Are We Overmedicating America's Children? Psychosocial, Pharmacological, Combined, and Sequenced Interventions for ADHD

Rethinking Children's Mental Health

September, 2016, New York

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Disclosures

Past Consultant, scientific advisor, speaker, grant recipient:

McNeil/Alza (Concerta)

Abbott

Shire (Adderall, Adderall XR, guanfacine)

Noven (Daytrana)

Lilly (Strattera)

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UNC: Mike Foster, Patrick Curran, Mike Willoughby

Chicago: Benjamin Lahey

Penn State Medical Center: James Waxmonsky, Daniel Waschbusch, Dara Babinski

Current Funding Sources: NIMH (6) NIAAA, NIDA, IES (4), NICHD, UB, FIU, The Children's Trust

ADHD: Importance to Professionals

Prevalence: 9-12% of population in the U.S.--higher in boys —similar prevalence across many countries

Children dealt with by:

- –
- –
- –
- –

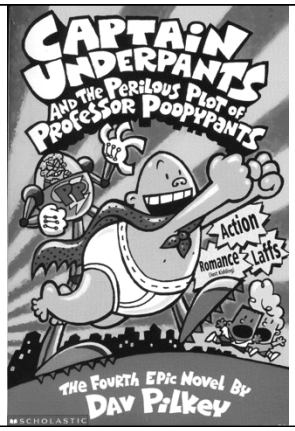
Most common behavioral referral to health care professionals

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, 2011; Pelham, Fabiano & Massetti, 2005)



“ ‘ ’

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.***!”

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

ADHD: Core Symptoms--Same Over Past 50 Years

Inattention

Impulsivity

Hyperactivity

DSM-5 Definition of ADHD

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

(1) Inattention:

- 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-5 Definition of ADHD

(2) Hyperactivity-Impulsivity

- 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-5 Definition of ADHD

B. Some symptoms that caused impairment were present before age 12.

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.

BUT….Are DSM Symptoms important for Treatment Conceptualization and Implementation in ADHD?

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**
  - –
  - – 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

(Barkley, Murphy, & Fisher, 2008; Lee et al, 2011; Molina et al, 2009; Molina & Pelham, 2014)

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	**$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)	**$30-40 billion**
Alzheimer's	**$100 billion**
Alcohol abuse/dep.	**$180**

(Pelham, Foster & Robb, 2007)

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

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, 2008; Evans et al, 2014)

Evidence-Based Short-term Treatments for ADHD

(1) Behavior modification
-185 studies
(2) CNS stimulant medication
>300 studies
(3) The combination of (1) and (2).
>30 studies
Moderate to large effect sizes across treatments

(AAP, 2001, 2011; AACAP, 2007; APA, 2007; Fabiano et al, 2009; Greenhill & Ford, 2002; Hinshaw et al, 2002; Pelham & Fabiano, 2008; Swanson et al, 1995)

Despite the Evidence, Medication is Universally Used as First-line Treatment for ADHD in the U.S.

The NIMH Collaborative MTA Study (MTACG, 1999) and the development of the long-acting preparations of stimulants and subsequent advertising and detailing have resulted in widespread agreement amongst psychiatric professionals, ADHD experts, pharmaceutical companies, media outlets, insurers, and advocacy groups that medication is first-line treatment for ADHD.

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

Guidelines on Treatments and Sequencing

- **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**
- **AAP 2011**

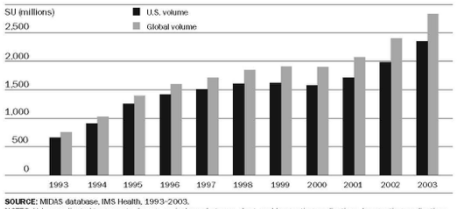
AAP Clinical Practice Guideline: Treatment of the School-Aged Child with Attention-Deficit/Hyperactivity Disorder
(Pediatrics, 2001, 2011)

- 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.

Psychoactive Medication Business is Booming in America

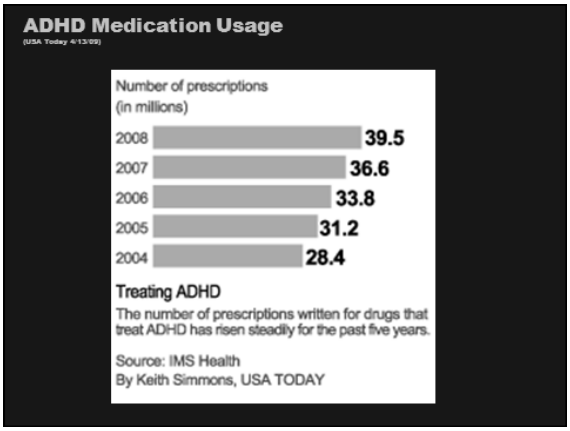
- Pediatric drugs are typically more expensive than in adults because of lack of generics—dramatic increases in expenditures in past decade
- Insurance plans now spend more money on psychotropics than antibiotics or asthma meds (17% total drug costs)
- 6+% of children in the U.S. took at least one psychotropic in 2005, with 1/5 of those taking 2+meds
- Recent increases in use of antipsychotic medications (10% increase in 2008)—18% of ADHD children in Medicaid
- Stimulants are the most prescribed child psychotropic--4%-7% of U.S. child population are medicated daily with stimulants for ADHD.

U.S. And Global Volume Of Attention Deficit Hyperactivity Disorder (ADHD) Medications, 1993–2003



SOURCE: MIDAS database, IMS Health, 1993-2003.
NOTES: Volume adjusted to generate dosage equivalence between short- and long-acting medications. Long-acting medications are weighted twofold over short-acting medications. SU is standard units.

Scheffler, R.M., Hinshaw, S.P., Modrek, S., & Levine, P. (2007). Trends: The global market for ADHD Medications. *Affairs, 26(2)*, 450-457.



Should this be the case?

Components of Effective, Comprehensive Treatment for ADHD

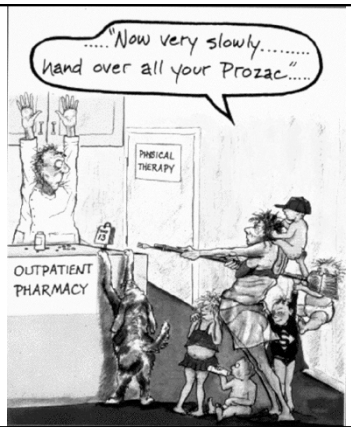
- **Behavioral Intervention**
  - Behavioral Parent Training
  - Behavioral School Intervention
  - Behavioral Child Intervention
- **Medication as adjunct**

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

Why is it Important to Include Parent Training, School Interventions, and Peer-focused Interventions in ADHD Treatment?

- **No one is taught how to be a parent and parents of ADHD children have significant stress, psychopathology, and poor parenting skills**
- **ADHD children have severe problems in school throughout the grades and teachers are not trained to work with them**
- **ADHD children have severely disturbed peer relationships that cannot be sufficiently modified by parents or teachers alone**

(DuPaul & Stoner, 2002; Johnston & Mash, 2001; Milich & Landau, 1982)



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)

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)

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)

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 independent of comorbidity
- However, room for improvement even after acute clinic-level treatment for many children
- Less evidence (few studies) for long-term benefits
- How do we maintain benefits from acute treatments and thus emphasis on chronic care model—that is sustained low dose maintenance intervention after acute treatment

Components of Evidence-based Treatment for ADHD

Psychostimulant Medication

- Need determined <u>following</u> initiation of behavioral treatments; timing depends on severity and responsiveness
- Cycle through methylphenidate and amphetamine-based compounds and atomoxetine before other drug classes
- Dosing should be based on objective data regarding impairment at home and school independently
- Use at minimal rather than maximal effective dose - minimal times of day and days of week—to reduce SE
- Continue for as long as need exists (typically years--evaluate need and dose annually)
- Plan for possible emergent iatrogenic effects (e.g., growth suppression)
- Lack of evidence for long term benefit (Molina et al, 2009) and lack of evidence of long term safety (Swanson & Volkow, 2008)

(Pelham, 2009)

Main Beneficial <u>Short-term</u> Effects of Pharmacological Treatments

1. Decrease in classroom disruption
2. Improvement in teacher and parent ratings of behavior
3. Improvement in rule following and compliance with adult requests and commands
4. Increase in on-task behavior and daily academic productivity and accuracy (but not achievement)
5. Improvement in peer interactions
6. Improvement on a variety of laboratory tasks of cognition

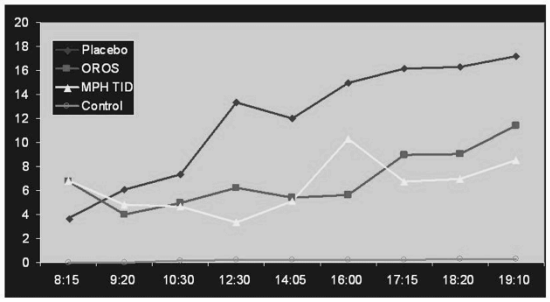
(Greenhill, 2002)

Limitations of Pharmacological Interventions When Used Alone

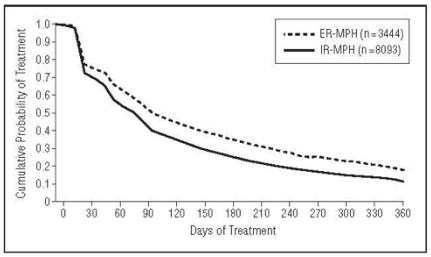
1) Rarely sufficient to bring a child to the normal range of functioning
2) Works only as long as medication taken
3) Not effective for all children
4) Does not affect several important variables (e.g., academic achievement, concurrent family problems, peer relationships)
6) Poor Compliance in long-term use
7) Parents are not satisfied with medication alone
8) Removes incentive for parents and teachers/schools to work on other treatments
9) Uniform lack of evidence for beneficial long-term effects (MTA, 2009)
10) Reduction in growth and ultimate adult height (MTA)
11) Lack of information about long-term safety (e.g., later substance use) (Swanson and Volkow, 2008)

(Pelham, 2009)

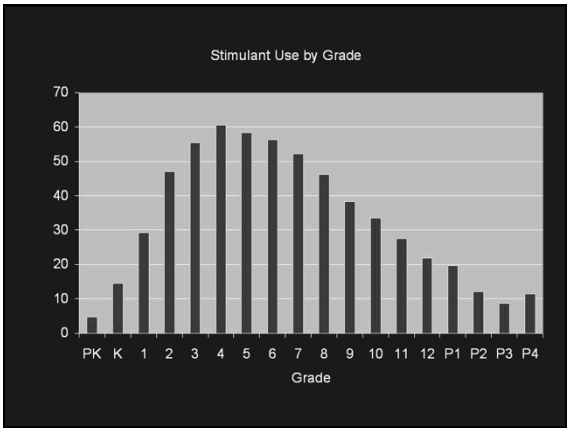
Classroom Rule Violations



Survival distribution of attention-deficit/hyperactivity disorder (ADHD) treatments for extended-release (ER-MPH) and immediate-release (IR-MPH) methylphenidate hydrochloride preparations for ADHD. Treatments for ADHD include methylphenidates, mphetamines, pemoline, and atomoxetine.



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.



Would Parent Recommend Treatment?

(Pelham & MTA Coop. Group, under review)

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%

Trends in Medication Use: A BOE Analysis

- **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
  - IS THIS INCREASE SAFE IN THE LONG RUN?

Summary: Components of Effective, Evidence-based, Psychosocial Treatment for ADHD

- Parent Training--Use always
- School Intervention--Use always
- Child Intervention--Use when indicated because of complexity/ expense
- Medication—Use in low doses as short-term adjunct when behavioral treatments insufficient

What About Comparative and Combined Treatment Studies?

Comprehensive Psychosocial and Pharmacological Treatment for ADHD: The NIMH/USOE Multimodal Treatment Study
(MTACG, Archives of General Psychiatry, 1999)

Randomized Clinical Trial of four treatments:
- Community Comparison Control
- Psychosocial Alone
- Pharmacological Alone
- Combined Psychosocial and Pharmacological

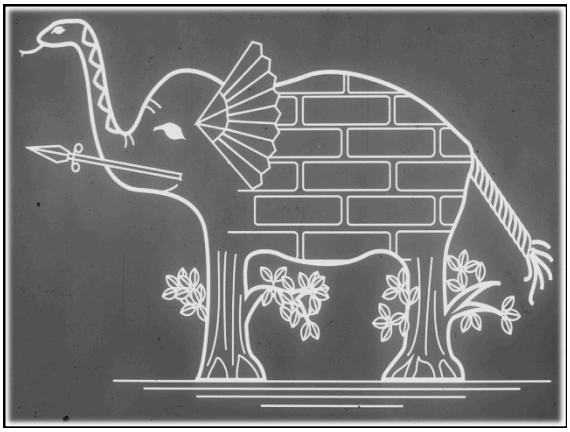
576 subjects, recruited from community, entered between January and May of three consecutive years across six sites

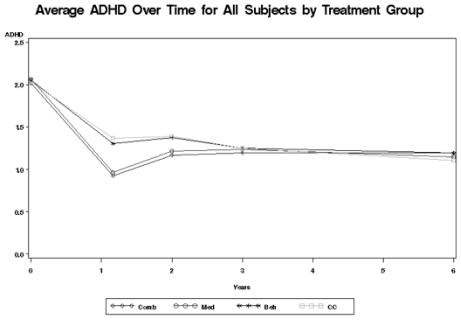
144 subjects per group overall; 24 per group per site

Treatment for 14 months; follow-up for 10 months

Extensive manualization and standardization of treatment:
- 1000+ pages of treatment manuals
- Coordinated staff training across sites
- Extensive measures of treatment fidelity for all components
- 10+ hours of weekly conference calls to standardize protocol

What Does the MTA Study Tell us about Treating ADHD?





Questions the MTA Study Did Not Answer

What treatments does a given child need?

Should behavioral treatment begin before medication (parent preference) or vice versa (physician practice) or should they be implemented simultaneously (as in the MTA).

What are the best "doses" of psychosocial, pharmacological, and combined treatments?

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 doses and sequences for treatment dosing, benefit, and risk of side effects?

These are the questions that families, practitioners, and educators face daily, but they have only recently begun to be studied.

Our Research Program in the Past Decade

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

Dose-Response Effects of Behavior Modification, Medication, and their Combination in ADHD Children in a Summer Setting

Pelham, Burrows-McLean, Gnagy, Fabiano, Coles, Hoffman, Massetti, Waxmonsky, Waschbusch, Chacko, Walker, Wymbs, Robb, Arnold, Garefino

(NIMH 2002-2007)

(Fabiano et al, 2007; Pelham et al, 2014; Pelham et al in preparation)

Summer Treatment Program Overview

- **Eight-week program, 9 hours daily**
- **Children grouped by age into groups of 12**
- **Groups stay together throughout the day**
- **5 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**

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

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 Behavioral Modification conditions: No behavioral treatment (NBM), low-intensity (LBM) treatment, and high-intensity (HBM) treatment (BM), varying triweekly in random order by treatment group

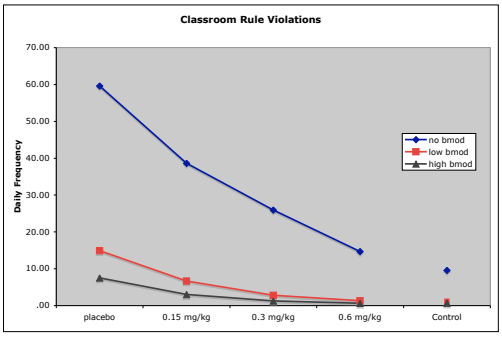
3-4 days per medication X Bmod condition.

NonADHD comparison group (24/summer).

Comparative and Combined Treatments for ADHD

3, 3-week Behavior Modification conditions assigned randomly:

High Intensity BMod	Low Intensity BMod	No BMod
Daily Crossover of 4 Med conditions: Placebo .15 mg/kg MPH .3 mg/kg MPH .6 mg/kg MPH	Daily Crossover of 4 Med conditions: Placebo .15 mg/kg MPH .3 mg/kg MPH .6 mg/kg MPH	Daily Crossover of 4 Med conditions: Placebo .15 mg/kg MPH .3 mg/kg MPH .6 mg/kg MPH



(Fabiano et al, School Psychology Review, 2007)

Fabiano et al, 2007; Pelham et al, 2014--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

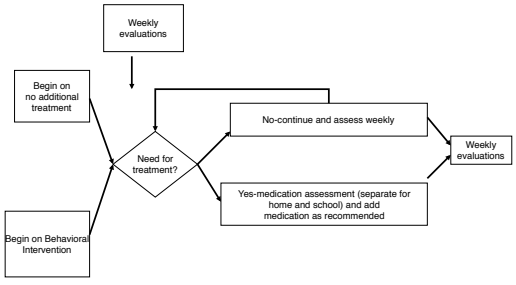
On most measures, the combination of the lowest dose of medication (a very low dose) and LBM produced as much and sometimes more change than did the four-times-higher doses of medication in the NBM condition and more change than LBM and HBM alone.

There were no medication 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

School Year Follow-Up

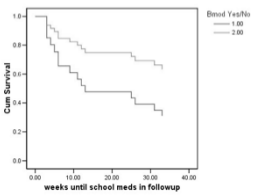
(Coles et al, under review)



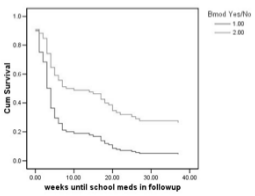
School Survival Curves

Coles et al, NCDEU, 2008

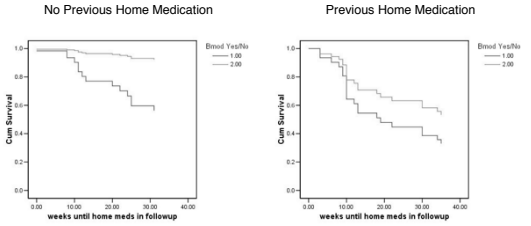
No Previous School Medication



Previous School Medication



Home Survival Curves
Coles et al, NCDEU, 2008

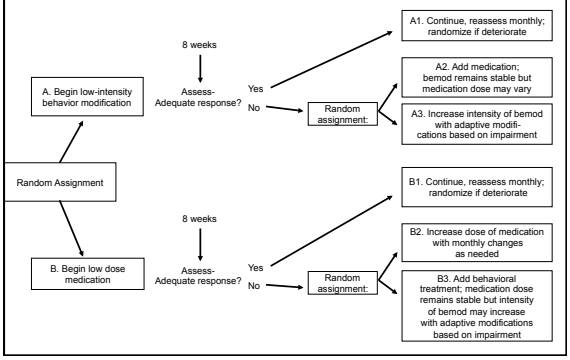


Adaptive Pharmacological and Behavioral Treatments for Children with ADHD: Sequencing, Combining, and Escalating Doses

William E. Pelham, Jr., Gregory Fabiano, Lisa Burrows-MacLean, James Waxmonsky, Susan Murphy, E. Michael Foster, Elizabeth Gnagy, Andrew Greiner, Timothy Page, William E Pelham, III, Jihnhee Yu, Stefany Coxe

(Pelham et al, JCCAP, 2016; Page et al, JCCAP, 2016)

Study Design



Indicator of Need for Additional Treatment at 8-week and Subsequent Assessments:

(1) Average performance on the ITB is less than 75% AND
(2) Rating by parents or teachers as impaired (i.e., greater than 3) on the IRS in at least one domain.

Treatment decisions and content are tailored to the specific domains of impairment rated on the IRS

Rerandomization in School Setting

- By the end of the school year, 44% in Medication First and 64% in Behavior First were rerandomized (required intervention beyond a .15 mg/kg dose b.i.d. of MPH or a Daily Report Card)

MODERATED BY PRIOR MEDICATION
- Children who had been previously medicated were far more likely to be rated as needing medication

Adaptive Treatment Assignment/ Outcome Group Ns

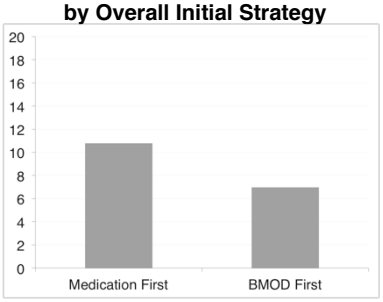
- **Groups at End of Treatment**
  - A.
  - B.
  - C.
  - D.
  - E.
  - F.

Adaptive Treatment Analysis Strategy

-
- **with medication vs. behavior modification (ABC vs. DEF)**
- **Compare increasing dose/intensity of medication vs. behavior modification (AB vs. DE)**
- **Compare sequencing of adding BMOD to med vs. adding med to BMOD (AC vs. DF)**
- **Within initial treatment strategies, compare increasing dose/intensity of treatment vs. switching to combined treatment (B vs. C; E vs. F)**

Classroom Observations: Rule Violations Per Hour

by Overall Initial Strategy



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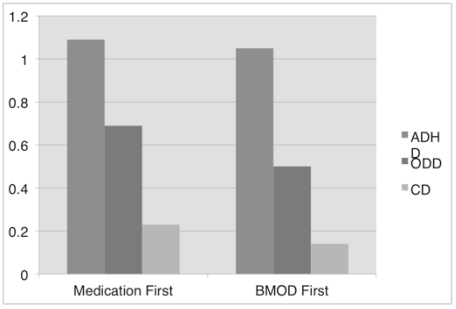
Endpoint Teacher DBD Rating Scale



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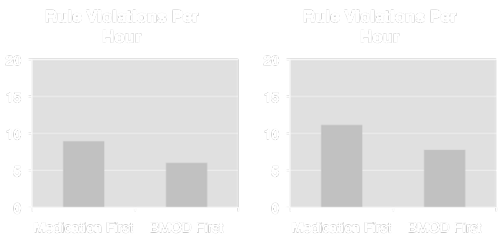
Adaptive Treatment Classroom Observations

Increased Initial Treatment

Switched to Combined Treatment



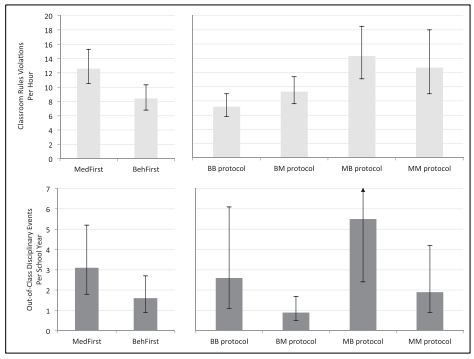
Rerandomization?

(Pelham et al, NDCEU, 2011)

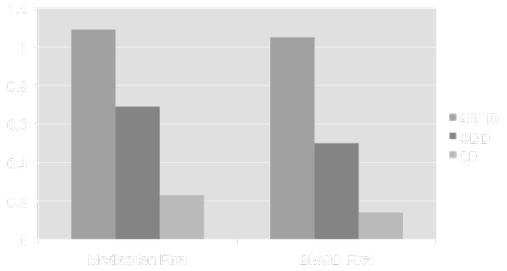
SCHOOL SETTING:
•By the end of the school year, 44%% of Med First and 64% in Bemod first were rerandomized (that is required intervention beyond a .15 mg/kg dose b.i.d. of MPH or a Daily Report Card)

MODERATED BY PRIOR MEDICATION
•Children who had been previously medicated were far more likely to be rated by parents as needing medication for home and school settings.

Outcomes on Objective Measures by Treatment Group



Adaptive Treatment
Endpoint Teacher Ratings



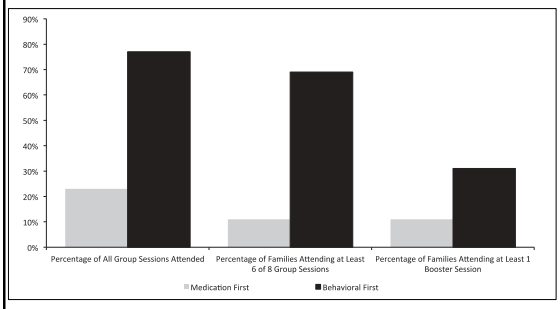
Main Outcomes

- **Overall strategy of starting with behavior modification first is superior to starting with medication first**
- **More (56%) children are adequate responders at school to medication at very low dose than are responders to a DRC alone at school (36%). However, responders to each modality are functioning equally well.**
- **Children rerandomized to combined treatment are significantly better if they began with bemod.**

Why Is BMOD-MED Sequence Superior to MED-BMOD Sequence?

- **Treatment uptake?**

Parent Training Attendance—Treatment Engagement



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; 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

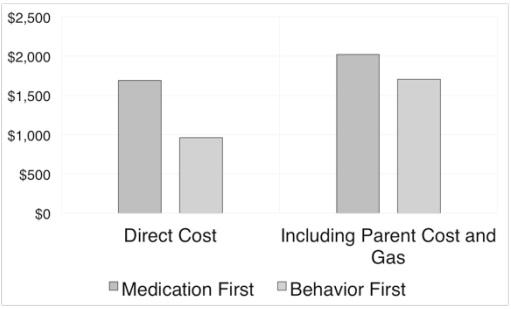
Costs of Treatment Sequences

- **Only previous comparison of treatment costs is MTA (Jensen et al., 2005)**
- **Limitations of MTA cost study:**
  - –
  - –
    need
  - – At the time of the MTA, inexpensive immediate-release methylphenidate was standard
  - – Now, children are medicated with new, extended-release formulations that are much more costly--$7.50 daily vs. 30 cents

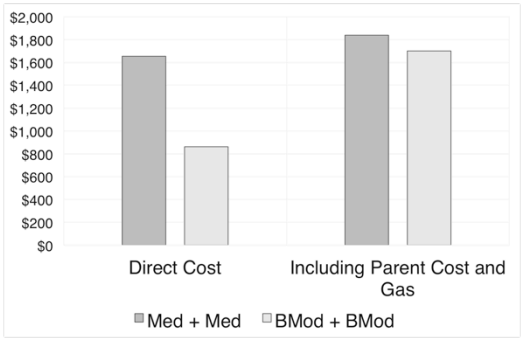
Cost Analyses
(Page et al, JCCAP, 2016)

- Quantity of resources expended on each child's treatment was determined from detailed records.
- Inputs considered were doctor time, clinician time, paraprofessional time, teacher time, parent time, medication, and gasoline. National estimates were used from public sources (e.g., Bureau of Labor Statistics).

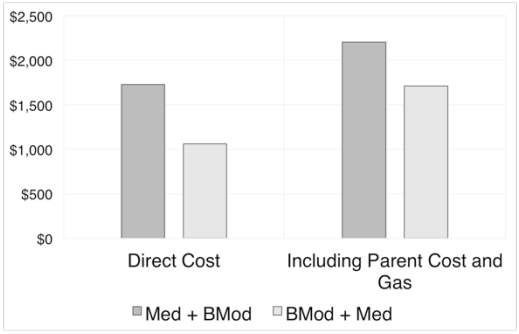
Costs Based on Initial Assignment



Costs of Enhanced Unimodal Treatment



Costs of Combined Treatments



Cost Summary

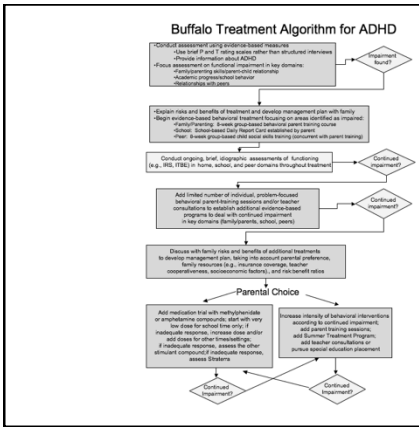
- Behavioral First was significantly less expensive than Medication First
- Behavioral plus Behavioral if necessary was superior to Medication plus medication if necessary
- Behavioral plus medication if necessary was less expensive than Medication plus behavioral if necessary
- $4 billion could be saved in US healthcare economy if medication were NOT the first-line treatment

Clinical Recommendations for Evidence-based 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 low dose behavioral treatment (parent, teacher, child) and evidence-based academic interventions if needed
- Add medication or more intensive Behavioral interventions when impairment is not minimized– parental choice
- Use low med dose of medication (not optimal) so as not to remove need for behavioral/educational treatments and to minimize SE & risks
- Once medication is used initially as first line tx, the average child's outcome will be worse than otherwise no matter what subsequent treatments are used.

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 and Videos (Free) on our Websites (http://ccf.fiu.edu and www.effectivechildtherapy.fiu.edu)

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
Initial Teacher Interview

Information

What Parents and Teachers Should Know about ADHD
Medication Fact Sheet for Parents and Teachers
Psychosocial Treatment Fact Sheet for Parents and Teachers
Many reprints
Videos of lectures on child treatments

"How to" Handouts

How to Establish a School-Based Daily Report Card
How to Begin a Summer Treatment Program—video and print

Thank you!