A Comprehensive Functional Assessment of the Effects of Methylphenidate on the Disruptive Behavior of Children With Severe Mental Retardation.

Victoria C. Swanson
Louisiana State University and Agricultural & Mechanical College

Follow this and additional works at: https://digitalcommons.lsu.edu/gradschool_disstheses

Recommended Citation
https://digitalcommons.lsu.edu/gradschool_disstheses/7018

This Dissertation is brought to you for free and open access by the Graduate School at LSU Digital Commons. It has been accepted for inclusion in LSU Historical Dissertations and Theses by an authorized administrator of LSU Digital Commons. For more information, please contact gradetd@lsu.edu.
INFORMATION TO USERS

This manuscript has been reproduced from the microfilm master. UMI films the text directly from the original or copy submitted. Thus, some thesis and dissertation copies are in typewriter face, while others may be from any type of computer printer.

The quality of this reproduction is dependent upon the quality of the copy submitted. Broken or indistinct print, colored or poor quality illustrations and photographs, print bleedthrough, substandard margins, and improper alignment can adversely affect reproduction.

In the unlikely event that the author did not send UMI a complete manuscript and there are missing pages, these will be noted. Also, if unauthorized copyright material had to be removed, a note will indicate the deletion.

Oversize materials (e.g., maps, drawings, charts) are reproduced by sectioning the original, beginning at the upper left-hand corner and continuing from left to right in equal sections with small overlaps. Each original is also photographed in one exposure and is included in reduced form at the back of the book.

Photographs included in the original manuscript have been reproduced xerographically in this copy. Higher quality 6" x 9" black and white photographic prints are available for any photographs or illustrations appearing in this copy for an additional charge. Contact UMI directly to order.

Bell & Howell Information and Learning
300 North Zeeb Road, Ann Arbor, MI 48106-1346 USA
800-521-0600

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
A COMPREHENSIVE FUNCTIONAL ASSESSMENT OF THE EFFECTS OF METHYLPHENIDATE ON THE DISRUPTIVE BEHAVIOR OF CHILDREN WITH SEVERE MENTAL RETARDATION

A Dissertation

Submitted to the Graduate Faculty of the Louisiana State University and Agricultural and Mechanical College in partial fulfillment of the requirements for the degree of Doctor of Philosophy in The Department of Psychology

by

Victoria Swanson
B.S., University of Southwestern Louisiana, 1973
M.S., Northwestern State University of Louisiana, 1991
August, 1999
DEDICATION

This work is dedicated to my husband, Terry D. Swanson, and my daughter, Frankie Renee Humbles. My husband’s kindness, generosity, expertise, and assistance has been instrumental in my success. My daughter’s encouragement in my pursuit of a doctoral degree and tolerance of my frequent absences at an important transitional time in her own life has made this task much easier.
ACKNOWLEDGMENTS

I would like to acknowledge Dr. John Northup for his guidance and supervision in this project. Its completion and much of my development as a behavioral analyst are tributes to his patience and skill. I would also like to thank the members of my committee for input and participation. I would particularly like to acknowledge Dr. L.J. Credeur who actively collaborated as the physician of record in this work, Terry D. Swanson who participated as a therapist in every phase of this project, and Dalton Cooper who collected data, set up sessions, escorted children, corrected technical problems, and assisted in coordinating this project in countless ways. I would like to thank the staff at St. Mary's Training School and parents and guardians of the children in this study. I would also like to thank Karen Coor, the Coordinator of Psychological Services when this study was made, and Charlotte Creed, R.N., the Director of Nursing Services. A special acknowledgement goes to the five wonderful children who were participants in this study.
# LIST OF TABLES

1. Psychotropic Prevalence: Mean Percentage for Persons with Mental Retardation ............... 17

2. Participant Demographic Information ............. 52

3. Percentage of Interobserver Agreement across Conditions .................................. 59

4. Preference Assessment Indexes for Each Child ... 66

5. Instructional Tasks and Materials ................. 67

6. Analog Performance Measures across Conditions . 82

7. Mean Percentage of Intervals for Task Engagement across MPH Dosage and Placebo for the Attention (ATT) and No Interaction (NI) Conditions ........... 96

8. Classroom Functional Analysis Performance Measures 97

9. Mean Teacher and Support Worker Behavior Rating Scale Scores .............................. 99

10. Intervention Acceptability Ratings for Medication and Behavioral Treatments .................. 100

11. Disruptive and Engagement Behavior Percentage Means across Treatments .................... 104

12. Task Engagement for Treatments Compared to Baseline for Children Responding to MPH ..... 105

13. Task Engagement Percentage Means and Ranges for Joel and Mark’s Behavioral Treatments .... 107

14. Performance Measures across Treatment Conditions . 108

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
LIST OF FIGURES

1. Percentage of intervals of disruptive behavior across functional analysis conditions (alone, demand, control, attention) for Cade (upper panel) and Frankie (lower panel) ............... 79

2. Percentage of intervals of disruptive behavior across functional analysis conditions (alone, control, demand, tangible) for Joel (upper panel), Mark (middle panel), and Cooper (lower panel) ... 80

3. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Cooper's medication evaluation ....................... 84

4. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Cade's medication evaluation ....................... 86

5. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Frankie's medication evaluation ....................... 89

6. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Joel's medication evaluation ....................... 92

7. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Mark's medication evaluation ....................... 94

8. Percentage of intervals of disruptive behavior in baseline attention (ATTN) condition compared to Methylphenidate (MPH) and behavioral treatments for Cade (upper panel), Cooper (middle panel), and Frankie (lower panel) ................... 102

9. Percentage of intervals of disruptive behavior in baseline attention (ATTN) condition compared to behavioral treatments ................... 106
ABSTRACT

Methylphenidate (MPH) has proven efficacy with the disruptive behaviors of children with ADHD in regular education settings (Gully and Northup, 1997; Northup et al., 1999; in press). Blum, Mauk, McComas, and Mace (1996) researched the separate and combined effects of behavioral and MPH treatments on the task engagement and disruptive behavior of 3 children with severe to profound mental retardation. This study used a single-subject, multielement or alternating treatment design to assess the separate and combined effects of MPH and behavioral treatments on the performance of 5 children with severe to profound mental retardation. MPH effects were evaluated within and across dosages. Data collected in 4 to 5 analog assessments (alone, escape, attention, tangible, control) determined the two classroom functional analysis conditions used in the subsequent medication evaluation. Target behavior rates (disruptive behavior and task engagement), care provider ratings of child behavior, and academic or task performance measures provided comparisons across 2 or 3 levels of MPH and placebo. Data from analog and classroom analyses were used to develop an appropriate, function-related behavioral treatment for each child that included differential reinforcement of appropriate behavior and graduated compliance. Results indicated that 3 children demonstrated decreased disruptive behaviors and improved task engagement in response to MPH while 2 children demonstrated similar
improvement in response to the behavior intervention. Also, this study (a) determined the differential effects that stimulant medication may have on academic and behavioral performance both within and across dosages, (b) compared the effectiveness of stimulant medication and a function-related intervention in controlling problematic behavior, and (c) determined which medication dose, if any, was indicated for each participant. This study extends previous behavior pharmacological research by utilizing functional analysis of behavior disorders in relation to medication status and developmental task variables to assess the behavior mechanism of drug action in medication efficacy studies. Conclusions are interpreted in relation to the utility of functional analysis in identifying critical assessment parameters and selecting environmental stimuli useful in developing behavior treatments that maximize drug action.
REVIEW OF THE LITERATURE
Definition of Mental Retardation

The definition of mental retardation has been a controversial issue through the years (Deitz & Repp, 1989). Historically, mental retardation and mental illness have been strongly linked (Rosen, Clark, & Kivitz, 1976). The gradual differentiation between the two disabilities began in the 19th century with social incompetence viewed as the primary indicator of disability (Deitz & Repp, 1989). With the advent of memory and cognitive-perceptual tests, most classification systems began to distinguish between mental deficiency and mental illness on the basis of the individual's potential for reasoning and complex thought (Lewis & MacLean, 1982).

By the turn of the century, emotional impairment was considered the primary characteristic of mental illness, and a cognitive deficit was considered the defining characteristic of mental retardation (Ollendick, Oswald, & Ollendick, 1993). In 1919, Terman introduced the score-referenced classification levels of borderline, moron, imbecile, and idiot and used a score of less than 80 on the Stanford-Binet Intelligence Scale as the identifying criteria for retardation (Deitz & Repp, 1989). In the 1930s, the importance of developmental delays in behavior existing concurrently with retardation in mental processing was recognized (Madle & Neisworth, 1990). In 1947, the Vineland Social Maturity Scale was introduced to assess
basic social and daily living skills (Doll, 1947). Statistical distributions of intellectual scores and adaptive behavior estimates have been the basis of all subsequent definitions of mental retardation (Gresham, MacMillan, & Siperstein, 1995; Deitz & Repp, 1989).

Developmental disabilities are based on functional skill criteria and include mental retardation, autism, and pervasive developmental disorder not otherwise specified (APA, 1994). Public Law 95-602 (1978) defines developmental disability as attributable to a mental or physical impairment, manifested before the age of 22 years, likely to continue indefinitely, resulting in substantial limitation in three or more specified areas of functioning, and requiring specific, lifelong or extended care. Mental retardation is distinctive among disorders in that its diagnosis is statistically derived through a cultural deviance rather than clinically derived through a syndrome of specific behaviors and symptoms (Hamilton and Matson, 1992). The three criteria defining mental retardation are (a) significantly subaverage intelligence (i.e., greater than two standard deviations below the mean), (b) concurrent deficits in adaptive behavior, and (c) onset prior to age 18 (Grossman, 1983; APA, 1994). Adaptive behavior refers to the degree of independent functioning skills, physical development, language development, and academic competency expected for age and cultural group (Hamilton & Matson, 1992).
Four levels of mental retardation are specified by the individual's degree of intellectual and adaptive impairment (Madle & Neisworth, 1990; APA, 1994). Levels include mild (2 to 3 standard deviations below the mean), moderate (3 to 4 standard deviations below the mean), severe (4 to 5 standard deviations below the mean), and profound (greater than 5 standard deviations below the mean). When there are discrepant intellectual and adaptive standard scores the diagnosis corresponds with the higher score. Mental retardation, severity unspecified, is used when there is a strong presumption of mental retardation, but the individual is untestable with standard testing instruments (APA, 1994).

**Prevalence and Etiology**

Prevalence estimates of mental retardation range from less than 1% to 12% with the best estimate considered to be about 3% during the school years and approximately 1% during the remainder of the lifespan (Scheerenberger, 1981; Madle & Neisworth, 1990). Typically, the diagnosis is more common at school ages and in lower socioeconomic areas. Approximately 10% to 15% of the population have a discrete medical syndrome linked to their disability.

Mental retardation usually results from an interplay of genetic and environmental factors where no organic abnormalities are directly identifiable (Baumeister & Sevin, 1990; Deitz & Repp, 1989). Organic or genetic factors account for approximately 25% of all cases of
mental retardation. Educational, familial, and societal factors also contribute to mental retardation, and 40% to 90% of the individuals diagnosed with this disorder are identifiable as cultural-familial mental retardation with unknown etiology (Deitz & Repp, 1989).

Associated Disruptive Behaviors

Behavioral disorders were exhibited by 10% to 60% of the individuals with developmental disabilities (Sturmey, 1995), and coping with self-injury, aggression, and resistance to supervision accounts for 48% of the support worker time (Thompson, Hackenberg, Cerutti, Baker, & Axtell, 1994). Behavior disorder severity is the single most important variable influencing institutional placement and is an important factor in community placement failures (Bruininks, Rotegard, Lakin, & Hill, 1987; Aman & Singh, 1991). Behavior management is usually achieved through a combination of psychoactive medication, applied behavior analysis, and behavioral intervention (Baumeister & Sevin, 1990; Madle & Neisworth, 1990). Fundamental tenets of behavior analysis are that behavioral disorders have a significant learned component and functional assessment methodologies have a demonstrated utility in identifying useful treatments (Iwata, Vollmer, Zarcone, 1990). A brief description of the associated behavior disturbances follows emphasizing aggression and self-injury, which are the two behaviors most likely to result in referral for medication (Aman & Singh, 1991).
**Aggression**

Aggression is a behavior that occurs within a social context and is considered aversive to others. Included within most definitions are verbal and physical assault, fighting, destructive misuse of objects, and severe disruptive and noncompliant behaviors (Mulick, Hammer, & Dura, 1991). About 20% of the individuals living at home, 16% to 20% of the individuals residing in community residential facilities, and 30% to 45% of the individuals in institutional settings exhibit behavior that injure others (Eyman, Borthwick, & Miller, 1981; Hill & Bruininks, 1984). Statistically, aggression is 1.5 to 6 times more prevalent among institutional new admissions, community placement failures, and reinstitutionalizations (Schalock, Harper, & Genung, 1981). Physical violence toward others and property, tantrums, and explosive or disruptive acts interfere with the development of adaptive behaviors (e.g., social relationships and interactions) in a population defined by adaptive social deficits (Matson & Sevin, 1993; Sevin & Matson, 1994). Aggression is the primary source of psychiatric referral among individuals with mental retardation (Reiss, 1982; Benson, 1985).

**Stereotypy and Self-injurious Behavior (SIB)**

Stereotypy and SIB are multiply determined by neurobiological and environmental factors (Harris, 1992). Both behaviors are prevalent in many medical syndromes.
Stereotypies are rhythmical, highly consistent, repetitive behaviors or posturing responses that are excessive in rate, frequency, and/or intensity, clinically conspicuous, socially undesirable, and topographically heterogeneous (Baumeister, 1978; Rojahn & Sisson, 1990; Fee & Matson, 1992). Examples include repetitive movements, (e.g., rocking, swaying, waving, flapping, finger play), self-stimulatory behaviors (e.g., sniffing, humming, vocalizing, mouthing, saliva or mucous play), idiosyncratic mannerisms (e.g., object twirling, bruxism, air swallowing) and blindisms (e.g., eye rubbing, poking). Stereotypy is a characteristic of individuals with severe to profound mental retardation but is also common among other clinical populations (e.g., blind, autistic, geriatric, mentally ill). Prevalence estimates vary from one to two-thirds of the mentally retarded population with the higher reports being closely related with institutional placement, severity of diagnosis, and early childhood and adolescence (Rojahn & Sisson, 1990). Clinical problems arise in relation to the intensity and form of the repetitive behavior, and defining a behavior as a stereotypy or self-injury is dependent on potential for tissue damage (Madle & Neisworth, 1990; Fee & Matson, 1992). For example, innocuous but repetitive, nonfunctional behaviors (e.g., body rocking, hand waving) may preclude essential
educational or training programs. Repetitive head rocking may intensify into self-injurious head banging (Rojahn & Sisson, 1990). The most common treatments for stereotypy have included behavior modification or therapy, physical exercise, pharmacotherapy, and structural rearrangement of the environment (Rojahn & Sisson, 1990).

SIB is defined as a highly repetitive and rhythmic act or a class of behaviors resulting in direct physical harm to the person exhibiting the behavior, restricting spatial and temporal topographies, and occurring at a reliable, observable rate (Schroeder, 1991; Schroeder, Rojahn, Mulick, & Schroeder, 1990; Fee & Matson, 1992). Self-hitting, hair-pulling, self-scratching, and self-gouging of eyes, ears, mouth, throat, nose, and rectum are frequently reported types; however, head-banging and self-biting are the most common forms of SIB among persons with mental retardation (Thompson, Axtell, & Schaal, 1993). SIB occurs along a severity continuum from repetitive face rubbing to life-threatening head banging (Fee & Matson, 1992). Unlike suicidal gestures, self-neglect, and self-mutilation, SIB occurs without the apparent intent of self-harm.

SIB occurs in 6.5% of people with mental retardation living in community settings and in 15.4% of those living in public residential settings, with 20,000 to 25,000 displaying severe SIB (Thompson et al., 1994). SIB occurs in 40% of hospitalized children with psychotic diagnoses.
and in 7% to 30% of individuals with neurodevelopmental delays (Sandman, Hetrick, Taylor, & Chicz-DeMet, 1997). People with SIB are costly to serve. Time spent managing SIB accounts for 62% more staff time than does aggressive outbursts (Silverstein, Olvera, & Schalock, 1987).

SIB is viewed as an exacerbated form of stereotyped behavior, with a common etiologic base but marked idiosyncratic differences with regard to topography, severity, frequency, and duration (Baumeister & Forehand, 1973). In its most severe form, SIB may result in extensive tissue damage, fractures, amputation, and death, and is considered the most severe behavior problem encountered by service providers (Mace, Lalli, & Shea, 1992).

**Hyperactivity**

Hyperactivity refers to behavior that is excessive, situationally inappropriate, or specific to a psychological syndrome such as Attention Deficit Hyperactivity Disorder (ADHD) and may be associated with conditions including anxiety, mania, schizophrenia, hysteria, hypoglycemia, hyperthyroid, and akathisia (Coe & Matson, 1993; Chandler, Gualtieri, and Fahs, 1988). Differential diagnosis is difficult for individuals with profound or severe mental retardation, who characteristically exhibit attention deficits and activity excesses. A multimodal assessment, combining psychiatric, pharmacological, and direct observation techniques, is required with this population (Coe & Matson, 1993). Biochemical substrates assumed to
underlie hyperactivity include the catecholamines, dopamine, and norepinephrine; however, the primary evidence for these theories rest in the action of drugs used to treat hyperactivity on these transmitter systems (Baumeister & Sevin, 1990).

Hyperactivity has generally been considered an essential component of ADHD; however, ADHD has undergone a number of changes in the Diagnostic and Statistical Manual of Mental Disorders (DSM). Identified as hyperkinetic reaction of childhood in DSM-II and attention deficit disorder in DSM-III, the disorder continues as attention deficit/hyperactivity disorder in DSM-IV, and the criteria for the disorder also includes either symptoms of inattention or hyperactivity.

Behavioral Treatment Approaches

Interventions for persons with mental retardation have centered on behavioral approaches with less emphasis on psychiatric diagnosis (Fisher, Piazza, & Page, 1989). Behavioral theories of disruptive behaviors maintain that the aberrant behaviors frequently associated with individuals with mental retardation are learned behaviors maintained by their consequences (Beier, 1964; Gardner & Sovner, 1994). Carr's (1977) review of the SIB literature suggested three operant hypotheses related to the development and maintenance of self-injury: (a) socially mediated positive reinforcement, (b) socially mediated
negative reinforcement, and, (c) sensory or automatic reinforcement.

Socially mediated reinforcement is when consequences delivered by another person strengthen a behavior. An example of socially mediated positive reinforcement is a statement of concern or reprimand resulting in a behavioral increase when presented following incidents of SIB.

An example of socially mediated negative reinforcement is the removal of an instructional activity as a consequence for disruptive behavior, which results in increased rates of behavior on subsequent instructional presentations. Thus, a care provider responding to SIB by removing a task or instruction may inadvertently reinforce the behavior, and SIB becomes functional in escaping ongoing aversive or unattractive activities or avoiding anticipated unpleasant situations (Gardner & Sovner, 1994).

Automatic reinforcement refers to situations where behavior generates its own reinforcement. Common labels for automatically reinforced disruptive behaviors include stereotypy, self-stimulation, and repetitive mannerism (Vollmer, 1994). An example of automatic positive reinforcement is when eye poking automatically stimulates the area around the eye. Automatic negatively reinforced behaviors result in response-contingent termination of aversive physiological conditions (e.g., ear or tooth ache, chronic dermatitis). Examples include scratching the skin.
after an insect bite or ear-hitting when experiencing ear infections (Cataldo & Harris, 1982).

Behavioral Assessments and Treatments

Initially, within the field of developmental disabilities, interventions were developed and applied based on behavior topography rather than function. Clinical assumptions about the underlying psychopathology of an exhibited behavior (SIB) were made and behavioral or psychopharmacological treatments were prescribed accordingly. Treatments were applied sequentially in accordance with a least-to-most restrictive method and/or by reviewing the literature for previous treatment applications with that target behavior form or topography (Thompson, et al., 1993).

The current dual behavior assessment process includes (a) a topographical inventory of individual behavioral strengths and deficits and (b) functional analysis of behavior excesses (Sturmey, 1996). Standardized checklists and scales, observations, and interviews are used to identify behavioral strengths and weaknesses (Hamilton & Matson, 1992). Topographical assessments are used in group-based research and clinical outcome studies (Sturmey, 1996). The second level of behavior assessment is prescriptive, functional assessment to identify the controlling contingencies that will lead to appropriate and effective intervention selection (Madle & Neisworth, 1990; Rojahn & Sisson, 1990). Current trends are to use
functional analysis to incorporate more sophisticated rearrangements of existing consequences into natural counteracting interventions (Mace et al., 1992).

**Functional Analysis**

Current functional analysis procedures are designed to either identify or rule out social contingencies. Within the protocol, conditions are deliberately manipulated to expose participants to particular antecedents and consequences. Consistently high aberrant-behavior rates in a test condition suggest that a functional relationship exists (Iwata, Dorsey, Slifer, Bauman, & Richman, 1982/1994). Specifically, antecedent and consequent events particular to that condition are considered to be functionally related to the problem behavior.

Iwata et al. (1982/1994) empirically tested Carr's (1977) operant hypotheses in the assessment of SIB for nine individuals. Two types of contingencies (e.g., positive and negative reinforcement) and two sources of stimulus delivery or removal (e.g., socially mediated versus automatic) made up the four standardized components used to suggest different types of behavioral interventions for SIB. The experimental conditions were (a) academic demand, (b) reprimand, and (c) alone in an austere environment to determine if SIB persisted in the absence of social reinforcement. The control or play condition involved no instructional demands, noncontingent attention, and free access to leisure materials. Results demonstrated that the
functions of SIB were idiosyncratic across individuals. For example, SIB appeared to serve a positive reinforcement function for participants who engaged in increased rates of SIB during the reprimand condition. Higher rates of SIB during the demand condition suggest a negative reinforcement function. Finally, some participants exhibited high levels of SIB in the alone condition, suggesting that SIB was not maintained by social consequences.

In summary, the functional analysis protocol deliberately manipulates test conditions to expose participants to particular antecedents and consequences. Consistently high aberrant-behavior rates in one or more test conditions suggest that a functional relationship exists (Iwata et al., 1982/1994). Specifically, antecedent and consequent events particular to the condition are considered functionally related to the target behavior and incorporated into behavior reduction interventions.

Numerous other researchers have demonstrated the utility of functional analysis. For example, Sasso et al. (1992) used the same basic protocol to demonstrate the applicability and utility of functional analyses of disruptive behaviors (aggression and inappropriate language) in school settings with two children with autism. Fisher et al. (1989) and Northup et al. (1999; in press) have used functional analysis to evaluate the interaction
effects of concurrent behavioral and pharmacologic interventions.

Function-related Interventions

The goal of functional analysis is to match the intervention to the results of the functional assessment by utilizing existing environmental conditions. Functional analysis may also suggest eliminating some common treatments. The three guidelines for incorporating functional analysis results into treatment design are (a) eliminate or weaken reinforcers identified as following inappropriate behaviors, (b) provide the same reinforcer for alternative, appropriate behaviors, and (c) use antecedent manipulations identified in functional analysis (e.g., appropriate task or curriculum, instructional modifications). Thus, once a behavioral function is identified it may become possible to eliminate reinforcing contingencies (extinction), present reinforcement for more appropriate alternative behaviors (differential reinforcement), or alter the efficacy of the reinforcer maintaining the problem behavior (establishing operations).

Pharmacotherapy

Pharmacotherapy or psychopharmacology for individuals with mental retardation primarily involves psychotropic and psychoactive medications used to manage behavior considered to be harmful to the individual (SIB), to others (aggression), or to control behavior that may interfere with training or education (e.g., hyperactivity,
stereotypy). Less frequently, medications are also used to treat intellectual impairments or emotional disorders (Baumeister & Sevin, 1990). Psychotropic medication is any substance administered for the purpose of producing behavioral, emotional, or cognitive changes; a psychoactive drug is any agent that has such effects regardless of the purpose of prescribing the medication (Aman & Singh, 1988).

Research and clinical prescription of psychotropic medications for persons with mental retardation differ from other areas of neuropsychiatry. Typically, little consideration is given to the actions of the neural substrates that underlie the created conditions. Psychopharmacological treatment in the field of mental retardation is directed more toward suppression of behavioral symptoms than matching known agents to well-defined disorders as in adult psychiatry (Baumeister & Sevin, 1990; Aman & Singh, 1991). Pharmacologic treatments focus on the target behavior and generally serve suppressive functions (Thompson, et al., 1993). Thus, drugs used to control the behavior of persons with mental retardation without any clear theoretical rationale, may be countertherapeutic (Baumeister & Sevin, 1990).

**Commonly Used Medications**

Most drugs prescribed for behavior disturbance and psychopathology in individuals with mental retardation have been borrowed from other clinical populations. Before 1950, hypnotic drugs (e.g., chloral hydrate and paraldehyde) were
the primary pharmacological behavior management agents used with individuals exhibiting mental retardation. These medications were used as sleep-provoking medications at night and to sedate persons displaying aberrant behavior during the day (Thompson, Hackenberg, & Schaal, 1990; Schaal & Hackenberg, 1994). In 1955, Blair and Herold used chlorpromazine for behavior problems exhibited in people with mental retardation. Phenothiazines very quickly, became the treatment of choice for institutionalized people displaying agitation, aggression, or SIB. The use of modern psychiatric medications to treat behavior disturbance among individuals with mental retardation subsequently grew rapidly for two decades (Thompson et al., 1990).

The neuroleptics established a pattern of the treatment for severe behavior disturbances in individuals with mental retardation that has been replicated by virtually every available psychotropic medication. Generally, the goal is to reduce aggressive behavior, SIB, agitation, property destruction, and stereotypies (Schaal & Hackenberg, 1994).

Patterns of Drug Use

Persons with mental retardation are among the most medicated population in our society (Aman & Singh, 1991). From 30% to 50% of institutionalized individuals with mental retardation are medicated. Between 25% and 35% typically receive anticonvulsant medication. Thus, 50% to 67% of the residential population with mental retardation
are receiving either a psychotropic or anticonvulsant medication (Aman & Singh, 1991). The most often prescribed medications within institutions include psychotropic drugs (thioridazine, chlorpromazine, diazepam, haloperidol, mesoridazine, and hydroxyzine) and antiepileptic drugs (phenobarbital, phenytoin, primidone, carbamazepine, and sodium valproate). Stereotypies, aggression, and SIB are frequently treated with neuroleptics, anticonvulsants, antidepressant and antimanic drugs, anxiolytic drugs (benzodiazepines), and stimulant drugs.

Baumeister, Todd, and Sevin (1993) reviewed more than three dozen studies and reported prevalence differences for persons with mental retardation residing in institutions and community or school based settings reflect varying degrees of handicap and different rates of aberrant behavior. As noted in Table 1 below, the mean prevalence of psychotropic medication use in persons with mental retardation varied greatly in relation to the type of residential placement.

Table 1. Psychotropic Prevalence: Mean Percentage for Persons with Mental Retardation

<table>
<thead>
<tr>
<th>Drug</th>
<th>Institutions</th>
<th>Supported Living</th>
<th>Schools</th>
</tr>
</thead>
<tbody>
<tr>
<td>All psychotropics</td>
<td>57.4</td>
<td>41.4</td>
<td>22.8</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>31.6</td>
<td>21.6</td>
<td>15.4</td>
</tr>
<tr>
<td>Neuroleptics</td>
<td>31.8</td>
<td>19.0</td>
<td>4.4</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>2.9</td>
<td>5.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Anxiolytics</td>
<td>8.5</td>
<td>3.8</td>
<td>--</td>
</tr>
<tr>
<td>Sedative/hypnotics</td>
<td>6.0</td>
<td>2.6</td>
<td>--</td>
</tr>
<tr>
<td>Stimulants</td>
<td>0.5</td>
<td>0.5</td>
<td>0.1</td>
</tr>
</tbody>
</table>

The high prevalence of anticonvulsant use is related to the high incidence of convulsive disorder and the use of this
drug class to manage aberrant behavior in persons with mental retardation independently of their anticonvulsant effect (Beaumeister et al., 1993).

Tu and Smith (1983) noted the six most common problems and prevalences among medicated individuals with mental retardation are as follows: aggression (29%), hyperactivity (24%), SIB (19%), excitability (12%), screaming (10%), and anxiety (8%). Hyperactivity was the strongest predictor for neuroleptic use in community residential facilities; violent or destructive behavior was the strongest predictor for neuroleptic use in institutions (Intagliata & Rinck, 1985).

**Methodological Considerations**

Minimal requirements for a scientifically controlled drug study are as follows: placebo control, random assignment of subjects (group comparison designs), adequate baseline and reversal phases (single-subject or within-subjects designs), double-blind observations or evaluations of drug effects to minimize bias, standardized doses, direct or standardized (valid, reliable) measures of drug effect (behavior change), and appropriate use of inferential statistics (group designs) or visual analysis (single-subject designs) to measure drug-related changes (Sprague & Werry, 1971; Aman & Singh, 1988, 1991; Baumeister & Sevin, 1990; Thompson et al., 1990; Singh, Singh, & Ellis, 1992; Schaal & Hackenberg, 1994).
Pre-1975 studies in the field of mental retardation violated one or more of the above mentioned criteria and were clearly inferior to work occurring with other clinical populations (Aman & Singh, 1988). The difficulties in working with persons with developmental disabilities make it challenging to conduct elaborate research. The number of adequately controlled studies have consistently increased during the past twenty years (Aman & Singh, 1988; Baumeister et al. 1993). Additionally, studies are appearing with specific indications for the various psychotropic drugs prescribed for persons with mental retardation (Fisher et al., 1989; Johnson, Handen, Lubetsky, & Sacco, 1994; Aman, et al., 1997; Christian, Kerr, Sutphin, & Poling, 1997).

Well designed studies in the field of mental retardation (a) describe medication effects on specific behaviors, (b) separate the effects of different drugs, (c) separate the drug effects for participants with mental retardation from other individuals (Baumeister et al., 1993), and (d) control for environmental variables. Aman and Singh (1988; 1991) urge medication trials be free of other drug confounds and be compared to alternative interventions.

Measuring Dose-Response Relationships

The dose-response relationship is the orderly relationship between the quantity of a drug and the magnitude of effect. Psychopharmacological research

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
measurement techniques commonly used to measure drug
effects require adjustments for the cognitive and
behavioral deficits of persons with mental retardation.
Baumeister and Sevin (1990) are critical of studies that
lump disruptive behaviors and provide only a global measure
of change (e.g., percent improved). Drugs may have
differential effects on a given behavior or classes of
behavior at different doses. Singh et al. (1992) recommend
studies include measures of collateral behaviors (e.g.,
learning, adaptive and maladaptive behaviors) as well as
dosage effects to determine dose-dependent relationships.

Global impressions. Global impressions are ratings of
overall behavior change or clinical improvement based on
the rater's subjective impressions of the participant (Aman
& Singh, 1988; Baumeister & Sevin, 1990). Although useful
as general indicators of change from the subjective opinion
of service providers, global impression measures lack
objective criteria against which changes can be judged and
should not be used in isolation. For example, teachers will
rate changes in learning and cognition more positively than
support workers in custodial settings (Baumeister & Sevin,
1990).

Direct behavioral observations. Direct behavioral
observations are less prone to bias but have only recently
become common in psychopharmacological research with
persons with mental retardation (Aman & Singh, 1988).
Within the direct observation method, principles of applied
behavior analysis are used to select and define target behaviors, complete initial descriptive analyses, and sample a broad range of maladaptive and adaptive behaviors using standardized procedures of data collection (Singh & Beale, 1986).

**Rating scales.** Rating scales have been the major assessment procedure of behavior change in pediatric psychopharmacology but have less prevalence in studies with individuals with mental retardation (Aman & Singh, 1988). There are numerous scales designed for measuring behavior change in developmentally delayed populations, but most have not been used in psychopharmacological investigations (Aman & Singh, 1988). Only a small number of scales normed with this population have demonstrated adequate psychometric properties in psychopathological assessment (Aman & Singh, 1988).

**Learning measures.** Learning measures are indices of cognition and learning that are recommended for inclusion in the assessment of drug effects (Sprague & Werry, 1971; Aman & Singh, 1988). IQ tests, achievement tests, curriculum measures, vocational training tasks, and performance tests for attention or dexterity have been used as learning measures. Assessing drug-related change in learning performance is difficult with a population having major learning and cognition deficits. Aman and White (1986) reviewed a number of tasks (e.g., operant conditioning and discrimination learning tasks) that appear
to have some utility as learning measures in psychopharmacological research. In general, IQ and achievement tests appear to be the least sensitive to medication effects, and the literature suggests performance tests are most likely to be effected by medication (Werry & Sprague, 1972; Aman & Singh, 1988).

Physiological measures. Dependent measures in psychopharmacology research generally require the participant's active involvement. Functional level, associated physical impairments, and behavior problems may preclude compliance for persons with mental retardation. Physiological measures are an alternative method of assessing medication effects. Aman and White (1986) recommend physical measures of motor coordination, physiological measures (e.g., galvanic skin response, heart rate), and play or activity measures (e.g., mechanical transducers) as useful tools.

Behavior Pharmacology

Behavior pharmacology recognizes the significance of pharmacological variables (e.g., dose) as determinants of drug action, but places primary emphasis on behavioral and environmental variables that have been demonstrated to modulate drug effects.

To understand the mechanisms of a drug's action in changing behavior, it may be advantageous to search for behavior mechanisms of drug action. A behavioral mechanism of action describe a drug's behavioral effects in terms of
alterations made on environmental variables normally regulating that behavior (Thompson & Schuster, 1968; Thompson, 1984). Specifying the behavioral mechanisms responsible for an observed effect involves (a) identifying the environmental variables that typically regulate the behavior in question, and (b) characterizing the manner in which the influence of those variables is altered by the drug (Thompson, 1981). For example, a drug could weaken the effectiveness of known rewards or reinforcers, or diminish the efficacy of punishing events in suppressing destructive or aggressive behavior (Northup, et al., 1997).

A Functional Approach in Medication Studies

Schaal and Hackenberg (1994) criticize studies that select participants based on topographical features of the problem behavior (e.g., self-hitting) without considering the function of the behavior. These authors recommend a pharmacotherapeutic approach that includes functional analyses of behavior disorders with appropriate consideration of the pharmacological agent and developmental variables involved.

Thompson et al. (1993) recommend an analysis of the behavior mechanism of drug action in drug efficacy studies. For example, four classes of behavioral mechanisms of drug action relevant to SIB include (a) neuroleptic reduction of SIB when the behavior problem is maintained by terminating conditioned negative reinforcers, (b) neuroleptic reduced control of reinforcing stereotypic stimulation, (c) opiate
antagonist blocking of the reinforcing effects of endorphins binding to the opiate receptor, and (d) the benzodiazepine exacerbation of SIB with the antisuppressive effects diminished in strength by the natural painful results (Thompson et al., 1994). Thompson et al. (1993) advocates a tri-dimensional analysis of SIB that includes establishing the temporal pattern and repetitiveness of the SIB, the degree it is under external environmental control, and the degree pain serves as a maintaining event.

Stimulant Medications and Mental Retardation

CNS stimulant medications, such as methylphenidate (MPH) or Ritalin, dextroamphetamine (dexedrine), and pemoline (cylert), are the medications of choice for ADHD. MPH is the most prescribed stimulant medication and imipramine (Tofranil) and fenfluramine are the most prescribed for stimulant nonresponders (APA, 1994). Although it shares a similar pharmacologic profile with amphetamine, therapeutic doses of MPH have a more marked effect on cognitive functions than physical or motor activities.

Reported side effects of stimulant medications include stomach ache, headache, depressed appetite, insomnia, dizziness, and tics. Ahmann et al. (1993) systematically addressed the frequency and severity of associated stimulant-related side effects and found only four symptoms (stomach ache, headache, decreased appetite, and dizziness) were reported to increase over baseline with stimulant use.
Nolan and Gadow (1997) studied the differential effects of doses of MPH (0.1 to 0.5 mg/kg) and placebo in normal-IQ children with ADHD and chronic motor tics. Dramatic improvement was noted in 32% of the 34 children receiving the 0.5 mg/kg dose and no increases in tics were noted. Handen, Feldman, Gosling, Breaux, and McAuliffe (1991) found stimulant use induced motor tics (11.1%) and social withdrawal (7.4%) in 27 children dually diagnosed with mental retardation (IQs 48 to 74) and ADHD.

**Dosage**

MPH is a mild CNS stimulant and is manufactured in doses of 5, 10, 20 mg, and sustained release, 20 mg tablets. The drug has a relatively brief half-life with the behavioral effects of MPH peaking approximately 1½ hours after ingestion, and decreasing gradually until they disappear approximately 2 hours later. The time-response curve of MPH indicates that the behavioral effects increase for the first two hours after administration, and decrease in what is similar to a bell-shaped curve (Pelham, Jr., 1993). MPH is expected to be eliminated entirely from the body within 24 hours after ingestion. Some studies suggest that sustained-release MPH may be less effective in the first hours after administration. Thus, short-acting MPH is prescribed more often than the sustained-release dose (DuPaul, Barkley, & McMurray, 1991; Barkley, 1989).

Body weight (mg/kg) and blood levels are not always accurate predictors of dose-response to stimulant
medication. Additionally, idiosyncratic responses occur (a) across behaviors for the same child and (b) between children of the same weight, height, and gender for similar behavior (DuPaul & Barkley, 1993). A particular dose may increase a child's academic performance, but fail to make substantial decreases in disruptive classroom behaviors (Sprague & Sleator, 1977). Therefore, individualized evaluations of MPH effects are recommended.

**MPH Effects across Behavioral Classes**

The idiosyncratic effect of MPH across behavior classes (e.g., academic performance, attention, social interaction) has immediate and long-term implications when choosing behaviors to be targeted in assessment and intervention (Rapport & Kelly, 1991). Sprague and Sleator (1977) conducted the seminal study assessing multiple behaviors (social behavior, learning performance) across different doses of stimulant medication (placebo, 0.3 mg/kg, and 1.0 mg/kg) by using the Abbreviated Conners Teacher Rating Scale (ACTRS) and a picture recognition task at three levels of increasing difficulty (3, 9, and 15 pictures). Results indicated that learning performance was optimal at the lower MPH dose level but teacher ratings were optimal at the higher MPH dose level.

A series of clinic-based studies evaluated the effects of four doses of MPH (5, 10, 15, and 20 mg) and a placebo on the school and clinic behaviors of children diagnosed with ADHD (Rapport & Kelly, 1993). Weekly, clinic measures...
were compared to three classroom observations. Clinic measures included the Continuous Performance Task (CPT), the Matching Familiar Figures Test (MFFT), and the Paired Associate Learning (PAL) task. Classroom measures included academic performance, on-task behavior, and teacher ratings of overall classroom behavior. The classroom measures were highly sensitive to both overall and between dose effects while most of the clinic measures were found to be insensitive in detecting overall and between dose MPH differences. The MFFT did indicate overall and between dose differences with the 15 mg dose when compared to the lower doses (5 and 10 mg) and placebo (Rapport & Kelly, 1993).

Rapport, Stoner, DuPaul, Birmingham, and Tucker (1985) used a triple-blind, placebo-controlled, crossover experimental design to evaluate the performance of children receiving three dosages of MPH (5, 10, and 15 mg) on the clinic-administrated PAL measures and multiple, school-related behaviors (teacher ratings, on-task, work completion, and accuracy). An ANCOVA with repeated measures computed on all dependent variables indicated (a) significant dose effects on teacher ratings, percent on-task, and academic accuracy, (b) significantly higher teacher ratings for the placebo condition compared to all medication conditions, and (c) significant differences in all dependent measures, except the PAL task, with higher doses typically effecting the most change. When the PAL
task results were analyzed separately, the children showed response to medication dosage.

Rapport, DuPaul, Stoner, and Jones (1986) evaluated the utility of classroom observations and the CPT in detecting dose-response effects of three levels of MPH (5, 10, 15 mg) in a double-blind, placebo-controlled crossover design. CPT variables included CPT omission and commission errors and percent of on-task behavior, completed assignments, correctly completed assignments, and teacher ratings. Statistical analysis indicated significant overall effects for all dependent measures; however, analyses at the individual level showed an idiosyncratic response across children. The individual responses to MPH were task specific for some children.

Methodology in Stimulant Medication Evaluations

General Assessment Procedures

The ADHD-stimulant medication efficacy studies have been prominent in developing a systematic behavioral investigation to determine drug-behavior interaction. In clinical practice, the rationale for dosage selection is usually not determined in an objective manner (Gadow, Nolan, Paolicelli, & Sprafkin, 1991).

Physicians typically use a physical exam and a parental interview that stresses history and nature of the presenting symptoms (Barkley, 1987; DuPaul & Barkley, 1993; Gulley & Northup, 1997). A single office visit will often generate a diagnosis and a prescription for stimulant
medication at the lowest dose, to be titrated upward as indicated by parent reports at subsequent visits. The traditional prescriptive approach to stimulant medication fails to recognize the complexity of stimulant medication effects and the individual needs of the children for whom the medication is prescribed. Pelham, Jr., (1993) cautions that the traditional prescriptive practice may result in many children either receiving an inappropriate dose or being prescribed stimulant medication when it is contraindicated.

Recent research indicates most of the common assessment procedures do not adequately evaluate all the behavioral areas that stimulant medication affect (DuPaul & Barkley, 1993; Gulley & Northup, 1997). Behavioral assessment procedures (e.g., direct observations, academic performance measures, behavior ratings across raters) are adapted to stimulant medication assessments that require measures of behavior change, dosage effects, social validity, and convergent validity of observational measures with data from other sources (Pelham, Vodde-Hamilton, Murphy, Greenstein, & Vallano, 1991). The more common behavioral assessment procedures and traditional laboratory tests of attention and impulsivity are reviewed below.

Laboratory Assessments

Clinical evaluations of dose response use general performance tests that assess impulsivity and attention. The measures are considered sensitive to medication
effects; however, predictive validity related to the child's actual classroom behavior is low. The measures do not detect changes in the multiple areas of functioning that may be affected by stimulant medication (Rapport & Kelly, 1993).

**Continuous Performance Task (CPT; Rosvold, Mirsky, Sarason, Bransome, & Beck, 1956).** The CPT is a widely used laboratory measure of the vigilance or attention span of children with ADHD. The child presses a button when a previously specified number or letter appears in a rapidly presented numerical or letter sequence. The test yields scores of sustained attention (the number of correct responses, the number of missed stimuli or omission errors), and a score of impulsivity (the number of responses to inappropriate stimuli or commission errors).

**Gordon Diagnostic System (GDS; Gordon, 1983).** The GDS is a CPT variation that uses a computerized, 9-minute vigilance task. The child presses a large button after specified numerical sequences. The GDS has satisfactory normative data and test-retest reliability. It is considered sensitive to moderate to high doses of stimulant medication and discriminates ADHD from non-ADHD children (Barkley, 1990).

**Matching Familiar Figures Test (MFFT; Kagan, 1966).** The MFFT is the most widely used clinical measure of impulsivity. The child identifies one correct stimulus picture from six similar variations during 12 trials. The
test generates a total error score (number of incorrect identifications) and a latency score (mean time between the presentation of a stimulus card and the subject's initial response). Some studies have reported conflicting or negative results in regard to stimulant drug effects or failed to discriminate between children with and without ADHD (Barkley, 1990).

**Delay Task** (Gordon, 1983). The Delay Task is an 8-minute measure of impulsivity that incorporates the GDS program with a differential reinforcement of low rates paradigm. More points are earned if the child successfully delays button pressing following presentation of the specified sequence. The Delay Task has normative data and discriminates between ADHD and non-ADHD children; however, it may not be sensitive to stimulant drug effects and correlates poorly with parent and teacher ratings (Barkley, Fischer, Newby & Breen, 1988; Barkley, 1990).

**Teacher's Self-Control Rating Scale (TSCRS; Humphrey, 1982).** The TSCRS is a 15-item teacher rating scale that assesses self-control. Teachers rate behaviors on a 5-point Likert scale from 1 (*never happens*) to 5 (*often happens*). The scale yields scores for a behavioral/interpersonal factor score, a cognitive/personal self-control factor, and total self control. The TSCRS has demonstrated adequate psychometric properties and positive correlations with naturalistic behavioral observations (Rapport et al., 1985; Humphrey, 1982).
Paired Associate Learning (PAL). The PAL task was developed to determine optimal stimulant dose and stimulant responsiveness (Rapport et al., 1985). A series of familiar animal picture cards are presented, assigned specific zoo numbers, and shuffled. The child verbally matches the animal card with the appropriate zoo number from 10 trials.

Academic

Academic measures of stimulant medication effects must be administered repeatedly across doses. Standardized academic achievement tests are not sensitive to the productivity and accuracy changes that occur in repeated medication trials (DuPaul & Barkley, 1993).

Permanent work products. Academic performance response to medication effects is measured with permanent work products (e.g., academic productivity and accuracy ratings of routine, daily, teacher-assigned tasks). Academic productivity measures include the number of academic tasks completed (e.g., number of problems worked, number of words read) or the number of units produced. Accuracy is the number of items worked or completed correctly (percent correct).

Curriculum based measurement (CBM). CBM appears to be an effective measure of academic performance in stimulant medication trials (Gulley and Northup, 1997; Stoner, Carey, Ikeda, & Shinn, 1994). CBM uses a behavioral-assessment perspective to evaluate academic performance in reading, math, spelling, and written expression (Shinn, 1989). CBM
measures make direct and repeated assessments of a child's academic performance and use graphed results as time series data in ongoing decision making. CBM measures have compared favorably with teacher ratings on the Academic Performance Rating Scale (APRS; DuPaul, Rapport, & Perriello, 1991; the Child Attention Problems scale (CAP; Barkley, 1990), and the Side Effects Rating Scale (SDERS; Barkley, 1990).

Social Skills

Social difficulties and poor peer relationships are among the most pervasive problems children with ADHD experience and are considered significant predictors of long term maladjustment (Hoza, Pelham, Jr., Sams, & Carlson, 1992). The majority of medication studies have concentrated on authority rather than peer social relationships (Hinshaw, 1991; Klorman et al., 1988). Thus, most studies assess changes in the child's social skills with the parent or teacher (Hinshaw, 1991; Klorman et al., 1988), and a few studies have targeted social skills with peers (Pelham et al., 1987; Hinshaw, Henker, Whalen, Erhardt, & Dunnington, 1989; Gulley & Northup, 1997; Northup, Jones et al., 1997).

Hinshaw et al. (1989) evaluated the effects of stimulant medication on the noncompliance, aggressive, and social behaviors of 25 boys with ADHD with two doses of MPH. The nonsocial category was added to measure decrease in sociability or the zombie effect teachers or parents attribute to an overmedicated child. Main effects were
found for noncompliance and aggression during the medication trials, but no effects were found for prosocial or nonsocial behavior.

MPH may be effective in decreasing negative verbalizations, conduct problems, and negative peer interactions for some children with ADHD (Pelham & Bender, 1982; Pelham & Hoza, 1987). Most studies have combined medication with various behavioral treatments. Group studies of children with ADHD and average intelligence have found that behavioral treatments in combination with low doses of MPH are more effective than either intervention alone (Carlson, Pelham, Milich, & Dixon, 1992; Pelham Milich, & Walker, 1986). The degree to which these group studies characterize the response of individual children to these interventions is not known. More research is needed to determine the separate and combined effects that medication and behavioral interventions may have on the children's social and classroom behaviors (Blum, Mauk, McComas, & Mace, 1996; Gulley & Northup, 1997; Northup et al., 1999; in press). Current literature is limited by the narrow range of studies, the use of different doses of medication, and the lack of systematic dose manipulation (Cunningham, Siegel, & Offord, 1985).

**Multimethod Stimulant Medication Assessments**

**School Based Medication Evaluation (SBME)**

SBME (Gadow, 1991) is a standardized observation method that uses behavior rating scales and direct
observations of child behavior to evaluate medication effects. SBME uses a target behavior response rate at placebo and each level of medication to establish a minimal effective dose for each child. The protocol includes (a) a parent and teacher rating scale, (b) a stimulant side effects checklist, (c) direct observations of disruptive behaviors with the Classroom Observation Code (Abikoff & Gittelman, 1985), and (d) direct observations of social behavior with the Code for Observing Social Activity (COSA; Sprafkin & Gadow, 1987).

Other Multimethod Approaches

Fischer and Newby (1991) developed a clinical protocol to assess medication effects for children with ADHD using (a) a double blind procedure and a weekly randomized rotation of medication status at placebo and low (0.2 mg/kg BID) and high (0.4 mg/kg BID) doses of MPH, (b) an initial clinical evaluation that included the Child Behavior Checklist (CBCL; Achenbach & Edelbrock; 1993), (c) weekly parent and teacher rating scales, and (e) weekly laboratory measures (the Multi-Choice Reaction Timer, the GDS vigilance task, and a restricted academic task). Weekly parent rating scales included the Home Situations Questionnaire (HSQ; Barkley, 1991), the Conners' Parent Rating Scale-Revised (Goyette, Conners, & Ulrich, 1978), and the Side Effects Rating Scale. Weekly teacher rating scales were the School Situations Questionnaire (SSQ; Barkley, 1991), the Conners' Teacher Rating Scale-Revised.
(CTRS-R; Goyette et al., 1978), and the Side Effects Rating Scale. The protocol yields measures of reaction time, sustained attention, impulsivity, and a variety of child behaviors during the restricted academic situation.

Recent single-subject studies with children with ADHD have extended the Fischer and Newby (1991) protocol by developing a comprehensive assessment procedure across multiple behavior measures to determine (a) an optimal dose of stimulant medication, if any, (b) medication effect variations across doses, and (c) medication effects across child behaviors.

Gulley and Northup (1997) used a double-blind, placebo-controlled, single-subject experimental design to evaluate the effects of three doses of MPH (low, moderate, and high) across the behavioral domains of academic performance, classroom behavior, attention, social interactions, and teacher ratings of child behavior. Results suggested CBM and direct behavior observations were sensitive to medication response for all students. Northup et al. (1999; in press) used a double-blind, placebo-controlled, multielement design and functional analysis assessments within the classroom setting to demonstrate the differential effects that stimulant medication may have on student academic and behavioral performance with and without contingency management interventions in place (e.g., praise, reprimands, time out). These studies strongly indicate that classroom
interventions can be enhanced with stimulant medication; however, to be effective the treatments require thorough behavioral assessments or functional analyses.

Assessing Stimulant Medication Effectiveness for Individuals with Mental Retardation

Despite the demonstrated efficacy for treating hyperactivity in children with ADHD, stimulants are not a prevalent medication treatment in residential settings for individuals with developmental disabilities (Aman & Singh, 1991; Chandler et al., 1988). Early studies involving people diagnosed with mental retardation suggested stimulant medications were effective in reducing hyperactivity and improving intellectual functioning and performance on psychological tasks (Bell & Zubek, 1961; Morris, MacGillibary, & Mathieson, 1955). Subsequent investigations failed to clearly support the therapeutic efficacy of stimulants (Aman, 1982; Aman & Singh, 1982; Berkson, 1965; Davis, Sprague, & Werry, 1969; McConnell, Cromwell, Bialer, & Son, 1964; Shafto & Sulzbacher, 1977). Due to the potential for MPH to precipitate irreversible tics in hyperactive children with Tourette's disorder and seizure activity in hyperactive children with autism, physicians have been cautious in prescribing MPH for children with developmental disabilities (Klein, Gittelman, & Quitkin, 1980; Schaal & Hackenberg, 1994).

Most authorities currently agree that the probability of observing a beneficial stimulant response decreases as
functional level decreases (Aman & Singh, 1991). Recent placebo-controlled studies suggest children with mild to moderate mental retardation and hyperactivity respond to stimulants in a manner similar to children with average intelligence and ADHD (Aman, Marks, Turbott, Wilsher, & Merry, 1991a). Stimulant medications are the most common behavior modifying drugs prescribed for individuals with mild developmental disabilities in special public school placements to address problems with inattention, distractibility, and excessive activity that interfere with learning (Crnic & Reid, 1989; Gadow & Kalachnik, 1981). Stimulant medications are not generally recommended for students with severe or profound mental retardation (Aman & Singh, 1991; Chandler et al., 1988; Handen & Feldman, 1992).

Proponents of stimulant use with individuals with severe or profound mental retardation cite the methodological inadequacies of the early stimulant research with this clinical population (Aman & Singh, 1991). The majority of the drug studies with the developmentally delayed population omitted (a) basic methodological features necessary for making conclusions about drug efficacy (e.g., random assignment of subjects to groups, placebo control or crossover design, double-blind observations, and standardized or reliable measurements), (b) functional analyses of behavior disorders and/or failed to control environmental variables, (c) important
participant features (e.g., age, gender, other medications), (d) standardized dose increments, and (e) objective behavior measures (Schaal and Hackenberg, 1994). The initial stimulant studies used adult, institutionalized persons with mental retardation who exhibited behaviors not typically addressed by stimulant medications (Aman & Singh, 1991; Aman et al., 1993b).

**Group Efficacy Studies**

Recently, a number of sophisticated, large-group efficacy studies targeted MPH in children with mental retardation and ADHD or compared CNS stimulants with other medications (e.g., fenfluramine, thioridazine) and documented positive stimulant responses at efficacy rates approaching those observed in the average-IQ, ADHD population (Aman & Singh, 1986; 1991; Handen, Breaux, Gosling, Ploff, & Feldman, 1990; Handen et al., 1991; Handen et al., 1992). M.G. Aman and colleagues at the Nisonger Center for Mental Retardation and Developmental Disabilities at Ohio State University and B.L. Handen and colleagues in the Department of Pediatrics at the University of Pittsburgh School of Medicine have initiated independent efficacy series with MPH and other medications (thioridazine, fenfluramine) among intellectually subaverage and developmentally delayed children with ADHD.

**Nisonger Center Studies**

The Nisonger Center research has targeted (a) the clinical effects of MPH, fenfluramine, and thioridazine on
intellectually subaverage children (Aman et al., 1991a), (b) the cognitive-motor performance of low-IQ children with ADHD receiving MPH and thioridazone (Aman, Marks, Turbott, Wilsher, & Merry, 1991b), (c) the laboratory effects of fenfluramine and MPH (Aman et al., 1993a) and (d) clinical and side effects of fenfluramine and MPH (Aman et al., 1993b; Aman et al., 1997). Overall, Aman and colleagues found differential effects with MPH in relation to MA, IQ, and sustained attention. Specifically, MA and IQ may be important determinants of drug response; higher functioning individuals with ADHD show a more favorable response to MPH, and children with lower IQs show an adverse or indifferent response on both teacher and parent rating scales (Aman et al., 1991a; 1991b).

The Pittsburgh School of Medicine Studies

The University of Pittsburgh School of Medicine research team studied stimulant medication use with children dually diagnosed with mental retardation and ADHD. Studies targeted MPH (a) efficacy (Handen et al., 1990; Handen et al., 1992), (b) response predictor variables (Handen, Janosky, McAuliffe, Breaux, and Feldman, 1994; Handen, McAuliffe, Janosky, Feldman, & Breaux, 1995), (c) adverse side effects (Handen et al., 1991), and (d) efficacy with behavioral interventions on classroom behavior (Johnson et al., 1994). Results indicated that overall drug response rates ranged from 64% to 75% but that a greater number of adverse side effects (e.g., motor tics,
social withdrawal) were reported in comparison to studies of children with average intelligence.

Both the Nisonger and Pittsburgh research groups found effects of MPH with this population that are consistent with research conducted with children with ADHD but not diagnosed with mental retardation (Aman et al., 1991a; 1991b; 1993a, 1993b, 1997; Handen, et al., 1990; 1991; 1992; 1994; 1995). Specifically, children with mental retardation in the high moderate to mild range and ADHD appear to respond to MPH at similar rates and in similar domains to that of the nonretarded population. The MPH side-effect studies indicated that children with mental retardation and ADHD may be at a greater risk for developing these side effects than the nonretarded population (Handen, et al., 1991). In a recent review of the literature, Aman (1996) concluded (a) children dually diagnosed with mental retardation and ADHD do respond to stimulant medication, (b) stimulant response rate is lower in children with mental retardation as compared to children with ADHD and average IQs, and (c) response rate may be positively related to functioning level (e.g., IQ, MA).

**Within-Subject Stimulant Efficacy Studies**

Most studies evaluating the interactive effects between medication and specific environmental variables have used between-group designs that did not control for environmental contingencies. Poling and Cleary (1986) recommended applying behavior analysis research strategies
to clinical psychopharmacology by (a) increasing the use of within-subject or single-subject designs (e.g., withdrawal, multiple baseline), and (b) using drugs as independent variables to determine how drugs affect carefully defined and measured target behaviors. The few research attempts at a multimethod approach to stimulant medication evaluations have the following limitations: (a) overreliance on subjective measures (self-report and rating scales); (b) limited definitions of the primary problem behaviors (e.g., academic performance, compliance, inattention); and, (c) limited clinical observations.

During the 1970s and 1980s, five methodologically sound, single-subject studies compared MPH to behavioral treatments and demonstrated beneficial effects for MPH with contingency management facilitating appropriate behavior. (Ayllon, Layman, & Kandel, 1975; Pelham, Schnedler, Bologna, & Contreras, 1980; Shafto & Sulzbacher, 1977; Wulbert & Dries, 1977; Schell et al., 1986). Pelham et al., (1980) found combined drug and behavioral treatment to be more effective than either component alone. These studies demonstrated the utility of applied behavior analysis research in comparing medications to alternative treatments and in assessing behavioral side effects of pharmacological interventions.

During the past 10 years, the number of applied studies demonstrating the utility of single-subject designs in evaluating the relative and combined clinical
effectiveness of medication and behavioral interventions have increased (e.g., Blum et al., 1996; Johnson et al., 1994; Shell et al., 1986; Stoner et al., 1994). Schell et al. (1986) investigated the separate and combined effects of a behavioral intervention and one dose (0.3 mg/kg) of MPH on a child with mild mental retardation and found additive effects of the two interventions on correct responding to task. Johnson et al. (1994) used an alternating treatment, double-blind, placebo-controlled design with three children with ADHD and mental retardation and reported differential effects with interventions across MPH and placebo similar to those reported in single-subject studies within the average-IQ ADHD population (Northup, Jones et al., 1997; Northup et al., 1999; in press). Blum et al. (1996) used a single-subject experimental methodology to investigate the separate and combined effects of behavioral and pharmacologic intervention concurrently. Behavioral treatments based on functional analysis have been included in a few stimulant medication studies (Cooper et al., 1993; Fisher et al., 1989; Kayser, et al., 1997; Northup et al., 1999; in press).

**Environmental Variables in Stimulant Efficacy Studies**

Programmed consequences and MPH have demonstrated efficacy in reducing the disruptive behavior of children with ADHD. A growing body of research is evaluating the interactive effects between MPH and environmental variables (e.g., the behavioral mechanism of the drug action of MPH.
in applied settings). Whalen, Henker, Collins, Finck, and
Dotemoto (1979) used a between-group design to demonstrate
a possible interactive effect between MPH and classroom
antecedent conditions varying by noise level and task
pacing. Wilkison, Kircher, McMahon, and Sloane (1995) used
a between-group design to demonstrate boys with a diagnosis
of ADHD earned significantly more of a generalized
reinforcer (pennies) when they received MPH as compared to
placebo.

Northup and colleagues have developed a single-subject
methodology for concurrently assessing (a) the effects of
common classroom contingencies (e.g., peer attention) and
MPH within a multielement design (Northup, Jones et al.,
1997), (b) the differential effects for reinforcer
assessments with children receiving MPH and placebo
(Northup, Fusilier, Swanson, Roane, & Borrero, 1997), and
(c) the separate and interactive effects between common
classroom contingencies (e.g., timeout, teacher reprimand)
and MPH on disruptive and off-task behaviors (Northup et
al., 1999; in press).

Blum et al. (1996) conducted a controlled comparison
of baseline conditions, a behavioral intervention alone,
MPH alone, and a combination of MPH and a behavioral
intervention for the treatment of disruptive behavior in
three children with severe to profound mental retardation.
The primary dependent variable was the percentage of time
engaged in disruptive behavior during a 10-minute task
session (i.e., placing blocks or books into a specific container). Engagement with task, defined as the child picking up or walking with a toy or book in the direction of the container was also measured. The behavioral intervention involved differential reinforcement (DRA) and guided compliance to decrease the disruptive behavior and increase task engagement. A forced-choice preference assessment (Fisher et al., 1992) was used to identify the reinforcers used in the differential reinforcement of alternative behavior (DRA) procedure. Two of the children demonstrated decreases in disruptive behavior with concurrent increases in task engagement in response to MPH. Three children demonstrated similar improvement in response to the behavioral intervention. The relative efficacy of the two interventions varied for the two children responding to MPH and behavioral treatments. Blum et al. (1996) demonstrated the idiosyncratic character of response to MPH and behavioral treatment in children with severe to profound mental retardation and recommended both behavioral and pharmacologic interventions be considered when treating disruptive behaviors in this population.

Summary

Methodology in the field of psychopharmacology with the developmentally delayed population has been historically poor (Aman & Singh, 1988). Dosage adjustments have been a problem with both individualized and standardized regiments commonly used (Aman & Singh, 1988).
The dominant measure of drug response has traditionally been clinical global impressions; however, recent studies have relied on direct observations, standardized rating scales, and tests of learning (Thompson et al., 1993; Baumeister & Sevin, 1990).

The basic assumption in behavior analysis is that most disruptive behaviors are operants sensitive to reinforcing contingencies. Behavior pharmacology uses single-subject designs in medication efficacy studies to determine the effects of pharmacological variables (e.g., dose) on behavioral mechanisms of action (Schaal, & Hackenberg, 1994; Baumeister & Sevin, 1990). Behavioral pharmacologists attempt to determine what are the drug effects on environmental variables that normally regulate the behavior of interest. For example, analysts attempt to determine what environmental contingencies the behavior is naturally responsive to and determine if any post-medication behavior change is the result of dose response. Behavior pharmacology recommend medication studies include a multidimensional analysis to establish the temporal pattern and repetitiveness of the target behavior, determine behavioral or cognitive deficits that might be maintaining the behavior, and specify the degree the behavior is under environmental control (Thompson, 1993).

Behavioral pharmacology assesses drug effects on problem behavior; functional analysis of serious behavior problems has demonstrated utility with behavior disorders.
Surprisingly, behavioral treatments based on functional analysis have been included in only a few medication studies (Cooper et al., 1993; Fisher et al., 1989; Kayser, et al., 1997; Northup et al., 1999; in press).

The idiosyncratic effect of MPH across behavioral classes directly impacts which behaviors and measures will be included in ADHD-stimulant medication studies. Pelham et al. (1991) recommends direct observations, standardized dose increments, academic performance measures, behavioral ratings across raters, direct measures of behavioral change to determine dosage effects, measures of social validity, and convergent validity of observational measures with data from other sources. Although single-subject methodology can easily be adapted to meet these goals, most medication studies have used between-group designs and used direct observations as supplementary rather than primary measures (Gulley & Northup, 1997).

Many group studies with children with ADHD and average IQs have combined medication and behavioral treatments. The general consensus of these studies is that behavioral treatments in combination with low doses of MPH are more effective than either intervention alone for children with ADHD and average intelligence (Carlson, Pelham, Milich, & Dixon, 1992; Pelham Milich, & Walker, 1986). The degree to which these group studies are able to reflect the response of individual children to these interventions is not known. Blum et al. (1996) used a single-subject experimental
methodology to investigate the separate and combined effects of behavioral and pharmacologic intervention concurrently and found no evidence of an additive or synergistic effect of the two interventions; no studies have used functional analysis to determine effective behavioral and medication treatments or investigate the separate and combined effects of these treatments.

MPH has established efficacy in average IQ and mild disability populations for the treatment of disruptive behaviors in educational and training settings. It would appear to be an appropriate choice in a medication efficacy study comparing medication status and function-related intervention with clinically significant disruptive behaviors.

Treatment prevalence studies have shown psychotropic and anti-epileptic drugs are prescribed frequently in the mental retardation population (Aman & Singh, 1988; Aman, Sarphare, & Burrow, 1995). Traditionally, lower IQ, adult, and institutionally placed individuals with disruptive behaviors have been treated with medications that have dangerous side effects (e.g., neuroleptics, antiepileptics). Stimulant medication has been infrequently used among individuals with mental retardation, especially in residential facilities (Aman & Singh, 1991). In contrast to other drugs commonly used to control disruptive behaviors in the mental retardation population, MPH has
virtually no long-term side-effects. Stimulant medications have been considered too short-acting (e.g., half-life of 2 to 3 hours) to meet the long-term and 24-hour needs of these individuals. Recent research showing positive effects has rekindled interest in stimulant medications to control disruptive and destructive behaviors in individuals with severe to profound mental retardation.

Purpose

The purpose of this study was to demonstrate the utility of a single-subject design and functional analysis in determining the separate and combined effects of short-action stimulant medication and behavioral treatments with disruptive behaviors of persons with severe to profound mental retardation. This study developed an individualized, comprehensive assessment of medication effects that includes multiple behavior measures in a variety of settings to determine (a) an optimal dose, if any, of stimulant medication, (b) differential medication effects at various doses and across various target behaviors, (c) changes in academic or training performance and care provider ratings in relation to child behavior, and (d) separate and combined effects of stimulant medication and behavioral treatments on the disruptive behavior and task engagement of children with severe to profound mental retardation.

This study extended single-subject stimulant medication efficacy research within the ADHD population by
(a) targeting children in the severe to profound range of mental retardation, (b) evaluating individual MPH effects on academic or training tasks unique to this population, (c) including a functional analysis assessment component, and (d) analyzing the individual separate and combined effects of mediation and behavioral treatments on disruptive behaviors and task engagement.

This study extended previous MPH-efficacy studies within the mental retardation population by (a) using multiple assessments of different behaviors conducted in a variety of settings in a single-subject design, (b) exploring the utility of analog functional analysis in drug and behavioral treatments for disruptive behaviors and task engagement of children diagnosed with severe to profound mental retardation, and (c) evaluating drug-behavior interactions (i.e., possible behavioral mechanism of drug actions).
METHOD

Participants

Five children, ages 10 to 15, with severe to profound mental retardation participated in this study. All children engaged in severe disruptive behavior and resided in a private, Intermediate Care Facility for Mental Retardation (ICF-MR). Inclusion criteria required that each child (a) have a current Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) diagnosis of Mental Retardation (severe to profound range), (b) display referral behaviors considered to be harmful to self or others or to significantly interfere with training or educational development, (c) be between ages of 6 and 18, (d) have a physician recommendation for a trial of methylphenidate (MPH), and (e) have signed authorizations from the facility, prescribing physician, and parents or legal guardians consenting to the participation in a medication evaluation to identify the therapeutic dose, if any, of MPH for optimal functional training and social behavior. Demographic information for the children is provided in Table 2.

Cade was a 12-year-old, white male who had resided at the facility for six years. He called out words and phrases (go on the bus, missing toys, find the toys) disruptively in the classroom. He followed simple commands (sit down, stand up, bring) and knew his daily routine.
Cooper was a 10-year-old black male, who had resided at the facility for six months. He could recite the alphabet and say his name and some words, but he rarely spoke. He vocalized loud noises in the classroom and laughed when corrected. He could copy the numbers 1-10 and the alphabet, count to 20, and identify shapes. His

Table 2. Participant Demographic Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Medication</th>
<th>Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cade</td>
<td>12</td>
<td>MR-Profound</td>
<td>None</td>
<td>Hyperactivity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-injurious</td>
<td></td>
<td>Out of seat</td>
</tr>
<tr>
<td></td>
<td></td>
<td>behavior (SIB)</td>
<td></td>
<td>Calls out</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Twirls in circles</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Head bangs wall</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wrist/elbow hits</td>
</tr>
<tr>
<td>Cooper</td>
<td>10</td>
<td>MR-Severe</td>
<td>None</td>
<td>Hyperactivity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hyperactivity</td>
<td></td>
<td>Runs away</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pinches</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Screams</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Plays with toilet</td>
</tr>
<tr>
<td>Frankie</td>
<td>12</td>
<td>MR-Profound</td>
<td>None</td>
<td>Hyperactivity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overactivity</td>
<td></td>
<td>Throws objects</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Out of seat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Grabs glasses</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Destroys property</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Noncompliance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(flops to ground; verbal refusal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Disrobes</td>
</tr>
<tr>
<td>Joel</td>
<td>15</td>
<td>MR-Severe</td>
<td>None</td>
<td>Body rocks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hyperactivity</td>
<td></td>
<td>Runs away</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Calls out</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tantrums (cries, rolls on floor)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hits knees, hands on floor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Throws objects</td>
</tr>
<tr>
<td>Mark</td>
<td>13</td>
<td>MR-Severe</td>
<td>None</td>
<td>Hyperactivity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hyperactivity</td>
<td></td>
<td>Distractable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Excessive talking</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Hits, kicks, trips</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Runs away</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Destroys property</td>
</tr>
</tbody>
</table>
academic performance was generally contingent on one-to-one staff attention. He would throw paper in the air, overturn his desk, or make disruptive noises if the aide left his side.

Frankie was a 12-year-old, white female who had resided at the facility for six years. She was marginally verbal, and communication was restricted to inconsistent gestures (point, wave, smile, head shake), vocals, some words (ball, eat, mama), and signs (toilet, eat). Although capable of performing many self-help tasks, Frankie usually waited on others to dress and toilet her. She required one-to-one supervision and engaged in disruptive behaviors harmful to herself or others if ignored (e.g., pulling on electrical cords, appliances, throwing herself on the ground), property destruction (pulling papers from walls, throwing objects), or aggression (throwing objects at people, pinching, pulling or pushing). For example, prior to being included in this study, Frankie had broken her arm by throwing herself on the side of a concrete sidewalk.

Joel was a 15-year-old, white male who had resided at the facility for nine years. He was marginally verbal (mommy, bye, dada, wawa, coke, baba, eat). He communicated his needs by pointing, vocalizations, and some functional signs. He responded to his name, identified common environmental objects by pointing, and followed most simple commands. He exhibited stereotypies (body rocking, twirling
objects in his hands). A preferred item was a clear plastic bottle, and he would throw himself on his knees and slam his hands on the floor when his teacher or support workers removed the bottle to engage him in a training activity.

Mark was a 13-year-old, black male who had lived at the facility for 4 years. Mark was verbal, spoke in short sentences, and repeatedly sought adult attention. For example, he would inappropriately recruit attention by calling out in class (Is this right?, Come see?, Hey, did I do good?). Ignoring him usually resulted in his leaving his seat and engaging in disruptive, attention-seeking behaviors (arm pats and tugs, repetitive verbal requests, opening the teacher’s desk, tripping a peer, and destroying property).

Signed informed consent forms were obtained from the parents or legal guardians (Appendix A). In addition, approval for this study was obtained from the facility’s Human Rights Committee. A written description of the assessment was provided to the prescribing physician and a signed agreement to participate was obtained.

Settings and Materials

The preference assessments and analog analyses were conducted at the residential facility in a training room equipped with a one-way observational window and intercom with no peers present. Medication and intervention observations were conducted in self-contained classroom settings unless the teacher indicated the session might be
disruptive to some on-going activity. Each self-contained classroom housed 6 to 8 students, the teacher, and two aides. Due to the normal flow of school activities, the number of students and professional staff in the classroom varied during the observation.

In analog assessments, the child was seated with an individualized task or preferred toys at a table. When assessed in the classroom, the child was seated either at a desk or a table located to the side or back of the classroom. For one child (Frankie), who threw blocks during the assessment procedure, some classroom observations were conducted with a partition (5 by 8 feet) separating her and the other children.

Response Definition and Measurement

Independent Variables

Medication Status

The primary independent variable was medication status at placebo, low (0.3 mg/kg), moderate (0.6 mg/kg), and high (0.9 mg/kg) dose of MPH. The physician initially prescribed a placebo and a low dosage of MPH and titrated upward if indicated. Cade received placebo and two dose levels of MPH (5, 10 mg). Cooper, Joel, and Mark received placebo and two dose levels of MPH (10, 15 mg). Frankie received placebo and three dose levels of MPH (5, 10, and 15 mg).

Behavioral Interventions

Secondary independent variables were the behavioral treatments that were developed for each child based on the
prior functional analysis. Behavioral treatments were evaluated both alone and in combination with MPH to determine the effectiveness of a behavior intervention as an alternative to MPH and the maximal effectiveness of the combined treatments. The behavioral treatment involved differential reinforcement of appropriate behavior following a verbal prompt or model with graduated compliance to complete the task. The child earned a reinforcer if he or she performed the task following the verbal request or model. A time out procedure was used with three of the children if a disruptive behavior occurred during the task.

**Dependent Variable and Response Definitions**

The primary dependent variable was the percentage of 10-second intervals the child engaged in disruptive behavior. Specific targeted disruptive behaviors were determined by individual referral concerns and pre-assessment classroom observations, and included the following: (a) inappropriate vocalizations (any vocal sound or verbalization disruptive to the situation, not preceded by the child raising his or her hand), (b) playing with objects (touching any object that was not part of the assigned educational or training task), (c) out-of-seat behavior (full body weight not supported by chair or the child's buttocks being removed from the chair for longer than 3 seconds), (d) aggressive behavior (e.g., hitting, slapping, biting, kicking, pinching, scratching, pushing
others and throwing/pushing objects), (e) repetitive, nonfunctional behaviors injurious to self (e.g., hitting, slapping, biting, pinching, scratching self) or disruptive to training or educational task (e.g., hand or finger gazing/playing, body/head rocking), and (f) resistive or refusal behaviors (e.g., pushing material away, verbal or gestural refusal, turning body or head from task).

Other dependent measures were task engagement, and scores from the behavior rating and side-effect scales. Task engagement was defined as the percentage of intervals in which the child touched, picked up, or walked with a task material in the direction of the work site (e.g., held a pencil, turned his paper over). Engagement was coded from the onset of the behavior until disengaged for 5 seconds. Engagement was not coded if the child exhibited disruptive behaviors or was placed in time out.

Data Collection and Reliability

Data collected included (a) the percentage of intervals in which disruptive behaviors occurred, (b) percentage of intervals in which the child was task engaged, (c) productivity or the amount of academic work completed, (d) accuracy or the percentage of work completed correctly, and (e) the integrity of the assessment condition or intervention (percentage of target responses followed by correct therapist response).

All child responses were manually recorded using a 10-second partial interval recording procedure with a tape
recorder signaling each interval during 10-minute sessions. A second observer independently recorded data simultaneously with a primary observer to establish interobserver agreement. Observers were required to complete the following training procedures: (a) average at least 90% agreement with previously trained observers during two videotaped sessions, and (b) train in vivo with an experienced graduate student until the trainee averaged at least 90% agreement with previously trained observers.

In all cases, interobserver agreement was calculated on an interval-by-interval basis for each response definition by (a) dividing the session into consecutive 10-second intervals, (b) dividing the number of agreements (occurred/did not occur during the interval) by the sum of agreements and disagreements and multiplying by 100%, and (c) averaging that number across sessions (Kazdin, 1982).

Interobserver agreement was assessed during 30% of all sessions (range 20% to 67%) for each child. Interobserver agreement was obtained on an average of 32% (range, 25% to 50%) for Cade, 35% (range, 20% to 50%) for Cooper, 29% (range, 25% to 33%) for Frankie, 30% (range, 20% to 67%) for Joel, and 35% (range, 25% to 67%) for Mark. Interobserver agreement exceeded 90% for all dependent variables. Table 3 presents interobserver agreement for each child across all conditions.
Table 3. Percentage of Interobserver Agreement across Conditions

<table>
<thead>
<tr>
<th></th>
<th>Cade</th>
<th>Cooper</th>
<th>Frankie</th>
<th>Joel</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1 Condition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention</td>
<td>100</td>
<td>91</td>
<td>96</td>
<td>96</td>
<td>99</td>
</tr>
<tr>
<td>Alone</td>
<td>98</td>
<td>99</td>
<td>96</td>
<td>96</td>
<td>98</td>
</tr>
<tr>
<td>Control</td>
<td>98</td>
<td>99</td>
<td>100</td>
<td>100</td>
<td>99</td>
</tr>
<tr>
<td>Demand</td>
<td>98</td>
<td>94</td>
<td>100</td>
<td>99</td>
<td>96</td>
</tr>
<tr>
<td>Tangible</td>
<td>N/A</td>
<td>97</td>
<td>N/A</td>
<td>99</td>
<td>99</td>
</tr>
<tr>
<td>Total (Phase 1)</td>
<td>98</td>
<td>95</td>
<td>98</td>
<td>98</td>
<td>98</td>
</tr>
<tr>
<td><strong>Phase 2 Conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attention</td>
<td>98</td>
<td>99</td>
<td>97</td>
<td>98</td>
<td>99</td>
</tr>
<tr>
<td>No Interaction</td>
<td>99</td>
<td>99</td>
<td>98</td>
<td>97</td>
<td>98</td>
</tr>
<tr>
<td>Total (Phase 2)</td>
<td>98</td>
<td>99</td>
<td>98</td>
<td>97</td>
<td>99</td>
</tr>
<tr>
<td><strong>Phase 3 Conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPH</td>
<td>98</td>
<td>100</td>
<td>98</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>MPH plus BI</td>
<td>99</td>
<td>99</td>
<td>98</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>BI</td>
<td>98</td>
<td>95</td>
<td>97</td>
<td>100</td>
<td>98</td>
</tr>
<tr>
<td>BI plus Placebo</td>
<td>97</td>
<td>99</td>
<td>96</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Total (Phase 3)</td>
<td>98</td>
<td>98</td>
<td>97</td>
<td>100</td>
<td>98</td>
</tr>
</tbody>
</table>

**Procedural Integrity**

Child and therapist behaviors were observed to assess the degree to which intervention sessions were conducted as intended. The therapist (experimenter) behaviors of toy presentation, demands, time out, tangible deliverance, and attention were recorded during relevant conditions to ensure the procedural integrity of all sessions. Demands were defined as the first verbal instruction provided during a three-prompt instructional sequence from the therapist directed toward the child. Compliance was scored when the child completed the instruction after the initial vocal or modeled prompt. Time out was defined as removal of work materials and therapist attention during a 10-second interval. Tangible delivery was defined as the therapist providing the child access to preferred toys during a 10-second interval. Attention was defined as the therapist...
providing the child with a brief vocal reprimand, praise, and/or physical contact during a 10-second interval.

Procedural integrity was calculated by two methods in all sessions for each child. First, integrity was calculated as a percentage of target behaviors that were followed by the therapist responses specified for each assessment condition or intervention, and the nonoccurrence of any other dependent variable during the same or subsequent 10-second interval. Second, a percentage of intervals was calculated for the occurrence of intervention independent variables that were not contingent upon a target behavior, in order to indicate experimental control. Procedural integrity during analog and classroom functional analysis sessions averaged 96% for all conditions (range 90% to 100%) and 96% for all children during the treatment analyses (range 90% to 99%).

Rating Scales

Teachers and direct support workers (DSWs) completed daily behavior rating scales when the child received medication or placebo. The scales were based on the School Situation Questionnaire-Revised, the Home Situation Questionnaire-Revised, the Child Attention Profile, and the Side Effects Rating Scale (Barkley, 1990). The Intervention Rating Profile-15 (Martens, Witt, Elliott, & Darveaux, 1985) was administered prior to treatment and at the end of the study. The authors of these scales have given permission to duplicate or alter these scales for clinical
or research purposes. The Child Attention Profile and the Side Effects Rating Scale were retyped on separate pages and retitled, Behavior Rating Scale. Written instructions directed the rater to mark the items as they applied to the child’s behavior that day. Two versions of the Intervention Rating Profile-15 were used to obtain pre- and post-treatment ratings from teachers and direct support workers. A description of the scales follows.

**The Child Attention Profile (CAP)**

The CAP is a 12-item scale developed to measure inattention and overactivity (Barkley, 1991) and is frequently used in stimulant drug efficacy studies (Barkley, 1990). The child’s behavior is rated on a 3-point Likert scale ranging from 0 (not true) to 2 (very or often true). Five items loading on the overactivity scale and the seven loading on the inattention scale were chosen to create a brief instrument to assess stimulant drug effects. Higher CAP scores (84 to 108) correspond with severe levels of inattention and disruption. Mid-range scores (37 to 83) indicate moderate problems and lower scores (0 to 36) indicate mild to no problems with inattention and disruption.

**The Home Situations Questionnaire-R (HSQ-R)**

The HSQ-R is a 14-item scale that assesses specific problems with attention and concentration across a variety of home and public situations (Barkley, 1991). The primary support worker first endorses all items as **Yes** or **No** and
then rates Yes items for severity on a 9-point Likert scale from 1 (mild) to 9 (severe). The scale yields scores for the number of problem settings (e.g., alone, with children, at meals) and an overall problem severity score. Higher HSQ-R scores (98 to 126) correspond with severe levels of inattention and poor concentration in home situations. Mid-range scores (48 to 97) are associated with moderate levels of inattention, and lower scores (0 to 47) indicate mild to no problems in these areas.

The School Situations Questionnaire-Revised (SSQ-R)

The SSQ-R is an 8-item scale assesses specific problems with attention and concentration across a variety of school settings (Barkley, 1991). The teacher or aide is asked to indicate whether the child displays behavior problems in each of 8 common educational settings. The rater first endorses the items as Yes or No and then rates Yes responses for severity on a 9-point Likert scale from 1 (mild) to 9 (severe). The scale yields a score for the total number of problem settings and an overall problem severity score. Higher SSQ-R scores (56 to 72) correspond with severe levels of inattention and poor concentration in home situations. Mid-range scores (32 to 55) are associated with moderate levels of inattention and lower scores (0 to 31) indicate mild to no problems in these areas in the home.
Side Effects Rating Scale

The Stimulant Drug Side Effects Rating Scale (SDSERS; Barkley, 1990) is a 17-item, 9-point Likert scale ranging from 0 (absent) to 9 (serious) that is used to report whether the individual is experiencing common side effects (e.g., headaches, stomachaches, insomnia) associated with the use of stimulant medication. The scale was retyped and titled, Behavior Scale. Four additional items were included (i.e., mood changes quickly, hostile/angry, nervous/anxious, and agitated) to assess side-effects in individuals with profound and severe developmental delays. Higher SDSERS scores (147 to 189) correspond with severe levels of observed MPH side effects. Mid-range scores (64 to 146 are associated with moderate levels of MPH side effects and lower scores (21 to 63) indicate mild levels to no observed problems. Side-effect scales were reviewed daily for individual items and a total side effects score was obtained by averaging daily ratings across all items for each child.

The Intervention Rating Profile-15

The Intervention Rating Profile-15 (Martens et al., 1985) is a 15-item survey with items scored on a 6-point Likert scale ranging from strongly disagree to strongly agree. Scores range from 15 to 90 with higher scores representing greater acceptability. The purpose of the questionnaire is to obtain information about the care provider’s reaction to a proposed or completed intervention.

63

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
In this study, two questionnaire versions were used to determine factors that may be related to the use of the medication or behavior interventions. The Behavior Intervention Rating Form evaluated the teacher and support worker's assessment of the acceptability of the behavior interventions used in this study prior to and following implementation. The Medication Intervention Rating Form assessed the teacher and support worker's opinions regarding the acceptability of a medication intervention prior to and following the medication evaluation.

Design

All functional analysis conditions were conducted in a single-subject multielement or alternating treatment design. All medication evaluations were conducted in an alternating treatments design in which each dosage of MPH randomly alternated with a placebo. After an optimal dosage of MPH was determined for three of the children, behavioral interventions were randomly alternated with MPH, a placebo, or no pill.

Procedures

Phase 1: Preference Assessment and Functional Analysis

Preference Assessment

Potential reinforcers for the functional analysis were identified for each child in free operant preference assessments based on procedures developed by Roane, Vollmer, Ringdahl, and Marcus (1999). The preference
assessments were used to identify potential reinforcers that could be used during the functional analysis and/or incorporated into behavior interventions (phase 3). For each child, 10 stimuli were included in the assessment. Preference assessment stimuli were selected based upon teacher or support worker report, the child's endorsement (if verbal), and preassessment observations. Assessments were conducted in an empty observation room with observations made through a one-way window. Prior to each assessment, stimuli were presented individually for 45 seconds. Then, the 10, equally spaced, stimuli were presented concurrently on the floor. The children were free to ignore all items or interact with any of the items individually or collectively during the session. No items were removed during the assessment. Each child was exposed to a minimum of two 5-minute sessions. All contact between the child's hands or fingers with a stimulus item were scored using a 10-second partial interval recording method.

Each 5-minute session was divided into 30, 10-second intervals. The percentage of partial 10-second intervals in which the child manipulated each stimulus was divided by the total number of intervals and multiplied by 100 to yield a preference index per item. One to three stimuli with the largest index of preference were considered for use in the functional analysis.

Table 4 presents the preferred items identified during the free-operant assessments for each of the children. The
primary preferred item was also used in the subsequent academic and behavioral interventions developed for Joel and Mark.

Table 4. Preference Assessment Indexes for Each Child

<table>
<thead>
<tr>
<th>Child</th>
<th>Items</th>
<th>Preference Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frankie</td>
<td>Person (social interaction)</td>
<td>67%*</td>
</tr>
<tr>
<td></td>
<td>Favorite song on cassette</td>
<td>37%</td>
</tr>
<tr>
<td></td>
<td>Toy Guitar</td>
<td>33%</td>
</tr>
<tr>
<td>Cade</td>
<td>Person (social interaction)</td>
<td>3%</td>
</tr>
<tr>
<td>Cooper</td>
<td>Waterfall tube</td>
<td>100%</td>
</tr>
<tr>
<td>Mark</td>
<td>Toy guitar</td>
<td>82%</td>
</tr>
<tr>
<td></td>
<td>Social interaction</td>
<td>35%</td>
</tr>
<tr>
<td></td>
<td>Radio</td>
<td>33%</td>
</tr>
<tr>
<td>Joel</td>
<td>Plastic bottle</td>
<td>52%</td>
</tr>
<tr>
<td></td>
<td>Person (social interaction)</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Pen and paper</td>
<td>18%</td>
</tr>
</tbody>
</table>

* Frankie sat in person’s lap and manipulated toys.

Functional Analysis

The functional analysis was based on procedures described by Iwata et al., (1994/1982), Sasso et al. (1992), and Northup et al. (1999, in press). The analog analysis was conducted by the therapist in a room with a one-way observation window. The classroom functional analysis was conducted by the therapist in the class or training room. During the functional analyses, each child was exposed to four to six experimental conditions (escape, attention, tangible, alone, control, and no interaction). Five trained therapists conducted the sessions wearing shirts color-coded for each condition. When possible, the same therapist conducted all sessions across that condition for the child. Table 5 describes the training task and materials used in the attention, tangible, alone, and no interaction conditions for each child.
<table>
<thead>
<tr>
<th>Child</th>
<th>Task in Attention, Alone, No Interaction, Tangible</th>
<th>Materials</th>
<th>Task in Demand</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frankie</td>
<td>Shape discrimination and sorting</td>
<td>Playskool 8&quot; x 8&quot; cube, 18 insertable forms</td>
<td>Discrimination</td>
<td>4 shapes, 5 containers</td>
</tr>
<tr>
<td>Cade</td>
<td>Shape discrimination and sorting</td>
<td>Playskool 8&quot; x 8&quot; cube, 18 insertable forms</td>
<td>Discrimination</td>
<td>4 shapes, 5 containers</td>
</tr>
<tr>
<td>Cooper</td>
<td>3 Copy worksheets</td>
<td>Name model, 10 copy lines, 1-10 model, 10 copy lines, A-L model, 10 copy lines</td>
<td>Discrimination</td>
<td>4 shapes, 5 containers</td>
</tr>
<tr>
<td>Mark</td>
<td>Color sheets</td>
<td>Bunny on 8½&quot; x 11&quot; paper, Jumbo crayon</td>
<td>Discrimination</td>
<td>4 shapes, 5 containers</td>
</tr>
<tr>
<td>Joel</td>
<td>Three-piece bolt-set assembly</td>
<td>3 assembly trays, 15 3-inch bolts, 15 washers, nuts</td>
<td>Discrimination</td>
<td>4 shapes, 5 containers</td>
</tr>
</tbody>
</table>
Demand condition. Instructional tasks were similar to those presented in the child’s educational or training environment, but were identified as difficult (i.e., less than 70% accuracy in previous trials). A graduated, three-prompt sequence was used to present instructions (Horner & Keilitz, 1975). The therapist (a) verbally requested the child to perform a task, (b) modeled compliance with the instruction following five seconds of noncompliance with the verbal request, and (c) physically guided the child (hand over hand) to comply with the instruction after five seconds of noncompliance with the modeled request. Praise was delivered contingent on a correct response following the first or second request. The three-prompt, demand sequence trial was completed at pre-set intervals (15 to 30 seconds) dependent upon the identified performance rate of the child. Occurrence of a targeted disruptive behavior resulted in termination of the instruction trial for 30 seconds. Thus, the child escaped the demand sequence or task contingent through a target response (e.g., aggression). The purpose of this condition was to test for behavioral responsiveness to escape as a reinforcing consequence.

Attention condition. During this condition, the child was seated at a table with a training task that could be completed with 70% to 90% accuracy following an initial instruction and model (e.g., assembling bolt-washer-nut units). The therapist gave the initial instruction (e.g.,
Sit quietly and put these together), moved away from the child, and appeared to be busy and not attending to the child. The therapist only attended to the child to deliver statements of concern or reprimands following each target response. The purpose of this condition was to determine responsiveness of the target behavior to positive reinforcement in the form of attention.

**Materials or tangibles condition.** This condition was included for children who exhibit a targeted behavior when preferred stimuli were blocked or withdrawn. The preferred stimulus was exposed to the child for 2 minutes prior to the session. The stimulus was removed from reach but remained visible once the session began. The child was seated at a table with the same training task and initial instruction used in the attention condition. The therapist monitored the task while walking about the room. The therapist made the preferred stimulus available to the child for 30 seconds contingent upon a target response. When the target behavior occurred, the therapist immediately moved the preferred stimuli to the side of the table within reach of the child for 30 seconds, and removed the stimuli to the initial position after allowing 30 seconds of access. The purpose of this condition was to determine responsiveness of the target behavior to positive reinforcement in the form of tangible stimuli.

**Alone condition.** During this condition, the child was alone in a room with a one-way observational window. All
neutral stimuli were removed. The child was seated at a table with the same training task described in the attention and materials conditions. The therapist left the room after placing the task on the table and delivering the instruction. No programmed consequences were provided for any targeted behavior, and no interaction occurred between the therapist and the child. The purpose of this condition was to determine if the target behavior would persist independent of social consequences in a relatively barren environment.

**Play (control) condition.** During this condition, the child was seated at a table with a preferred task or toy (e.g., radio, musical instrument). The therapist sat at the table with the child and provided attention (praise, conversation, pats or rubs to arms or back) on a differential reinforcement of other behavior (DRO) schedule with a mean inter-reinforcement time (IRT) of 15 seconds and no programmed consequences for a target behavior. The schedule of reinforcement delivery varied for each child dependent upon his or her current disruptive behavior rate. This condition served as a control condition in that the child had access to attention and there were no instructional demands to complete the task during the session (Iwata et al., 1994/1982).

**No interaction (ignore) condition.** The child was once again seated at his desk in the classroom with the same training task used in the attention, tangible, alone, and
play conditions. The therapist walked about the room ignored all appropriate and inappropriate behavior, and delivered no attention. This condition is similar to the alone condition but assesses the effects of the presence of a noninteracting adult or class peers on the disruptive behavior.

Phase 2: Medication Evaluation

General Procedures

Following the initial functional analysis, 10-minute baseline probes were conducted in the classroom using the two functional analysis conditions in which the highest levels of target behavior were exhibited. The children were then observed in one-day (low dose) or two-day (medium or high dose) blocks while receiving placebo or MPH, once each morning and afternoon for 4 days (low dose) or 8 days (medium or high dose). All behavioral observations were conducted at the same time daily in the classroom while the child completed a task supervised by the therapist. Observations were made 1 to 2 hours after administration of either medication or placebo.

The purpose of the classroom analysis was to determine the effects of medication status on disruptive behaviors in academic or training settings under two controlled environmental conditions (e.g., no interaction or attention) for which analog functional analysis effects had been previously demonstrated.
Phase 3: Behavioral Intervention

Phase 3 was designed to evaluate the effects of different treatments in reducing disruptive behavior and increasing task engagement in the following treatment conditions: behavioral intervention alone, behavior intervention plus placebo, MPH alone, and MPH plus behavior intervention. This phase compared the effects of MPH and a function-related behavioral intervention alone and together in effectively reducing disruptive behavior and increasing task engagement for the children identified as MPH responders. For the children who were non-responsive to MPH, this condition evaluated whether a function-related intervention would effectively reduce the target behavior while concurrently increasing task engagement.

Intervention Development

In general, the behavioral intervention was based on removing or interrupting the environmental contingency associated with the highest levels of inappropriate behavior and, whenever possible, providing the same reinforcement for appropriate behavior; however, as the functional analysis indicated high levels of disruptive behavior during the alone condition for all children, a variety of antecedent manipulations were also included in the behavior intervention. For some of the children, assessment observations indicated the task or task presentation could be altered to better meet the child’s current functional level or increase overall task
performance. Whenever a functional analysis condition was associated with increased task engagement or reduced levels of disruptive behavior, essential components of that condition were included in the intervention. For example, disruptive behavior decreased and task completion increased during the demand condition for all participants. Thus, a DRA with graduated compliance procedure was modeled on the three-prompt, demand sequence (prompt, model, graduated compliance). For Mark and Joel, the items used during the materials or tangible condition were incorporated with the DRA for functional communication training.

Cade. Cade’s task was to correctly place a square, triangle, and circle from left to right in a large form board with generalization to similar tasks (i.e., a smaller, similar form board, Formfitter cube used in the initial analysis). An analysis of the shape sorting task was conducted and differential reinforcement with graduated compliance in a three-prompt sequence (verbal prompt, model, graduated compliance) was selected to train the concept of putting in the multiple shapes. Stereotypies that were neither task disruptive nor precursors to more serious SIB were ignored. Verbal interruption (No) with a 5-second basket hold was the intervention for head banging, striking wrist or elbow with objects and pre-SIB stereotypies (elevated arm and hand posturing that preceded elbow and wrist strikes). The procedure also had an escape extinction component that prevented escape from the task.
The basket hold was followed by re-presenting the task using the **hands down and get ready** intervention in his current IEP. The therapist would release Cade from the hold, and say, "Hands down, get ready", guide Cade's hands to midline on the table, and restart the task. The brief time out was used only with behaviors that had been observed to precede to self-injurious behaviors (head or elbow hitting). It was gradually faded to a verbal prompt (**hands down, get ready**).

**Cooper.** Cooper's academic task involved verbally identifying letters presented in a Curriculum Based Measurement (CBM) format. Previous observations indicated Cooper would disrupt the learning task by leaving his seat and disruptive behavior would increase when verbally corrected. Pats to the back or arms and extended verbal praise directed to Cooper resulted in loud disruptive laughing, call outs, or aggressive behavior toward the teacher. Thus, the academic setting was rearranged to limit physical contact, and the need to verbally reprimand out of seat behavior. The therapist was seated to the left and slightly behind Cooper at a table, and Cooper's right side was immediately next to the wall. Cooper could escape the task only by sliding under the table.

Differential reinforcement with graduated compliance in a three-prompt sequence was selected to train the task. A 30-second time out was the intervention for disruptive behavior. The therapist would point at a letter with a
pencil, and say "This is ...". If there was no response in 3 seconds, he would put Cooper’s finger on the letter and say "This is ...". If there was no response in 3 seconds, he would put Cooper’s finger on the letter and say "This is a __". Compliance on step one or two earned a one-word, praise statement (Good). The therapist removed the task and turned away for 30 seconds when a disruptive behavior occurred (time out). At the end of the time out period, Cooper was returned to his chair and the first prompt was presented again.

**Frankie.** Frankie’s academic task was identical to Cade’s except for the forms used in the large form board. Frankie’s forms were made of cardboard and packing tape for noise reduction and to reduce the possibility of injury to others when the forms were thrown. Frankie’s behavioral intervention used alternate seating, differential reinforcement with graduated compliance, and a 30-second time out with an in-seat requirement. The therapist removed the task and attention for 30 seconds when a disruptive behavior occurred. During the time out, the therapist averted his face and positioned his arm and shoulder to block her efforts to pull his hair and scratch his face and used his leg to secure her chair. The therapist continued to present commands at 5- to 10-second intervals and provide praise (good job) for successful attempts when no disruptive behavior occurred. In order to limit her opportunities to misbehave, the table was placed beside the
wall, the therapist's chair was positioned slightly behind Frankie, and the therapist removed glasses and other breakable items and wore long sleeves to protect his arms during the time out.

Joel. A task analysis of existing class rules was conducted to train the concepts of in-seat behavior, hand signaling for attention, waiting, and appropriate requesting. Differential reinforcement in the form of functional communication training (FCT) with graduated compliance was used to train Joel to say *baba* and signal with his hand to access a clear plastic bottle. After giving Joel 1-minute access to the bottle, it was removed, and he was trained to raise his hand to recruit the therapist's attention, wait appropriately in increments (5, 10, 15, 20, 30 seconds), until a timer signaled the end of the interval, and then appropriately sign for the bottle when asked, "What do you want?" Behavioral interventions included a three-prompt sequence to manage out-of-seat behavior, verbal interruption for loud talk-outs, and ignoring all quiet self-talk or movements not disruptive to the task.

Mark. Mark's academic task was identical to Joel's. Differential reinforcement with graduated compliance was used to train Mark to appropriately signal for attention (*How do you ask?*), verbally request his toy guitar (*What do you want?*), and wait appropriately in increments (5, 10, 15, 20, 30 seconds) until a timer signaled the end of the
wait interval. Behavioral interventions included guided compliance to manage out-of-seat behavior, verbal reprimand for loud talk-outs, and ignoring all quiet self-talk or movements not disruptive to the task.
RESULTS

Phase 1: Functional Analysis

Figure 1 shows the results of the functional analysis for Cade (upper panel) and Frankie (lower panel) and figure 2 shows the results for Joel (upper panel), Mark (middle panel) and Cooper (lower panel). For all children, data are plotted as the percentage of intervals of disruptive behavior (e.g., calling out, throwing or tearing objects, leaving seat, hitting, kicking, or pinching others, throwing or tearing objects, hitting self) across sessions.

For Cade, disruptive behavior occurred at high and stable levels during the alone condition (mean, 94%; range, 90% to 100%). Relatively low levels of disruptive behavior occurred during the attention condition (mean, 4%; range, 2% to 7%). No disruptive behavior occurred during the demand condition and low levels were recorded during the control condition (mean, 2%; range, 0% to 3%). Based on these results, Cade’s disruptive behavior did not appear to be maintained by socially-mediated reinforcement.

For Frankie, disruptive behavior occurred at high and stable levels during the alone condition (mean, 93%; range, 83% to 100%). Moderate and stable levels of disruptive behavior occurred during the attention condition (mean, 39%; range, 27% to 48%). Disruptive behavior was reduced in the demand condition (mean, 12%; range, 3% to 25%) and in the control condition (mean, 1%; range, 0% to 4%). Thus, the results for this analysis suggested that disruptive
Figure 1. Percentage of intervals of disruptive behavior across functional analysis conditions (alone, demand, control, attention) for Cade (upper panel) and Frankie (lower panel).
Figure 2. Percentage of intervals of disruptive behavior across functional analysis conditions (alone, attention, control, demand, tangible) for Joel (upper panel), Mark (middle panel), and Cooper (lower panel).
behavior was most likely related to socially mediated reinforcement in the form of attention or some unknown variable associated with the alone condition.

For Joel, disruptive behavior occurred at high levels in the alone condition (mean, 78%; range, 52% to 93%), relatively low but variable levels in the attention (mean, 6%; range, 0% to 12%), tangible (mean, 7%; range, 0% to 22%), demand (mean, 1%; range, 0% to 2%), and control (mean, 6%; range, 0% to 23%) conditions. Based on these results, Joel’s disruptive behavior did not appear to be maintained by socially-mediated reinforcement.

For Mark, disruptive behavior occurred at high levels in the alone condition (mean, 81%; range, 58% to 93%) and moderate levels in the attention (mean, 26%; range, 25% to 28%) and tangible (mean, 16%; range, 14% to 19%) conditions. Disruptive behavior levels were low and stable in the demand (mean, 1%; range, 0% to 2%) and control (mean, 0%) conditions. These results indicated the disruptive behavior was highest in the alone condition but was also responsive to socially mediated positive reinforcement in the form of attention and tangible items.

For Cooper, disruptive behavior was high and stable in the alone condition (mean, 96%; range, 90% to 97%) and attention condition (mean, 86%; range, 77% to 97%). Disruptive behavior was moderate to high during the demand (mean, 39%; range, 6% to 65%) and tangible (mean, 57%; range, 50% to 71%) conditions, and low and stable during
the control condition (mean, 10%; range, 0% to 18%). Thus, the results for this analysis might be considered either multiple controlled or undifferentiated. The level of disruptive behavior was highest in the alone condition, was responsive, to a lesser degree, to positive reinforcement in the form of attention or tangible items, and remained low during the control condition.

Table 6 shows the task performance results for all children during the demand, attention, and alone conditions.

Table 6. Analog Performance Measures across Conditions

<table>
<thead>
<tr>
<th>Child</th>
<th>Measures</th>
<th>Demand</th>
<th>Attention</th>
<th>Alone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cade</td>
<td>Mean Task Completion</td>
<td>35</td>
<td>23</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>39%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Frankie</td>
<td>Mean Task Completion</td>
<td>52</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>37%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Joel</td>
<td>Mean Task Completion</td>
<td>44</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>62%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Mark</td>
<td>Mean Task Completion</td>
<td>51</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>49%</td>
<td>26%</td>
<td>31%</td>
</tr>
<tr>
<td>Cooper</td>
<td>Mean Task Completion</td>
<td>39</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>48%</td>
<td>18%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Overall, the results indicated that each child's target behavior persisted at the highest rate in the alone condition. Behavior that persists at high levels in the absence of socially mediated consequences is more likely to be responsive to treatment with medication. For three of the children, the results suggested that target behaviors might also be responsive to positive reinforcement in the form of attention or tangible items to various degrees. Thus, the no interaction and attention conditions appeared
to be appropriate functional assessment conditions to evaluate the effects of MPH and placebo in classroom settings.

Phase 2: Medication Evaluation

Classroom Functional Analysis

Two functional analysis conditions (attention, no interaction) were first conducted in the regular classroom when the child was not receiving medication to further determine baseline levels of disruptive behavior and task engagement as compared to analog conditions. The no interaction condition was used as the classroom equivalent of the analog functional analysis alone condition. For all children, the percentage of intervals in which disruptive behavior occurred were collected during baseline, when receiving no medication, and across each dosage and placebo in the attention (top panel of Figures 3 through 7) and no interaction (lower panel of Figures 3 through 7) conditions.

Cooper. Figure 3 shows disruptive behavior levels during Cooper's medication evaluation. During baseline, disruptive behavior occurred at high rates with an increasing trend in the attention (mean, 79%; range, 61% to 100%) condition sessions and in 100% of the intervals during the no interaction condition sessions. Disruptive behavior was high in the attention condition when Cooper received either placebo (mean, 66%; range, 25% to 92%) or 10 mg of MPH (mean, 70%; range, 3% to 98%). During the no
Figure 3. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Cooper's medication evaluation.
interaction condition, disruptive behavior occurred at high, stable rates when Cooper received either 10 mg of MPH (mean, 96%; range, 90% to 100%) or placebo (mean, 90%; range, 60% to 100%).

The physician reviewed all results and recommended increasing Cooper's dosage to a medium level of 15 mg of MPH and a placebo to alternate every two days for eight days. Alternating every 2 days was selected to minimize possible multiple treatment interference effects. When Cooper received the medium dose, disruptive behaviors decreased quickly and occurred at relatively low and stable levels during both the attention (mean, 16%; range, 2% to 55%) and no interaction (mean, 32%; range, 0% to 100%) conditions. Disruptive behavior remained at baseline levels when Cooper received placebo in the attention (mean, 77%; range 42% to 97%) and no interaction (mean, 95%; range, 63% to 100%) conditions.

After reviewing all results, the physician determined the 15 mg dose of MPH was effective for Cooper and recommended terminating the medication evaluation.

Cade. Figure 4 shows the results of Cade's medication evaluation. During baseline, disruptive behavior was moderately high during the attention (mean, 55%; range, 53% to 60%) and no interaction (mean, 45%; range, 41% to 50%) condition sessions.

Disruptive behavior was moderately high with a downward trend in the attention condition when Cade
Figure 4. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Cade's medication evaluation.
received placebo (mean, 16%; range, 3% to 25%) and moderately high and variable when he received 5 mg of MPH (mean, 20%; range, 7% to 55%). During the no interaction condition, disruptive behavior occurred at similar rates when he received 5 mg of MPH (mean, 53%; range, 8% to 87%) or placebo (mean, 54%; range, 11% to 91%). Disruptive behavior decreased below baseline levels and was showing a downward trend when receiving either placebo or 5 mg of MPH. The downward trend for placebo is unusual, and it is possible that unexplained sequence effects or multiple treatment interference may have occurred.

The physician reviewed all results and recommended increasing Cade's dosage to a medium level of 10 mg of MPH and a placebo to alternate every two days for eight days. Disruptive behaviors occurred at a lower and more stable rate when Cade received 10 mg of MPH (mean, 12%; range, 7% to 17%) as compared to placebo (mean, 46%; range 32% to 57%). In the no interaction condition, disruptive behavior occurred at a lower but more variable rate when Cade received 10 mg of MPH (mean 36%; range 7% to 83%) as compared to placebo (mean, 82%; range, 52% to 97%). The medium dose appeared to stabilize disruptive behavior more quickly during the attention condition than during the no interaction condition; however, disruptive behavior did show a downward trend when Cade received 10 mg of MPH in the no interaction condition. At the end of the evaluation phase, disruptive behavior was on a downward trend when
Cade received 10 mg of MPH and an upward trend with placebo.

After reviewing all results, the physician determined the 10 mg dose of MPH was effective for Cade and recommended terminating the medication evaluation.

Frankie. Figure 5 shows the results of Frankie's medication evaluation. During baseline, disruptive behavior occurred at high rates with increasing trends in the attention (mean, 86%; range, 67% to 100%) and no interaction (mean, 92%; range, 78% to 100%) condition sessions.

Disruptive behavior occurred at high and variable rates during the attention condition when Frankie received 5 mg of MPH (mean, 59%; range, 40% to 72%), and at high rates with an increasing trend when she received placebo (mean, 56%; range 32% to 83%). During the no interaction condition, disruptive behavior occurred at high rates with an increasing trend when she received 5 mg of MPH (mean, 81%; range, 59% to 94%) and at high rates with a decreasing trend when she received placebo (mean, 84%; range, 68% to 93%). The downward trend for placebo in the no interaction condition is unusual and contradicts the downward trend shown with MPH and upward trend with placebo in the attention condition over the same days. It is possible that unexplained sequence effects or multiple treatment interference may have occurred.
Figure 5. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Frankie’s medication evaluation.
The physician reviewed all results and recommended increasing Frankie's dosage to a medium level of 10 mg of MPH and a placebo to alternate every two days for eight days. During the attention condition, disruptive behavior was moderately high with a variable but downward trend when Frankie received 10 mg of MPH (mean 41%; range, 13% to 82%). Disruptive behavior occurred at a higher rate when she received placebo (mean, 81%; range, 61% to 94%). During the no interaction condition, disruptive behavior occurred at highly variable rates when she received 10 mg of MPH (mean, 65%; range, 15% to 100%) and high and stable rates with placebo (mean, 89%; range, 78% to 100%).

The physician reviewed all results and recommended increasing Frankie's dosage to a high level of 15 mg of MPH to alternate every two days for eight days. During the attention condition, disruptive behavior levels decreased in the attention condition when she received 15 mg of MPH (mean, 24%; range, 7% to 53%) as compared to placebo (mean, 73%; range, 40% to 100%). During the no interaction condition, disruptive behavior showed a downward but somewhat varied rate when she received 15 mg of MPH (mean, 24%; range, 3% to 58%) and was significantly reduced compared to placebo (mean, 72%; range, 32% to 97%) at the 15 mg dose.

After reviewing all results, the physician determined the 15 mg dose of MPH was effective for Frankie and recommended terminating the medication evaluation.
Joel. Figure 6 shows the results of Joel’s medication evaluation. During baseline, disruptive behavior occurred at moderately high levels with an increasing trend in the attention condition (mean, 39%; range, 17% to 83%) and high levels with an increasing trend in the no interaction condition (mean, 63%; range, 17% to 93%).

In the attention condition, disruptive behavior levels were moderately low and stable when Joel received 10 mg of MPH (mean, 14%; range, 8% to 22%) or placebo (mean, 13%; range, 7% to 17%). During the no interaction condition, disruptive behavior was moderately low and showed decreasing trends when Joel received 10 mg of MPH (mean, 33%; range, 13% to 58%) or placebo (mean, 27%; range, 17% to 45%). Disruptive behavior levels decreased compared to baseline when Joel received either 10 mg of MPH or placebo in both the attention and no interaction conditions.

The physician reviewed all results and recommended increasing Joel’s dosage to a medium level of 15 mg of MPH to alternate every two days for eight days. During the attention condition, disruptive behavior levels increased and became highly variable when Joel received 15 mg of MPH (mean, 24%; range, 2% to 73%) but remained low and relatively stable when he received placebo (mean, 15%; range 2% to 85%). During the no interaction condition, disruptive behavior occurred at moderate and variable rates when he received either 15 mg of MPH (mean, 37%; range, 0% to 73%) or placebo (mean, 35%; range, 3% to 70%).
Figure 6. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Joel's medication evaluation.
After reviewing all results, the physician determined the 15 mg dose of MPH was also ineffective for Joel and recommended terminating the medication evaluation.

**Mark.** Figure 7 shows the results of Mark’s medication evaluation. During baseline, disruptive behavior levels were moderately high in the attention condition (mean, 28%; range, 20% to 35%) and high in the no interaction condition (mean, 70%; range, 55% to 87%).

During the attention condition, disruptive behavior occurred at moderately low and stable levels in the attention condition when he received 10 mg of MPH (mean, 14%; range, 2% to 25%) and at somewhat higher but stable levels when he received placebo (mean, 20%; range 13% to 33%). During the no interaction condition, disruptive behavior occurred at higher levels when he received 10 mg of MPH (mean, 62%; range, 0% to 94%) than when he received placebo (mean, 46%; range, 36% to 63%). In both conditions, disruptive behavior was lower than baseline with a downward trend when Mark received placebo and higher than baseline with an upper trend when he received MPH. These results are unusual and may be related to unexplained sequence effects or multiple treatment interference.

The physician reviewed the results and recommended increasing Mark’s dosage to a medium level of 15 mg of MPH and a placebo to alternate every two days for eight days. Disruptive behavior occurred at higher rates with an increasing trend when Mark received the 15 mg dose of MPH.
Figure 7. Percentage of intervals of disruptive behavior in baseline and across each dosage compared to placebo in the attention (upper panel) and no interaction (lower panel) conditions of Mark's medication evaluation.
(mean, 31%; range, 0% to 75%) and at lower levels with a downward trend when he received placebo (mean, 13%; range 5% to 32%). During the no interaction condition, disruptive behavior occurred at high and variable levels when he received 15 mg of MPH (mean, 69%; range, 0% to 100%) and a lower level when he received placebo (mean, 40%; range, 2% to 100%).

After reviewing all results, the physician determined the 15 mg dose of MPH was also not effective for Mark and recommended terminating the medication evaluation.

**Task Engagement**

Table 7 gives the levels of task engagement for each child across dosages of MPH and placebo in each condition of the classroom functional analysis assessments. Engagement was undifferentiated between low dose of MPH and placebo in the attention condition for all children. Engagement improved with the increase in MPH dose over placebo for Cooper, Cade, and Frankie and remained essentially unchanged for Joel and Mark. There was a small decrease in engagement in the attention condition when Frankie moved to the highest dose of MPH. Joel and Mark's task engagement were higher when they received placebo than when they received the medium dose of MPH.

The effects of MPH were not as significant in the no interaction condition for task engagement; however, Cooper, Cade, and Frankie showed some improvement from the low to medium dose. Task engagement decreased for Joel and Mark.
Table 7. Mean Percentage of Intervals for Task Engagement across MPH Dosage and Placebo for the Attention (ATT) and No Interaction (NI) Conditions

<table>
<thead>
<tr>
<th>Child</th>
<th>ATT Low Dose Mean Range</th>
<th>ATT Placebo Mean Range</th>
<th>ATT Medium Dose Mean Range</th>
<th>ATT Placebo Mean Range</th>
<th>ATT High Dose Mean Range</th>
<th>ATT Placebo Mean Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooper</td>
<td>29 (0.92) 33 (4.75) 62 (12.98) 18 (3.45) N/A N/A</td>
<td>3 (0.12) 8 (0.32) 20 (0.100) 8 (0.61) N/A N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cade</td>
<td>76 (45.92) 79 (65.97) 83 (75.90) 63 (40.92) N/A N/A</td>
<td>46 (13.92) 45 (5.88) 67 (17.93) 16 (2.50) N/A N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frankie</td>
<td>31 (25.37) 42 (17.62) 56 (33.82) 20 (6.39) 49 (23.72) 11 (0.30)</td>
<td>19 (6.42) 10 (3.18) 39 (0.85) 11 (0.17) 38 (4.97) 11 (2.43)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joel</td>
<td>77 (62.90) 82 (70.90) 72 (38.97) 85 (67.98) N/A N/A</td>
<td>60 (38.82) 71 (58.83) 58 (16.100) 45 (2.97) N/A N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mark</td>
<td>74 (27.98) 79 (66.87) 68 (25.100) 85 (72.95) N/A N/A</td>
<td>30 (5.93) 48 (36.64) 28 (0.80) 59 (0.80) N/A N/A</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
from the low to medium dose. Task engagement was higher for Mark when he received placebo than when he received either the low or medium doses of MPH. Task engagement remained stable in both conditions when Frankie received MPH and placebo in the high dose evaluation.

**Performance Measures**

Table 8 gives the performance measures collected during the classroom functional analysis conditions when the children were receiving MPH. The data were analyzed in conjunction with data collected during the functional analysis analogs (see Table 6) and used to develop the interventions in the final phase of the study.

<table>
<thead>
<tr>
<th>Child</th>
<th>Measures</th>
<th>Attention</th>
<th>No Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooper</td>
<td>Mean Task Completion</td>
<td>31</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>13%</td>
<td>0%</td>
</tr>
<tr>
<td>Cade</td>
<td>Mean Task Completion</td>
<td>40</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>Frankie</td>
<td>Mean Task Completion</td>
<td>16</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Joel</td>
<td>Mean Task Completion</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>Mark</td>
<td>Mean Task Completion</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>9%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Cade completed more tasks in the attention condition than during the interaction condition. There was no difference in task accuracy (percent correct) between the conditions.

Cooper's task completion was higher in the attention condition. Task accuracy improved in the attention condition.
Frankie's task completion was higher in the attention condition. Frankie completed no task correctly in either condition.

Joel completed an equal number of tasks in both conditions. He was more accurate during the attention condition.

Mark's mean number of completed tasks was higher in the attention condition. His accuracy was slightly improved in the attention condition.

**Behavior Rating Scales**

Table 9 shows the rating scores given by the teachers and support workers for each of the children when they received placebo and low, medium, or high dose of MPH. Across all scales some of the highest scores were given to Mark when he received placebo and all dosages of MPH even though the direct observations indicated he did not respond to MPH. Joel also received consistently high scores when he received placebo and all dosages of MPH on almost all scales. For Cade, Cooper, and Frankie, CAP scores were higher or essentially the same as baseline scores across all dosages of MPH. The HSQ-R and SSQ-R scales generated low scores across all dosages and placebo for all children except Mark. For Mark, the HSQ-R and SSQ-R generated moderately high to high scores across all dosages and placebo.
Table 9. Mean Teacher and Support Worker Behavior Rating Scale Scores

<table>
<thead>
<tr>
<th></th>
<th>Cade Placebo</th>
<th>MPH</th>
<th>Cooper Placebo</th>
<th>MPH</th>
<th>Frankie Placebo</th>
<th>MPH</th>
<th>Joel Placebo</th>
<th>MPH</th>
<th>Mark Placebo</th>
<th>MPH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAP/ Support Worker</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>63</td>
<td>N/A</td>
<td>21</td>
<td>N/A</td>
<td>30</td>
<td>N/A</td>
<td>39</td>
<td>N/A</td>
<td>100</td>
<td>N/A</td>
</tr>
<tr>
<td>Low-dose Evaluation</td>
<td>28</td>
<td>57</td>
<td>19</td>
<td>13</td>
<td>0</td>
<td>17</td>
<td>66</td>
<td>52</td>
<td>100</td>
<td>107</td>
</tr>
<tr>
<td>Medium-dose Evaluation</td>
<td>53</td>
<td>40</td>
<td>20</td>
<td>15</td>
<td>29</td>
<td>20</td>
<td>64</td>
<td>44</td>
<td>70</td>
<td>96</td>
</tr>
<tr>
<td>High-dose Evaluation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>30</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>CAP/ Teacher Form</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>36</td>
<td>N/A</td>
<td>67</td>
<td>N/A</td>
<td>65</td>
<td>N/A</td>
<td>9</td>
<td>N/A</td>
<td>108</td>
<td>N/A</td>
</tr>
<tr>
<td>Low-dose Evaluation</td>
<td>3</td>
<td>31</td>
<td>54</td>
<td>56</td>
<td>63</td>
<td>27</td>
<td>63</td>
<td>30</td>
<td>104</td>
<td>60</td>
</tr>
<tr>
<td>Medium-dose Evaluation</td>
<td>36</td>
<td>40</td>
<td>10</td>
<td>48</td>
<td>44</td>
<td>43</td>
<td>23</td>
<td>35</td>
<td>64</td>
<td>93</td>
</tr>
<tr>
<td>High-dose Evaluation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>59</td>
<td>38</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>HSQ-R/ Support Worker</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>33</td>
<td>N/A</td>
<td>11</td>
<td>N/A</td>
<td>1</td>
<td>N/A</td>
<td>7</td>
<td>N/A</td>
<td>16</td>
<td>N/A</td>
</tr>
<tr>
<td>Low-dose Evaluation</td>
<td>20</td>
<td>26</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>20</td>
<td>29</td>
<td>50</td>
<td>71</td>
</tr>
<tr>
<td>Medium-dose Evaluation</td>
<td>24</td>
<td>12</td>
<td>12</td>
<td>24</td>
<td>8</td>
<td>6</td>
<td>17</td>
<td>24</td>
<td>55</td>
<td>39</td>
</tr>
<tr>
<td>High-dose Evaluation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>21</td>
<td>27</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>SSQ-R/ Teacher</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>14</td>
<td>N/A</td>
<td>5</td>
<td>N/A</td>
<td>38</td>
<td>N/A</td>
<td>15</td>
<td>N/A</td>
<td>72</td>
<td>N/A</td>
</tr>
<tr>
<td>Low-dose Evaluation</td>
<td>3</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>30</td>
<td>8</td>
<td>38</td>
<td>29</td>
<td>59</td>
<td>42</td>
</tr>
<tr>
<td>Medium-dose Evaluation</td>
<td>18</td>
<td>19</td>
<td>19</td>
<td>14</td>
<td>22</td>
<td>19</td>
<td>11</td>
<td>17</td>
<td>27</td>
<td>44</td>
</tr>
<tr>
<td>High-dose Evaluation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>42</td>
<td>4</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>SDSERS/ Support Worker</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>69</td>
<td>N/A</td>
<td>20</td>
<td>N/A</td>
<td>23</td>
<td>N/A</td>
<td>34</td>
<td>N/A</td>
<td>40</td>
<td>N/A</td>
</tr>
<tr>
<td>Low-dose Evaluation</td>
<td>31</td>
<td>37</td>
<td>14</td>
<td>26</td>
<td>0</td>
<td>23</td>
<td>85</td>
<td>65</td>
<td>61</td>
<td>112</td>
</tr>
<tr>
<td>Medium-dose Evaluation</td>
<td>42</td>
<td>11</td>
<td>18</td>
<td>31</td>
<td>25</td>
<td>25</td>
<td>59</td>
<td>51</td>
<td>56</td>
<td>27</td>
</tr>
<tr>
<td>High-dose Evaluation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>47</td>
<td>39</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>SDSERS/ Teacher</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>16</td>
<td>N/A</td>
<td>29</td>
<td>N/A</td>
<td>17</td>
<td>N/A</td>
<td>27</td>
<td>N/A</td>
<td>63</td>
<td>N/A</td>
</tr>
<tr>
<td>Low-dose Evaluation</td>
<td>2</td>
<td>24</td>
<td>34</td>
<td>37</td>
<td>26</td>
<td>6</td>
<td>46</td>
<td>30</td>
<td>23</td>
<td>15</td>
</tr>
<tr>
<td>Medium-dose Evaluation</td>
<td>7</td>
<td>17</td>
<td>10</td>
<td>9</td>
<td>9</td>
<td>26</td>
<td>0</td>
<td>9</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>High-dose Evaluation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>12</td>
<td>5</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
The Intervention Rating Profile-15 (IRP-15)

The IRP-15 acceptability rating was given to the teacher and primary direct support worker (DSW) prior to and following implementation of the medication and behavioral treatment evaluations for each child. Table 10 gives the results of the pre- and post-treatment measures for the children.

Overall teacher acceptability ratings of the medication intervention corresponded with the medication evaluations for each child; however, teacher behavioral intervention ratings did not correspond with the direct observations made of these treatments. Following the medication evaluation, teacher acceptability ratings for the medication intervention improved for Cade, Cooper, and Frankie and decreased for Joel and Mark. Teacher acceptability ratings for the behavioral intervention increased for Cooper and Frankie, did not change for Cade, and decreased for Joel and Mark.

<table>
<thead>
<tr>
<th></th>
<th>Cade</th>
<th>Cooper</th>
<th>Frankie</th>
<th>Joel</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre Post</td>
<td>53 75</td>
<td>73 100</td>
<td>94 98</td>
<td>63 57</td>
<td>94 50</td>
</tr>
<tr>
<td>DSW</td>
<td>61 89</td>
<td>83 91</td>
<td>63 66</td>
<td>73 70</td>
<td>77 89</td>
</tr>
<tr>
<td>Behavior</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre Post</td>
<td>60 60</td>
<td>37 81</td>
<td>96 100</td>
<td>74 46</td>
<td>97 23</td>
</tr>
<tr>
<td>DSW</td>
<td>92 92</td>
<td>61 91</td>
<td>78 78</td>
<td>46 89</td>
<td>63 89</td>
</tr>
</tbody>
</table>

Support worker acceptability ratings of the medication intervention corresponded with the medication evaluations for all children except Mark. The support worker post-intervention ratings were higher for the medication.
intervention for Cade, Cooper, Frankie, and Mark, and decreased for Joel. The support worker medication post-treatment ratings for Mark increased even though the medication evaluation indicated the MPH was not effective. Post-treatment support worker acceptability ratings for the behavioral interventions generally supported the treatment evaluations for all children but Frankie.

Phase 3: Treatment Evaluation

Behavioral treatments to reduce disruptive behavior and increase task engagement were developed after analyzing the levels of disruptive behavior, task engagement, and performance measures across the analog and classroom functional analysis condition sessions. In phase 3, the three children who responded to MPH received the following four treatments: (a) the optimal dose of MPH alone (no behavioral intervention), (b) MPH plus the behavioral intervention, (c) the behavioral intervention with no pill, and (d) behavioral intervention plus placebo. For the two children not responding to MPH, a behavioral intervention was developed targeting the behavioral deficits observed during the functional analog and classroom conditions.

Behavioral and Medication Treatments for Children Responding to MPH

Medication and Behavioral Treatment Evaluations

Figure 8 shows the results of the treatment evaluations made in phase 3 for the three children for whom an effective dose of MPH was established. The levels of
Figure 8. Percentage of intervals of disruptive behavior in baseline attention (ATTN) condition compared to Methylphenidate (MPH) and behavioral treatments for Cade (upper panel), Cooper (middle panel), and Frankie (lower panel). Behavior treatment was differential reinforcement of alternative behavior (DRA) and graduated compliance (GC) with a time out (TO) intervention for disruptive behavior.
disruptive behavior in the baseline attention condition (left panel) is compared to disruptive behavior levels when the children received MPH or behavioral treatment alone for Cade (upper right panel), Cooper (middle right panel), and Frankie (lower right panel).

**Cade.** Figure 8 shows Cade's baseline levels of disruptive behavior in the classroom attention condition were moderately high and stable (mean, 55%; range 53% to 60%). Disruptive behavior was reduced when Cade received MPH alone (mean, 16%; range, 8% to 25%) and the behavioral treatment alone (mean, 19%; range, 11% to 38%); however, both treatments were equally successful in reducing disruptive behavior to a stable and relatively low rate.

**Cooper.** Figure 8 shows Cooper’s baseline level of disruptive behavior (mean, 79%; range, 61% to 100%) was high and increasing in the attention condition. Disruptive behavior was significantly low and stable when he received MPH alone (mean, 3%; range, 0% to 10%) and was stable and higher than baseline levels when only a behavioral treatment was used (mean, 87%; range, 80% to 95%).

**Frankie.** Figure 8 shows Frankie’s baseline levels of disruptive behavior in the classroom attention condition were high with an increasing trend (mean, 86%; range, 67% to 100%) during the attention condition. Disruptive behavior was reduced in the MPH alone (mean, 25%; range, 5% to 42%) and the behavioral treatment alone condition (mean, 39%; range, 30% to 44%). MPH initially reduced disruptive
behavior to a low level; however, there was an increasing trend over the four doses.

Effects of Behavioral Treatment Alone and with MPH

Table 11 gives the results of the MPH plus behavioral treatment (MPH + BT) and behavioral treatment plus placebo (BT + Placebo) conditions on disruptive behavior and task engagement for the three children for whom an effective MPH dose was established.

<table>
<thead>
<tr>
<th></th>
<th>MPH + BT</th>
<th>BT + Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disruptive</td>
<td>Disruptive</td>
<td>Disruptive</td>
</tr>
<tr>
<td>Mean% Range</td>
<td>Mean% Range</td>
<td>Mean% Range</td>
</tr>
<tr>
<td>Cade</td>
<td>15  7-30</td>
<td>16  7-32</td>
</tr>
<tr>
<td>Cooper</td>
<td>13  0-33</td>
<td>66 28-100</td>
</tr>
<tr>
<td>Frankie</td>
<td>44 32-62</td>
<td>57 39-67</td>
</tr>
</tbody>
</table>

For Cade, combining behavioral treatment with either placebo or MPH had similar effects on disruptive behavior levels; however, task engagement increased when he received MPH and behavioral treatment. For Cooper, disruptive behavior decreased and task engagement increased when he received MPH rather than placebo during the behavioral treatment. For Frankie, disruptive behavior decreased in the MPH plus behavioral treatment condition; however, there was a slight decrease in task engagement when she received MPH rather than placebo with the behavioral treatment.

Task Engagement

Table 12 shows the mean levels of task engagement maintained by Cade, Cooper, and Frankie during baseline, during MPH alone conditions, and during behavioral
treatment conditions (i.e., with placebo, with no pill). Both treatments increased task engagement for all three children; however, MPH alone was more effective in increasing task engagement than the behavioral intervention alone.

Table 12. Task Engagement for Treatments Compared to Baseline for Children Responding to MPH

<table>
<thead>
<tr>
<th>Child</th>
<th>Baseline Mean</th>
<th>Baseline Range</th>
<th>MPH Mean</th>
<th>MPH Range</th>
<th>Behavioral Treatment Mean</th>
<th>Behavioral Treatment Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cade</td>
<td>46%</td>
<td>40%-50%</td>
<td>77%</td>
<td>70%-87%</td>
<td>56%</td>
<td>49%-67%</td>
</tr>
<tr>
<td>Cooper</td>
<td>20%</td>
<td>0%-44%</td>
<td>100%</td>
<td>100%</td>
<td>44%</td>
<td>17%-85%</td>
</tr>
<tr>
<td>Frankie</td>
<td>11%</td>
<td>0%-25%</td>
<td>88%</td>
<td>83%-100%</td>
<td>73%</td>
<td>58%-84%</td>
</tr>
</tbody>
</table>

Behavioral Treatment Evaluations for Children Who Did Not Respond to MPH

Behavioral Treatment Results

Figure 9 shows the results of the phase 3 treatment evaluations for the two children for whom an effective dose of MPH was not established. The levels of disruptive behavior in the baseline attention condition (left panel) is compared to disruptive behavior levels when the children received a function-related behavioral treatment for Joel (right upper panel) and Mark (right lower panel).

Joel. Figure 9 shows Joel's baseline level of disruptive behavior in the attention condition (mean, 39%; range, 17% to 83%) was moderately high with an upward trend. Disruptive behavior occurred at stable and low rates when Joel received a behavioral treatment (mean, 4%; range, 0% to 9%).
Figure 9. Percentage of intervals of disruptive behavior in baseline attention (ATTN) condition compared to behavioral treatments. For Joel (upper panel), behavioral treatment was functional communication training (FCT) with verbal reprimand for disruptive behavior. For Mark (lower panel), behavior treatment was differential reinforcement of alternative behavior (DRA) and graduated compliance (GC) with verbal reprimand for disruptive behavior.
Mark. Figure 9 shows Mark’s baseline level of disruptive behavior in the attention condition (mean, 28%; range, 20% to 35%) was moderately high and stable. Disruptive behavior occurred at stable and low rates when Mark received a behavioral treatment (mean, 4%; range, 0% to 14%).

Task Engagement during Behavioral Treatment

Table 13 shows the mean levels of task engagement maintained by Joel and Mark during baseline and behavioral treatments. Task engagement increased significantly for Joel and marginally for Mark.

<table>
<thead>
<tr>
<th>Child</th>
<th>Baseline Mean</th>
<th>Baseline Range</th>
<th>Behavioral Mean</th>
<th>Behavioral Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joel</td>
<td>35%</td>
<td>0% - 68%</td>
<td>93%</td>
<td>86% - 100%</td>
</tr>
<tr>
<td>Mark</td>
<td>72%</td>
<td>67% - 78%</td>
<td>85%</td>
<td>53% - 100%</td>
</tr>
</tbody>
</table>

Performance Measures

Table 14 shows the performance measures collected during the phase 3 treatments. The data can be compared to the measures collected in the functional analysis analogs (Table 6) and classroom functional assessments (Table 8) to compare task productivity (mean task completion) and accuracy (percent correct) across treatments.

MPH and behavioral treatment had similar effects on Cade’s productivity; however, productivity increased when the treatments were combined (MPH+BT). Accuracy was higher with MPH than with behavioral treatment but was highest when the two treatments were combined.
Table 14. Performance Measures across Treatment Conditions

<table>
<thead>
<tr>
<th>Child</th>
<th>Measures</th>
<th>MPH</th>
<th>BT</th>
<th>MPH+BT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cade</td>
<td>Mean Task Completion</td>
<td>27</td>
<td>26</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>43%</td>
<td>39%</td>
<td>63%</td>
</tr>
<tr>
<td>Cooper</td>
<td>Mean Task Completion</td>
<td>94</td>
<td>16</td>
<td>83</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>97%</td>
<td>45%</td>
<td>99%</td>
</tr>
<tr>
<td>Frankie</td>
<td>Mean Task Completion</td>
<td>7</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>27%</td>
<td>67%</td>
<td>88%</td>
</tr>
<tr>
<td>Joel</td>
<td>Mean Task Completion</td>
<td>N/A</td>
<td>46</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>N/A</td>
<td>93%</td>
<td>N/A</td>
</tr>
<tr>
<td>Mark</td>
<td>Mean Task Completion</td>
<td>N/A</td>
<td>40</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Percent Correct</td>
<td>N/A</td>
<td>79%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Cooper’s productivity was highest with MPH and lowest with behavioral treatment. Combined treatments had a lower task completion rate than MPH alone. Accuracy was higher when he received MPH than behavioral treatment. Combining the treatments showed minimal improvement; however, a ceiling effect may have been in place.

Frankie’s productivity was highest in the MPH condition but low across all treatments. Accuracy was low with MPH, increased with the behavioral treatment, and increased again when the treatments were combined.
DISCUSSION

The current study uses a three-phase, individualized assessment with multiple behavior measures across several domains to determine individual medication effects for five children with severe to profound mental retardation. This study also demonstrates the utility of a single-subject design and functional analysis in determining the separate and combined effects of stimulant medication and behavioral treatments on disruptive behavior and task engagement for individual participants.

In the first phase, the analog functional analyses for each child showed that the highest levels of disruptive behavior occurred in the alone and attention conditions. The results identified two children with disruptive behaviors that did not appear to be influenced by any socially mediated reinforcement. Disruptive behaviors appeared most likely related to socially mediated reinforcement in the form of attention or some unknown variable associated with the alone condition for the remaining three children.

The second phase used direct classroom observation and behavior rating scales to evaluate MPH-related changes in disruptive behavior and task engagement in attention and no interaction conditions within a multielement design. Positive effects for MPH were found for three of the five children (i.e., reductions in disruptive behavior concurrent with increased levels of task engagement).
The third phase investigated the separate and combined effects of MPH and behavioral interventions for three of the children and behavioral treatment alone for the two children not responding to MPH. The results suggest that there were individual medication and behavioral treatment effects for these children.

The majority of the studies evaluating MPH treatment effects have targeted children with average intelligence, used subjective care provider reports and behavior rating scales, reported results based on between-group statistical analyses, and limited assessments to one area of functioning (Gulley & Northup, 1997). A limited number of stimulant medication efficacy studies with children with ADHD and average intelligence have combined a single-subject experimental design, standardized drug evaluation procedures, and multiple behavioral assessment measures across dosages (Gulley & Northup, 1997; Northup, et al., in press; 1999).

A small number of methodologically sound, single-subject designs have compared MPH to behavioral treatments for children with mental retardation (Ayllon et al., 1975; Pelham et al., 1980, Shafto & Sulzbacher, 1977; Wulbert & Dries, 1977). Two studies have used single-subject designs to make controlled comparisons of baseline conditions, a behavioral intervention alone, and the combination of MPH and a behavioral intervention for the treatment of disruptive behavior in children with mild retardation.
to moderate mental retardation (Schell et al., 1986; Johnson et al., 1994). Blum et al. (1996) targeted the disruptive behaviors of children with severe to profound mental retardation in a single-subject experimental design with a significantly large number of data points over multiple medication conditions to document the simple and combined beneficial effects of stimulants and behavioral treatments.

This study extends Blum et al. (1996) by using a single-subject design and functional analysis to evaluate the effects of MPH and behavioral treatment for 5 children. This study also extends the Gulley and Northup (1997) and Northup et al. (1999; in press) classroom evaluations of MPH effects for children with average intelligence and ADHD to children with severe to profound mental retardation and disruptive behavior. As with these earlier studies, this protocol systematically assesses a variety of behaviors (e.g., disruptive classroom behaviors, engagement, performance) and uses several methods (e.g., behavior scales, direct observations, preference assessments, functional analyses).

A limited number of stimulant efficacy studies have included behavioral treatments based on functional analysis (Cooper et al., 1993; Fisher et al., 1989; Kayser et al., 1997; Northup et al., 1999; in press). This study used functional analysis to describe medication effects on specific classroom behaviors as well as to determine

111

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
effective function-related behavioral treatments. Analog data were used to select pertinent controlled conditions for classroom evaluation of MPH effects. Thus, this study replicated the use of classroom functional analysis to establish the function of disruptive classroom behaviors and illustrated a strategy for evaluating the treatment effects of medication interventions across multiple behaviors (Northup et al., 1999; in press).

The Northup et al. (1999; in press) conclusions on drug-behavior interactions were based on analog conditions in a university lab setting. This study extends functional assessments directly into the child’s actual classroom with instructional tasks taken from the child’s current curriculum. The treatment evaluation (phase 3) also attempts to assess the more complex differential reinforcement programs associated with greater treatment effects in the literature.

Using an analog analysis to set up the classroom assessment conditions may be a useful protocol to identify components of behavioral and medication treatment packages for children with disruptive behaviors that do not clearly differentiate in traditional functional analysis. This method accomplishes an effective classroom analysis of medication effects and allows a more complete evaluation of within-subject effects.

Failure to control for antecedent and consequent events and contextual variables has been a major limitation
in many previous drug studies conducted for persons with mental retardation (Aman & Singh, 1991). Thus, the functional analysis procedure used in this study provided controlled environmental conditions to evaluate MPH effects in the classroom. In phase 2, the children who responded to MPH displayed less disruptive behavior in both the no interaction and attention conditions when receiving an effective dose of MPH as compared to placebo. There did not appear to be any differential effect across the two types of consequences for any participant.

These results are consistent with previous studies that suggest MPH effects are most likely to be mediated by antecedent events (Northup et al., 1997; 1999; in press; Whalen et al., 1979, Wilkison, Kircher, McMahon, & Sloane, 1995). For example, Northup et al. (1999; in press) showed teacher proximity to interact with MPH effects across ignore, reprimand, and time-out conditions. One possible explanation is that the discriminative properties of the adult were altered when the child received MPH.

Medication is frequently prescribed for the disruptive behavior of children with mental retardation; however, medication efficacy studies with this population should consider the degree to which the behavior is influenced by environmental conditions (Thompson et al., 1993). Functional analysis has proven utility in developing behavioral treatments for persons with mental retardation. This study suggests that similar functional analysis
procedures should be considered when assessing medication treatments for this population (Baumeister et al., 1993; Blum et al., 1996).

During the past 10 years, numerous between-group studies have validated stimulant use in the ADHD population for children with average intelligence and mild to moderate mental retardation; however, the between-group studies targeting children with severe to profound mental retardation have not demonstrated consistent positive effects. The cognitive and adaptive deficits of children with mental retardation make it more difficult to assess behavioral improvement and stimulant side effects. Direct observation of medication effects may be a more beneficial method for children with severe to profound mental retardation.

The treatment of choice for the disruptive behavior of children with mental retardation is generally medication prescribed by physicians and behavioral treatments developed by behavior analysts. Traditionally, the two disciplines have worked independently. Blum et al. (1996) urged medical practitioners and behavior analysts to collaborate in order to more accurately monitor dose response and drug-behavior interactions. Physicians typically rely on subjective reports, whereas behavior analysts can collect objective data useful to treatment teams making pharmacological decisions.
These results are also consistent with other studies that have shown positive medication effects may not always be apparent to the classroom teacher (e.g., Gulley and Northup, 1997). In this study, support worker ratings of MPH side-effects for Cade were highest during baseline when he received no pill as compared to direct observations which indicated reduced disruptive behavior and increased task engagement when he received MPH. Teachers rated Frankie’s attentiveness and disruptive behavior low when she received either placebo or MPH. These results support previous suggestions that teacher and care provider reports are subject to informant bias (Stoner et al., 1994; Shapiro & Kratochwill, 1988). Thus, teacher and parent ratings can be useful supplements to direct observations of relevant behavioral variables within the classroom setting and during academic tasks but have limited utility as repeated daily measures (Gulley & Northup, 1997).

The care provider acceptability ratings deserve special mention. Poling and LeSage (1995) report acceptability ratings are important in assessing the social validity of psychotropic treatments. In this study, the post-treatment acceptability ratings for both the behavioral and medication interventions varied according to medication response. In general, post-treatment care provider ratings of both the medication and behavioral treatments improved for Cade, Cooper, and Frankie.

Post-treatment care provider ratings for Mark and Joel’s...
behavioral treatments were inconsistent. Post-treatment teacher acceptability ratings for Joel and Mark's highly effective behavioral interventions decreased from pre-treatment acceptability ratings. Support worker acceptability ratings of MPH did not decrease even though neither child responded to MPH. Unlike the daily administered rating scales, the acceptability scales were only administered as pre- and post-treatment measures. Therefore, these results were not influenced by repetitive, daily ratings. In an effort to develop a standardized methodology, the same acceptability measure was adapted for both interventions. Future studies should consider developing separate measures for alternate treatments.

A number of procedural issues and limitations should be noted. First, the analog assessments were highest during the alone condition for all children and identified a likely environmental influence on disruptive behavior for two of the children. The behavioral treatments were limited to antecedent manipulations and attempts to identify effective competing reinforcers. Thus, the inability to identify a maintaining variable for the disruptive behavior that could be removed or modified limited the effectiveness of the behavioral treatment.

Second, this evaluation involved a large number of sessions (mean, 90; range, 78 to 120) and required that the therapist and one to two observers be available for thirty minutes one-hour after medication administration for each
child. Additionally, the two, 10-minute, classroom conditions required approximately 30 minutes, twice daily, to set up and complete. The behavior interventions were labor intensive, and teacher implementation was not explored. Future research should explore a briefer assessment method (e.g., minute-by-minute analysis), a teacher inservice protocol, and follow-up booster sessions.

Placebo was alternated with MPH to control for observer bias and to rule out the possibility that the child might respond differently on "no pill" days. This alternating treatment procedure appears to have contributed to an unusual downward trend for placebo that was possibly related to unexplained sequence effects or multiple treatment interference; this effect was found at some dose levels for both the children that responded to medication and those that did not.

As noted by Thompson et al. (1993), drug efficacy studies including children with developmental delays should also assess behavior deficits that might be associated with the disruptive behavior. Joel and Mark’s disruptive behaviors appear to have been related to deficits in basic communication skills and appropriate classroom behaviors (e.g., recruiting, waiting). Neither child benefitted from medication and their interventions did not require the more complex treatments generated from the functional analyses of the other children. In fact, their two 5-minute preference assessments were probably more beneficial in the
development of their behavioral interventions than the 54 functional analysis sessions. Future research is needed to develop a systematic protocol to identify, assess, and train necessary classroom behaviors (e.g., appropriate attention seeking, waiting skills) in this population.

The literature indicates children with severe to profound mental retardation are more likely to develop side-effects with stimulant medication use; however, the behavior rating scales used with the average-IQ ADHD population have limited utility with the children in this study. Rather than eliminating these children from future studies, researchers should develop operational definitions of behaviors commonly exhibited by children medicated with MPH (e.g., behavior tics, social withdrawal) and make brief, controlled observations in natural settings during medication trials.

To summarize, this study has extended a growing body of behavioral analytic research that evaluates stimulant dosage effects on an individual basis using multiple assessment measures across several behavioral variables. It is the second study to use an experimental design to document beneficial effects of stimulants in children with severe to profound mental retardation (Blum et al., 1996).

The current study is unique in its use of functional analysis to assess medication effectiveness as well as develop appropriate behavioral treatments. Future research might include this method to evaluate the functional
properties of problem behaviors in relation to medication status or develop a relatively practical and efficient model for assessing the simple and combined effects of MPH and function-related behavioral interventions within natural classroom settings.
REFERENCES


American Academy of Child and Adolescent Psychiatry, 30, 816-824.


121


124

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.


126

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.


132

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.


Wulbert, M., & Dries, R. (1977). The relative efficacy of methylphenidate (Ritalin) and behavior-modification
APPENDIX

CONSENT FORM

LSU LOUISIANA STATE UNIVERSITY
AND AGRICULTURAL AND MECHANICAL COLLEGE

Department of Psychology
236 Audubon Hall
Baton Rouge, LA 70803-5501

PARENTAL PERMISSION FOR RESEARCH PARTICIPATION

Project Title: A Comprehensive Functional Assessment of the Effects of Methylphenidate on the Disruptive Behavior of Children with Severe Mental Retardation

Performance Site: St. Mary Training School

Investigators: The following investigators are available for questions at the phone numbers below:
Name: Victoria Swanson John Northup, Ph.D.
LSU Dept. of Psychology LSU Dept. of Psychology
(318) 640-2501 (504) 388-4112

Purpose of Study: This is a research project designed to assist St. Mary Training School's psychology and medical personnel in developing a comprehensive assessment procedure using multiple behaviors in a variety of settings (a) to determine an optimal dose, if any, of Ritalin, (b) to establish any differences in medication effects at various doses as well as across various child target aberrant behaviors, and (c) to assess academic or training performance, class or training room behavior, attention, social interactions, and teacher or care provider ratings of child behavior. A methodology will be developed by which existing staff will be able to assess the usefulness of present medication status (medication, no medication) with children who have exhibited disruptive behavior or whose behavior has significantly impacted their educational and training progress.

Number of Participants: This study will include 5 to 8 children residing at St. Mary's Training School and currently receiving methylphenidate (Ritalin).

Inclusion Criteria: The study includes children with severe to profound mental retardation, aged 6-18 years who have been prescribed Ritalin for the treatment of disruptive and attentive behaviors in educational and/or training settings.

Exclusion Criteria: Children younger than 5 or older than 18, who are not enrolled at St. Mary's Training School, who receive additional psychoactive medication, for whom the facility does not currently have consent to administer Ritalin, and those children not previously referred to the Interdisciplinary team for medication consideration will be excluded from this study.

Description of the Study: As a participant in this study, your child's care providers will be asked to complete questionnaires, and participate in interviews. An initial functional analysis will be conducted when the child is not on medication, and will assist in determining the environmental events that may be affecting the disruptive behavior. Brief assessment observations will be made in situations which simulate problematic times for your child. For example, assessment situations will include accomplishing a training task, working one-on-one with a support provider, and when alone and unengaged. This information will be used to develop an effective behavior intervention. The child's behavior will then be evaluated on and off medication in the classroom. This will be accomplished by administering the child various therapeutic doses of medication and a placebo (fake pill) on alternating days and evaluating his or her behavior in social, classroom, and one-on-one training situations. Direct observations and rating scales will be used to determine the most effective dose in each situation. The placebo assesses whether or not medication is as effective as medication without the child or care providers being aware that no medication has been given. This design uses a double blind procedure to ensure that participants, medication givers, and observers are not influenced by prior knowledge of the research design. All participants will know the child received a pill prior to assessment; however, no one will know if the pill was a placebo or Ritalin. Thus, the medication will be

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.
dispensed and packaged by the pharmacist in a coded order that only the prescribing physician will know. All doses will be the same color and each dose will be blister packed in a manner that doses cannot be confused by the nursing staff. At the end of each dose level assessment, the code will be broken by the prescribing physician and the assessments and observations will be matched to dose level and placebo. This information will be used by the physician to make decisions about future medication trials. A behavior intervention based on the initial functional analysis will be developed for your child. Your child will then receive a placebo ("fake pill") the same assessments will be completed but a behavior intervention will be used to manage the behavior. This assessment will tell you whether or not medication is more effective than an appropriate behavior intervention. Your child will be involved in this assessment for 3 to 5 weeks.

Benefits: Potential benefits of this study is the development of effective behavioral and medication interventions which may help your child increase appropriate behavior, social interaction, and academic engagement. Parents and St. Mary's staff will be offered feedback on each child's performance. The information can be used to develop an appropriate behavior treatment program.

Risks/Discomforts: This study does not provide any additional risks for your child. The only known risks will be the side-effects of the Ritalin for which your child has already been prescribed. Your consent for administration of this medication has already been obtained. An explanation of potential side-effects of this medication was provided by the training facility when the medication was prescribed.

Right to Refuse: Your agreement to allow your child to participate in this project is voluntary. You have the right to withdraw your child from this project at any time, and you may do so by contacting the investigators.

Withdrawal/removal: The medication administered in this study is being supervised by the medical staff at St. Mary's Training School. The medical staff may discontinue the medication if warranted or remove the child from the study if indicated.

Alternatives: This study evaluates three treatments (e.g., medication, no medication, and behavior intervention) and several types of assessments. Every participant will be evaluated in each treatment. At the end of this study, alternatives will be available to each participant.

Privacy: The results of this study may be published. The privacy of participants will be protected and the identity of participants will not be revealed. All information will be kept confidential.

Release of Information: The facility and school records of the participants in this study may be reviewed by investigators, but participant identify will be kept secret.

Financial Information: There will be no cost for participation in this study.

Signatures: The study has been discussed with me and all my questions have been answered. I understand that if I have questions about subject rights, or other concerns, I can contact the Vice Chancellor or the LSU office of Research and Economic Development at 388-5833. I agree with the terms above and acknowledge I have been given a copy of the consent form.

Signature of the Parent/Guardian Date

Witness Date

Investigator(s) Date

The parent/guardian has indicated to me that they are unable to read. I certify that I have read this consent form to the parent/guardian and explained that by completing the signature line above the parent/guardian has given permission for their child to participate.

Signature of Reader Date
VITA

Victoria Cooper Swanson was graduated from Bolton High School in Alexandria, Louisiana, in 1969. She received a bachelor of science degree in psychology from the University of Southwestern Louisiana in 1972, and a master of science degree in clinical psychology from Northwestern State University in 1991. She has worked in the field of mental and developmental disabilities for more than 25 years. She completed an externship in clinical psychology at Pinecrest Developmental Center in 1991 and is currently enrolled in an internship in New Orleans, Louisiana. She will complete all requirements for the degree of Doctor of Philosophy upon completion of her internship in July, 1999.
Candidate: Victoria Swanson

Major Field: Psychology

Title of Dissertation: A Comprehensive Functional Assessment of the Effects of Methylphenidate on the Disruptive Behavior of Children with Severe Mental Retardation

Approved:

[Signature]
Major Professor and Chairman

[Signature]
Dean of the Graduate School

EXAMINING COMMITTEE:

[Signature]

[Signature]

[Signature]

Date of Examination:

1-25-99