Practical Evaluation of Psychotropic Medication

Lynne E. Turner
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PRACTICAL EVALUATION OF PSYCHOTROPIC MEDICATION

by

Lynne E. Turner

A Thesis
Submitted to the
Faculty of the Graduate College
In partial fulfillment of the
requirements for the
Degree of Master of Arts
Department of Psychology

Western Michigan University
Kalamazoo, Michigan
December 2002
Surveys indicate that 25-40% of students with mental retardation or other developmental disabilities receive one or more psychotropic medications, however, almost nothing is known concerning how the effects of the medications are monitored. Parents/guardians and teachers were interviewed to ascertain information regarding current monitoring procedures in the home and in the school setting. Additionally information was gathered to ascertain their knowledge regarding: 1) the reason for which their students were prescribed psychotropic medications; 2) the behavioral domains that those medications are intended to affect, 3) the current status of those behavioral domains, and 4) consumers’ satisfaction with the pharmacological intervention. The results suggest that both at home and at school there is a lack of systematic monitoring of the effects of psychotropic medications, that parents/guardians and teachers are not satisfied with the results produced by the medication and that there is a general lack of knowledge about the rationale for the prescribed medication and the side effects of these medications. Additionally, the results suggest that both the parents/guardians and teachers have a lack of knowledge regarding the side effects of the medications prescribed.
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INTRODUCTION

Historical Background

In the early 1950s it was serendipitously discovered that chlorpromazine had a calming effect on persons diagnosed as psychotic. Subsequently, chlorpromazine and related drugs were widely prescribed for people with psychiatric disorders. These drugs also were often prescribed for persons with developmental disabilities (Caldwell, 1970). In 1958, Thomas Greiner predicted that, “In the years to come, the retarded may claim an all-time record, of having the greatest variety and largest tonnage of chemical agents shoveled into them” (p. 346). Data from subsequent prevalence studies of psychotropic medication use by persons with disabilities during the past 43 years have proven this prediction to be true (Singh, Ellis, & Wechsler, 1997). For example, Aman and Singh (1988) found psychotropic medication to be one of the most prevalent forms of treatment for inappropriate behavior (e.g., self-injurious behavior, aggressive behavior) in persons with mental retardation.

A psychotropic medication is any drug that is prescribed with the intent of improving mood, thought processes, or overt behavior (Poling & Byrne, 2000). The use of psychotropic medication for treatment of behavioral problems in people with mental retardation and other developmental disabilities (e.g., autism) has been common and controversial for many years (Aman & Singh, 1988; Gadow & Póling, 1988). Psychotropic medications historically were often used incautiously and at
excessive doses in people with developmental disabilities. These problems were first recognized over 20 years ago and at least partially corrected through legislations and legal activity.

Regulations for Medication Usage in Institutions

Laws regulating the use of psychotropic medications in institutional settings, which is where most people with developmental disabilities resided in years past, emerged in 1971 with the landmark case of Wyatt v. Stickney. In this case, the federal district court in Alabama ruled that conditions in three state hospitals for persons with mental retardation violated the patients constitutional right to appropriate treatment. That is, the court held that the patients were entitled to be free from unnecessary and excessive medication and "unusual or hazardous treatment procedures" (as cited in Singh, Guernsey, & Ellis, 1992). Further litigation followed and by 1985 relatively clear standards for the use of psychotropic drugs in institutional settings were established in most states (Kalachnik, 1994). Sprague (1982) published a careful review of the relevant court cases and their resolutions. Kalachnik (1994) has described these emergent standards set forth as a result of litigation, legislation, and regulations as follows:

1. Psychotropic medications are to be prescribed and administered according to the exercise of professional judgment by a qualified professional.

2. Periodic attempts to reduce the drug dosage are required and the minimal effective dose must be used.
3. Appropriate evaluation procedures are to be used by an interdisciplinary team to assess the effects of medications on target behaviors and to detect adverse (i.e., side) effects.

4. Decisions conveying the continuation of, or decisions in, a patient’s medication has to be data based.

5. Written informed consent must be obtained from competent patients or from a representative of incompetent patients before drugs are administered.

6. There must be an individualized treatment program that delineates specific target behaviors for which the medication is prescribed.

7. There must be an integration of behavioral, educational, and medical interventions.

Individuals Not Protected by Laws

When these standards are enforced, persons with developmental disabilities are generally safe from harmful, ineffective, and unnecessary drug treatments. That is, if the goals of drug treatment are clear and if decisions concerning the effectiveness of medication are based on valid data, then pharmacological interventions are being used in an appropriate and ethical manner (Poling, 1994; Poling & Ehrhardt, 1999). At the present time, however, relatively few people with mental retardation (or other developmental disabilities) reside in institutions. Standards regulating the use of psychotropic drugs in institutions typically do not apply to drug use in community setting.
It is widely recognized that psychopharmacological treatments of childhood emotional and behavioral disorders in school-aged children have increased significantly over the past several years (Brown & Sawyer, 1998). Although the exact percentage is unknown (Gadow, 1997), surveys indicate that 25-40% of students with mental retardation or other developmental disabilities receive one or more drugs intended to improve behavior (Reiss, 1998). Failure to monitor the effects of these drugs adequately, which is necessary to optimize treatment for individual students, is a serious and widespread problem (Gadow; Kollins, Ehrhardt, & Poling, 2000; Poling, 1994).

Monitoring Medication in School-aged Children

The need for monitoring medications has been emphasized by professionals for many decades. In 1971, the Report of the Conference on Stimulant Drugs stated: “The decision to use drug treatment depends on the commitment to diagnose and to monitor the response to the treatment in the best traditions of medical practice. When there is informed parental consent, parents, teachers and professionals can collaborate in organizing and monitoring treatment programs” (as cited in Weithorn & Ross, 1975 p. 60). Effective systematic monitoring may be accomplished in several ways. These include the use of structured interviews, rating scales, direct observations of behavior, and measures of performance, achievement, and activity (Brown & Sawyer, 1998).
Regardless of the system, judicious monitoring of the efficacy of psychotropic medications prescribed for children with developmental disabilities is important for several reasons (Brown & Sawyer, 1998). First, and foremost, the vast majority of research on the effectiveness of psychotropic medication has focused mainly on adults. The effects of psychotropic medication in children often differ from those reported for adults (Barkley et al., 1990; Taylor, 1994). Thus, physicians need to weigh carefully possible deleterious effects that could occur. Second, there is not a specific psychotropic medication treatment for specific behavioral problems and few indicators accurately predict children's responses to specific medication or dosages (Taylor). Therefore, careful monitoring of children's responses to the different drugs and different dosage levels is essential for identifying the most effective treatment.

Third, children are constantly changing as they mature, making monitoring of medication effects imperative (Brown & Sawyer, 1998). That is, drug effects may vary with development (Brown & Sawyer). Fourth, children are less capable than adults of reporting the presence of adverse effects (Brown & Sawyer). Customarily, adults will inform their physician when a medication is causing problems or is not producing the desired effects. Children with developmental disabilities sometimes lack the cognitive ability to recognize such problems, or lack the verbal capacity to provide information about them. Furthermore, the approach of asking people about how they have benefited from a medication does not accurately evaluate the degree of change because, “people simply do not remember how they were in the beginning” (Streiner & Norman, 1995, p. 165). Finally, decisions to prescribe psychotropic
medications or change dosage levels typically are based on informal global assessments provided by parents or teachers (Brown & Sawyer; Gadow, 1982, 1983; Singh & Winton, 1984; Fredericks & Hayes, 1995). Children’s actual behavior may have little influence on these decisions. Singh and Winton (1984), for example, examined the correlation between behavioral observations of the target symptoms and a physician’s decision to change a patient’s medication. Naturalistic observations were made of a 15-year-old profoundly mentally retarded boy with self-injurious behavior while he received medications to treat the self-injury. The results suggested that the physician’s decisions to change medication dosages were often not based on related changes in the target behavior, but rather on the global impressions of the ward staff. Interestingly, such physician practices appear not to have changed in 11 years, as these exact findings were replicated in another, more recent study (Fredericks & Hayes).

Almost nothing is known concerning how the effects of psychotropic medications typically are monitored in students with developmental disabilities. There is, however, a sizable literature concerning students with a diagnosis of attention deficit/hyperactivity disorder (ADHD). Parents usually depend on their physician to diagnose ADHD and prescribe a medication for it without understanding the consequences of administering such medication (Werry, 1999). Lamentably, monitoring of the efficacy of psychotropic medications tends to be haphazard (Gadow, Nolan, Paolicelli, & Sprafkin, 1991). Gadow et al. found that contacts between physicians and classroom teachers and the use of well-validated assessment
instruments often occur sporadically. Teachers were often uninformed about the medication being used and physicians generally had limited knowledge about a child’s behavior at school. Furthermore, the decision to medicate and to continue medication use typically is made by a pediatrician based on informal information provided by parents.

Importance of School Involvement in Monitoring Medication

Children spend a significant portion of their lives in school, therefore, the involvement of school personnel in monitoring drug effects would appear to be essential to determine the efficacy of prescribed medications (Brown, Dingle, & Landau, 1994; Gadow, 1982). That is, school personnel are in contact with children for prolonged periods within a structured setting and have opportunities to observe children in situations to which the parents may not have access (Gadow & Nolan, 1993). Thus, input from school personnel is invaluable for making decisions regarding the effects of medications (Brown, Dingle, & Landau, 1994; Gadow, 1982, 1983; Weithorn & Ross, 1975). It appears, however, that this does not occur regularly. Two studies by Gadow (1982, 1983) found that school personnel characteristically fail to play an important role in monitoring the effects of psychotropic medications in students with mental retardation or other developmental disabilities. Teachers in early childhood special education programs and in classrooms for trainable mentally retarded students who had at least one student receiving medication for a behavior or a learning disorder were surveyed. The results
indicated that teachers were often not involved in referral, diagnosis, or the withdrawal of medication. Furthermore, 60% of the teachers reported drug effects even though there were no systematic monitoring procedures in place and standardized evaluation instruments were rarely used. Although teachers and other school personnel are in a good position to collect data relevant to desired and adverse effects of pharmacological treatments, that information typically is not systematically shared with physicians (Brown & Sawyer, 1998; Gadow, 1982, 1983). Additionally, special education teachers often make use of behavior-modification techniques than can affect the same behaviors that are altered by medication (O’Leary & Pelham, 1978). Consequently, the teacher and the physician may have identical therapeutic objectives, however, this is unknown to both parties involved (Gadow, 1982).

Moreover, school personnel may fail to obtain relevant data that could be collected easily because they frequently are not informed about the desired effects of medication. In fact, they may not even be informed that a given student is receiving medication. That is, unless the child receives the medication at school, the parents are not required by law to inform the school. Furthermore, parents are not required to inform the school of any increases or decreases in the medication unless this affects the dosage administered at the school.

The ADHD literature suggests that treatment decisions regarding the use of psychotropic medications in schools are based primarily on physician's reactions to reports from parents, who may have little opportunity to observe a child’s behavior at school, where the problems that define ADHD are particularly likely to occur (Brown
& Sawyer, 1998). Sleator and Sprague (1978) note the importance of this issue and recommend that monitoring of drug effects must include reports from the teacher. They further recommend that the medical profession should play an active role in facilitating communication between physicians and school personnel. It appears, however, that this has not occurred during the 24 years since their recommendation appeared. Gadow (1997) noted "there was little evidence of interdisciplinary collaboration or the use of standardized instruments to assess therapeutic or untoward drug effects" (p. 225). No studies have followed up on the findings of Gadow (1982, 1983), and in a 1997 article he lamented: "Unfortunately, there remains little information on current practices in treatment evaluation for children with mental retardation [who attend public schools]" (p. 225).

The purpose of the present study was to determine if parents and teachers of students with mental retardation and/or autism are currently monitoring the effects of psychotropic medication(s) prescribed to their child/student and how much they know regarding the reason for which these medications were prescribed. The intent of the teacher interview was to obtain information comparable to that secured from parents to determine the degree of agreement about the goals and efficacy of treatment. Additionally, the study investigated 1) the combinations of psychotropic medications that students currently are receiving, 2) the behavioral domains that those medications are intended to affect, 3) the current status of those behavioral domains, and 4) consumers' satisfaction with the pharmacological intervention.
METHOD

Participants and Setting

Information was collected regarding medication usage in 21 school-aged children identified by school nurses and teachers. These students attended three different school districts in two small Midwestern cities. Each student had a diagnosis of mental retardation and/or autism and was currently receiving one or more psychotropic medications. Seventeen of these students attended a center-based program, one student attended an elementary school and three students attended a middle school. The students in the elementary and middle schools received special education services and attended some general education classes.

Written notification was sent home with all of these students requesting parents/guardians permission for the investigator to contact them (See Appendix A). Interested parents/guardians contacted the student’s teacher or school psychologist via phone call or written permission, who provided the investigator with the parent’s/guardian’s identifying information. The investigator contacted these parents/guardians via phone call and an interview time was arranged. Twenty-one parents/guardians consented to an interview.

After the completion of the parent/guardian interview, the student’s primary teacher was contacted via phone call and an interview time was arranged. Fourteen
teachers consented to an interview. Ten teachers were employed by a center-based program, one teacher was employed at an elementary school, and two teachers were employed at a middle school. Six teachers were interviewed for multiple students. Information for each student was provided by only one teacher.

Procedure

Interviews took approximately 15 minutes during which the parents/guardians and teachers completed a brief questionnaire. Parent/Guardian interviews were conducted in the family’s home, at a designated meeting place or by phone. Consent was obtained at the onset of the interview (See Appendix B). Consent also was obtained for the investigator to contact the child’s primary teacher and conduct a similar interview. Teacher interviews were conducted at the relevant school. Consent was obtained at the onset of the interview (See Appendix C). The investigator asked all of the questions in a semi-structured interview format.

Instrument

The instrument used in the semi-structured interview comprised two sections (See Appendix D, E, F). The first section, displayed in Figure 1, requested: a) information pertaining to current medication monitoring systems; b) information about the student’s prescribed medication; c) information regarding knowledge about the intended effects of the medication; and d) information about the degree of satisfaction with the drug treatment that the student currently is receiving.
Figure 1

Medication Information Form

Questions

1. What medication is this child currently taking to improve his/her mood, cognitive status, or behavior?

2. How much of this medication does this child take each day?

3. How long has this child been taking this medication?

4. Do you know the potential side effects for this medication (Yes or No)

1. How satisfied are you with your current method of evaluating the medication(s) listed above?
   - I am very satisfied
   - I am somewhat satisfied
   - I am not at all satisfied

2. How satisfied are you with the results produced by the medication listed above?
   - I am very satisfied
   - I am somewhat satisfied
   - I am not at all satisfied

3. How much do you know about the changes in mood, cognitive status, and behavior that the medication listed above should produce?
   - I know a great deal
   - I know a moderate amount
   - I know a moderate amount or nothing
The second section, displayed in Figure 2, included questions ascertaining parent/guardian and teacher knowledge about whether the medication was prescribed to treat behaviors in each of the five general domains for which psychotropic medications are commonly prescribed for people with mental retardation (Aman & Singh, 1986), whether these behaviors were being monitored in any manner; the current status of those behavioral domains, and; whether there was any communication between the school personnel, parents/guardians, and physicians regarding the status of the behavior and/or efficacy of the medication. The behavioral domains of interest were: a) irritability, agitation and crying (domain I); b) lethargy and social withdrawal (domain II); c) hyperactivity and noncompliance (domain III); d) stereotypic behavior (domain IV), and; e) inappropriate speech (domain V). Along with the questions listed in Figure 2, the teacher form included two additional questions ascertaining if they provided any information about the students behavior to the parent/guardian or to the physician.
### Kind of Behavior

#### I. Irritability, Agitation, and Crying

Examples of such behavior include, but are not limited to:
- Hurting himself/herself deliberately
- Being aggressive to other children
- Crying or screaming at inappropriate times
- Having temper outbursts or tantrums when s/he does not get his/her own way

<table>
<thead>
<tr>
<th>Was a medication prescribed to deal with this kind of behavior?</th>
<th>Is this kind of behavior a problem at the present time?</th>
<th>Are you keeping track of this kind of behavior?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>Don’t Know</td>
</tr>
</tbody>
</table>

#### II. Lethargy and Social Withdrawal

Examples of such behavior include, but are not limited to:
- Being sluggish and inactive
- Seeking isolation from others
- Resisting physical contact
- Being unresponsive to structured activities
- Preferring to be alone

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</thead>
</table>

#### III. Hyperactivity and Noncompliance

Examples of such behavior include, but are not limited to:
- Acting without thinking first
- Not sitting still for a reasonable length of time
- Being disobedient or difficult to control
- Failing to pay attention to instructions
- Fidgeting and moving around
Table 1: Behavior Experiences

<table>
<thead>
<tr>
<th>Kind of Behavior</th>
<th>Was a medication prescribed to deal with this kind of behavior?</th>
<th>Is this kind of behavior a problem at the present time?</th>
<th>Are you keeping track of this kind of behavior?</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV. Stereotypic Behavior</td>
<td>YES</td>
<td>NO</td>
<td>Don’t Know</td>
</tr>
<tr>
<td>Examples of such behavior include, but are not limited to:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• Moving hand, body, or head repeatedly</td>
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<tr>
<td>• Waving or shaking the extremities repeatedly</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• Rocking body back and forth repeatedly</td>
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<td></td>
<td></td>
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<tr>
<td>V. Inappropriate Speech</td>
<td></td>
<td></td>
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<tr>
<td>Examples of such behavior include, but are not limited to:</td>
<td></td>
<td></td>
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<tr>
<td>• Talking excessively</td>
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<tr>
<td>• Talking loudly to him/herself</td>
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<td></td>
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<tr>
<td>• Repeating a word or phrase over and over</td>
<td></td>
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</tbody>
</table>
RESULTS

Section 1

Parents/Guardians

Medication Report. The medications that students were prescribed are displayed in Table 1. Students received anywhere from one to seven prescribed psychotropic medications. Of the twenty-one students, 23% (N = 5) received one medication, 19% (N = 4) received two medications, 23% (N = 5) received three medications, 14% (N = 3) received four medications, 5% (N = 1) received five medications, 10% (N = 2) received six medications, and 5% (N = 1) received seven medications. The two most commonly prescribed medications were the antipsychotic risperidone (Risperdal) and the antihypertensive katapres (Clonidine).

Side effects. The results of the parent’s/guardian’s knowledge of side effects are displayed in Table 2. Fifty-seven percent (N = 12) of the parents/guardians were familiar with the side effects of at least one of the prescribed medications. Thirty-eight percent (N = 8) were familiar with all of the side effects of the prescribed medications.
Table 1

List of Student’s Prescribed Medications

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</thead>
<tbody>
<tr>
<td>Student 1</td>
<td>catapres</td>
<td>risperidone</td>
<td>amphetamine</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>(Clonidine)</td>
<td>(Risperdal)</td>
<td>(Adderal)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Student 2</td>
<td>valproic acid</td>
<td>risperdone</td>
<td>benzotropine</td>
<td>eskalith</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Depakote)</td>
<td>(Risperdal)</td>
<td>(Cogentin)</td>
<td>(Lithium Carbonate)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 3</td>
<td>lamotrigine</td>
<td>phenytoin</td>
<td>quetiapine</td>
<td>fluvoxamine</td>
<td>topiramate</td>
<td>trazadone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Lamictal)</td>
<td>(Dilantin)</td>
<td>(Lonegran)</td>
<td>(Seroquil)</td>
<td>(Luvox)</td>
<td>(Topomax)</td>
<td></td>
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<tr>
<td>Student 4</td>
<td>buspiron</td>
<td>methylphenidate</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(Buspar)</td>
<td>(Ritalin)</td>
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<tr>
<td>Student 5</td>
<td>fluoxetine</td>
<td>lamotrigine</td>
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<tr>
<td></td>
<td>(Prozac)</td>
<td>(Lamictal)</td>
<td></td>
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<tr>
<td>Student 6</td>
<td>sertraline</td>
<td>catapres</td>
<td></td>
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<tr>
<td></td>
<td>(Zoloft)</td>
<td>(Clonidine)</td>
<td></td>
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<tr>
<td>Student 7</td>
<td>trazadone</td>
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<tr>
<td></td>
<td>(Deseryl)</td>
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<tr>
<td>Student 8</td>
<td>sertraline</td>
<td>catapres</td>
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<tr>
<td></td>
<td>(Zoloft)</td>
<td>(Clonidine)</td>
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<tr>
<td>Student 9</td>
<td>quetiapine</td>
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</tr>
<tr>
<td></td>
<td>(Seroquil)</td>
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<td>Student 10</td>
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<td>topiramate</td>
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<td>eskalith</td>
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<td>(Risperdal)</td>
<td>(Topomax)</td>
<td>(Depakote)</td>
<td>(Effexor)</td>
<td>(Lithium Carbonate)</td>
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<td>gabapentin</td>
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<td></td>
<td>(Dilantin)</td>
<td>(Depakote)</td>
<td>(Neurotin)</td>
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<tr>
<td>Student 12</td>
<td>gabapentin</td>
<td>risperidone</td>
<td>catapres</td>
<td>benzotropine</td>
<td>dextroamphetamine</td>
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<td></td>
</tr>
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<td></td>
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<td>(Risperdal)</td>
<td>(Clonidine)</td>
<td>(Cogentin)</td>
<td>(Adderall)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 13</td>
<td>catapres</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>(Clonidine)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Student 14</td>
<td>methylphenidate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Ritalin)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Student 15</td>
<td>trazadone</td>
<td>benzotropine</td>
<td>quetiapine</td>
<td>fluvoxamine</td>
<td>dextroamphetamine</td>
<td></td>
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</tr>
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<td></td>
<td>(Deseryl)</td>
<td>(Cogentin)</td>
<td>(Seroquil)</td>
<td>(Luvox)</td>
<td>(Dexedrine)</td>
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</tr>
<tr>
<td>Student 16</td>
<td>risperidone (Risperdal)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 17</td>
<td>lorazepam (Ativan)</td>
<td>risperidone (Risperdal)</td>
<td>carbamazepine (Tegretol)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 18</td>
<td>catapres (Clonidine)</td>
<td>olazapine (Zyprexa)</td>
<td>methylphenidate (Concerta)</td>
<td></td>
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</tr>
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<td>Student 19</td>
<td>haloperidol (Haldol)</td>
<td>benzotropine (Congentin)</td>
<td>lorazepam (Ativan)</td>
<td>valproic acid (Depakote)</td>
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</tr>
<tr>
<td>Student 20</td>
<td>risperidone (Risperdal)</td>
<td>hydroxyzine (Atarax)</td>
<td>methylphenidate (Ritalin)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Student 21</td>
<td>catapres (Clonidine)</td>
<td>lorazepam (Ativan)</td>
<td>carbamazepine (Tegretol)</td>
<td></td>
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</tr>
<tr>
<td>Student</td>
<td>No. of prescribed medications</td>
<td>No. of medications with knowledge of side effects</td>
<td></td>
<td></td>
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<td>3</td>
<td></td>
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<td>Student 2</td>
<td>4</td>
<td>4</td>
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<tr>
<td>Student 3</td>
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<td>Student 4</td>
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<tr>
<td>Student 5</td>
<td>2</td>
<td>0</td>
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<td></td>
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<td>Student 6</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Student 7</td>
<td>1</td>
<td>1</td>
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<td></td>
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<td>Student 8</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Student 9</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Student 10</td>
<td>6</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 11</td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 12</td>
<td>6</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Student 13</td>
<td>1</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 14</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 15</td>
<td>5</td>
<td>4</td>
<td></td>
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<tr>
<td>Student 16</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Student 17</td>
<td>3</td>
<td>3</td>
<td></td>
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</tbody>
</table>
Table 2 – Continued

<table>
<thead>
<tr>
<th>Student</th>
<th>No. of prescribed medications</th>
<th>No. of medications with knowledge of side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student 18</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Student 19</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Student 20</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Student 21</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

**Satisfaction.** The parent/guardian satisfaction with current methods of evaluating the medication(s), satisfaction with the results of the medication(s) and knowledge about the changes produced by the medication(s) are displayed in Figure 3. In general, reports were mixed. That is, while the majority of parents/guardians reported being satisfied with their current method of evaluating the medication(s), they were mixed with being satisfied and not satisfied with the results of the medication, and the majority reported knowing a moderate amount about changes produced by the medication(s).

**Teachers**

**Satisfaction.** The teacher satisfaction with current methods of evaluating the medication(s), satisfaction with the results of the medication(s) and knowledge about the changes produced by the medication(s) are displayed in Figure 3. Unlike the
Parents/Guardian and Teacher Satisfaction with Current Methods of Evaluating the Medication(s), Satisfaction with the Results of the Medication(s) and Knowledge About the Changes Produced by the Medication(s)

<table>
<thead>
<tr>
<th></th>
<th>Parents/Guardian</th>
<th>Teachers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How satisfied are you with your current method of evaluating the medication(s) listed above?</strong></td>
<td><strong>How satisfied are you with your current method of evaluating the medication(s) listed above?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Number of responses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>47%</td>
<td>I am very satisfied</td>
<td>14%</td>
</tr>
<tr>
<td>28%</td>
<td>I am somewhat satisfied</td>
<td>9%</td>
</tr>
<tr>
<td>24%</td>
<td>I am not at all satisfied</td>
<td>61%</td>
</tr>
<tr>
<td><strong>How satisfied are you with the results produced by the medication listed above?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of responses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38%</td>
<td>I am very satisfied</td>
<td>14%</td>
</tr>
<tr>
<td>24%</td>
<td>I am somewhat satisfied</td>
<td>47%</td>
</tr>
<tr>
<td>38%</td>
<td>I am not at all satisfied</td>
<td>28%</td>
</tr>
<tr>
<td><strong>How much do you know about the changes in mood, cognitive status, and behavior that the medication listed above should produce?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of responses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28%</td>
<td>I know a great deal</td>
<td>0%</td>
</tr>
<tr>
<td>47%</td>
<td>I know a moderate amount</td>
<td>14%</td>
</tr>
<tr>
<td>19%</td>
<td>I know a moderate amount or nothing</td>
<td>76%</td>
</tr>
</tbody>
</table>
parents/guardian, the teachers were not satisfied with the medication evaluation process. Additionally, 76% of teachers indicated knowing a moderate amount or nothing about the changes in mood, cognitive status and behavior that the medication(s) prescribed should produce.

Section II

Parent/Guardian

Domain knowledge. The results of parents/guardians knowledge about the domains for which the medication was prescribed indicate that medication was most often prescribed for irritability, agitation, and crying followed by hyperactivity and noncompliant behaviors. Seventy-one percent (N = 15) indicated that their child was prescribed a medication targeting irritability, agitation and crying. Of this 71%, 66% (N = 10) indicated that these kinds of behaviors are a problem at the present time and 60% (N = 6) of these parents/guardians are keeping track of these behaviors in some manner.

Sixty-six percent (N = 14) of parents/guardians indicated that their child was prescribed a medication targeting hyperactivity and noncompliance behaviors. Of this 66%, 35% (N = 5) indicated that these kinds of behaviors are a problem at the present time and 40% (N = 2) of these parents/guardian are keeping track of this behavior in some manner.

Four percent (N = 1) reported that their child was prescribed a medication targeting lethargy and social withdrawal and 9% (N = 2) reported that their child was prescribed a medication targeting stereotypic behavior. No parents/guardians reported
that their child was prescribed a medication targeting inappropriate speech.

**Teachers**

**Domain knowledge.** The results of the teacher knowledge about the domains for which the medication was prescribed indicate that many of them did not know the behaviors targeted by the medication. Forty-seven percent (N = 9) of teachers indicated that medication was prescribed for irritability, agitation and crying behaviors and 52% (N = 10) reported that medication was prescribed for hyperactivity and noncompliance behavior. However, 31% (N = 6), 47% (N = 9), 36% (N = 7), 42% (N = 8), and 42% (N = 8) indicated that they did not know if a medication was prescribed for irritability, agitation and crying behaviors, lethargy and social withdrawal behavior, hyperactivity and noncompliance behavior, stereotypic behavior, or inappropriate speech behavior, respectively.

Fifty-seven percent (N = 11) of teachers indicated that irritability, agitation and crying behaviors were a problem at the present time and 57% (N = 11) indicated that inappropriate speech behaviors were a problem at the present time. All of the teachers that were monitoring behaviors also were providing parents/guardians with the monitoring information. There were teachers, however, who were not monitoring relevant behaviors, but were still providing parents/guardians with information about these behaviors (See Table 3). That is, the teacher would not be systematically monitoring the behavior, but would inform the parents/guardians about the status of important behaviors. For example, if a student displayed incidents of self-injurious
behavior (SIB), the teacher would not inform the parent of the number of times the SIB occurred. The teacher would report that the student had a "good day" or a "bad day" with regards to SIB behavior. This generic information, however, does not indicate what constitutes as a good or bad day. It only indicates whether the behavior occurred or did not occur. All but one of the teachers indicated not being directly involved in providing the physician with any information. One teacher accompanies the parent to the physician appointments. Additionally, one teacher indicated writing reports for the parents to take to the physician.

Table 3

<table>
<thead>
<tr>
<th>Domain Type</th>
<th>Percentage of Teachers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain I</td>
<td>42% (N = 8)</td>
</tr>
<tr>
<td>Domain II</td>
<td>36% (N = 7)</td>
</tr>
<tr>
<td>Domain III</td>
<td>47% (N = 9)</td>
</tr>
<tr>
<td>Domain IV</td>
<td>42% (N = 8)</td>
</tr>
<tr>
<td>Domain V</td>
<td>31% (N = 6)</td>
</tr>
</tbody>
</table>

Overall, there were 28 different psychotropic medications and 8 different drug classes prescribed for the students (See Table 4). Table 5 specifies the students and the behaviors the medications were prescribed to target. Comparing the results from tables 1,
4, and 5 shows that several of the medications were prescribed for an off-label usage. Medications that are approved for dispersement have specific conditions for which they have been proven to be effective (See Table 4). When a medication is used for a condition for which it has not been approved, it is said to be an off-label use of the medication. That is, the FDA has not approved the medication for the prescribed rationale. For example, student 13 was prescribed catapres to target hyperactive and noncompliant behaviors, however, this medication is only indicated for use in the treatment of hypertension. Student 18 was prescribed catapres, olazapine, and methylphenidate to target irritability, agitation, crying, hyperactive, and noncompliant behaviors, however, catapres is only indicated for use in the treatment of hypertension and olazapine is only indicated for use in the management of psychotic disorders. Student 20 was prescribed risperidone, to target irritability, agitation, crying, hyperactive, and noncompliant behaviors, however, risperidone is only indicated for the use in the management of psychotic disorders.

When physicians prescribe a psychotropic medication for an off-label use they are in essence conducting a mini-experiment. That is, the physician is hypothesizing that administering a specific drug will produce a desired effect (Sprague and Werry, 1971). In such cases, it is essential that sufficient data be collected to confirm or reject this hypothesis. Moreover, to ensure appropriate off-label usage of drugs, physicians must be familiar with current research and established usage of medications because as indicated earlier, parents will depend on them to diagnose problems and prescribe medications without understanding the consequences of administering such medication (Werry 1999).
Polypharmacy is also a concern with many of the students. Polypharmacy is the simultaneous use of two or more drugs of the same basic type. For example, both student 3, and student 15 were prescribed two antidepressant medications, (i.e., fluvoxamine and trazadone). According to Bates, Smeltzer, and Arnoczky (1986) polypharmacy “is always inappropriate because it involves increased risk without likelihood of increased benefit” (p. 365).
Table 4
Frequency of Medications Prescribed and Approved Usage

<table>
<thead>
<tr>
<th>Major Groupings/Specific Drugs</th>
<th>Frequency</th>
<th>Approved Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antianxiety Drugs</td>
<td></td>
<td>Management of anxiety disorders or for the short-term relief of the symptoms of anxiety or anxiety associated with depressive symptoms</td>
</tr>
<tr>
<td>hydroxyzine (Atarax)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>lorazepam (Ativan)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>buspiron (Buspar)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Antidepressant Drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>fluoxetine (Prozac)</td>
<td>1</td>
<td>Treatment of depression, obsessions and compulsions in persons with obsessive compulsive disorder, panic disorder, and binge-eating and vomiting behaviors in patients with moderate to severe bulimia nervosa. Trazadone and venlafaxine are for the treatment of depression only.</td>
</tr>
<tr>
<td>fluvoxamine (Luvox)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>sertraline (Zoloft)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>trazadone (Deseryl)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>venlafaxine (Effexor)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Anticholinergic Drugs</td>
<td></td>
<td>Use as an adjunct in the therapy of all forms of parkinsomism and for control of EPS due to neuroleptics.</td>
</tr>
<tr>
<td>benzotropine (Cogentine)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Antiepileptic Drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>carbamazepine (Tegretol)</td>
<td>2</td>
<td>Treatment of seizures.</td>
</tr>
<tr>
<td>gabapentin (Neurotin)</td>
<td>2</td>
<td>The safety and effectiveness of the use of lamictal in children below the age of 16 has not been established.</td>
</tr>
<tr>
<td>lamotrigine (Lamictal)</td>
<td>2</td>
<td>Depakote is also used to control manic episodes that occur in bipolar disorder.</td>
</tr>
<tr>
<td>phenytoin (Dilantin)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>topiramate (Topomax)</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>valproic acid (Depakote)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Antihypertensive Drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>catapres (Clonidine)</td>
<td>7</td>
<td>Treatment of hypertension</td>
</tr>
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Table 4 – Continued

<table>
<thead>
<tr>
<th>Major Groupings/Specific Drugs</th>
<th>Frequency</th>
<th>Approved Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antipsychotic Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>haloperidol (Haldol)</td>
<td>1</td>
<td>Use in management of manifestation of psychotic disorders, for the control of tics and vocal utterances of Tourette’s disorder, treatment of severe behavior problems in children, and treatment of hyperactive children (Note: Should be reserved for these last two groups of children only after failure to respond to medication other than antipsychotics). Olazapine, risperidone, and quetiapine are for use in the management of psychotic disorders only.</td>
</tr>
<tr>
<td>olazapine (Zyprexa)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>quetiapine (Seroquel)</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>risperidone (Risperdal)</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td><strong>Antimanic Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>eskalith (Lithium Carbonate)</td>
<td>2</td>
<td>Treatment of manic episodes of manic-depressive illness.</td>
</tr>
<tr>
<td><strong>Stimulant Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>dextroamphetamine (Adderall, Dexedrine)</td>
<td>3</td>
<td>Treatment of attention deficit hyperactive disorder; Narcolepsy.</td>
</tr>
<tr>
<td>methylphenidate (Concerta, Ritalin)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>Target Behaviors</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Student 1</td>
<td>irritability, agitation, crying, hyperactivity, and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 2</td>
<td>irritability, agitation, crying, and Schizo Affective Disorder</td>
<td></td>
</tr>
<tr>
<td>Student 3</td>
<td>Do not know</td>
<td></td>
</tr>
<tr>
<td>Student 4</td>
<td>irritability, agitation, crying, hyperactivity, and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 5</td>
<td>irritability, agitation, and crying</td>
<td></td>
</tr>
<tr>
<td>Student 6</td>
<td>irritability, agitation, crying, lethargy, social withdrawal, hyperactivity, noncompliance, and to help sleep</td>
<td></td>
</tr>
<tr>
<td>Student 7</td>
<td>irritability, agitation, and crying</td>
<td></td>
</tr>
<tr>
<td>Student 8</td>
<td>hyperactivity, and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 9</td>
<td>irritability, agitation, crying, hyperactivity, and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 10</td>
<td>Do not know</td>
<td></td>
</tr>
<tr>
<td>Student 11</td>
<td>Mainly for seizures, aggression</td>
<td></td>
</tr>
<tr>
<td>Student 12</td>
<td>Schizophrenia, to help sleep, irritability, agitation, crying, hyperactivity, noncompliance, and stereotypic behavior</td>
<td></td>
</tr>
<tr>
<td>Student 13</td>
<td>hyperactivity and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 14</td>
<td>hyperactivity and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 15</td>
<td>ADHD, aggression, sexual deviancy, and sleep</td>
<td></td>
</tr>
<tr>
<td>Student 16</td>
<td>irritability, agitation, and crying</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>Target Behaviors</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Student 17</td>
<td>irritability, agitation, and crying</td>
<td></td>
</tr>
<tr>
<td>Student 18</td>
<td>irritability, agitation, crying, hyperactivity, and noncompliance; supposed to calm him down</td>
<td></td>
</tr>
<tr>
<td>Student 19</td>
<td>irritability, agitation, and crying; hyperactivity and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 20</td>
<td>irritability, agitation, crying, hyperactivity, and noncompliance</td>
<td></td>
</tr>
<tr>
<td>Student 21</td>
<td>hyperactivity and noncompliance</td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

Discussion

The results of this study suggest that both at home and at school there is a lack of systematic monitoring of the effects of psychotropic medications. While a high percentage of parents/guardians indicated that they were satisfied with the current method of evaluating their child’s medications, none of them employed a systematic monitoring system. That is, a number of parents/guardians mentioned they had a journal that they used to track medication changes, (i.e., increases or decreases in dosage level or addition of new medication), but none of them monitored the number of occurrences of targeted behaviors for which the medication was prescribed. Consequently, the efficacy of the psychotropic medication is not being evaluated systematically. A number of parents/guardians did mention they might make note of their general impressions of the child’s behavior, which was later relayed to the physician. One parent indicated that she independently adjusted her child’s medication based on her impressions of her child’s status. For example, if she thought her child’s behavior warranted an increase in medication then she would call the physician’s office, inform them that the medication was being increased, and proceed with adjusting the medication to a dosage she deemed appropriate. This parent also noted that the call to the physician did not always occur before she increased the medication dosage. In general, the findings of this survey concur with the results of
previous research in suggesting that physician's decisions to change medication is not based on related changes in the target behavior, but on global impressions by parents and teachers (Singh & Winton, 1984; Fredericks & Hayes, 1995).

Additionally, the results suggest that teachers had a lack of knowledge regarding the reasons for which students were prescribed medications and about what medications the students received. Several teachers referred the interviewer to the school nurse when queried about the exact medication a student received. This suggests that if teachers are tracking behaviors targeted by the medication, they may not know it. In such cases, data collected are not likely to be communicated to the parents/guardians to be relayed to the physician.

The results further suggest that both the parents/guardians and teachers have a lack of knowledge regarding the side effects of the medications prescribed. Forty-three percent of the parents/guardians did not know the side effects of all medications and none of the teachers knew any of the side effects of the medications prescribed for the students. The parents of student 3 and student 12 did not know any of the listed side effects for any of the prescribed medications. These two students were prescribed the largest number of medications.

The results of the survey indicated a lack of communication among teachers, parents/guardians, and physicians with respect to information related to the student's prescribed medication. Several teachers indicated they send home daily notes providing global impressions about the student's behavior. However, these notes may not indicate impressions relevant to the behavior targeted by the medication.
In general, it was the researcher's impression that the parent's/guardian's knowledge about their child's behavior was often related to the intensity of the child's behavior problems, but not the socioeconomic status, education level, or school district. For example, one parent, a single mother, appeared to the researcher to not have much by way of economic resources. She resided in a low-income neighborhood and accessed state-funded waiver services for assistance with her child, who displayed intense aggressive behaviors and required one-on-one care at school. This parent, however, was fully knowledgeable of all of her child's prescribed medications, reasons for the medication and the side effects. She monitored her child's behavior and kept a journal of the child's medication changes and physician appointments. She also communicated regularly with the school about her child's behavioral status.

Another parent, a mother, who was married and resided in an affluent neighborhood, did not appear to have as much knowledge about her child's prescribed medications, the reasons for the use of medication, and it's side effects. This parent did not monitor her child's behavior and communicated infrequently with the school about her child's behavioral status.

There were some general limitations to the current study. The most important one is that the participants selected for this study are a small and nonrandom sample of the population of parents whose school-aged children have a diagnosis of mental retardation and/or autism and currently receiving one or more psychotropic medications. Thus, a generality of the present results is limited. Another limitation is that the survey form did not directly query the parents/guardians requesting whether
their child had a specific psychiatric or medical diagnosis. It only asked what behaviors the medications were prescribed to address. Knowledge regarding diagnostic labels would have been helpful for reporting if the medications were prescribed for an off-label use. That is, if a student were prescribed catapres, it would be useful to know if s/he had a diagnosis of hypertension or a psychotic condition (e.g., schizophrenia). A third limitation is the language of the survey may have been difficult for respondents to understand. For example, one parent requested that the researcher read the survey to her.

Future Directions

Because of the high number of psychotropic medications prescribed to school-aged children, systematic monitoring of the effects of these medications could be very valuable. In this regard, first, teachers need to be better informed of who in their class is taking medications. Currently, parents are not required to inform the school personnel if their child is prescribed a medication. This information is only required if a dosage administration is necessary during the school day. Also, parents are not required to inform school staff if there is a decrease or increase in medication dosage. Again, this information is only required if it pertains to the dosage administered at the school.

Second, school personnel (i.e., teachers, school psychologists, social workers) need to become better informed regarding the effects of commonly prescribed medications. They should acquire knowledge about the rationale for their use, effects
on academic and social behavior, and common side effects. Such knowledge could be provided through required in-service trainings, with information presented at a level that is understandable by all who attend.

Third, school personnel should be trained on how to monitor systematically the behaviors that medications are prescribed to target. Monitoring should occur before, during, and after the use of drug therapies. Fourth, school personnel should take the initiative in establishing policies for ensuring that the data they collect are communicated to parents and physicians.

Finally, monitoring of the effects of all psychotropic medication is likely to be needed if substantial progress is to occur. As previously discussed, medication usage in institutions did not change until laws were established regulating its usage. It would seem that if schools personnel and physicians were required by law to monitor systematically the effects of psychotropic medications prescribed for school-aged children, this would be a major step in the right direction.
REFERENCES


prescribing practices on the behavior of persons with mental retardation.

*Journal of Developmental and Physical Disabilities, 7*, 105-122.


*The Journal of Special Education, 16*, 385-399.


Child and psychiatry: Modern approaches (pp. 880-899). Melbourne, Australia: Blackwell.


Appendix A

Flier
Dear Parent,

We are faculty members and students in the Department of Psychology at Western Michigan University. We are doing research to find out what types of medication monitoring procedures are being used in school and at home for children with developmental disabilities who are receiving psychotropic medications. The goal of our research is to help parents and school staff to develop an effective and practical medication monitoring system.

We will be contacting you by phone within the next two weeks and providing further details about this research project. If you would like to speak with someone immediately, please feel free to contact one of us at the numbers listed below, or you may speak with Sandy Beiter, R.N., B.S.N., N.S.C.N., your child’s school nurse, at 373-3275.

Al Poling, Ph.D.             Kristal Ehrhardt, Ph.D.
Professor                  Professor
387-4483                    387-4478

Lynne Turner               Lanai Jennings
Doctoral Student           Doctoral Student
387-4560                   387-4560
Appendix B

Parent Consent Form
Western Michigan University  
Department of Psychology  
Principal Investigator: Alan Poling & Kristal Ehrhardt  
Research Associate: Lynne Turner & Lanai Jennings

Parent Permission

I have been invited to participate in a research project entitled “Monitoring of Psychotropic Medication at School and at Home”. The purpose of the study is to evaluate how medication is monitored in the schools and at home and to establish an ongoing monitoring system if one is not currently in place. This project is being conducted to fulfill Lynne Turner & Lanai Jennings’ theses requirements.

This project will be conducted in two phases. I agree in the first phase to be interviewed to complete a brief questionnaire. The questionnaire includes questions about my child’s current medication and my satisfaction with this medication. The interview will take no more than 60 minutes to complete. I also agree in the second phase to monitor my child’s behaviors and side effects by completing either the Aberrant Behavior Checklist and the Detection of Side Effects Scale (15 minutes total) or a condensed version of the scales. Phase two will involve 13 weekly sessions, each lasting no more than 20 minutes. Phase two may also entail a single problem-solving interview lasting 30-60 minutes.

My permission also means that my child’s teacher may be contacted for an interview to complete a similar questionnaire about my child’s medication and behavior in the classroom. In addition, my permission serves as a release allowing the researchers to access confidential medical information from the school nurse and my child’s physician regarding my child.

The interview responses will be confidential. This means that my child’s name will be omitted from all forms and a code number will be attached. The principal investigator will keep a separate master list with the names of the children and the corresponding code numbers. Once the data are collected and analyzed, the master list will be destroyed. All other forms will be retained for three years in a locked file in the principal investigator’s office. No names will be used if the results are published or reported at a professional meeting.

If I chose to participate, I may gain knowledge about the effects of the medication that my child is taking. Additionally, I may find that my child’s medication is being used appropriately.
If I choose to participate, I may find that I am dissatisfied with the medication my child is prescribed. However, it is not the researchers’ purpose to bring about changes in medication, but to monitor the effects of prescribed medication. If I am unhappy with my child’s medication at any time, I should consult with my child’s physician to share my concerns before making any changes to my child’s treatment. As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, not compensation or additional treatment will be made available to the subjects except as otherwise stated in this consent.

I am free to terminate my involvement in the project at any time during either phase one or phase two. If I choose to terminate my involvement, there will be no negative consequences or penalties and my choice will not affect my child’s enrollment in the K/RESA school system. If I have any questions, I may contact Lynne Turner and Lanai Jennings at 387-4650, Kristal Ehrhardt at 387-4478 or Alan Poling 387-4483. I may also contact the chair of the Human Subject Institutional Review Board at 387-8293 or the Vice President for Research at 387-8298 with any concerns that I have.

This permission document has been approved for use for one year by the Human Subjects Institutional Review Board as indicated by the stamped date and signature of the board chair in the upper right corner. Subjects should not sign this document if the corner does not have a stamped date and signature.

Date ____________ Time ____________
You are making a decision whether or not to participate. Your signature indicates that you have decided to participate having read the information provided above.

Signature of Parent/Guardian ___________________________________ Signature of Investigator ___________________________________
Appendix C

Teacher Consent Form
Teacher Permission

I have been invited to participate in a research project entitled "Monitoring of Psychotropic Medication at School and at Home". The purpose of the study is to evaluate how medication is monitored in the schools and at home and to establish an ongoing monitoring system if one is not currently in place. This project is being conducted to fulfill Lynne Turner and Lanai Jennings' theses requirements.

This project will be conducted in two phases. I agree in the first phase to be interviewed to complete a brief questionnaire that includes questions about (name of child)'s current medication and behavior. The interview will take no more than 60 minutes to complete. I also agree in the second phase to monitor student behaviors and side effects by completing either the Aberrant Behavior Checklist and the Detection of Side Effects Scale (15 minutes total) or a condensed version of the scales. Phase two will involve 13 weekly sessions, each lasting no more than 20 minutes. Phase two may also entail a single problem-solving interview lasting 30-60 minutes.

The interview responses will be confidential. This means that your name and the student's name will be omitted from all forms and a code number will be attached. The principal investigator will keep a separate master list with the names of the children and the corresponding code numbers. Once the data are collected and analyzed, the master list will be destroyed. All other forms will be retained for three years in a locked file in the principal investigator’s office. No names will be used if the results are published or reported at a professional meeting.

If I choose to participate, I may gain knowledge about the intended effects of the medication that my student is taking. I will also have the opportunity to provide critical feedback to the investigators about monitoring medication in school settings. My feedback may facilitate changes that would make such a monitoring system more feasible for teachers like myself to implement.

If I choose to participate, I may find that I am dissatisfied with the medication my student is prescribed. However, it is not the researchers’ purpose to bring about changes in medication, but to monitor the effects of prescribed medication.

I am free to terminate my involvement in the project at any time during either phase one or phase two. Doing so will have no negative consequences or penalties,
although, there is a possibility that the student's parents may be upset with my decision.

If I have any questions, I may contact Lynne Turner at 387-4650, Lanai Jennings at 387-4345, Kristal Ehrhardt at 387-4478 or Alan Poling at 387-4483. I may also contact the chair of the Human Subject Institutional Review Board at 387-8293 or the Vice President for Research at 387-8298 with any concerns that I have.

This permission document has been approved for use for one year by the Human Subjects Institutional Review Board as indicated by the stamped date and signature of the board chair in the upper right corner. Subjects should not sign this document if the corner does not have a stamped date and signature.

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<th>Date</th>
<th>Time</th>
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You are making a decision whether or not to participate. Your signature indicates that you have decided to participate having read the information provided above.

| Signature of Parent/Guardian | Signature of Investigator |
Appendix D

Medication Information Form
Child's Name: ____________________________

Respondant: ____________________________

<table>
<thead>
<tr>
<th></th>
<th>Med I</th>
<th>Med II</th>
<th>Med III</th>
<th>Med IV</th>
<th>Med V</th>
</tr>
</thead>
<tbody>
<tr>
<td>What medication is this child currently taking to improve his/her mood, cognitive status, or behavior?</td>
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<tr>
<td>How much of this medication does this child take each day?</td>
<td></td>
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</tr>
<tr>
<td>How long has this child been taking this medication?</td>
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<tr>
<td>Do you know the potential side effects for this medication? YES or NO</td>
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Please answer the following questions with respect to your child.

How satisfied are you with your current method of evaluating the medication(s) listed above?
- □ I am very satisfied
- □ I am somewhat satisfied
- □ I am not at all satisfied

How satisfied are you with the results produced by the medication listed above?
- □ I am very satisfied
- □ I am somewhat satisfied
- □ I am not at all satisfied

How much do you know about the changes in mood, cognitive status, and behavior that the medication listed above should produce?
- □ I know a great deal
- □ I know a moderate amount
- □ I know a moderate amount or nothing

Are you interested in developing a system for systematically monitoring medication effects?
- □ Yes
- □ No
- □ Undecided
Appendix E

Teacher Interview Form
Behavioral Domain Information Form  
Teacher and Nurse Version

### Kind of Behavior

#### I. Irritability, Agitation, and Crying

Examples of such behavior include, but are not limited to:
- Hurting himself/herself deliberately
- Being aggressive to other children
- Crying or screaming at inappropriate times
- Having temper outbursts or tantrums when s/he does not get his/her own way

#### II. Lethargy and Social Withdrawal

Examples of such behavior include, but are not limited to:
- Being sluggish and inactive
- Seeking isolation from others
- Resisting physical contact
- Being unresponsive to structured activities
- Preferring to be alone

#### III. Hyperactivity and Noncompliance

Examples of such behavior include, but are not limited to:
- Acting without thinking first
- Not sitting still for a reasonable length of time
- Being disobedient or difficult to control
- Failing to pay attention to instructions
- Fidgeting and moving around
Behavioral Domain Information Form  
Teacher and Nurse Version

<table>
<thead>
<tr>
<th>Kind of Behavior</th>
<th>YES</th>
<th>NO</th>
<th>Don’t Know</th>
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<tbody>
<tr>
<td>IV. Stereotypic Behavior</td>
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<tr>
<td>Examples of such behavior include, but are not limited to:</td>
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<td>- Moving hand, body, or head repeatedly</td>
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<tr>
<td>- Waving or shaking the extremities repeatedly</td>
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<tr>
<td>- Rocking body back and forth repeatedly</td>
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| V. Inappropriate Speech |     |    |            |
| Examples of such behavior include, but are not limited to: |     |    |            |
| - Talking excessively |     |    |            |
| - Talking loudly to him/herself |     |    |            |
| - Repeating a word or phrase over and over |     |    |            |
Appendix F

Parent/Guardian Interview Form
<table>
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<tr>
<th>Behavioral Domain Information Form</th>
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<td>Parent Version</td>
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**Was a medication prescribed to deal with this kind of behavior?**

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<th>YES</th>
<th>NO</th>
<th>Don't Know</th>
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**Is this kind of behavior a problem at the present time?**

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<th>YES</th>
<th>NO</th>
<th>Don't Know</th>
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**Are you keeping track of this kind of behavior?**

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<th>YES</th>
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### Kind of Behavior

**I. Irritability, Agitation, and Crying**

Examples of such behavior include, but are not limited to:
- Hurting himself/herself deliberately
- Being aggressive to other children
- Crying or screaming at inappropriate times
- Having temper outbursts or tantrums when s/he does not get his/her own way

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**II. Lethargy and Social Withdrawal**

Examples of such behavior include, but are not limited to:
- Being sluggish and inactive
- Seeking isolation from others
- Resisting physical contact
- Being unresponsive to structured activities
- Preferring to be alone

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**III. Hyperactivity and Noncompliance**

Examples of such behavior include, but are not limited to:
- Acting without thinking first
- Not sitting still for a reasonable length of time
- Being disobedient or difficult to control
- Failing to pay attention to instructions
- Fidgeting and moving around

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### Kind of Behavior

#### IV. Stereotypic Behavior

Examples of such behavior include, but are not limited to:

- Moving hand, body, or head repeatedly
- Waving or shaking the extremities repeatedly
- Rocking body back and forth repeatedly

<table>
<thead>
<tr>
<th>Was a medication prescribed to deal with this kind of behavior?</th>
<th>Is this kind of behavior a problem at the present time?</th>
<th>Are you keeping track of this kind of behavior?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>Don't Know</td>
</tr>
</tbody>
</table>

#### V. Inappropriate Speech

Examples of such behavior include, but are not limited to:

- Talking excessively
- Talking loudly to him/herself
- Repeating a word or phrase over and over
Appendix G

Approval Letter From the Human Subjects Institutional Review Board
This letter will serve as confirmation that your research project entitled “Practical Evaluation of Psychotropic Medication” has been approved under the full category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: 21 February 2002