our school interventions with ADHD children; studies have shown DRCs effective in changing behavior at school
- Effective in changing ADHD children's behavior at school
- Cost little and take little teacher time
- Provide for daily communication between teachers and parents, which is critical
- Provide positive reinforcement for a child who has already been singled out by other children
- Reduce the need for notes home and phone calls to parents
- Once they are set up, DRCs reduce the amount of time that teachers must spend dealing with the child's problematic behaviors
- Provide a tool for ongoing monitoring of the child's progress
- Can be used to titrate the appropriate dose of medication
- Daily reports are necessary because children with ADHD need specific feedback and rewards/consequences for their behavior more frequently than once per week

Daily Report Card

Child's Name: _____ **Date:** ____

	LA		Math		Reading		SS		Sci.	
Follows class rules with no more than 3 rule violations per period.	Y	N	Y	N	Y	N	Y	N	Y	N
Completes assignments within the designated time.	Y	N	Y	N	Y	N	Y	N	Y	N
Completes assignments at 80% accuracy.	Y	N	Y	N	Y	N	Y	N	Y	N
Complies with teacher requests. (< 3 noncompliance per period)	Y	N	Y	N	Y	N	Y	N	Y	N
No more than 3 teasings per period.	Y	N	Y	N	Y	N	Y	N	Y	N

OTHER

Follows lunch rules (<3 violations).	Y	N
Follows recess rules (<2 violations).	Y	N

Total Number of Yeses/Nos: _____
Teacher's Initials:

Comments: _____

_____

_____

Downloadable at our website

Daily Report Card: Bad Example

Child Name: Date:

Ratings:

1. Follows directions ____
2. Gets along with other children ____
3. Completes work ____

KEY: 1 (needs improvement) to 5 (excellent)

Teacher Signature:_____
____

Classroom Behavioral Interventions

6. Premack or “when-then” contingencies (e.g., recess time contingent upon completing work, assigning less desirable work prior to more desirable assignments).
7. Response cost/reward point or token system for the target child.

Classroom Behavioral Interventions

8. Classwide interventions (e.g., class lottery)/group contingencies (e.g., "good behavior game", child earning a reward for the entire class); response cost/reward point or token system for the entire class.
9. Time out (classroom, office, systematic exclusion).

Why is it Important to Use Behavioral Treatments for ADHD Children's Problems in Peer Relationships?

Peer Relationships

- **Are seriously disturbed in the majority of ADHD children—particularly negative relationships with peers**
- **Are the best predictors of adverse adult outcomes for children**
- **Are the best mediators of adverse adult outcomes**

(Barkley, 2006; Milich & Landau, 1982)

Peer Perceptions of ADHD Children

Those who: (% named)	ADHD Boys	Controls
Try to get other people into trouble	51	17
Play the clown and get others to laugh	40	19
Tell other children what to do	41	16
Are usually chosen last to join in group activities	27	13
Start a fight over nothing	48	19

- **Pupil Evaluation Inventory Items** (Pelham & Bender, 1982)

Components of Evidence-based, Treatment for ADHD

Child Intervention

- Behavioral and developmental approach
- Focus on teaching academic, recreational, and social/behavioral competencies, decreasing aggression, increasing compliance, developing close friendships, improving relationships with adults, and building self-efficacy
- Paraprofessional or teacher-based
- Intensive treatments such as summer treatment programs, and/or in-school, after-school, and Saturday sessions (NOT clinic-based social skills—social validity of setting is important)
- Don't expect instant changes--improvement (learning) gradual
- Continued support and contact as long as necessary--multiple years or if deterioration occurs
- Program for generalization and relapse prevention (e.g., integrate with school and parent treatments--link all through home/school report card systems and parent oversight)
- Reestablish contact for major developmental transitions (e.g., adolescence

(Pelham & Burrows-MacLean, 2004; Pelham et al, 2010)

Why Treat ADHD in a Summer Setting?

- Work on peer relationships in an ecologically valid setting (e.g., playing common games in peer group settings)
- Teach sports skills and knowledge and team cooperation and therefore self efficacy
- Build friendships with other ADHD children
- Minimize summer learning loss that characterizes low achieving children
- Teach compliance skills to child and parents
- Teach daily report card concept to child and parents

Comprehensive and Intensive Treatment for ADHD: Summer Treatment Program

- Named in 1993 as one of the country's model service delivery program for children and adolescents by the Section on Clinical Child Psychology of the American Psychological Association.
- Used successfully in clinical trials at NIMH, CMHS, and NIDA
- Innovative Program of the Year, 2003, CHADD
- SAMHSA list of Evidence Based Practices (NREPP), 2008

Summer Treatment Program Sites

- FIU (both campuses in Summer 2011)
- Buffalo (Summit Educational Resources)
- New York City (NYU Medical Center)
- Cleveland, OH (Cleveland Clinic)
- Irvine, CA (UCIrvine)
- Birmingham AL (UAB Medical Center)
- Boston (Harvard/JBCC)
- Chicago (Univ IL Medical Center/ & Chicago Parks
- Kurume, Japan (Kurume University and Kurume schools)
- Erie, Johnstown, and Indiana PA (4 Community Agencies with 20 different sites)
- Other community sites in SLC Utah, WVA, NJ, WNY (Chatauqua), WA
- Smaller, shorter camps in many U.S. cities that use parts of STP

Summer Treatment Program Overview

- Children grouped by age into groups of 12-16
- Groups stay together throughout the day
- 4-5 paraprofessional counselors work with each group all day outside of the classroom
- One teacher and an aide staff the classroom for each group
- Treatment implemented in context of recreational and academic activities
- Focus on Impairment and teaching skills--not symptoms
- Parent training incorporated
- Medication is second line treatment

Typical STP Schedule

Time	Activity
7:30-8:00	Arrivals
8:00-8:15	Social Skills Training
8:15-9:00	Soccer Skills Training
9:15-10:15	Soccer Game
10:30-11:30	Art Class
11:45-12:00	Lunch
12:00-12:15	Recess
12:15-2:15	Academic/computer class
2:30-3:30	Softball Game
3:30-4:30	Swimming
4:45-5:00	Recess
5:00-5:30	Departures

Summer Treatment Program Overview

Treatment Components:

Point System

Social Skills Training, Cooperative Tasks,

Team Membership, and Close Friendships

Group Problem Solving

Time out

Daily Report Cards

Sports Skills Training and Recreation

Summer Treatment Program Overview 2

Treatment Components:

Positive Reinforcement & Appropriate Commands

Classrooms--Regular, Peer Tutoring, Computer, and Art

Individualized Programs

Parent Training

Medication Assessments

Adolescent Program

Beneficial Effects of Behavioral Treatments

(Fabiano et al, 2009)

- Improved functioning in home (e.g., improved compliance and parent ratings), school (e.g., improvement in classroom disruptive behavior and teacher ratings), and peer settings (e.g., improved positive and negative interactions)
- Evidence for benefit throughout the age range (4 to 15) but fewer studies at younger and older ages
- moderate to large effect sizes across treatments and measures
- Benefits generally independent of comorbidity
- However, room for improvement even after acute clinic-level treatment for many children
- Less evidence (few studies) for long-term benefits
- Little evidence on how to maintain benefits and thus recent emphasis on chronic care model

Presenter's Disclosure (past 3 years): James Waxmonsky, M.D.

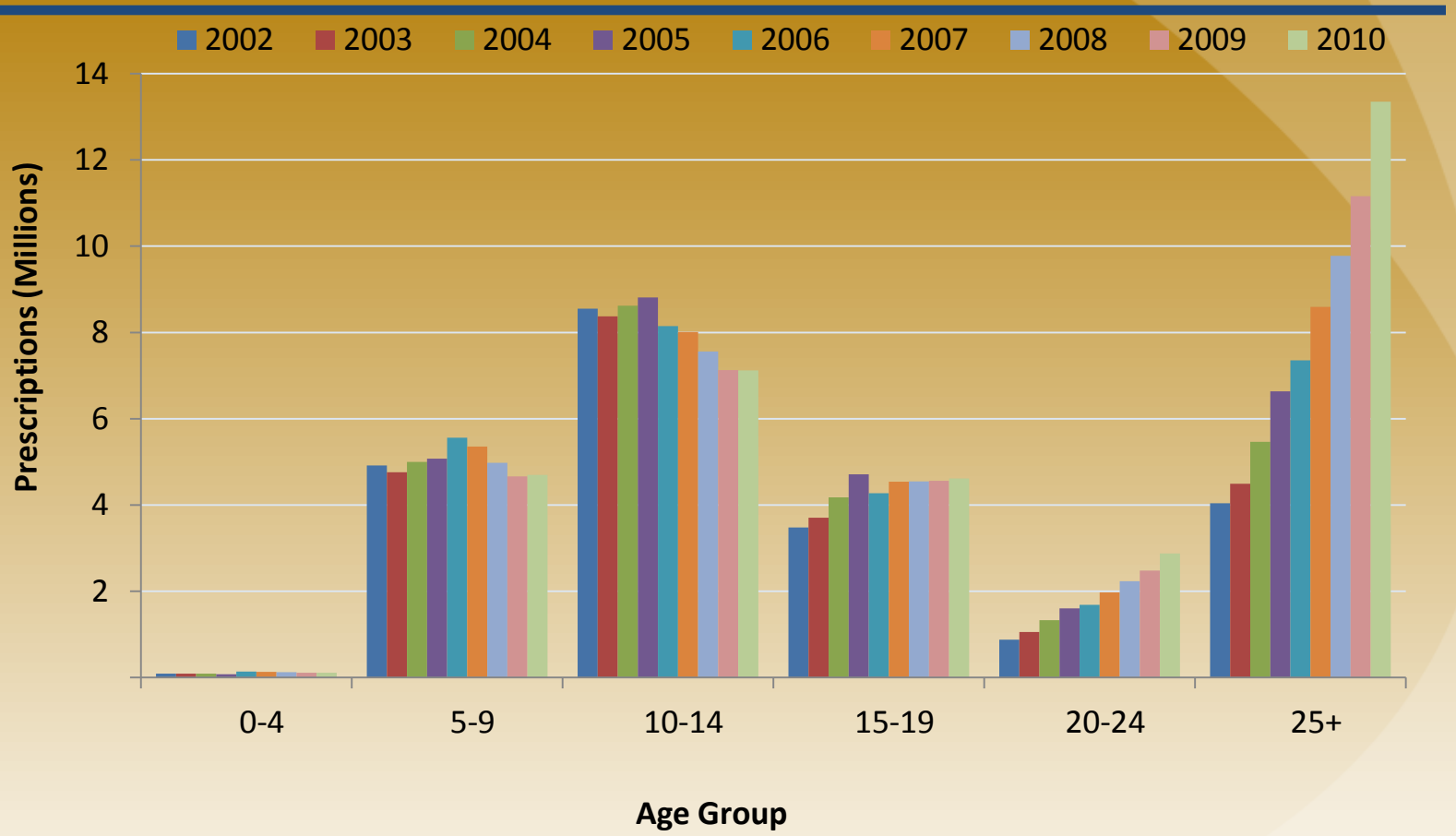
Source	Consultant	Advisory Board	Stock Equity >$10,000	Speaker's Bureau	Research Contract
Novartis				**X**	
Shire					**X**
Noven		X			
Janssen					**X**
NIH					**X**

This presentation will discuss treatment options that are not FDA approved.

Current Trends in Psychopharmacology

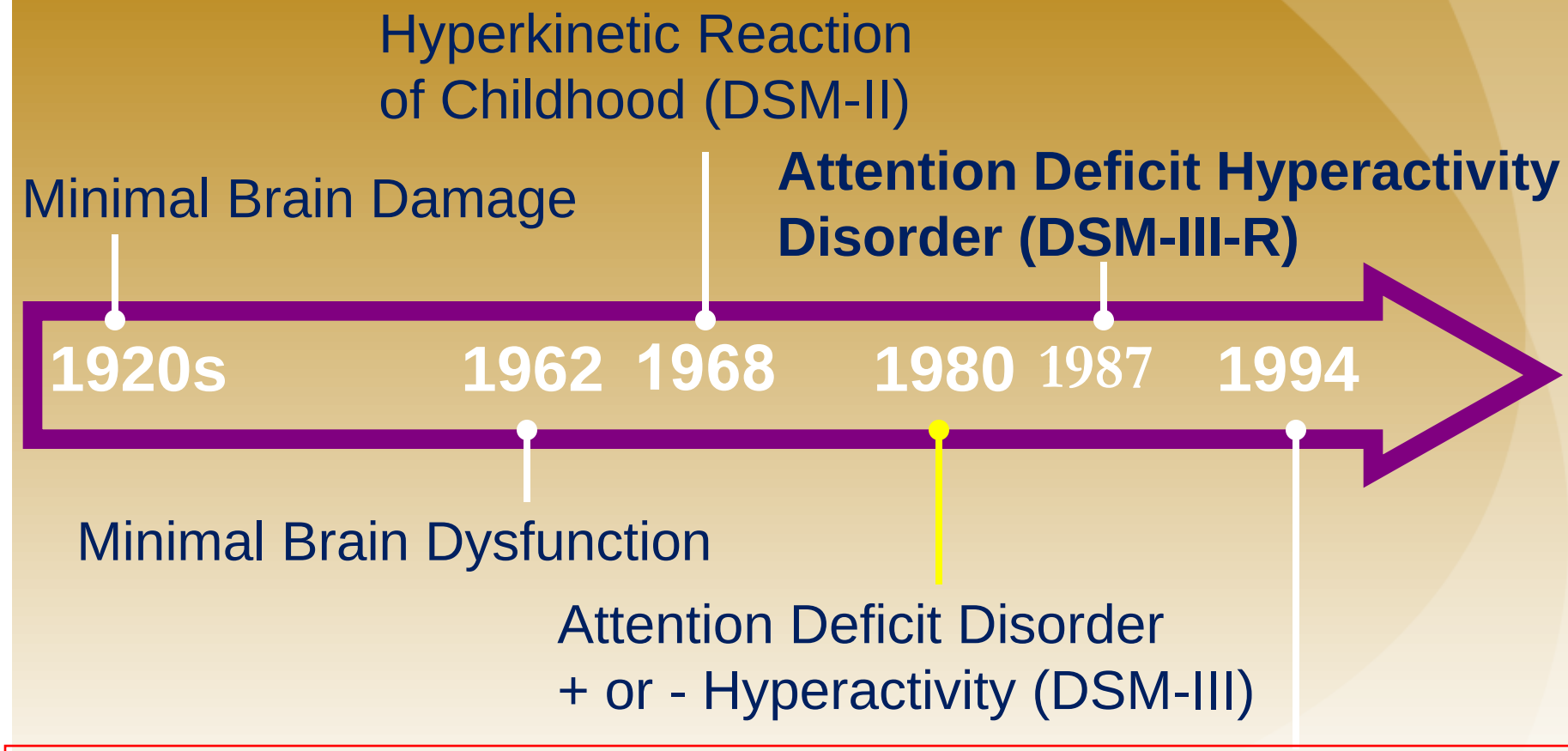
- 7.2% of children ages 4-17 with current diagnoses of ADHD and nearly 5% are medicated for the disorder (CDC, 2010)
- 39.5 million ADHD prescriptions written in 2008 (IMS Health, 2009)
- Stimulants are the most prescribed child psychotropic but use in school aged children has stabilized (Zuvekas, 2011)
- Largest % increase seen in preschoolers, adolescents and adults (CDC, 2010)
- Most psychotropics for youth written by non psychiatrists
- Recent increases in the combination use of stimulants and antidepressants or stimulants and antipsychotics (Comer et al., 2010)

Amphetamine and Methylphenidate Stimulant Medications: Projected Number of *Total* Prescriptions Dispensed by US Retail Pharmacies, 2002- 2010



Source: SDI, Vector One® National, (VONA), extracted February 2011

A History of ADHD:
1937 Dr Bradley prescribes benzedrine



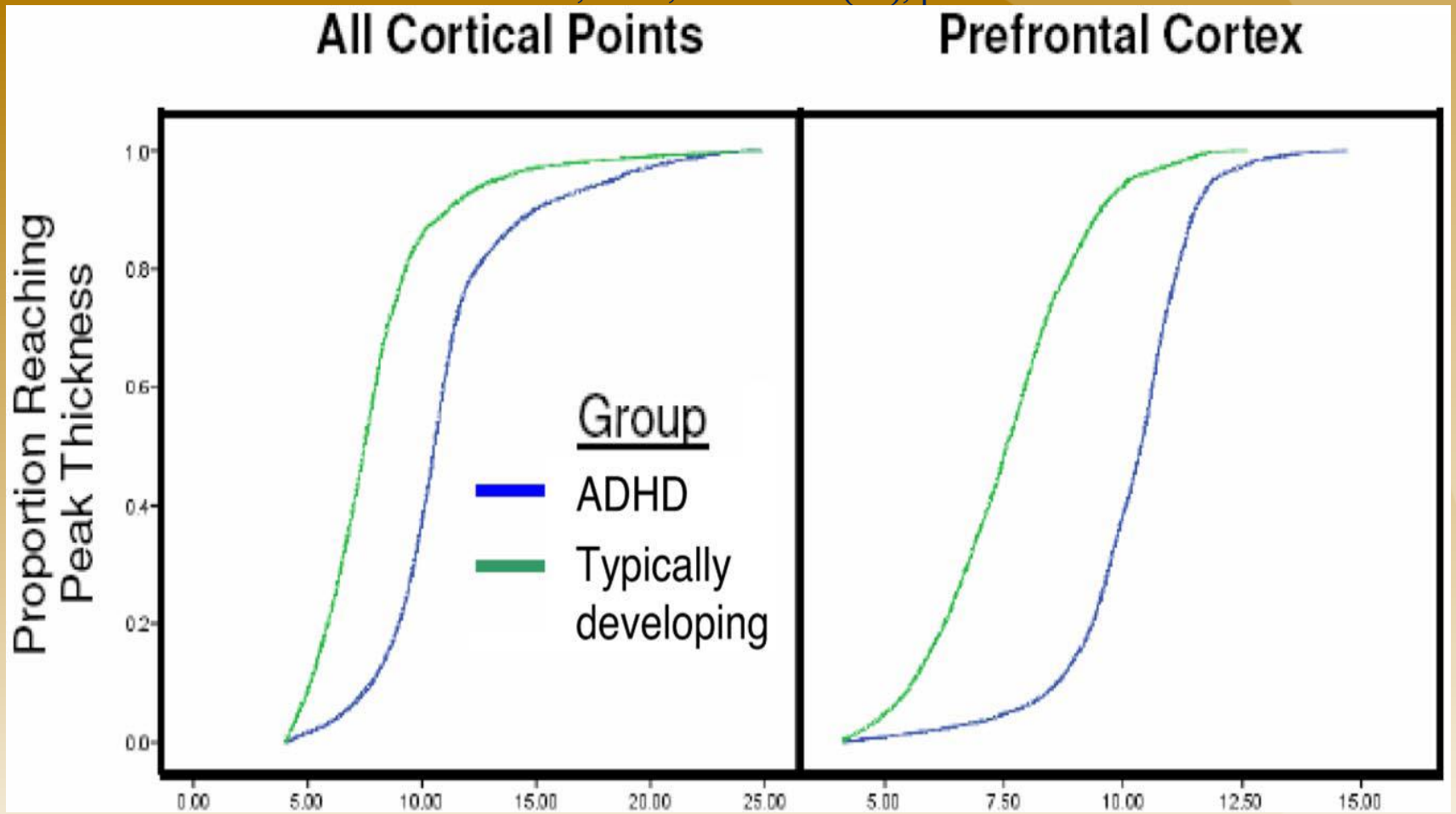
Attention-Deficit/Hyperactivity Disorder (DSM-IV and IV-TR)

DSM-IV Definition for Attention-Deficit/Hyperactivity Disorder

- A. 6/9 inattentive or hyperactive impulsive symptoms
- B. Some symptoms that caused impairment were present before age seven.
- C. Some symptoms that cause impairment are present in two or more settings (e.g. at school, work, and at home).
- D. There must be clear evidence of clinically significant impairment in social, academic, or occupational functioning.
- E. Not better accounted for by another disorder

Maturational Deficits in ADHD

Shaw et al., 2007, PNAS 104(49), p19651



The primary motor cortex develops earlier in ADHD youth while the prefrontal cortex (planning center) develops later.

Reward Deficit Theory of ADHD

(Volkow, et al., 2009)

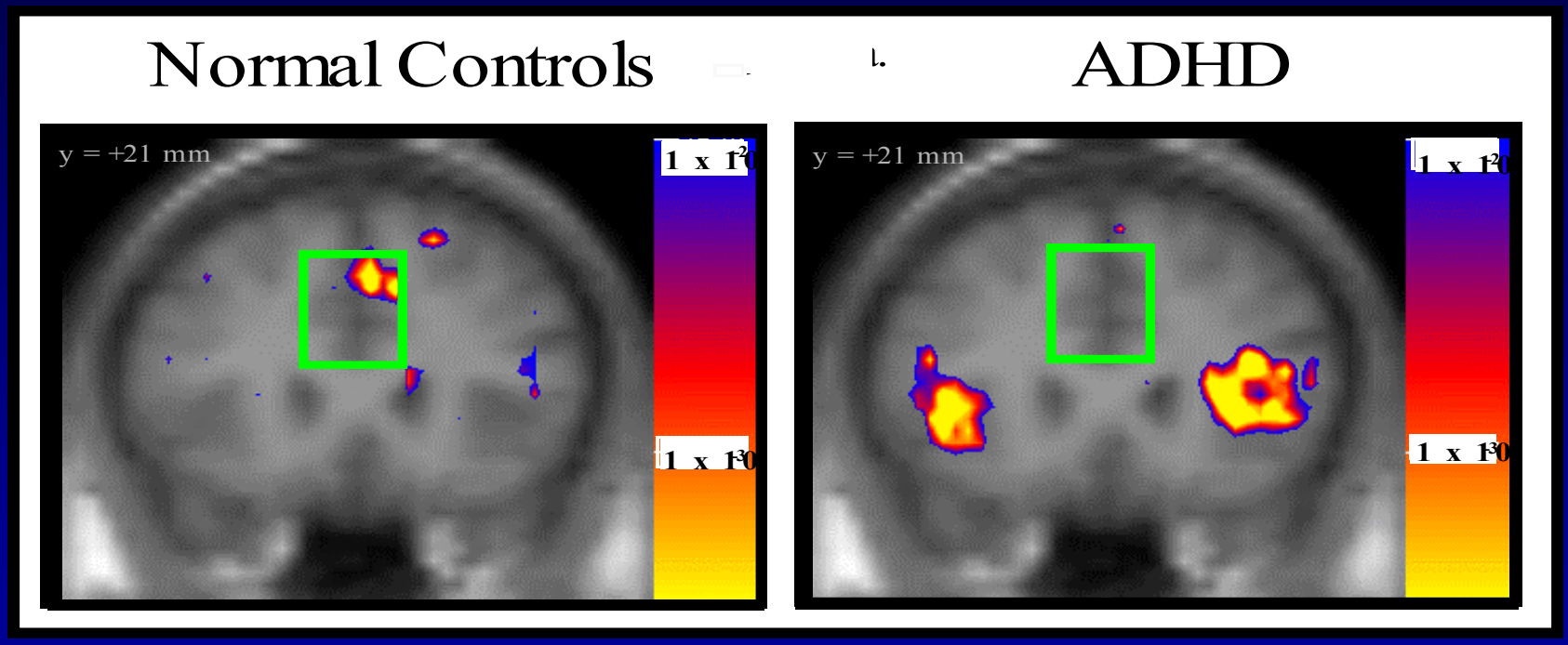
- When you get a reward, dopamine (DA) gets released
- More DA= stimuli experienced as more rewarding
- DA fires in response to anticipated reward
- Over time, the expectation alone triggers the DA burst
- In ADHD, this is thought not to happen so they do not experience any anticipatory motivation.
- Children with ADHD **more dependent on external motivation** because of these deficits
- Failure to provide reward decreases DA release

Dopamine

(Swanson et al., 2007)

- DA projections originate in the midbrain
- Project to caudate, putamen, nucleus accumbens, amygdala, hippocampus and cortex
- Dopamine neurons have a tonic release (baseline state) and a phasic response to stimuli
- Theorized that ADHD patients have low tonic state (under aroused) and excessive phasic bursts (distractibility)
- Dopamine Transporter (DAT) clears DA from synapse terminating the DA signal
- Glut, GABA, 5HT, noradnergic and cholinergic inputs to DA cells in midbrain so more complex than just synaptic DA levels

Anterior Cingulate (Cognitive Division) Fails to Activate in Attention-Deficit/Hyperactivity Disorder



MGH-NMR Center & Harvard- MIT CITP

Bush et al., 1999

Pediatric study showing stimulants correct this abnormal activation in youth with ADHD (Peterson et al., AJP 2009)

Part 2 of 2

The Multimodal Treatment Study of Children with ADHD (MTA)

(*Arch Gen Psych*, 1999.56:1073-86)

- 14 month clinical trial at 6 different sites
- 579 children ages 7-10 years all with ADHD with about 25% previously medicated
- Subjects randomized to 1 of 4 conditions:
  - Medication management (mostly TID methylphenidate)
  - Behavior management (parent, school and individual)
  - Combined treatment (meds plus behavior)
  - Community-based treatment (mostly BID stimulant)

Trends in Medication Use

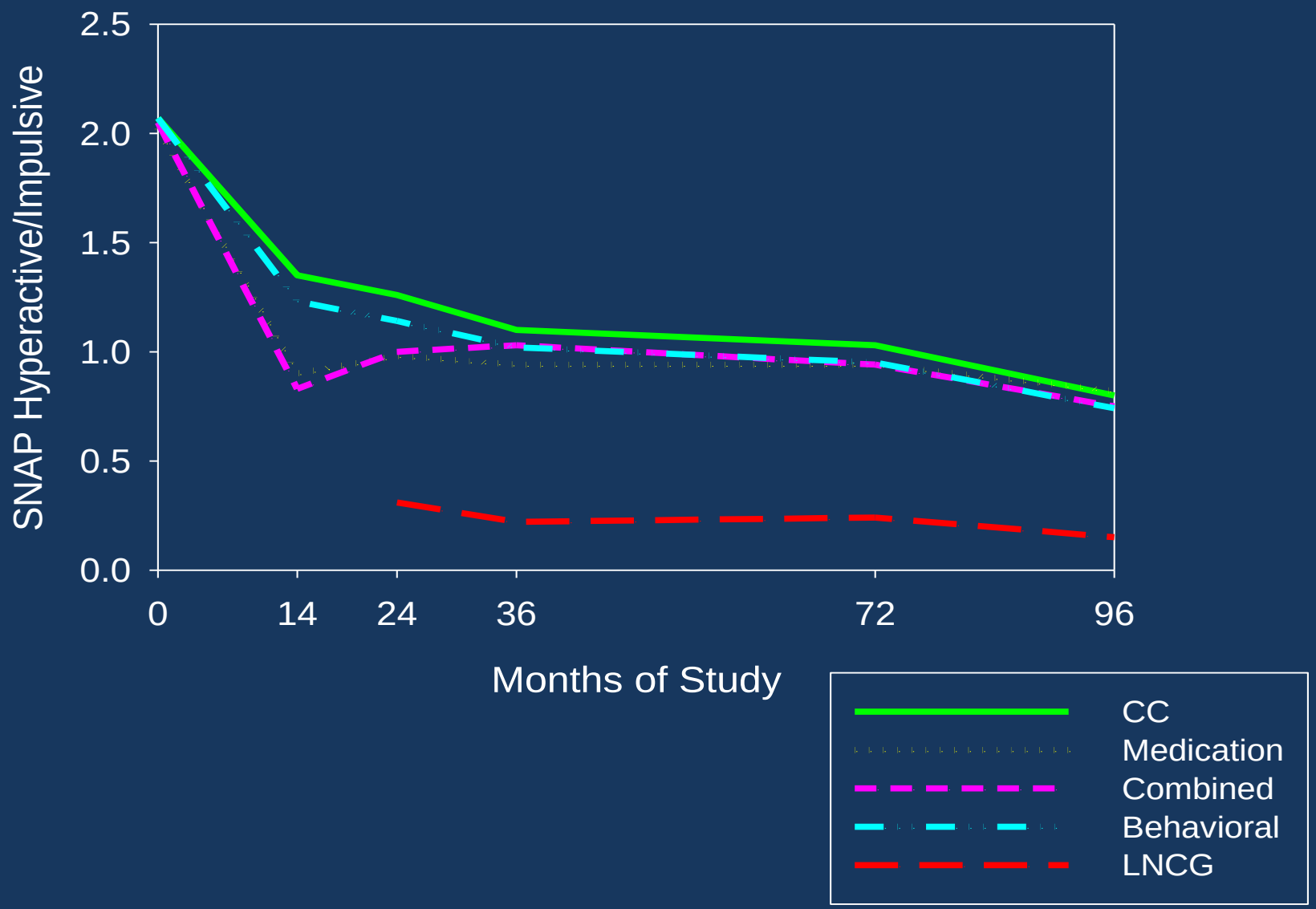
- Before MTA, Concerta, and Adderall XR
  - Meds for school hours only-184 days per year
  - Modal total daily dose: 15-20 mg MPH; 10 mg Adderall
  - Weekends and summers medication free
  - Most children medicated 1-3 years
  - Lifetime dose: 5400 mg to 10,800 mg MPH
- After MTA, Concerta, and Adderall XR
  - Meds for school and home
  - Equivalent total daily doses: 36 mg Concerta; 20 mg Adderall XR
  - Weekends and summers medicated (so 365 days per year)
  - Current recommendations (e.g., MTA): start early and medicate for all 12 school years
  - Lifetime dose: 14,600 mg/year X 12 =175,000 mg MPH

Summary of MTA Results

- **All** four groups **improved** dramatically during the 14 months of active treatment (treatment works)
- **Medication** (40mg MPH/day) was superior to Behavior therapy for ADHD **symptoms** at 14 months
- **Combo** (31 mg MPH/day) was more likely to "**normalize**" at lower doses than Med group and was much **preferred by parents** (Conners et al., 2001)
- Intensive behavior therapy worked as well as the Community treatment (BID MPH)
- 8 years out, no differences between children who were medicated vs. those who were not as subjects were still more impaired vs. those without ADHD (Molina, 2009)
- Meds quicker to work but not clearly more effective
- Need better treatments using a maintenance model

Parent-Rated Hyperactivity-Impulsivity

(8 year data, Molina et al., JAACAP 2009)



MTA 8 Year Outcomes

(Molina, 2009 JAACAP, p 497)

- "data fail to provide support for long term advantage of medication treatment beyond 2 years for the majority of children- at least as medication is monitored in community settings…Decisions about medication may have to be made on an individualized basis avoiding untested assumption about continuing benefit and using periodic trial discontinuations to check for need and benefit."

What ADHD Medications Can Do

- Typically lead to a 25-75% reduction in symptoms of hyperactivity (restlessness, talkativeness)
- Typically lead to a 25-75% reduction in symptoms of impulsivity (interrupting, reckless behaviors)
- Typically lead to a 25-75% reduction in symptoms of inattention (easily distracted, problems listening)
- Typically see improvements in the accuracy and efficiency of academic work especially for repetitive problems like Math
- Typically see reductions in arguing and other aggressive behaviors

What ADHD Medications Do NOT Do

- Leads to complete resolution of symptoms
- Leads to sustained improvements once medication is stopped (at least this has been hard to show)
- Leads to improved social relationships
- Leads to large improvements in organizational skills
- Leads to large improvements in symptoms of depression, anxiety or substance abuse (but does not typically make them worse either).
- Leads to large changes in parenting practices (does reduce parental stress)

Stimulants

- 70 years of data on them
- Two classes: methylphenidate (MPH) and amphetamine (AMPH)
- Similar efficacy but up to 40% of children have preferential response to either MPH or AMPH (Arnold, 2000)
- 75% will respond to one stimulant and 85% will respond to either MPH or AMPH (Arnold, 2000; Greenhill, 1996)
- No way to tell which children will do best on which medication
- Decide based on duration of effect, cost, past experience and family preference
- Pliszka 2007 or Greenhill 2002 (Journal of The American Academy of Child and Adolescent Psychiatry)

Attention-Deficit/ Hyperactivity Disorder
d-, l-methylphenidate: Delivery vehicles

Immediate release tablets (30 min to 4-6 hours)	•Methylphenidate* (5-20mg TID) •Ritalin** •Focalin** (2.5mg-10mg TID) •Methylin** (liquid also)
Osmotic pump (1-12 hrs)	•Concerta* (18-72mg)
Double pulse beaded (1-10hrs)	•Ritalin LA (10-40mg) (50/50 ratio) •Focalin XR (5-40mg) (D-MPH) •Metadate CD (10-60mg) (30/70)
Transdermal patch (2 hrs –flexible endpoint)	•Daytrana (10,15,20,30mg)
Wax matrix Liquid	•Ritalin SR** •Metadate ER •Methylin ER •Methylin**

*generic **available generic

Attention-Deficit/ Hyperactivity Disorder
d-, l-amphetamine: Delivery vehicles

Immediate release tablets (30 min to 6hrs)	•Dextroamphetamine (5-20mg bid) * •Dexedrine** (d only) •Dextrostat** •Adderall** : (mixed salts; 5-30mg)
Osmotic pump	Not available
Double pulse beaded (1-12 hrs but variable across patients)	•Dexedrine Spansule (5-15mg BID)** •Adderall XR (5-30mg)**
Transdermal patch Lysine bound soluble (1-13hrs) Liquid	• in development •Vyvanse (20-70mg) • LiquADD

*generic **available generic

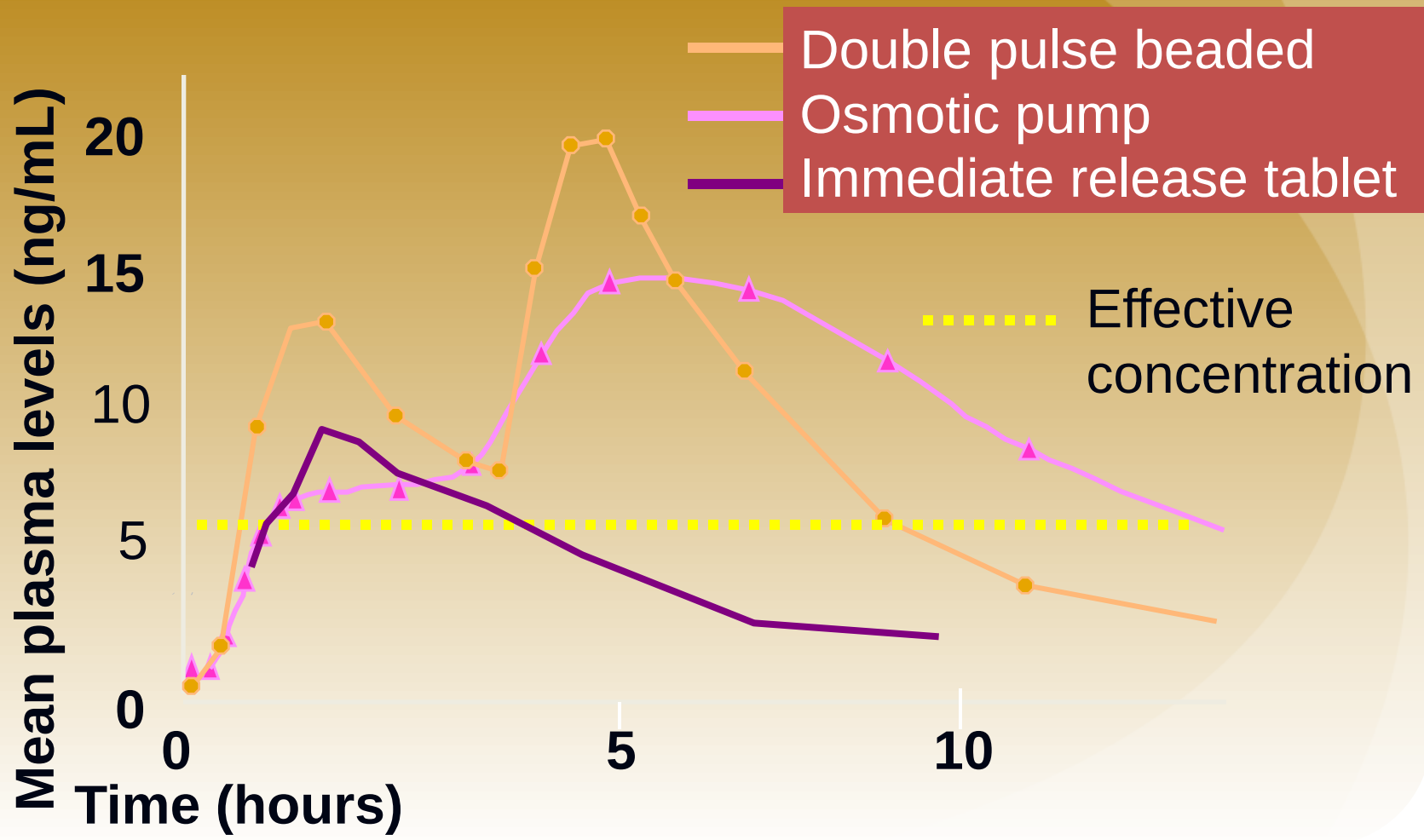
Methylphenidate (MPH)

- Starting dose of .3mg/kg/day or 5-10mg per day
- Standard dose range of .5mg to 1.5mg/kg/day
- Works by blocking DAT and increasing synaptic DA
- Branded extended release caps vs. generic: ITS ALL THE SAME ACTIVE MEDICNE
- ER Preps: **same immediate effect**, differential duration, possibly some differences in side effect profile
- Key is finding the time of day that symptoms cause the most problem (Comacs Study, 2004)

MPH Preparations

- Instant release (IR) MPH works in 30 mins and last 3-4 hours
- OROS-MPH (Concerta) is meant to mimic 3xday short acting MPH with 10-12 hrs of effect
- Beaded Capsules (Metadate CD, Ritalin LA, Focalin XR) closer to 2xday MPH with 8-10hrs of effect with > AM symptom relief
- Patch (Daytrana)- lasts up to 4 hours post removal but slower to start working (Wilens, 2009)
- DexMPH (Focalin)- dexmethylphenidate isomer only in IR and ER forms

Extended Release MPH Preps



Amphetamine (AMPH)

- Twice as potent as MPH (5mg=10mg MPH)
- Longer therapeutic duration than IR MPH by 25-33%
- Enhances synaptic dopamine through multiple pathways unlike MPH (at best slight efficacy advantage- Faraone, 2002)
- Starting dose of .15mg/kg/day or typically 2.5-5mg
- Standard dosing is .25mg to 1mg/kg/day
- Similar side effects to MPH except for possibly more appetite loss and feeling “medicated”

AMPH Preparations

- Mixed Amphetamine salts XR (Adderall XR)= BID IR AMPH
  - Double beaded capsule with highly variable duration
- Dexedrine Spansule- R isomer only; comparable to IR AMPH
- Lisdexamfetamine (Vyvanse): pro-drug version initially designed to decrease abuse risk but also provides more consistent and possibly longer therapeutic duration
  - Onset prior to two hours is not well established
- Patch form under development

Starting Doses of Stimulants
(child/teen or adult)

- IR methylphenidate (MPH) 5/10mg (1/2 for d-mph)
- IR dextroamphetamine (DEX) 2.5-5/5 mg
- Double pulse beaded MPH 10/20mg
- Double pulse beaded MAS 5-10/10mg
- Double pulse beaded *d*-MPH 5/10mg
- Osmotic pump MPH 18mg
- Transdermal MPH 10 mg
- *lis*dexamfetamine 20/30mg
- Titrate once weekly in the increments above
- *Recommended starting doses drop by half if under age 6 and only DEX is FDA approved under 6*

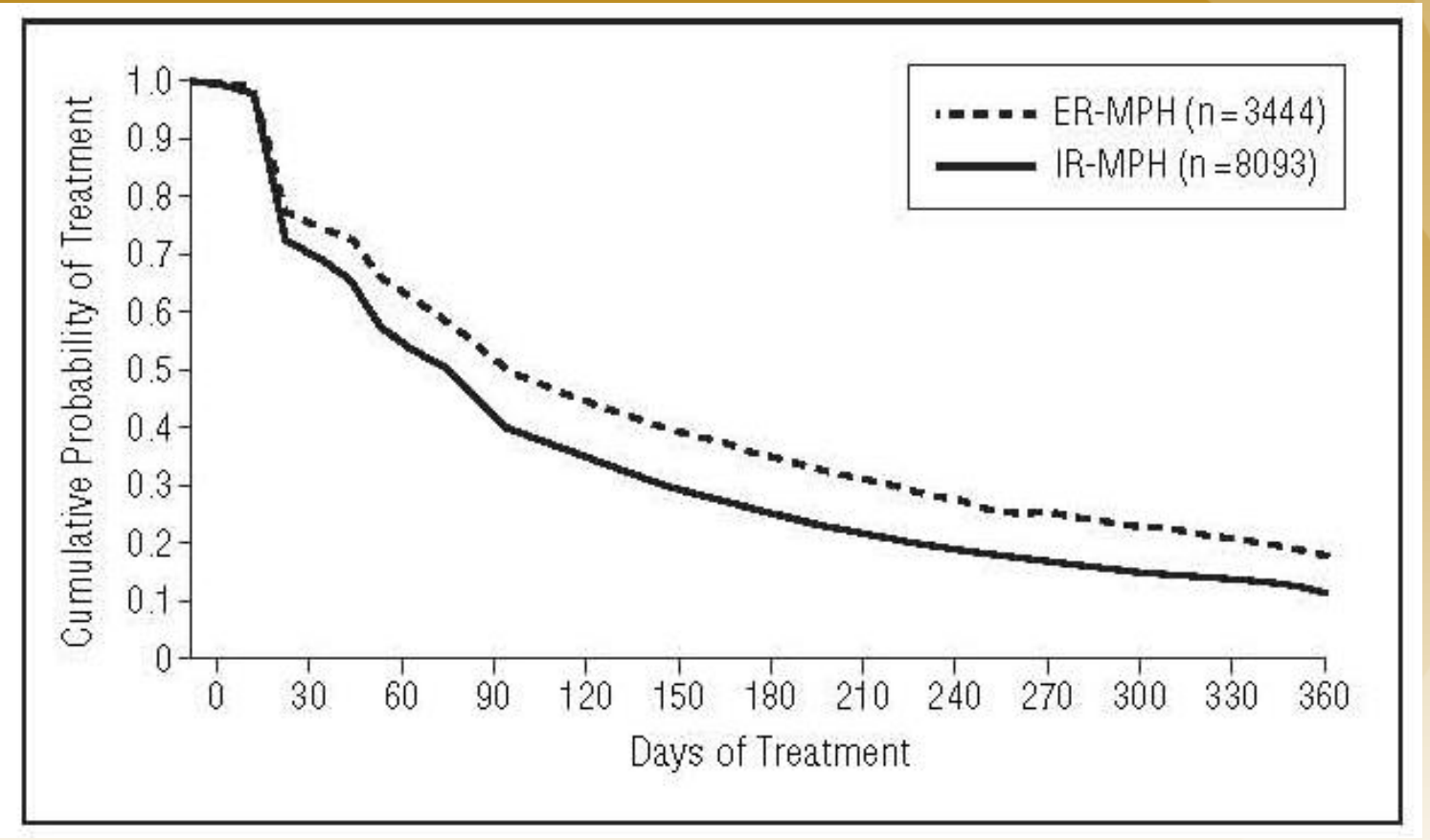
What to do Next?

- If lack of effect/partial effect, increase dose (if under1to 1.5mg/kg/day for MPH or .5 to 1mg/kg for AMPH)
- If duration too short, add extra dose (IR) or switch preps
- True rebound (worse symptoms than before med is rare (<5%) but may happen
- Some data that increasing dose of AMPH or Dex-MPH will increase duration of effect
- For OROS-MPH, increasing dose will shorten time to onset
- If side effect at peak, decrease dose
- If evening side effects, move dose earlier in the day
- Works right away so titrate quickly – as soon as you can get feedback from school and home

Common Adverse Effects of CNS Stimulants

- 1. Insomnia
- 2. Loss of appetite, growth suppression
- 3. Stomachaches, headaches
- 4. Irritability, moodiness (high placebo rates)
- 5. Blood pressure, pulse elevations
- 6. Tics
- 7. Evening rebound (meds wear off)
- 8. Noncompliance

Noncompliance is the #1 “Adverse Event”



Marcus, S.C., Wan, G.J., Kemner, J.E., & Olfson, M. (2005). Continuity of methylphenidate treatment for Attention Deficit/Hyperactivity Disorder. *Archives of Pediatric and Adolescent Medicine, 159*, 572-578.

Tics: Not what They Used to Be

- Black box contraindication for stimulants
- 1 in 3 children with ADHD experience a tic but tics add little additional impairment beyond ADHD (Spencer, 1999)
- Tics typically onset when ADHD meds onset
- Use of stimulants not associated with significantly higher rates of tics in children with ADHD or extended duration of tics (Spencer, 1999)
- 20% of children with ADHD and tics experienced tic exacerbation with MPH (placebo-22%) with mean tic severity decreasing with all treatments (TSG, 2002)
- In a child with severe tics, consider nonstimulants as the tic risk is roughly similar risk for all stimulants

Substance Abuse and ADHD

- Misuse is more common than abuse
- Teens/college students most likely to misuse (to stay up), abuse (to get high) (22%) or sell meds (11%) (Wilens et al., 2008)
- Stimulants have been used as replacement therapy for cocaine addiction and to treat ADHD in substance abusing youth (Waxmonsky & Wilens 2005)
- Substance abuse correlates more strongly with delinquency than ADHD (Brook 2010; Charach, 2011)
- However, ADHD predicts earlier nicotine & alcohol use and heavier alcohol use as young adults (Molina & Pelham, 2007)
- Most studies have found no link between stimulants for ADHD and future substance abuse (Faraone & Wilens, 2007)
- Nonstimulants have the lowest abuse risk
- Among stimulants, the longer acting capsules have the least abuse risk while the pills are the easiest to abuse

Stimulants and Growth

- ER stimulants may prolong the duration of associated side effects, especially insomnia and anorexia.
- It has been known for 30 years that stimulant medications decrease appetite, but they were not thought to suppress growth (Safer, 1972).
- The largest ADHD study to date (NIH funded MTA) suggests there may be an impact of around ¾ to 1 inch depending on age of initiation and chronicity of use.
- Impact on final height not clear but they are stimulant medication are associated with slowing of growth in prepubertal children that does not recover during childhood without stopping medication

American Heart Association Warning

(Vetter 2008)

Do stims increase risk of Sudden Cardiac Death?

•Before starting med assess:

- Personal HX – palpitations, syncope
- Family HX of SCD/cardiac illness
- Physical Exam- listen to hearts
- EKG?- "it can be useful to add an ECG to increase the likelihood of identifying significant cardiac conditions. We recognize that the ECG cannot identify all children with these conditions but will increase the probability (pg 2416)."
- Current standard is targeted screening for those with a risk factor or polypharmacy

Adverse Emotional Effects?

- In 2007, FDA issued warning about aggression, suicidal thoughts and manic symptoms (but no Black Box unlike antidepressants)
- There is very **little controlled data** on this- mostly cases reports and personal testimony
- Children with impulse control problems are prone to over reacting, which improves with treatment
- At high doses, children can become subdued
- Studies of stimulants in children with anxiety, depression or Bipolar Disorder show that they can be safely used to treat ADHD but do not improve comorbid mood symptoms (Daviss, 2008, Findling 2007; Jensen 2001; Scheffer 2005)
- Risk of paradoxical mood reactions is probably **less than with antidepressants**

Preschool ADHD Treatment Study (PATS, 2006)

- 70 week study of 300 preschoolers with ADHD (4.4 yrs)
- All treated with IR MPH doses from 1.25 to 7.5 tid (small)
- All doses outperformed placebo at school including 1.25mg
- Doses of 2.5mg or higher outperformed placebo at home
- Mean dose was 14mg per day (5tid) or .7mg/kg/day (1mg/kg in MTA)
- 30% had noticeable side effects and 11% dropped due side effects: irritability, moodiness which could have been from lack of effect
- ADHD subjects were larger than average (2cm/2kg) but growth rates slowed by about 20% on meds (1.4cm/year) and decreased further over the next year

NEW AAP Guidelines for Preschoolers

(PEDIATRICS Volume 128, Number 5, November 2011)

- Guidelines state it is appropriate to make the diagnosis before the age of 6
- Initial treatment for children under the age of 6 should be behavior therapy
- If behavior therapy is insufficient, then used of MPH is acceptable
- Most evidence for MPH but actually only generic amphetamine carries FDA approval
- In areas where behavioral treatments are not readily available, weigh risks of starting medication against the harm of delaying treatment

Why Use a Non-stimulant?

1) **Lack of effect-** about 15% of children with ADHD are stimulant non-responders

2) **Residual symptoms-** especially before morning dose or after evening dose wears off

3) **Tolerability-** appetite, growth, sleep, tics, emotional lability, cardiovascular effects

4) **Comorbidity concerns-** how do stimulants impact other psychiatric disorders?

5) **Stigma issues-** abuse and side effect concerns

❖Behavior therapy is the most evidence based nonstimulant

Daily Report Card

- An integral part of all of our school interventions with ADHD children
- Serves as a means of identifying, monitoring, and changing the child's classroom problems
- Doubles as an avenue of regular communication between the parents and the teacher
- Costs little, takes little teacher time, and is highly motivating to the children if parents have selected the right rewards for home back-up
- Effectiveness documented in numerous studies
- Can be used to optimize medication dose

Atomoxetine (Strattera)

- Inhibits presynaptic norepinephrine transporter
- Leads to increase in prefrontal dopamine
- Minimal abuse liability; not a controlled substance
- Less risk of weight loss and no issues with sleep delay or tics
- Somewhat less efficacious than stimulants with about 50% of children responding to it (Newcorn et al. 2009)
- Takes 2-4 weeks for onset of therapeutic effect
- Black Box warning for suicidal thoughts as is structurally similar to some antidepressants but actual rate of occurrence is very low (.5%)
- May work when stimulants fail but little data to support its use as augmenter except to reduce the stimulant dose

Extended Release Guanfacine (Intuniv)

- Approved for children ages 6-17
- Selective a1 agonist
- Onset seen in 1-2 weeks and full effect in 2-4 weeks
- Effective for hyperactive and inattentive symptoms and oppositional behaviors with ES between .6 to .8 (Biederman et al., 2008)
- Strength of effect strongest in in children <9 with failure to separate from placebo in adolescents
- Main side effect is sedation (36%) but no issues with insomnia or weight loss
- Need to watch for drop in blood pressure and possible syncopal episodes (rare)
- Now also extended release clonidine (Kapvay) now available and both are approved for combined use with stimulants
- Adding XR Guanfacine to a stimulant improved ADHD symptoms by 20-25% over placebo (Wilens,2010)

Other ADHD Meds (Not FDA approved)

- **Guanfacine (Tenex)**- 6 hr generic tablet that requires BID dosing
- **Clonidine**- less selective and more sedating alpha agonist with four hour duration of effect so TID dosing
- **Modafinil (Provigil)**- narcolepsy med that increases synaptic dopamine like stimulants but has possible risk of Steven's Johnson Syndrome
- **Bupropion (Wellbutrin)-** antidepressant and smoking cessation drug
- **Tricyclic antidepressants-** effective but problematic side effect profile

Serotonin Reuptake Inhibitors

- No clinical evidence of efficacy in ADHD
- Some concern that SSRIs worsen hyperactivity symptoms in anxious children
- Helpful with comorbidity and safe with stimulants (watch with atomoxetine)
- Venlafaxine (Effexor): case reports and open data for adult and pediatric ADHD but no controlled data; retrospective analysis (N = 17) showing effect for MDD and ADHD[1]

1. Hornig-Rohan et al. 2002.

Limitations of Pharmacological Interventions When Used Alone

1) Not sufficient to bring many children into the normal range of functioning
2) Works only as long as medication taken
3) Not effective for all children
4) Does not appreciably affect several important variables (e.g., organizational skills, concurrent family problems, peer relationships)
6) Poor compliance in long-term use
7) Parents are not satisfied with medication alone
8) Removes incentive for parents and teachers/schools to work on other treatments
9) Little evidence for beneficial long-term effects of treatment (MTA, 2009)

Atypical Antipsychotics for Aggression

- Despite increasing use of atypicals in combination with stimulants there are no controlled data published except for trial of MPH and Aripiprazole in Pediatric BP (Tramontonia, 2009)
- Controlled data to support effect of Depakote (Blader, 2010) but not Lithium (Dickstein, 2009)
- Most of the data comes from monotherapy trials in BP or autism and risperidone in MR/subaverage IQ
- One year maintenance dose of risperidone in these trials was 1.5mg (Aman, 2004)
- Risperdal led to decreased rates of hyperactivity and disruptive behaviors in those on and off stimulants
- Significant wt gain and metabolic effects
- Ongoing controlled trial of risperidone (TOSCA)

Rationale for a Combined Behavioral and Pharmacological Intervention

- 1. The two treatments used separately have clear limitations for some children and both fall short of maximizing response at low doses in many children.
- 2. For children who need it, the combined intervention typically produces additive or interactive effects on many domains, thus bringing children closer to normalized functioning.
- 3. Behavior therapy can be used in the home setting at bedtime, where medication typically cannot due to side effects on sleep, or wake time before onset of effects.

Rationale for a Combined Behavioral and Pharmacological Intervention

- 4. Maximal improvement may be reached in school both with a less complex and less restrictive behavioral intervention (e.g. special class placement can often be avoided) and with a lower dose of medication--as low as one fourth of what would be needed without a behavioral intervention.

Rationale for a Combined Behavioral and Pharmacological Intervention

- 5. Because (a) behavioral interventions in a combined intervention are sufficiently simple for a teacher to conduct unaided for a long period of time, and (b) compliance with lower medication doses may be better and side effects are less severe than with higher doses, combined interventions may be more likely to be maintained over time with continued effects than the separate treatments.

Rationale for a Combined Behavioral and Pharmacological Intervention

- 6. Medication has the potential to facilitate learning, but there is as yet no indication that medication alone improves academic achievement. Appropriate psychoeducational interventions may enhance achievement when combined with medication, but there are not yet studies demonstrating this.
- 7. The two treatments sometimes have complementary effects, with each affecting different symptoms. Thus, the combined treatment may have a broader coverage of symptoms than the separate treatments.

Rationale for a Combined Behavioral and Pharmacological Intervention

- 8. Because concurrent medication enables a less intensive behavioral intervention to be implemented, a combined intervention may be more cost effective than a behavioral intervention alone.

Summary of MTA Results

(MTACG, 1999, 2004, 2007, 2009)

- **At End of Treatment**
  - All four groups improved dramatically with time
  - Active Med (study: 39 mg MPH/day) was superior to faded Beh on ADHD symptom measures and some measures of impairment
  - Combined treatment was better than behavioral alone but not medication alone
  - However, combined treatment produced more normalization at lower doses (and lower rates of increase in dose) than Med and was much preferred by parents
- **One year, three years, and six years later**
  - All groups better than baseline
  - 50% of medication incremental benefit lost at one year, all at 3 years
  - All groups equivalent on functional outcomes after one year
  - All groups equivalent on all outcomes after 3 years through 6 years

Would Parent Recommend Treatment?

(Pelham & MTA Coop. Group, under review)

	Medmgt	Comb	Beh
Declined/dropped out	12%	4%	0%
Not recommend	8%	3%	5%
Neutral	8%	1%	2%
Slightly Recommend	4%	2%	2%
Recommend	31%	15%	24%
Strongly recommend	38%	76%	67%

Current State of the Treatment Literature

- Behavioral and pharmacological treatments both have a solid evidence base for the treatment of children with ADHD. There is debate about relative efficacy.
- Though also effective, the combination of the two treatments has been understudied, particularly with respect to doses of treatment and whether all children need combined treatment.
- Most comparative and combined studies (e.g., the MTA) have involved low-dose or faded levels of behavior therapy, while medication has typically been implemented at high doses and has been sustained
- No-treatment controls have not been systematically included for behavioral treatments (problem of background rates of behavior modification, especially in schools), minimizing behavioral effects in studies, while placebo controls ensures appropriate control for medication.
- Although combined treatments are explicitly (e.g., CHADD) or implicitly (e.g., AAP, 2001) recommended by influential bodies in the ADHD field, no studies have addressed the question of how the components of combined treatments should be sequenced and whether sequencing influences need for combined treatment.

How Should Treatments Be Sequenced and What Doses Should be Used: Questions Not Answered by the MTA and Previous Research

- Should behavioral treatment begin before medication (parent preference) or vice versa (physician practice) or should they be implemented simultaneously (as in the MTA).
- What is the best “dose” of psychosocial and pharmacological treatment? Should “dose” always be increased if the child/family is still having problems?
- If one or the other modality is begun first, how long should it be conducted and at what dose before adding in the second modality?
- What are the implications of different sequences for treatment dosing, benefit, and risk of side effects?

- These are the questions that practitioners, parents, and schools face daily, but they have not been studied.

Program of Research

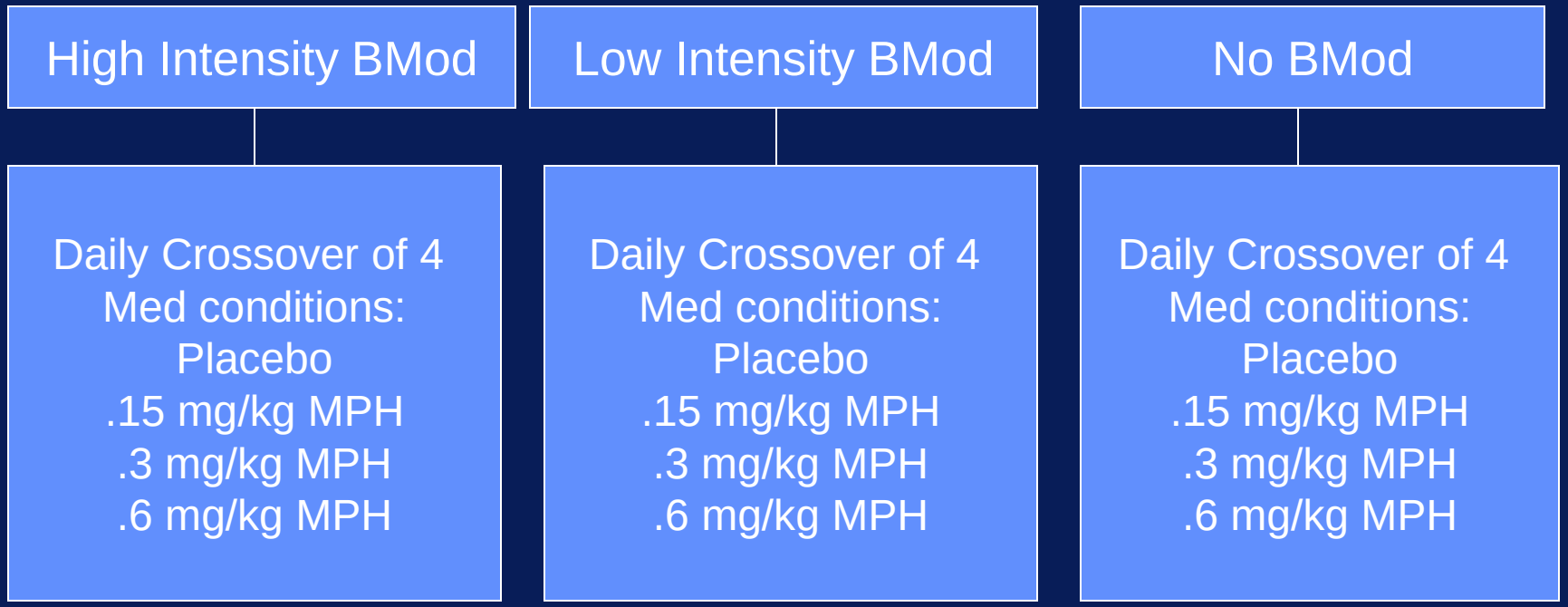
- **Four studies funded by NIMH and IES that examine dose effects and sequencing effects:**
  - (1) Controlled examination of 3 levels of behavior modification (none, low intensity, high intensity) crossed with 4 doses of medication in a summer program setting and at home
  - (2) Follow up to (1): School-year evaluation of effectiveness and need for medication after beginning the year on one of 3 behavior modification levels (none, low intensity, high intensity)
  - (3) Evaluation of effectiveness and need for medication in young ADHD children beginning treatment (home, school, peers, academic) with one of the same behavior modification levels as above (with adaptive components) and continuing without fading for 3 years (to pass peak period for medication use)
  - (4) SMART (sequential, multiple, adaptive, randomized trial) design to examine whether to begin treatment with medication or behavior therapy and, when nonresponse, whether to add the other modality or increase the intensity of initial modality

Study 1 Design

- 48-52 ADHD children per summer for 3 summers
- 4 Medication conditions: placebo and 3 doses of methylphenidate (.15mg/kg, .3 mg/kg, .6 mg/kg, t.i.d.), with order varying daily within child for 9 weeks
- 3 Behavior Modification conditions: No behavioral treatment (NBM), low-intensity (LBM) treatment, and high-intensity (HBM) treatment (BM), varying triweekly in random order by treatment group
- 3-4 days per medication X Bmod condition.
- NonADHD comparison group (24/summer).

Comparative and Combined Treatments for ADHD

3, 3-week Behavior Modification conditions assigned randomly:



Participants

- Data available on 154 ADHD subjects (130 boys and 24 girls) and 72 controls, ages 5-12.
- Controls matched to ADHD subjects by gender, ethnicity, and age (no medication--otherwise same participation).
- All participants had full-scale IQ ≥ 80; ADHD children were DSM IV-diagnosed using the DISC parent interview and parent and teacher ratings.
- Control subjects could not meet ADHD diagnostic criteria on the same measures.

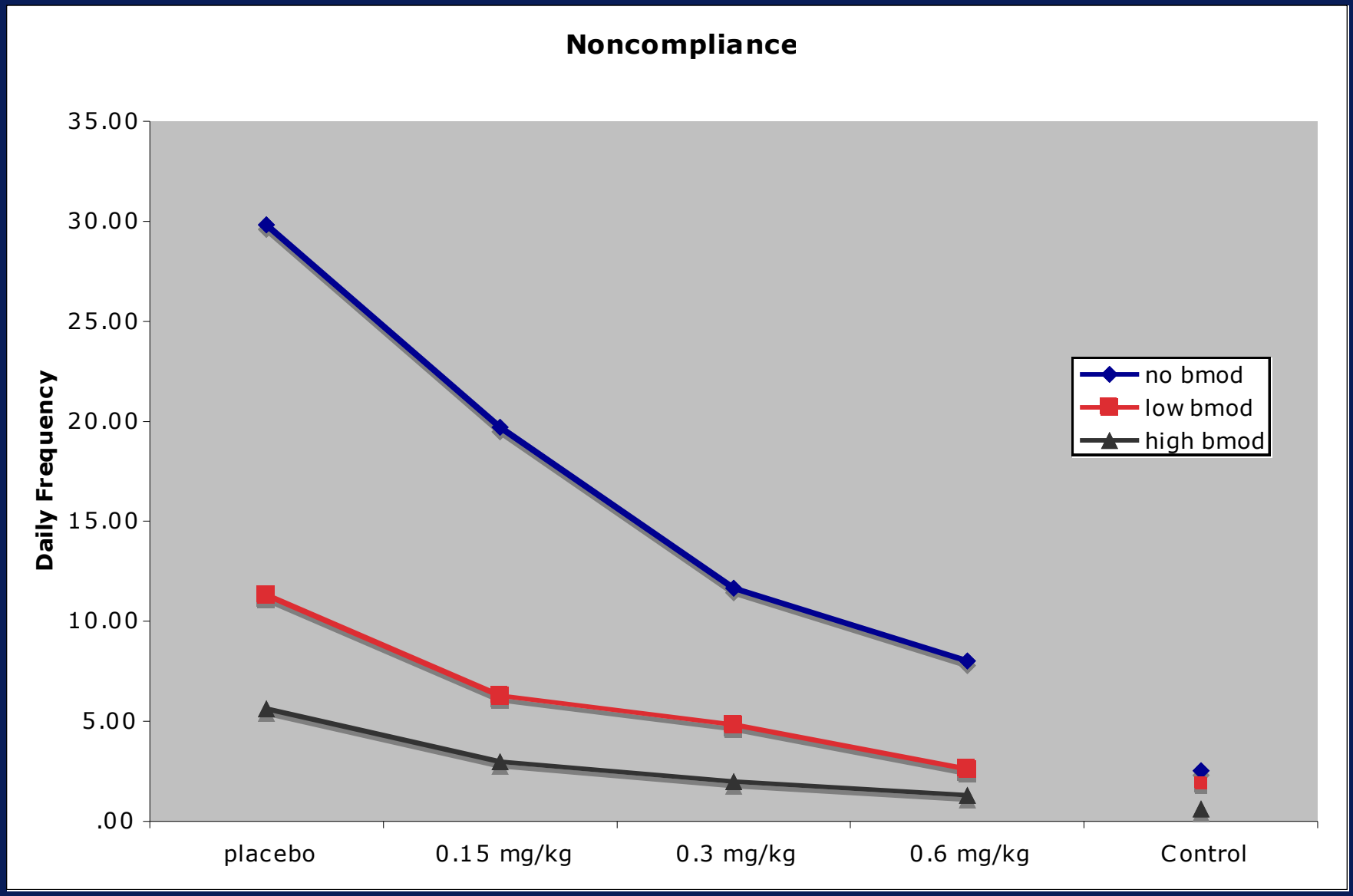
Dependent Measures

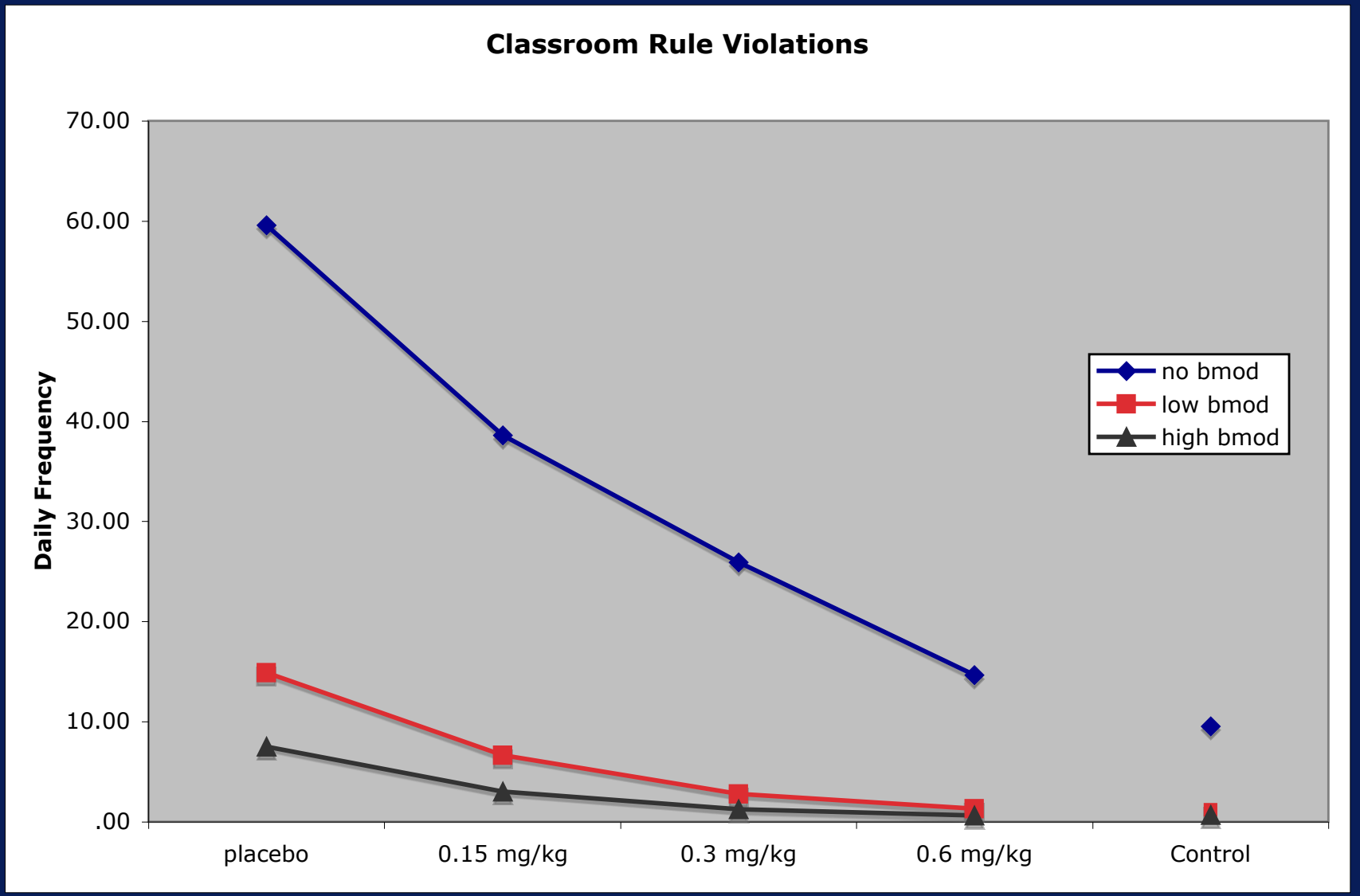
- **Counselor-Recorded Daily Behavior**
  - Following Activity Rules
  - Noncompliance
  - Interrupting
  - Complaining
  - Conduct problems
  - Negative verbalizations
- **Classroom Behavior**
- **Seatwork productivity and accuracy**
- **Staff and parent behavior ratings**
- **Staff and parent ratings of treatment effectiveness and distress**

Results

- On all behavioral measures, both medication and BMOD produced significant main effects.
- The two treatments interacted such that the dose-response curve was flattened in the presence of behavioral treatment compared to medication alone
- The majority of the medication effect occurred at the lowest dose in the LBM and HBM conditions. A more linear dose-response relationship was found for the NBM condition.

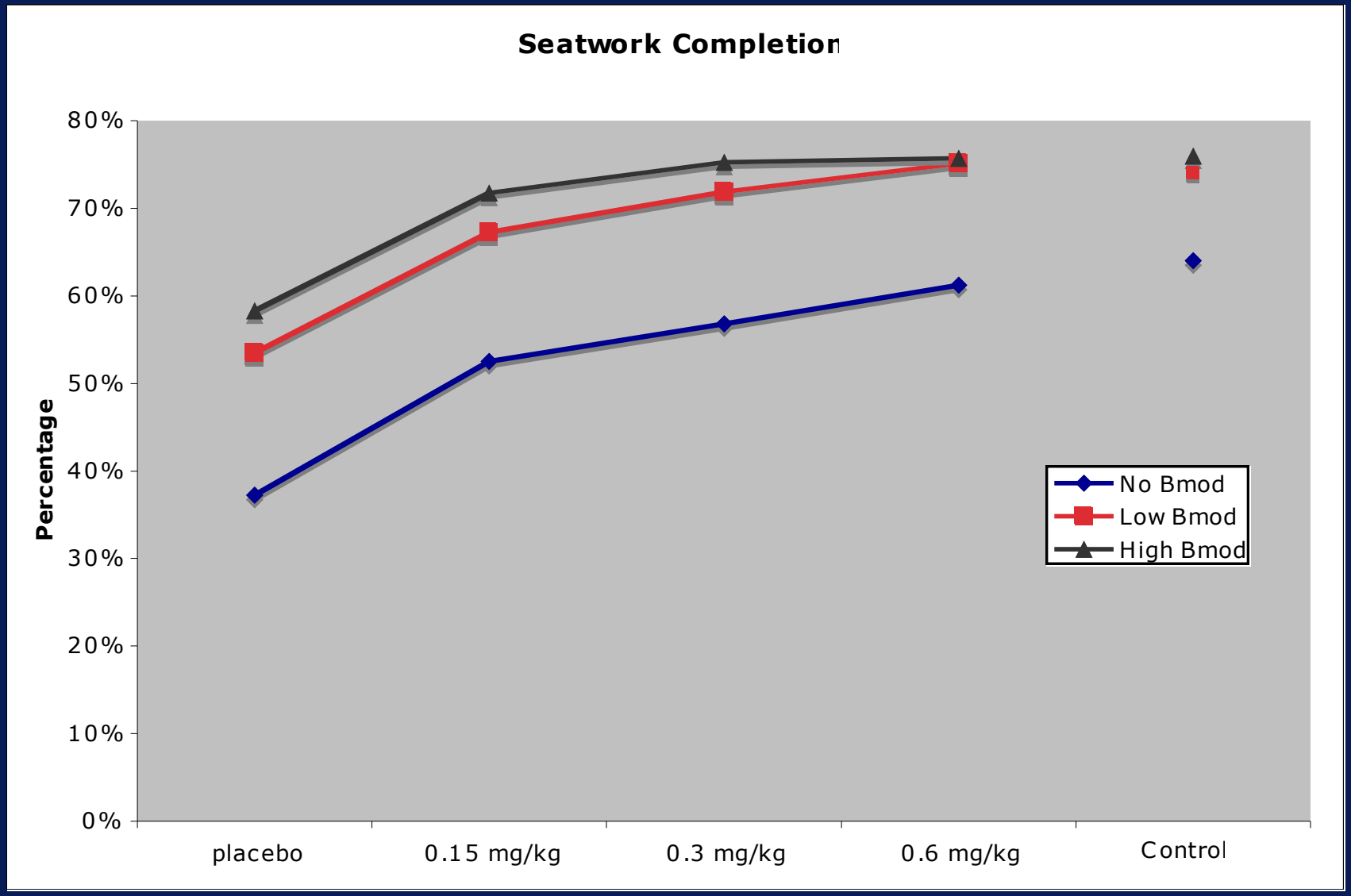
Pelham et al, under review





(Fabiano et al, School Psychology Review, 2007)

Fabiano et al, 2007



Fabiano et al., 2007, Summary

- Both medication and behavioral treatment produced significant and generally comparable effects (moderate to large effect sizes) on nearly all measures of functioning in recreational and classroom settings.

- Relatively low doses of both modalities produced benefit

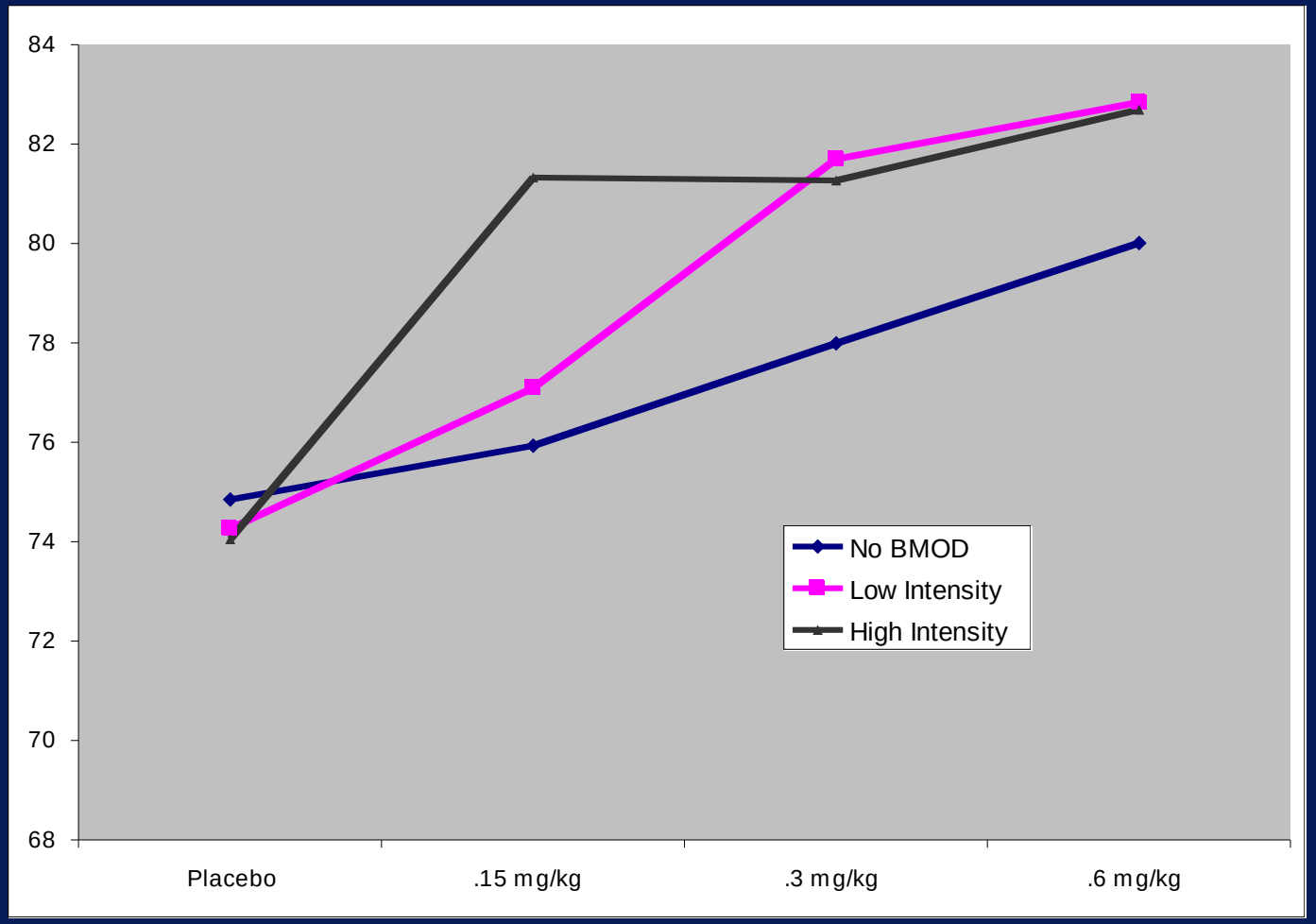
- On most measures, the combination of the lowest dose of medication (a very low dose) and LBM produced as much and sometimes more change than did the four-times-higher doses of medication in the NBM condition and more change than LBM and HBM alone.

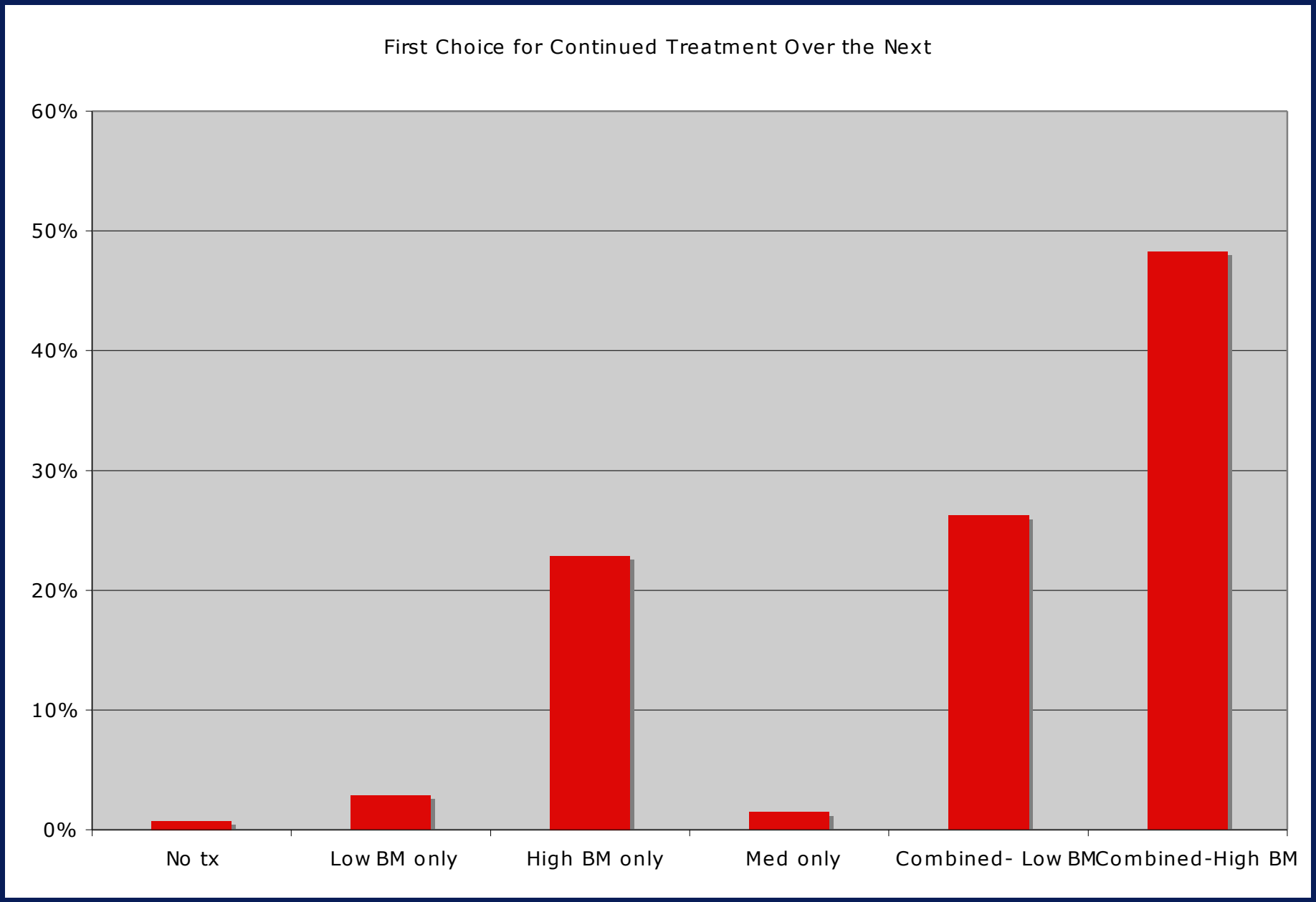
- There were no side effects at this dose and many side effects at the higher doses.

- Thus, combined treatment allows low doses of medication and lower doses of behavior modification

Performance on Home Target Behaviors

(Pelham et al, almost under review)



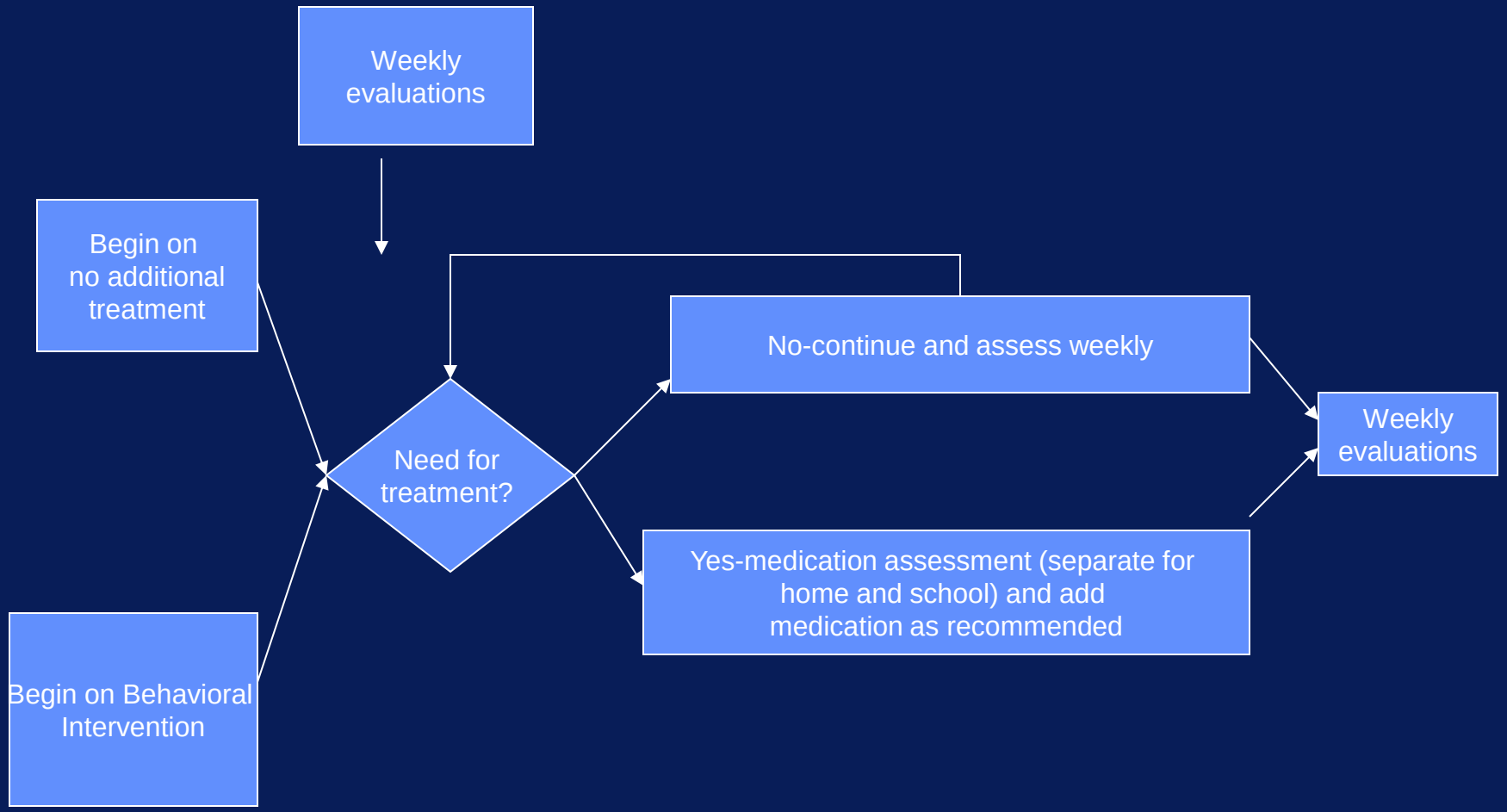

First Choice for Continued Treatment Over the Next
60%
50%
40%
30%
20%
10%
0%
No tx
Low BM only
High BM only
Med only
Combined- Low BM
Combined-High BM

Study 2 Design

- 128 participants from the Study 1 were randomly assigned to one of three groups for follow-up treatment:
  - High behavior modification consultation (HBC; N=44)
  - Low behavior modification consultation (LBC; N=43)
  - No behavior modification consultation (NBC; N=41)

School Year Follow-Up

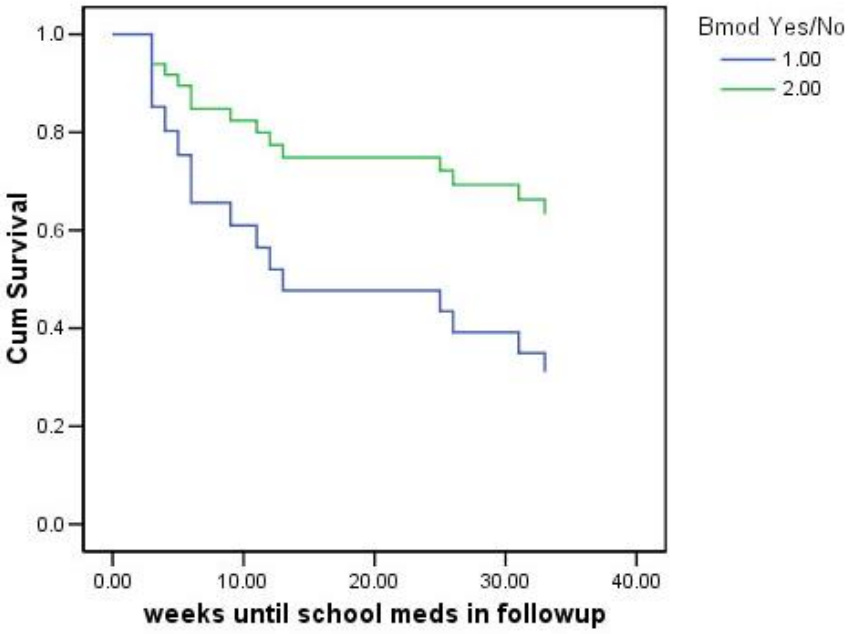
(Coles et al, NCDEU, 2008)



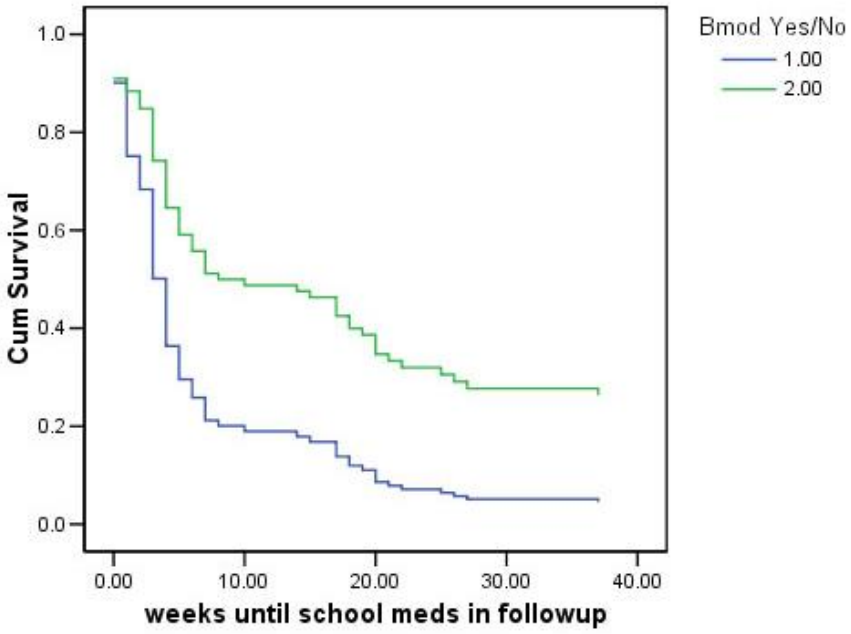
School Survival Curves

Coles et al, NCDEU, 2008

No Previous School Medication



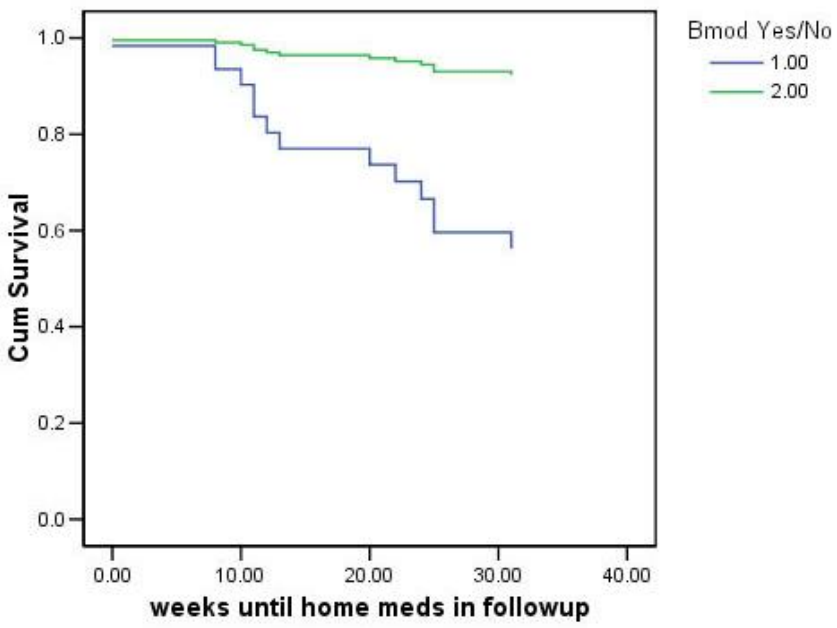
Previous School Medication



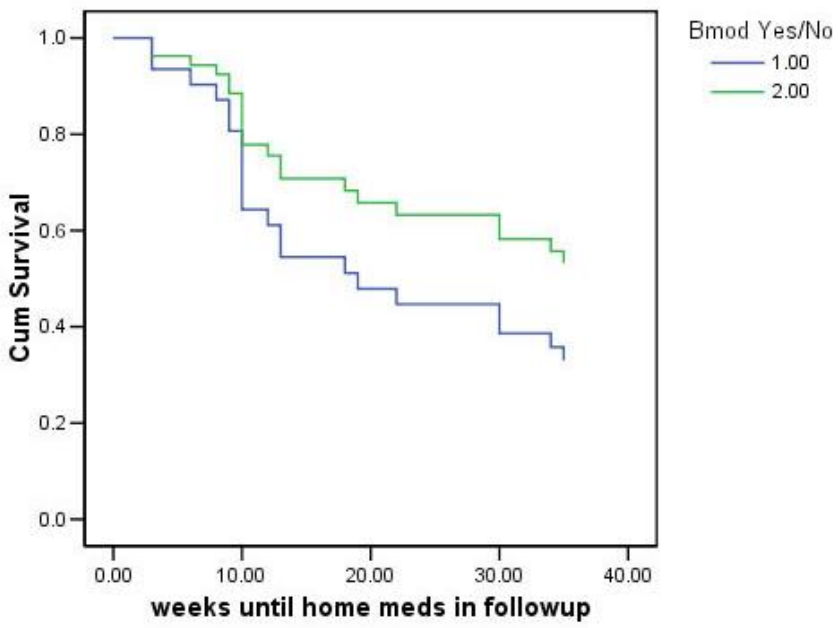
Home Survival Curves

Coles et al, NCDEU, 2008

No Previous Home Medication



Previous Home Medication



Guidelines on Treatment Sequencing

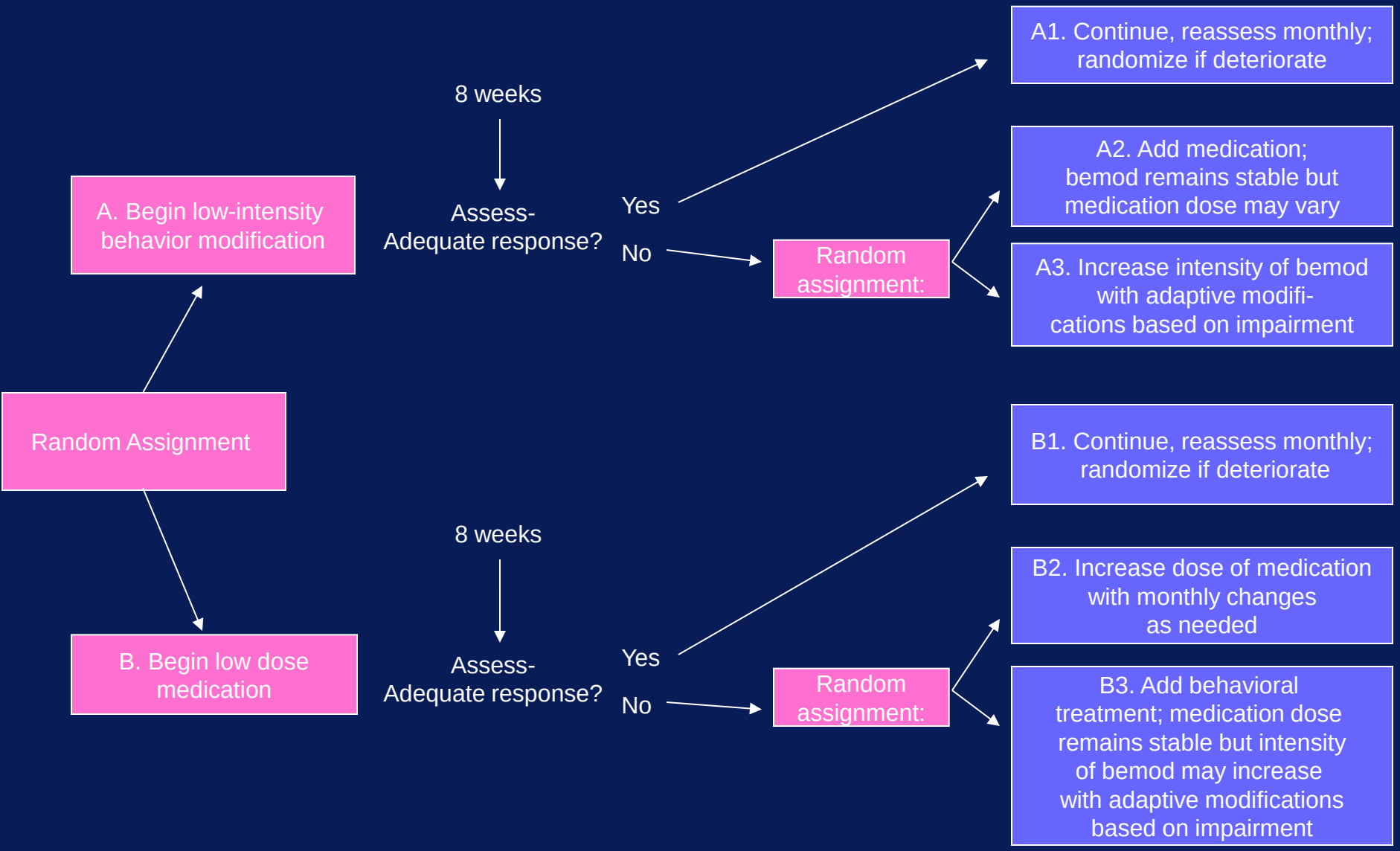
- AAP guidelines
- Task Force of APA (2007) says psychosocial first
- Guidelines of the AACAP (2007) say medication first
- Japanese pediatric guidelines (2008) say behavioral/educational first
- British guidelines (NICE, 2009) say behavioral first in mild to moderate cases
- CHADD says simultaneous

Adaptive Pharmacological and Behavioral Treatments for Children with ADHD: Sequencing, Combining, and Escalating Doses

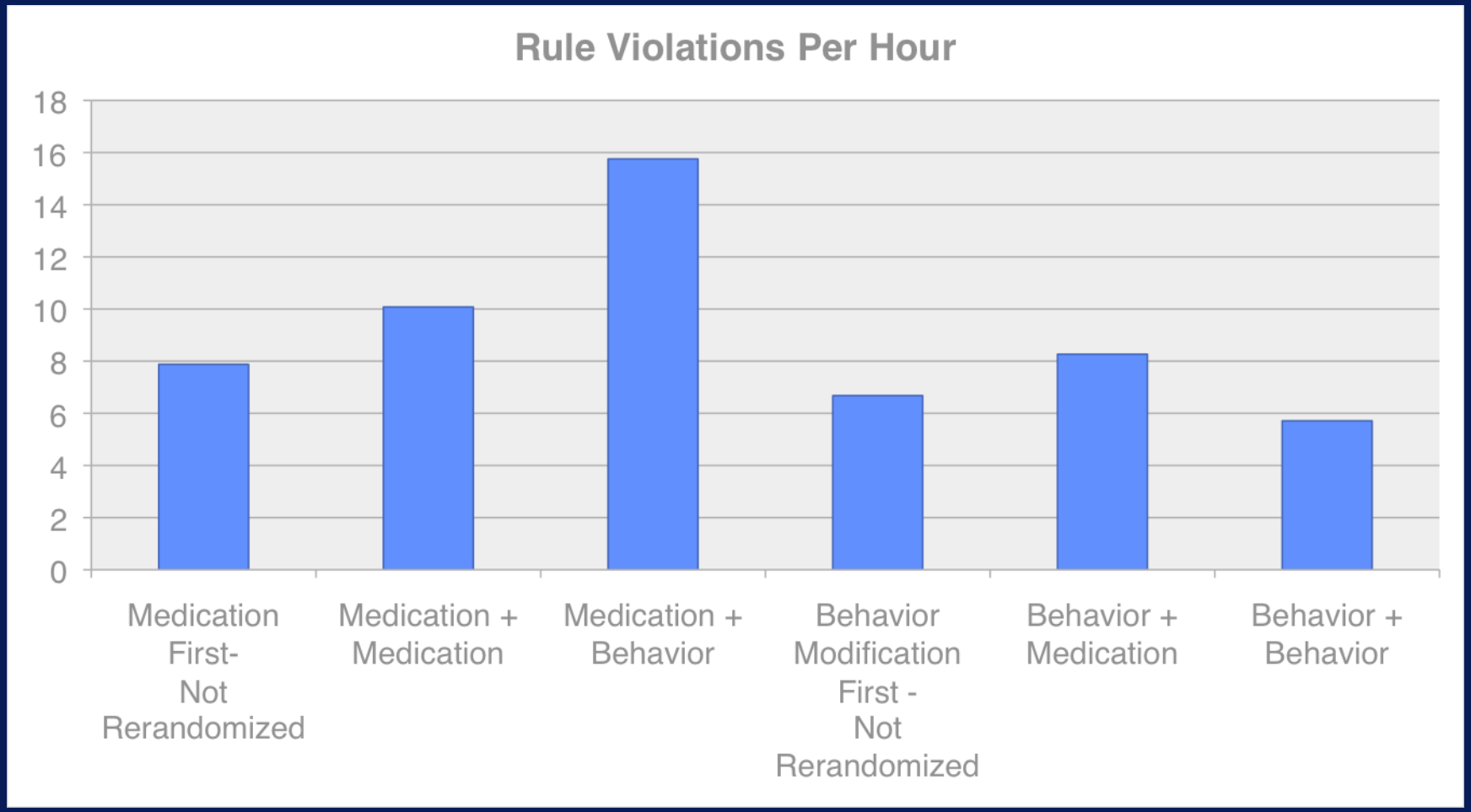
William E. Pelham, Jr., Lisa Burrows-MacLean, James Waxmonsky, Greta Massetti, Daniel Waschbusch, Gregory Fabiano, Martin Hoffman, Susan Murphy, E. Michael Foster, Randy Carter, Elizabeth Gnagy

(IES 2006-2010)

Study Design

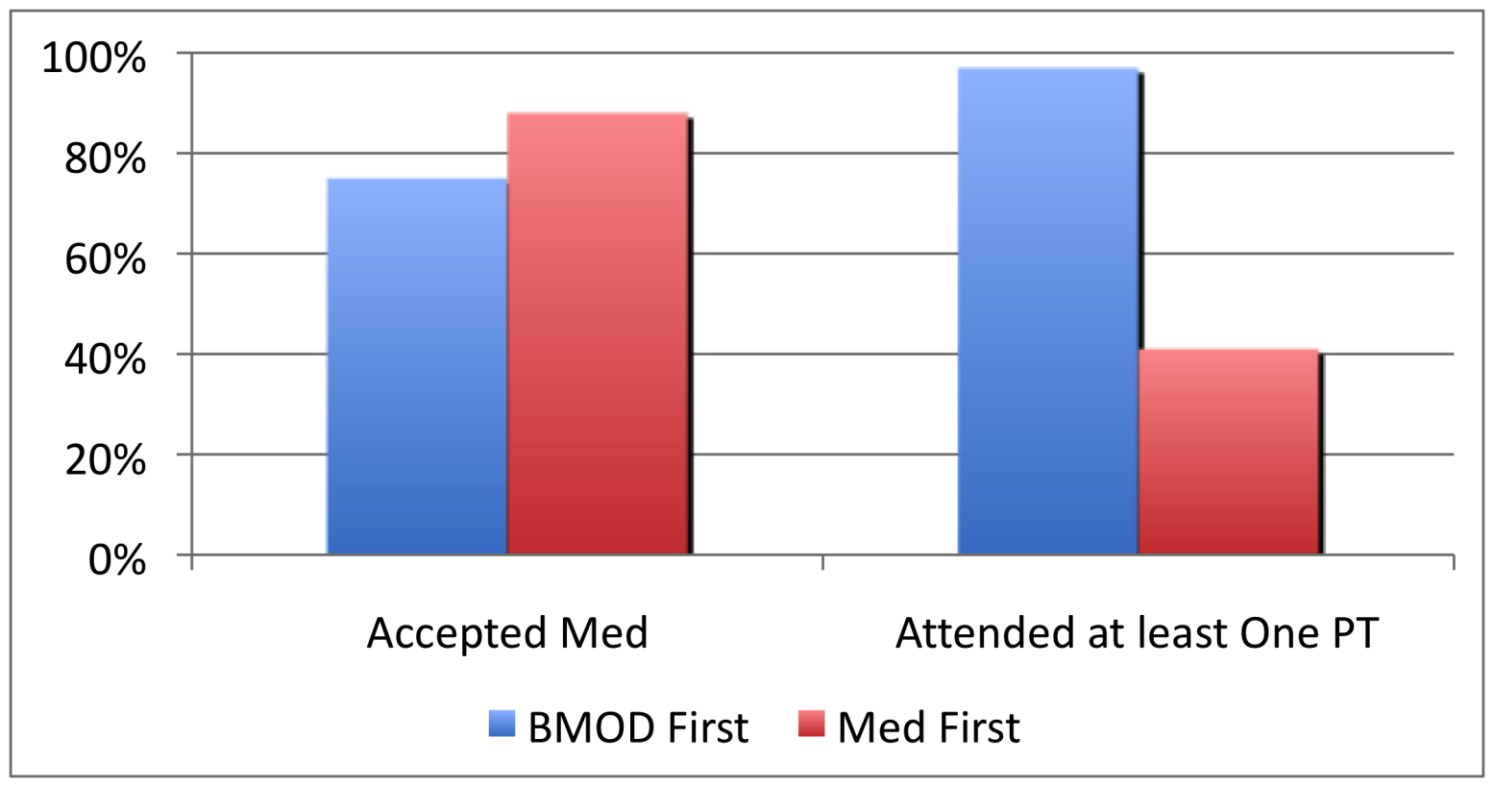


Adaptive Treatment Classroom Observations



Overall mean = 8.39 violations per hour

Treatment Acceptance as a Function of First Treatment



Preliminary Conclusions

(Pelham et al NCDEU, 2011)

- Sequence of treatment impacts outcomes

- Behavioral treatment THEN medication if necessary resulted in better outcomes in school on direct observations and teacher ratings

- Medication THEN behavioral treatment reduced attendance at PT.

- Thus improvement in parental skills at home and parental involvement with the children's schools (e.g., backing up the DRC, communicating with teachers) were limited dramatically when medication was begun first

- 8 sessions of group PT and a teacher implemented DRC is sufficient for 36% of ADHD children but 64% need either more group or individual sessions or combined treatment with medication

- Prior experience with medication moderated these effects

- Combined low dose multimodal intervention produced good functioning with no side effects

How to Decide Whether an ADHD Child Needs Combined Treatment Regimen At School?

- Always establish a Daily Report Card
- School can do a functional assessment of various additional behavioral interventions
- If those treatments are insufficient, then proceed to randomized, clinical medication assessment conducted by team (physician/nurse, pharmacist, teacher/counselor, psychologist)

Daily Report Card

Child's Name: _____ **Date:** ____

	LA		Math		Reading		SS		Sci.	
Follows class rules with no more than 3 rule violations per period.	Y	N	Y	N	Y	N	Y	N	Y	N
Completes assignments within the designated time.	Y	N	Y	N	Y	N	Y	N	Y	N
Completes assignments at 80% accuracy.	Y	N	Y	N	Y	N	Y	N	Y	N
Complies with teacher requests. (< 3 noncompliance per period)	Y	N	Y	N	Y	N	Y	N	Y	N
No more than 3 teasings per period.	Y	N	Y	N	Y	N	Y	N	Y	N

OTHER

Follows lunch rules (<3 violations).	Y	N
Follows recess rules (<2 violations).	Y	N

Total Number of Yeses/Nos: _____
Teacher's Initials:

Comments: _____

_____

_____

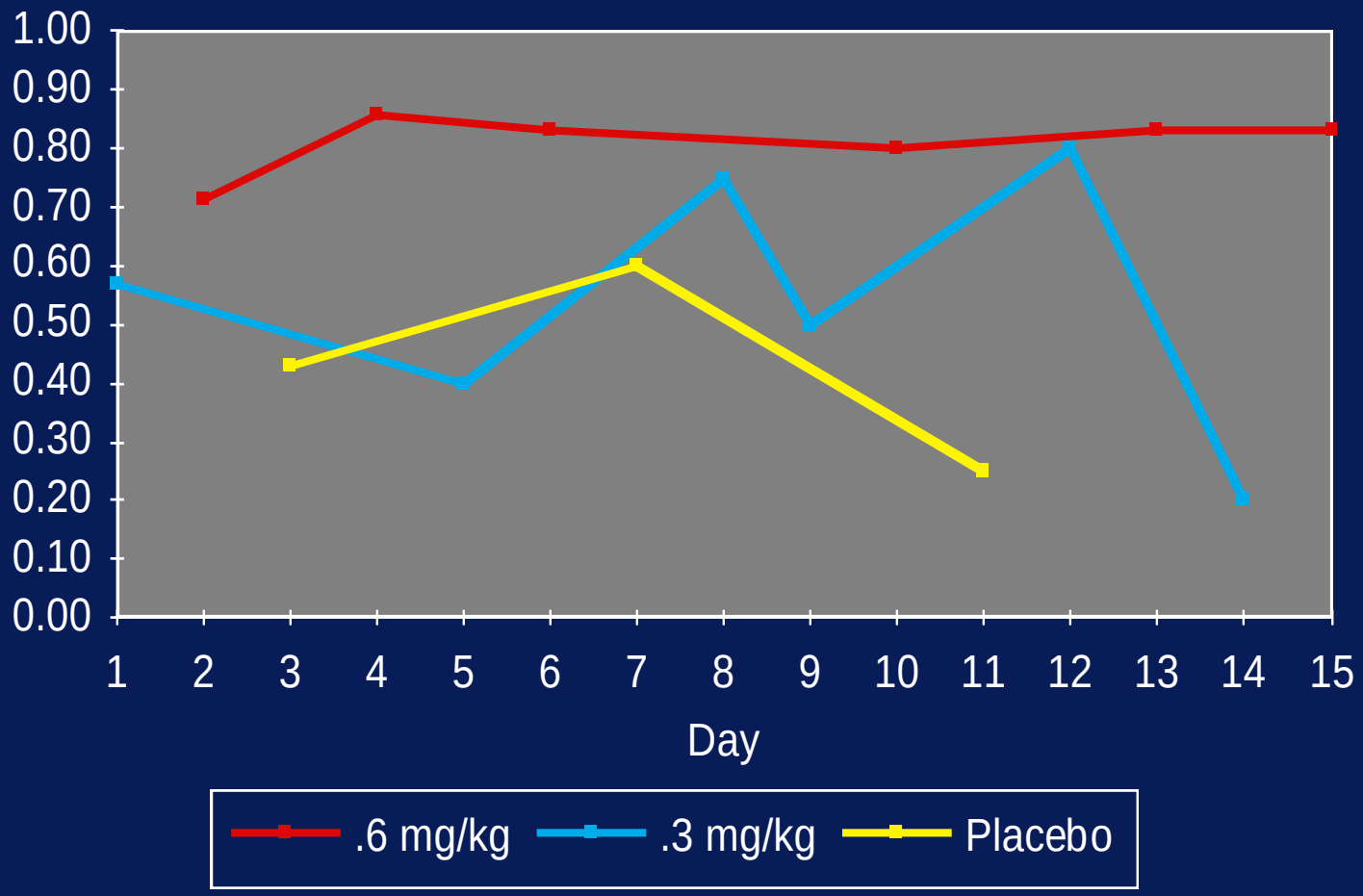
Downloadable at our website

Medication Titration

- **Standard Procedure**
  - Gradually increase dose on a weekly basis:
  - Week 1: 5 mg qam
  - Week 2: 5 mg bid
  - Week 3: 10 mg bid
  - Week 4: 15 mg bid
- **Random Order with Weekly Dose Changes**
  - Week 1: 5 mg
  - Week 2: 15 mg
  - Week 3: Placebo
  - Week 4: 10 mg

School-Based Medication Assessment for BL

Completes assignments within a given time



Summary of Treatment Literature for ADHD

- Behavioral and pharmacological interventions are the only two evidence-based treatments for ADHD
- Behavioral treatments teach skills and maintain after fading; medication must be continued for long term change
- Parents prefer behavioral treatments to medication
- If behavioral treatments are started first and continued, 50-75% of ADHD children do not need medication (fewer at school and more at home) and doses are dramatically (75%) lower in those who do need medication
- For children who need them, multimodal (Beh and Pharm) interventions produce (1) better effects acutely, especially in impairment, with lower doses, (2) lasting behavioral effects if medication is withdrawn, and (3) are strongly preferred by parents and teachers to medication alone and thus more likely to be utilized in the long run
- There are large individual differences in response to behavioral (and stimulant) treatments
- There are few studies of dose effects and sequencing effects

Clinical Recommendations for Evidence-based Psychosocial Treatment of ADHD

- **Focus on impairment in daily life functioning rather than DSM symptoms, treat for settings and domains of impairment, and monitor impairment to modify treatment**

- **Depending on severity, start with behavioral treatment (parent, teacher, child) and evidence-based academic interventions**

- **Add medication when impairment is not minimized and parents prefer medication or resources limit more intensive behavioral treatments**

- **Dose meds low (not optimally) so as not to remove need for behavioral and educational treatments and to minimize SE & risks**

Clinical Recommendations for Evidence-based Psychosocial Treatment of ADHD

- Start behavioral and academic interventions early and continue—reading example and severity of social problems
- Stay in regular contact with family to monitor both behavioral treatments and medication--chronic condition model of treatment
- Make interventions feasible for and palatable for families so they will be maintained in the long run
- Effective treatment requires systems cooperation (e.g., collaboration between families, schools, mental health clinics, primary care) and a public health perspective

Downloadable Materials (Free) on our Websites

- **Instruments**
- Impairment Rating Scales (Parent and Teacher)
- Disruptive Behavior Disorder Symptom Rating Scale (Parent and Teacher)
- Pittsburgh Side Effect Rating Scale
- DBD Structured Interview
- Parent Application Packet and Clinical Intake Outline
- Parent and Teacher Behavior Management Ratings and Interviews
- **Information**
- What Parents and Teachers Should Know about ADHD
- Medication Fact Sheet for Parents and Teachers
- Psychosocial Treatment Fact Sheet for Parents and Teachers
- References to all of our papers and posters
- Recent posters and PowerPoint presentations
- **"How to" Handouts**
- How to Establish a School-Based Daily Report Card
- How to Conduct a School-based Medication Assessment
- How to Establish a Home-Based Daily Report Card
- How to Begin a Summer Treatment Program
- **http://wings.buffalo.edu/adhd/**

For more information, please go to the main website and browse for videos on this topic or check out our additional resources.

Additional Resources

Online resources:

1. Center for Children and Families website: http://ccf.fiu.edu
2. Children and Adults with ADHD (CHADD):http://www.chadd.org/
3. Society of Clinical Child and Adolescent Psychology website: http://effectivechildtherapy.com

Books:

1. Hinshaw, S. P., Klein, R. G., & Abikoff, H. B. (2002). Childhood Attention-Deficit Hyperactivity Disorder: Nonpharmacological treatments and their combination with medication. In P. E. Nathan & J. M. Gorman (Eds.). A Guide to Treatments That Work (2nd ed., pp. 3-55). New York: Oxford University Press.
2. Pelham, W.E. (2007). Against the grain: A proposal for a psychosocial-first approach to treating ADHD – the Buffalo treatment algorithm. In, K. McBurnett, & L.J. Pfiffner (Eds.), *Attention Deficit/ Hyperactivity Disorder: Concepts, Controversies, New Directions* (pp. 301-316). New York: Informa Healthcare.

Selected Peer-reviewed Journal Articles:

1. American Academy of Pediatrics. *(*2011). Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics, 128* (5) 1-16
2. Molina, B. S., Hinshaw S.P., Swanson, J.M., Arnold, L.E.,Vitiello, B.V., Jensen, P.S., … Gibbons L. G. (2009). The MTA at 8 Years: Prospective follow-up of children treated for combined-type ADHD in a multisite Study. *Journal of the American Academy of child & Adolescent Psychiatry, 48* (5), 484-500.
3. Pelham, W.E., Carlson, C., Sams, S.E., Vallano, G., Dixon, M.J., & Hoza, B. (1993). Separate and combined effects of methylphenidate and behavior modification on boys with attention deficit-hyperactivity disorder in classrooms. *Journal of Consulting and Clinical Psychology, 61*, 506-515.

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