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EVIDENCE AND IMPACT OF EXPECTANCIES ASSOCIATED WITH
PSYCHOTROPIC MEDICATION REDUCTIONS IN PERSONS
WITH MENTAL RETARDATION

by

Christopher S. Baglio

Dissertation

Submitted to the Faculty of

Olivet Nazarene University

School of Graduate and Continuing Studies

in Partial Fulfillment of the Requirements for

the Degree of

Doctor of Education

in

Ethical Leadership

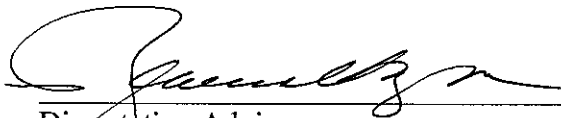
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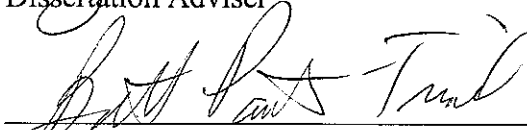
Christopher S. Baglio

Dissertation



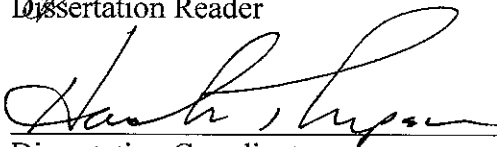
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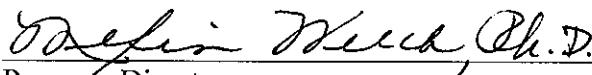
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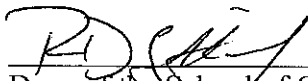
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While only a partial reflection of my interest and dedication to the field of developmental disabilities, the following pages represent an integration of my clinical experience with my passion for serving those who are part of this field. While there would be no way to capture all of the events that have brought me to this moment in time, there are a number of people I would like to thank for their contribution along the way.

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DEDICATION

I would like to dedicate this work to my children, Devyn, Thomas, and Amelia.
Nothing in life has taught me the importance of the moment like you have. I love you all
very much.

ABSTRACT

by

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This study was an attempt to understand the presence and impact of staff expectancies related to psychotropic medication reductions conducted with persons diagnosed with mental retardation. Within a state operated developmental center in the Midwest, results indicated that direct support staff overwhelmingly expected individuals to get worse following such a reduction. These expectancies significantly impacted data recording practice leading to discrepant elevations reported by staff expecting deterioration. Finally, while written communication about planned psychotropic medication reductions did not appear to elevate data recording as was hypothesized, reductions were associated with increases in both behaviors and psychiatric symptoms. This study has implications for the treatment integrity of pharmacological interventions used with persons diagnosed with mental retardation.

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CHAPTER I

INTRODUCTION

The United States Department of Justice documented that, for persons with mental retardation, there is a potential for misuse of psychotropic medications to control self-injurious behaviors and physical aggression (Baumeister, Todd, & Sevin, 1993; U.S. Department of Justice, 2008a). Current state and federal guidelines mandate the use of the most conservative psychotropic medication schedule to control these behaviors, and psychiatric symptoms in general (Davidson, Hemingway, & Wysocki, 1984; McDonald, 1998; U.S. Department of Health & Human Services, 2004).

In the state of Illinois, the Centers for Medicare and Medicaid Services (CMS) regulate use of psychotropic medications for persons with mental retardation. The CMS report states, “A gradual withdrawal occurs annually or sooner if warranted by progress to the criteria for reduction established in the individual program plan, by the particular drug which is being used, or the specific condition for which the drug is being prescribed” (U.S. Department of Health & Human Services, 2004, p. 163).

These CMS regulations have resulted in a decrease in use of psychotropic medication along with decreases in other restrictive procedures used to control behaviors (Valdovinos, Schroeder, & Kim, 2003; Davidson et al., 1984). Additional studies have found that levels of aggression, staff turnover, and use of other restrictive procedures remain stable following psychotropic medication reductions (Davidson et al.). In a study investigating reductions to psychotropic medication in adults with mental retardation,

Hancock, Weber, Kaza, and Her (1991) demonstrated the ability to maintain lower dosages of medication over time with no increased levels of decompensation. Similar results have been found with children and adolescents with severe emotional issues with Connor and McLaughlin (2005) finding that more than 66% of children and adolescents were able to be discharged from a residential treatment facility receiving less psychotropic medication.

Studies have shown that accurate data collection is essential to evaluate progress towards established reduction criteria (Barnhill, 2006; Pfadt & Wheeler, 2006). Data collection for the purpose of monitoring medication efficacy is also a requirement of State Operated Developmental Centers receiving CMS federal matching funds. Factors that may reduce the accuracy of this information include, but are not limited to, observer and expectancy effects (Rosenthal & Rubin, 1978).

Within the documented parameters of expectancy effects, observer behaviors can change based on expectations of treatment outcomes. This in turn causes the observed to alter their behaviors. The accuracy of recorded events is principally dependent on the observers who make them. As a consequence, expectancy effects may influence decisions related to appropriate pharmacological interventions as put forth by the Centers for Medicare and Medicaid Services (U.S. Department of Health & Human Services, 2004).

Another related phenomenon that may confound data collection accuracy is the placebo effect. According to Ernst (2007), the placebo effect may account for 35% of the total therapeutic effect, such as perceiving a non-existent therapeutic effect following the initiation of a medication. In an earlier study, Breuning, Ferguson, and Cullari (1980) found expectations of deterioration associated with discontinuation of psychotropic

medication for persons with mental retardation. In order to evaluate the effectiveness of psychotropic medication interventions, placebo and double-blind controls were recommended by Baumeister and Sevin (1990) and Sprague and Werry (1971). Reliability, validity, and generalization of data results form the basis for sound medication management. When more objective behavioral measures are used to reduce expectancy effects, researchers have found that single-blind procedures may be sufficient to control observational bias (Towns, Singh, & Beale, 1984). Without such controls, expectancy effects may influence information collected on psychiatric symptoms.

Statement of the Problem

Ethical and practical medication management limits the use of placebo and double-blind controls in clinical settings, such as residential facilities for individuals with mental retardation. There is, however, a need to understand and limit the impact that expectancy effects have on the evaluation of psychotropic medication used for this population. The purpose of the present study was to evaluate both the presence of staff expectations related to psychotropic medication reductions for persons with mental retardation and the impact of these expectations on the variability of recorded behavioral data. The specific focus of this paper was to identify fluctuations that were associated with either observer error or expectancy effects independent of treatment changes.

Background

Baumeister and colleagues (Baumeister & Sevin, 1990; Baumeister et al., 1993) conducted a review of pharmacological interventions for self-injurious behavior, stereotyped behavior, aggression, psychiatric disorders, and hyperactivity. These authors found frequent methodological flaws in the published studies within this area that

included lack of double-blind and placebo controls, lack of random assignment of subjects to treatment conditions, inadequate baseline and reversal phases, and limited use of direct measures suitable to assess behavioral changes. With these concerns, researchers who study prevalence rates of psychotropic medication in persons with mental retardation (Aman & Singh, 1986; Baumeister & Sevin; Baumeister et al.) have consistently documented negative attitudes towards the use of pharmacological interventions.

Potential misuse of psychotropic medication to control aberrant behaviors, such as self-injurious behavior and physical aggression, in persons with mental retardation (Baumeister et al., 1993) is a growing concern which has been documented in findings from Civil Rights of Institutionalized Persons Act (CRIPA) investigations conducted by the Department of Justice (U.S. Department of Justice, 2008a). In a recent study examining prevalence and prescription practices among adults with mental retardation, Holden and Gitlesen (2004) found that 37.4% of the sample examined received at least one psychotropic medication. Further, general practitioners (62.3%) as opposed to psychiatrists provided the majority of prescriptions. While it has been noted that support for pharmacological intervention within this population is inconclusive given the presence of long-term side effects, and misuse of medication (Aman & Singh, 1986), this treatment modality continues to be perceived as a viable option (Unwin & Deb, 2008).

In a study investigating antipsychotic use in Australia, Castle, Morgan and Jablensky (2002) examined 1,126 interviews associated with the Australian Low Prevalence (Psychosis) Study database. The authors found that, even with nearly 80% of persons receiving antipsychotic medication reporting side effects, the majority reported benefits from the medication. Subjects with no insight reported the least degree of

benefit. While this study pertained to the perceived benefits of psychotropic medication for persons diagnosed with psychosis, persons with mental retardation possess poor insight as a function of their cognitive delays.

In another study about perceptions of psychotropic medication use in persons with mental retardation, Christian, Syncerski, Singh, and Poling (1999) surveyed a group of direct service staff working in non-institutional settings. Results indicated that as many as 83.5% of respondents felt drug therapy was acceptable with a high percentage indicating likely use associated with self-injurious behavior (72.9%), delusions/hallucinations (72.8%), and aggression (67%). In a similar study utilizing the same survey to measure caregiver perceptions, Aman, Singh, and White (1987) found that staff perceived aggressive, destructive, and self-injurious behavior as appropriate for use of pharmacological intervention. While less frequently used, caregivers reportedly favored more objective measures. Finally, caregivers felt that they received insufficient training on psychotropic medication.

In a recent survey administered to 108 psychiatrists from the Royal College of Psychiatrists' Learning Disability Faculty in the United Kingdom, Unwin and Deb (2008) found that over one half reported use of medication under the following circumstances: failure of non-drug interventions, risk/evidence of harm/distress to self, and risk/evidence of harm/distress to others or property. Upon examination of the data, antipsychotics were the most frequently reported medication used for both aggression and self-injurious behavior with risperidone being the most common. With the continued use of pharmacological interventions for persons with mental retardation, some have shifted to

identification of the lowest dosage that is effective in the reduction of symptoms (Kalachnik, 1988).

Several studies have focused on reduced medication use in persons with mental retardation. Davidson et al. (1984), in a study targeting use of restrictive procedures, evaluated impact on seclusion, mechanical restraint, and psychotropic medication. Stability in aggression, staff turnover, and use of other restrictive procedures followed a decrease in psychotropic medication use. Researchers have also found sustained reductions over time (Hancock et al., 1991). In a 10-year study of residential intermediate care facilities for individuals with mental retardation, Hancock et al. demonstrated that 73% had antipsychotic medication discontinued after initiation of a multidisciplinary process. This multidisciplinary team included professionals from disciplines such as psychology, nursing, direct support staff, family, and the consumer throughout the treatment and review process.

Researchers have also studied changes in the magnitude of dosage, prevalence of polypharmacy, and off-label use (McDonald, 1998). In a study evaluating the impact of reductions of typical antipsychotics over time, Spreat, Seragin, Behar, and Leiman (1993) investigated a group of individuals residing within a 284-bed ICF/MR facility. Upon review of the descriptive data, 47% of the sample received a lower amount compared with only 27% requiring greater use of the medication. Taken together, these studies suggest the push towards medication reduction within this population is both warranted and achievable.

Agencies serving persons with mental retardation have developed programs designed to improve the quality of services received. Quality improvement initiatives

have included the facilitation of appropriate pharmacological use with persons with mental retardation (Davidson et al., 1984). As part of this approach, Pfadt and Wheeler (2006) suggest data related to more objective and operationally defined target behaviors gathered during both a baseline period and post-treatment are the best practice. However, they further note the limitations associated with review of one-dimensional sources of data (e.g., frequency counts) in determining functional benefits of pharmacological interventions. These researchers introduced the use of a continual quality improvement model along with analysis using statistical process control (SPC). Pfadt and Wheeler found that a multi-method approach to data collection was superior when evaluating the impact of pharmacological interventions for an adult with severe mental retardation.

Bays and King (1988) investigated staff attitudes towards collection of behavioral data for the purpose of evaluating treatment efficacy. The researchers administered a questionnaire designed to measure three areas: “The perceived importance and/or usefulness of information gained from data collection, the practical feasibility of data collection, and professional support aspect of data collection” (p. 20). Staff from 10 schools and one large residential setting participated in the study. The authors were able to obtain 489 questionnaires for analysis. Results indicated that the majority of respondents felt data collection was important and that, while data collection was time consuming, it was believed to be feasible. Further, Christian et al. (1999) found that direct support staff working in a non-institutional setting for persons with mental retardation reported behavioral observations to be the preferred assessment methods in 73.1% of surveys returned. While these studies demonstrate the perceived benefit of

direct observations, a number of limiting factors associated with data accuracy remain. One such area of concern is the experimenter effect.

Experimenter Effect

Rosenthal's (1977) seminal work on experimenter effects documented varying forms of bias that were present in both experimental and clinical settings. Noted within this work were three distinct experimenter effects: unintentional (e.g., impact psychologists have on the results of their research though no impact on subject data); intentional (e.g., fabrication of data or "cheating" related to data recording); and interactional (e.g., operated by affecting the actual response of the subject of the experiment). Unintentional experimenter and expectancy effects may also be present as observer bias (Rosenthal, 1977; Rosenthal, 1980; Rosenthal, 2002).

Unintentional Experimenter Effect. Unintentional experimenter effect may include observer effects when the accuracy of observations comes into question and interpreter effects when different raters interpret observations differently. The author noted interactional effects which could include the impact of: (a) biosocial effects, such as age, sex, and race of the investigator; (b) psychosocial effects, such as the personality of the experimenter; (c) situational effects, such as experimenter experience; (d) modeling effects associated with prior experience of the experimental condition; and finally (e) expectancy effects, when experimenter expectations alter experimenter behaviors, thus impacting the subject behaviors under investigation.

Expectancy effect. Self-fulfilling prophecy is a related form of expectancy effect. Rosenthal (1977) proposed four primary areas of behavioral change associated with expectancy effects: (a) climate (teachers create a warmer socio-emotional climate for

their “special” students [i.e., children that would be perceived by the teacher to be in more favor]), (b) feedback (give favored students more differential feedback), (c) input (teach more volume and more difficult material), and (d) output (provide favored students more opportunities for responding). These four primary areas of behavioral change associated with the self-fulfilling prophecy are associated with expected positive outcomes of a perceived strength previously noted in students.

Rosenthal and Rubin (1978) reviewed 345 studies pertaining to interpersonal expectancy effects and discovered that a significant relationship between experimenter and subject interactions existed. The studies reviewed were broken down into the eight areas of research such as reaction time, inkblot tests, animal learning, laboratory interviews, learning and ability, person perception, and everyday situations. Further, 43 of the 345 studies employed special methods to control for cheating or observer error suggesting that, in addition to expectancy effects, these are practical issues.

One specific form of an expectancy effect typically associated with pharmacological interventions is the placebo effect. The placebo effect influences outcomes when the patient perceives some affect from an administered agent or treatment when there was no clinical basis for it. Ernst (2007) noted that most placebo effects go unnoticed by the clinician, consequently negatively impacting the integrity of the evaluation process. Although few clinicians knowingly prescribe placebo treatments to a patient, given this may involve withholding established interventions, placebo effects account for up to 35% of the total therapeutic effect. The placebo effect is a potential confounder when determining the efficacy of a new pharmacological agent as patients may initially report improvement without concomitant physiological changes. A review

of the extant literature revealed a lack of evidence-based research on the role of experimenter effect (i.e., observer errors and expectancy effect) when data have been collected following a medication reduction.

A review of more recent research indicated that there is a renewed interest in greater control of experimenter effects when evaluating outcomes related to use of pharmacological agents in persons with developmental disabilities (Sandler, 2005). Within the area of methodological standards, Sprague and Werry (1971) noted the following six criteria for the study of pharmacological interventions: (a) placebo control, (b) double-blind, (c) standardized doses, (d) standardized evaluations, (e) appropriate statistical analysis, and (f) random assignment of subjects. According to these authors, single case studies are the most beneficial experimental design. Towns et al. (1984) further explored the differential control of expectancy effects related to single versus double-blind procedures. The authors concluded that, with use of carefully controlled behavior measures, the single-blind procedure was as effective as the double-blind procedure for controlling observer bias.

Rohsenow and Marlatt (1981) investigated other options to the double-blind placebo-controlled design that appear to facilitate the identification and control of expectancy effects. The authors utilized a balanced placebo design to differentiate subject expectancies from the pharmacological action associated with alcohol. The authors noted some methodological flaws with double-blind placebo-controlled designs. These include inability to differentiate pharmacological effects as opposed to expectancy effects (as both may be impacting behavior) and limited credibility assessment of the placebo or actual blindness of the participants or experimenter. The authors describe the balanced

placebo design, which for this study included two variables each manipulated two ways (expect to receive alcohol – yes/no, and receives alcohol – yes/no), or a 2 X 2 design. For these reasons it may not always be appropriate or practical to utilize either placebos or blind raters to control expectancies. Further, the integrity of the blind condition was not clear. Turner, Jensen, Warms, and Cardenas (2002) found that 70% of patients and 73% of nurses were able to correctly identify that the active medication, amitriptyline, was being used. For the placebo group, 55% of patients and 75% of nurses were correct. Further, with the need to provide information on side effects during the acquisition of informed consent, the ability to maintain true blindness to the placebo versus treatment condition is questionable (Brownell & Stunkard, 1982).

When initiating a new medication, the placebo effect can account for as much as 35% of the total therapeutic response (Ernst, 2007). With discontinuation of psychotropic medication, Breuning et al. (1980) found strong expectancies for behavioral deterioration. Specifically, these authors found that 70 of 74 staff questioned believed that individuals with mental retardation would have an increase in inappropriate behaviors following a medication discontinuation. From a review of the extant literature, it was unclear to what extent expectancies related to decreased psychotropic medication were present when carefully controlled behavioral observations were used. This study sought to measure such expectancies and further explore the impact they have on the integrity of recorded behavioral data following medication reductions.

Research Questions

The purpose of this study was to evaluate staff expectancies regarding medication reductions for individuals diagnosed with mental retardation living in a state operated

residential facility. Additionally, the impact that preexisting knowledge of psychotropic medication reductions have on data recording behavior were examined in order to determine whether a double-blind approach (vs. single-blind procedure) was necessary to control observer bias. This study investigated the following research questions:

1. What are the expectancies of direct support staff regarding behavioral changes concurrent with psychotropic medication reductions in a residential facility for persons with mental retardation?

H₀: Direct support staff will not disproportionately expect a worsening in an individual's behaviors or psychiatric symptoms following a psychotropic medication reduction.

2. What relationship exists between reported expectancies and data recording behavior if expectancies vary with psychotropic medication reductions?

H₀: Following the medication reduction, there will be no difference in data recorded between staff who expect deterioration and those who do not.

3. What effect does informing direct care staff of planned psychotropic medication changes have on data recording practice in a residential facility for persons with mental retardation?

H₀: Staff who are informed of upcoming medication reductions will not record post-reduction data with greater frequency than those who have not been informed.

Description of Terms

Aberrant behavior. Aberrant behaviors deviate from those considered normal. This would include behaviors considered maladaptive or problematic such as physical aggression or self-injurious behavior.

Atypical antipsychotic medication. A newer class of antipsychotic medication impacting serotonin and dopaminergic receptors in a different manner, resulting in lowered risk of side effects associated with typical antipsychotic medications. This group of medication would include risperidone, olanzapine, aripiprazole, ziprazidone, and quetiapine.

Biosocial effects. Interrelated biological effects such as age, sex, and race, and their influence on human perception, emotion, or behavior.

Expectancy effect. Some expectation of research results, which in turn lead investigators to unintentionally alter their behavior towards their subject.

Experimenter effects. Interaction between experimenter and subject.

Intentional experimenter effects. A form of experimenter effect in which the experimenter knowingly alters data being recorded on behavior being observed (e.g., cheating).

Interactional experimenter effects. A form of unintentional experimenter effect in which changes of an experimenter's behavior impacts the behavior of the person being studied.

Mental Retardation. A condition in which a person has an assessed intelligence score (i.e., IQ) below 70, sub-average adaptive behaviors such as daily living skills,

social skills, and communication abilities, with a noted onset prior to the age of 18. This condition has also been referred to as an intellectual disability.

Minimal effective dose. The lowest dose associated with the noted clinical benefit with the lowest risk of side effects. This has also been referred to as the lowest optimal dose.

Off label use. Use of a medication for a purpose not approved by the Food and Drug Administration (FDA).

Participant observer. Observers that are part of the environment and not introduced as part of the experiment.

Pharmacological interventions. Use of medication to treat psychiatric and behavioral issues.

Placebo effect. Perceived change in condition associated with the application of an inert or inactive medication.

Polypharmacy. Prescription of more than one medication.

Psychosocial effects. Individual characteristics such as personality variables that may impact interaction between two or more people.

Psychotropic medication. Medication that has the intended purpose of treating psychiatric or behavioral disturbance.

Reinforcement-based procedures. Procedures that lead behavior to occur with increased frequency and predictability.

Restrictive procedures. Procedures associated with a restriction of personal rights as a component of the intervention (e.g., restraints, property removal, seclusion).

Seclusion. Removal of an individual from the environment due to an elevation in agitation or behavior.

Self-fulfilling prophecy. A form of expectancy effect in which the perceived or hypothesized outcome influences the true outcome.

Self-injurious behavior. Behavior that is associated with risk of injury to self (e.g., head banging).

State Operated Developmental Center. Residential facilities owned and operated by a particular state. These centers provide services to persons with developmental disabilities typically with challenging behavioral and medical conditions.

Stereotyped behavior. Repetitive and non-meaningful behavior such as body rocking.

Typical antipsychotic medication. An older class of medication initially used to address psychotic symptoms which include thioridazine, chlorpromazine, haloperidol, and others.

Unintentional experimenter effects. A form of experimenter effect in which the experimenter does not knowingly alter his or her behavior.

Significance of the Study

This study was significant because information related to expectancy may result in increased treatment integrity associated with the appropriate and ethical use of psychotropic medication for persons with mental retardation. Identification of observer bias that results in recording of inaccurate information related to treatment changes may be associated with either continued use or increased dosage of medication that is not

effective, increasing risk of side effects. Resulting information will also provide further insight into the practice of informing observers of upcoming treatment changes.

Fluctuation in the data may be associated with observer bias as opposed to true change in display of measured behavioral and psychiatric symptoms. This may appear either in recording of elevated rates of behaviors or missed recording opportunities, which would result in a deceleration of data recorded. Rosenthal (1977, 1980) has termed this phenomenon observer effects. Intentional experimenter effects may take place when direct care staff artificially inflates the recorded data as a means to support their presumption. For example, this presumption may be that the person needed the medication, and/or was used to influence others to reinstate a higher dosage of the psychotropic medication. Finally, as participants, the direct care staff may also alter their behavior and induce an actual change in the recorded behavior.

Process to Accomplish

This study was carried out in two phases with Phase I focusing on identification of expectancies that direct support staff have about medication reductions to determine if differences existed (Question/H₀ 1), and then through the examination of data recording behavior to note inconsistencies in practice based on expectations of deterioration (Question/H₀ 2). Within Phase II, the impact that preexisting knowledge of a planned medication reduction had on data recording practice was explored to determine if this knowledge was associated with a relative increase in post reduction data (Question/H₀ 3). Medication reductions occurred within a population of individuals residing at one of nine Illinois State Operated Developmental Centers (SODC). All were adult residents presently diagnosed with mental retardation. Of the population, approximately 39%

receive one or more psychotropic medication. For this study, all information was gathered from direct support staff, consisting of those staff over a 24 hour period that are primarily responsible for both the care of the individuals and the data collection of any noted problem behaviors or psychiatric symptoms.

Phase I

Selection of participants within Phase I occurred through convenience sampling. For all individuals scheduled to have a psychotropic medication change within the first six months of the 2009 calendar year, direct support staff were provided a memo stipulating the date that the medication change was to occur. To assess staff expectancies regarding the psychotropic medication change, the following multiple-choice question was inserted within the memo (Appendix A):

Following this medication reduction, I believe the person will:

1. *Get better.*
2. *Have no change.*
3. *Get worse.*

In Phase I, both descriptive research and nonparametric statistics were utilized to explore staff expectancies. Examination of variables included age, diagnosed psychiatric condition, medication, and duration of services received at the center occurred. This evaluation included use of chi-square (χ^2) goodness-of-fit tests designed to compare observed frequencies of staff expectations with expected probabilities.

For all individuals included in the study, frequency or interval data were recorded for specific psychiatric symptoms, and also for behaviors being targeted for reduction through other means, for example, applied behavior analysis with structured data

collection forms and procedures (Appendix B). Specifically, data for 30 days prior to the medication change were compared with data for the 30 days following the change in dosage. As most cases included monitoring of multiple behaviors, the behavior with the highest rate prior to any changes in medication dosage was used.

To answer the second study question, comparison of pre-reduction and post-reduction data was conducted by analyzing data reported by individual staff. This allowed for analysis of behavioral change across expectancy conditions. Determination of significant differences occurred through use of an analysis of variance (ANOVA), with a post hoc comparison of means.

Phase II

To answer question three, Phase II was a quantitative analysis of variability in data related to staff reports of psychiatric issues. Consistent with an experimental design (Gay, Mills, & Airasian, 2006), this study utilized a random assignment of subjects to different conditions. With two independent variables each being manipulated two ways (i.e., two informed conditions, two medication change conditions), a 2 X 2 between-subjects factorial design was used. This allowed for analysis of both the main effects and interaction between the two variables. Application of this design determined the impact of medication changes under four distinct conditions.

Selection of the participants for this part of the study was done in the following way:

1. All individuals receiving a reduction in psychotropic medication during the first six months of the 2000 calendar year were identified. This year was selected, because it was the year prior to initiation of a policy of informing direct support

staff of medication changes. This would then closely resemble a single-blind methodology because the staff were unaware that the medication had been reduced. From this group, random selection of 60 cases occurred to form Group 1.

2. Group 2 was comprised of 60 randomly selected individuals not scheduled to receive a psychotropic medication reduction during the second six months of the 2000 calendar year.
3. All individuals receiving a reduction in psychotropic medication in the first half of the 2009 calendar year were identified in Phase I. Of these, 60 cases were randomly selected to be included in Group 3.
4. All individuals not receiving a psychotropic medication reduction during the second six months of the 2008 calendar year were identified. Group 4 was comprised of 60 randomly selected cases from these individuals.

For groups 1 and 3, individuals were excluded if the medication reduction resulted in discontinuation of a psychotropic medication because this would be a replication of the study conducted by Breuning et al. (1980). Individuals were also excluded if there was a change in another psychotropic medication during the period of 30 days before and after the reduction under investigation. This was required to isolate staff expectancies to the specific medication reduced as part of this study. As previously noted, facility staff recorded frequency or interval data for specific psychiatric symptoms and also for target behaviors. For groups 1 and 3, comparisons were made between the data for 30 days prior to the medication with data for the 30 days following the change in dosage. Because most cases included monitoring of multiple behaviors, the behavior with the highest rate prior to any changes in medication dosage was used. This allowed for a

percent change to be calculated providing an overall indication of change. For groups two and four, the date used was random to allow for designation of a time period for the 30 days before and after this point.

Analyses were conducted on age, gender, ethnicity, level of functioning, class of medication, number of medications, and diagnostic condition to determine any variability. Chi-square tests were used on demographic information to identify any significant difference across these variables. To answer the research questions, the dependent variable was analyzed using the ANOVA procedure. This allowed for testing the main effects of each independent variable along with the interaction between them through use of post hoc analysis.

The viability of this study was supported by direct access to over 10 years of objective data related to both psychiatric symptoms and problematic behaviors at a large state operated residential facility serving persons with mental retardation, along with information related to medication changes during that same time period. Further, through participation in policy development within this setting, procedural modifications related to staff knowledge of such reductions was also feasible. This study was consistent with ethical standards related to team participation through use of archival data.

While consent was not required given the archival nature of the data analyzed, Center approvals included the Center Research Committee, Human Rights Committee, and approval by the Center Director. Following approval through Olivet Nazarene University's Institutional Review Board (IRB), this study had to be further reviewed by the State of Illinois' Combined Clinical Review Team (CCRT), the Deputy Director and

Director for the Division of Developmental Disabilities, and the Secretary of the
Department of Human Services.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

Researchers (Aman & Singh, 1986; Holden & Gitlesen, 2004) and agencies providing regulatory oversight for persons with mental retardation (U. S. Department of Health and Human Services, 2004) have noted excessive psychotropic drug use. While intended for control of psychiatric conditions, persons with mental retardation frequently receive these drugs to suppress disruptive and dangerous behaviors (Baumeister & Sevin, 1990; Baumeister et al., 1993, Madrid, State, & King, 2000). This has been associated in the past with suppression of adaptive behaviors (Baumeister et al.), increased risk of side effects (Kalachnik, 1988), and risks associated with losing federal matching dollars.

State and federal guidelines requiring evaluation of medication effects and consideration of medication reductions are now in place (U. S. Department of Health and Human Services, 2004). Further, the U. S. Department of Justice has followed up on complaints and found rights restrictions to be unconstitutional with the lack of noted mental health conditions (U. S. Department of Justice, 2006a), resistance to drug reductions (U. S. Department of Justice, 2008b), and overall ignorance of efficacy data. Across the United States, state operated developmental centers have instituted more stringent policies related to medication use. These policies have resulted in a reduction of

not only psychotropic medication use (Nøttestad & Linaker, 2003; Valdovinos et al., 2003), but other restrictive procedures as well (McDonald, 1998). Use of outcome measures has increased, which has facilitated the review of drug effectiveness and side effects.

While more ambiguous measures pose an increased risk of experimenter effects (Harris & Lahey, 1982), even behavioral observations carry limitations associated with reliability and validity of data collected (Marsh & Hanlon, 2007). The primary threats to the integrity of the data used in clinical trials are associated with expectancies. Expectancies can lead to interactional effects between observer and subject (Rosenthal, 1977) and also non-interactional effects through what appears to be errors in the recording or interpretation of observed information. Within the field of pharmacology, expectancy and observer effects have been associated with placebos and the placebo effect (Ernst, 2007; Sandler & Bodfish, 2000).

In attempts to control for bias associated with expectancies, and improve the interpretation of medication trials, researchers have suggested use of training for direct observation, single- and double-blind placebo controlled studies, and use of videotaped sources of information (Poling, Gadow, & Cleary, 1991). While these controls are becoming ever more necessary given the increase in direct to consumer advertising (DTCA), many strategies are still not utilized in settings providing services to persons with mental retardation.

Psychotropic Medication Use

Prevalence

For persons with mental retardation, use of psychotropic medication has been reported at higher rates than for persons who are not developmentally disabled (Aman & Singh, 1986; Holden & Gitlesen, 2004). This has been particularly the case within intermediate residential care facilities (Hancock et al., 1991; Nøttestad & Linaker, 2003; Valdovinos et al., 2003). Further, the U. S. Department of Justice (2008b) has noted that, “Traditionally, persons with developmental disabilities, who also have a dual diagnosis of mental illness, have been under-diagnosed and over-medicated, especially if they lived in an institutional setting” (p. 22). Valdovinos et al. examined the prevalence of psychotropic medication use from 1970 to 2000. They found that overall 56.5% of persons residing in residential centers receive psychotropic medication. While this amount is slightly less than that reported in the 1970s, it is still substantially higher than in community settings (30.2%). In another study examining prevalence rates within community settings in the state of Hawaii, Bisconer, Sine, and Zhang (1996) evaluated 2240 clients receiving case management services from the Community Services for the Developmentally Disabled Branch (CSDDDB) of the Hawaii State Department of Health, Developmental Disabilities Division (DOH-DDD). Of the 1,645 that were 18 years or older, 21.4% (n = 352) were on psychotropic medication. International studies also document the high prevalence estimates.

Through an examination of 300 persons with mental retardation living within the county of Hedmark, Norway, Holden and Gitlesen (2004) found 37.4% (n = 110) of subjects were prescribed psychotropic medication. Of these, the majority were receiving

one medication (25.9%) with traditional antipsychotics (e.g., thioridazine, chlorpromazine) being the most frequently used class (19.4%). The authors found that those receiving psychotropic medication tended on average to be older (mean 51.1 compared to 42.1) with aggression being the primary indicator for 59 out of the 110 cases. Within a long-term care facility in Italy, Ruggerini, Guaraldi, Russo, Neviani, and Castagnini (2004) administered a survey on psychotropic medication use from 1994 through 1999. These authors found that there was not a significant reduction of psychotropic medication use during this period of time. This finding was supported by the evidence that 88.5% received psychotropic drugs in 1994 and 85% received these medications in 1999. The authors reported a significant reduction in number, dosage and polypharmacy for those receiving antipsychotic medication in 1994. Caution is advised when comparing the overall prevalence rates of this study with other similar studies because these authors included atypical psychiatric usage of an anticonvulsant medication.

Studies have examined the shift in both prevalence and prescription patterns of psychotropic medication over time. As an examination of the impact of deinstitutionalization, Nøttestad and Linaker (2003) examined use of psychotropic medication for 109 individuals before 1987 and then after 1995. Of those individuals studied, 54 (50%) were receiving at least one psychotropic drug prior to 1987. While they did not find a significant reduction in overall prevalence of psychotropic medication use, the authors were able to note a significant reduction in the average daily prescribed dosage. This finding is consistent with that of Ruggerini et al. (2004) noted previously. Valdovinos et al. (2003) found a significant decrease in the prevalence of psychotropic

medication use from 1970 to 2000 as a result of investigating a larger number of persons with mental retardation and through use of regression analysis to analyze the trends over the 30-year period. Broken down by decade, the authors found a mean of 47.1% psychotropic medication use from 1970 to 1979, 29.5% use from 1980 to 1989, and finally 30.0% psychotropic medication use from 1990 to 2000. The most significant finding was the reduction of psychotropic medication usage from the 70s to the 80s when deinstitutionalization was a focus of mental health care for persons that are developmentally disabled.

When examining residential settings alone, the results were more consistent with those noted by Nøttestad & Linaker. This was evidenced through an overall reduction of psychotropic medication use among individuals residing in residential facilities from 60.0% from the 1970s to 56.5% by the year 2000. Low rates of psychotropic medication noted in the 1980s (i.e., 47% in residential settings) contributed to this significant finding. The continued high rates of psychotropic medication may reflect changing attitudes about the usefulness of this treatment option and also increasing attention drawn to these drugs through elevated spending by pharmaceutical companies.

The state and federal government have increased spending on psychotropic medication over the past 15 years with drugs playing a more central role in mental health treatment (Frank, Conti, & Goldman, 2005). The total number of medications has also increased with two new classes of psychotropics, five new atypical antipsychotics, and nine new antidepressants. In 1996, 77% of cases treated for mental health issues included use of psychotropic medication. Since this time, the amount of money spent on this group of medication increased from \$2.8 billion to almost \$18 billion in 2001. Increased

insurance coverage and direct to consumer advertising have contributed to the increase in medication use. The authors report as much as \$193 million was spent on DTCA in 2004 for antidepressant medication alone.

For persons with mental retardation, the indication for use of psychotropic medication is not necessarily presence of a psychiatric condition. In fact, studies have found that between 23.7% and 38.0% of persons who were receiving psychotropic medication actually have a psychiatric diagnosis noted within their record (Bisconer et al., 1996, Holden & Gitlesen, 2004). A much stronger indication was the presence of disruptive or dangerous behavior such as physical aggression and self-injurious behavior (Baumeister & Sevin, 1990; Baumeister et al., 1993; Bisconer et al.; Holden & Gitlesen; King, 2002; Madrid et al., 2000). Other behavioral indications include impulsivity and hyperactivity (Baumeister & Sevin; Madrid, et al.), and stereotypic behaviors (Baumeister et al.). The lack of a psychiatric diagnosis and psychotropic medication use for behavioral suppression are two criticisms related to psychotropic medication use within persons with mental retardation.

Regulations and Impact

With the documented overuse of psychotropic medication in persons with mental retardation (Aman & Singh, 1986; Holden & Gitlesen, 2004) and complications such as suppression of adaptive skills and lack of appropriate monitoring noted in the research (Baumeister & Sevin, 1990; Bisconer et al., 1996; Singh, Matson, Cooper, Dixon, & Sturme, 2005), lawsuits and regulatory acts have become commonplace. Wyatt versus Stickney (1972) was a springboard for further lawsuits related to client care and excessive use of restrictive procedures. The provisions set forth by this suit were that,

(a) chemical restraints only be used when ordered by a physician, (b) medication not be used as punishment, substitutes for habilitation, or staff convenience, (c) appropriately trained staff administer medication and that training be received on a regular basis by staff, and (d) that monthly reviews of medication status be conducted. Further, patients have the right to be free from excessive or unnecessary medication (Prigmore & Davis, 1973).

The ruling in Wyatt versus Stickney (1972) also mandated that people be allowed to live in the least restrictive setting available. U.S. District Judge Frank Johnson expressed concerns about the substandard conditions and inadequate care within Bryce State Hospital and Partlow State School and Hospital in Alabama. During the 1970s, professionals worked together to establish care standards for this population including the appropriate use of psychotropic medication (Valdovinos et al., 2003). At the federal level, congress enacted the Patient Freedom from Restraint Act (2000) to protect the rights of individuals with developmental disabilities. The purpose of this act was to clarify the responsibility of state and federal governments to restrict transfer of public funds to residential centers that misused suppressive medications. This included use of chemical restraints on individuals or use of psychotropic drugs as punishment, a substitute for habilitation programs, or in quantities that interfere with services such as treatment or habilitation.

In order to ensure following of federal statutes, the U. S. Department of Health and Human Services (2004) has developed a state operations manual and guidance to surveyors who evaluate intermediate care facilities for persons with mental retardation (ICF/MR). This document provides support and guidance in a number of areas related to

individualized treatment services. Wyatt versus Stickney (1972) and the Patient Freedom from Restraint Act (2000) are two fundamental areas of review with the interdisciplinary team and periodic psychotropic medication reductions being specific areas of focus.

Interdisciplinary Team. As stated by the U. S. Department of Health and Human Services (2004) Guidelines §483.450(e)(2):

Although only a physician can prescribe medication, the decision to use medication for control of behavior must be based on input from other team members. The interdisciplinary team involvement in this decision-making process is inextricably linked to an obligation to develop and implement effective non-drug interventions that address the targeted behavior. This obligation requires constant monitoring of the non-drug interventions to determine their efficacy, and to determine whether the judicious use of drug therapy may at times be appropriate. (p. 22)

Integration of team members from varying disciplines improves total care for the individual, according to Natvig (1991). The typical team at a psychotropic medication review includes a psychologist, pharmacist, physician, nurse, and a qualified mental retardation professional. The team uses objective data gathered from their discipline to help guide prescribing practice. To work effectively towards a common goal, Natvig noted that:

Effective team members: desire to work as a member of a team, belief that better quality care can result from coordinated team efforts rather than individual efforts, openness and flexibility toward different approaches to care, recognition of the need to redistribute and reallocate power through group decision-making. (p. 5)

The interdisciplinary team (IDT) process and collaborative decision making is not currently part of the educational training of most health care professionals (Natvig, 1993). Natvig noted that the team concept is misunderstood and has been a point of concern for a number of physicians who may perceive the IDT as a means to usurp the physicians' authority. While the federal government requires it, Bisconer et al. (1996) found that few community respondents (9% of the 97 evaluated) actually participated in IDT medication reviews. Natvig noted that this should occur at least every three months.

Medication Reductions. According to the U.S. Department of Health and Human Services (2004), Facility Practices §483.450(e)(4)(ii): "A gradual withdrawal occurs annually or sooner if warranted by progress to the criteria for reduction established in the individual program plan, by the particular drug which is being used, or the specific condition for which the drug is being prescribed" (p. 25). Also as noted within the context of Wyatt versus Stickney (1972), patients have the right to be free from excessive medication (Prigmore & Davis, 1973). The U. S. Department of Justice conducts CRIPA investigations within residential facilities when concerns about civil rights violations for residents are present. Specific patterns of misuse arise after a review of investigations from the past two years. Objective and reliable data are frequently not available (U. S. Department of Justice, 2006a; U. S. Department of Justice, 2006b; U. S. Department of Justice, 2008b). Use of medication without identification of a proper and accurate diagnostic condition was also prevalent. At Lanterman Developmental Center in Pomona, California, as many as 20% of residents receiving psychotropic medication did not have mental illness noted (U. S. Department of Justice, 2006a). Residents at Beatrice State Developmental Center in Beatrice, Nebraska were exposed to unnecessarily high

psychotropic medication dosages and reductions were not occurring when clinically indicated (U. S. Department of Justice, 2008b). Federal matching dollars are guaranteed through incorporating government regulation into facility practice.

Evidence of this standard in practice comes from studies noting reductions in psychotropic medication from the date of Wyatt versus Stickney (1972) forward. In one such study, Valdovinos et al. (2003) noted the change in psychotropic medication use from 1970 to 2000 by decade. While rates of psychotropic medication usage appear consistent, the use of a regression analysis to analyze trends resulted in identification of a significant reduction in medication use from 1970 to 2000 with a decline from 47.1% to 30.0%. Other studies have utilized 10-year periods for review, noting the sustained medication reductions that have taken place (Janowsky, Barnhill, Khalid, & Davis, 2006; Hancock et al., 1991). Janowsky et al. conducted retrospective record reviews over a 10-year period for 151 persons with mental retardation. The authors determined that in 55% of cases their antipsychotic medication was successfully discontinued. After a period of 10 years, 66.3% of these individuals were able to remain off of antipsychotic medication. Even more significant, Hancock et al. were able to show that 73% of cases previously medicated with antipsychotic drugs were able to have sustained discontinuations over a 10-year period. The authors obtained these results with 139 individuals residing in an ICF/MR residential setting. They attributed this change in medication use to the IDT process.

Researchers found similar sustained reductions with residential children diagnosed with emotional disturbance. Upon examination of the 141 complete records of children admitted to a residential facility between 1992 and discharged before 2002,

Connor and McLaughlin (2005) identified 112 children who received psychotropic medication at the time of admission. Of these children, 66.1% ($n = 76$) were discharged on less medication without any deleterious effects.

State and federal regulations have also transitioned into facility practice (Davidson et al., 1984; McDonald, 1998). Administrative directives were implemented at the Coldwater Regional Center for Developmental Disabilities in an attempt to reduce the use of restraint and psychotropic medication. Davidson et al. collected data on hours of seclusion and restraint and also psychotropic medication use for over 883 individuals in a study on the outcomes of this regulative change. The authors found reductions in all restrictive treatment procedures after a policy revision directing such changes was established. Of particular note was a reduction from 36% to 20% in psychotropic medication use without an increase in behaviors such as physical aggression or use of other restrictive approaches.

In another study examining the impact of policy changes on psychotropic medication prevalence, McDonald (1998) examined 600 individuals residing in a large residential facility in Mississippi. After implementation of management procedures that included, (a) identification of target behaviors, (b) collection of baseline data, (c) descriptions of the behavior intervention program, (d) identification of medication, (e) description of side effects, (f) use of clear behavioral and diagnostic criteria for medication discontinuation, which is also objective and in measurable terms, and (g) inclusion of timelines, McDonald was able to record a reduction from 83.4% medication use to 32.1%. These reductions primarily occurred within those treated individuals who did not have a diagnosed psychiatric condition. Further, there was a 95% reduction in the

use of multiple medications or polypharmacy. Other researchers (e.g., Fielding, Murphy, Reagan, & Peterson, 1980; Kalachnik, 1988) have stressed the need to develop policies related to medication reductions emphasizing use of the minimal dosage necessary to obtain clinical benefits.

Fielding et al. (1980) identified individuals who could have their psychotropic medication discontinued or at least reduced as part of an overall study to reduce medication usage for all individuals with mental retardation. Of the initial 192 subjects, 109 were able to have their medication discontinued. The remaining 83 residents were included in a program to identify the lowest amount of medication that could still produce the desired clinical benefit. An additional nine residents were available for the second stage of this study. Sixty-eight of the remaining 92 obtained at least one reduction. Of these, all but eight were able to remain on a lower dose. Within a similar study conducted by Spreat et al. (1993), a sustained 47% reduction was able to be achieved after a shift in regulations pushing annual reductions in a 284-bed ICF/MR facility. With the directive provided by the U.S. Department of Health and Human Services (2004) to withdraw psychotropic medication gradually, researchers have examined approaches to determine the minimal effective dose (Kalachnik, 1988).

Swanson et al. (1996) evaluated 267 residents receiving antipsychotic medication who were residing at Lanterman Developmental Center in Pomona, CA. The intent of the study was to evaluate the longitudinal approach to establishment of a minimal effective dose program through use of systematic trials on successive reductions of their clinical doses. During their initial report on 40 cases, all participants received a lower dosage with an average dose of 226 mg compared with a dose of 351 mg for those yet to have

their minimal effective dose program initiated. Further, the authors noted that the presence of anticonvulsants during reductions of antipsychotic medication reduced the potential for development of withdrawal tardive dyskinesia.

Some researchers have argued that control over medication use with persons with mental retardation has become too conservative. Sovner (1988) proposed five myths about psychotropic drug therapy with persons with mental retardation. Listed as Myth #4, “A drug withdrawal program should always be built into any psychotropic drug therapy regimen” (p. 31). He further stated that there are some conditions in which one would continue a psychotropic medication indefinitely. When evaluating the minimal effective dose approach, researchers would argue for successful reductions based on objective behavioral criteria and not necessarily discontinuation, unless no exacerbation occurs during this process (Fielding et al., 1980; Swanson et al., 1996).

Evaluation of Medication Effects

According to the U.S. Department of Health and Human Services (2004), §483.440(c)(5)(iv) the type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives include the following guidelines:

The facility must determine the type of data necessary to judge an individual’s progress on an objective, and describe that data collection method in the written training program. The facility determines what data to collect, but the system chosen must yield accurate measurement of the criteria stated in the individual’s IPP objectives. For example, if the criterion in the individual’s IPP objective specified some behavior to be measured by “accuracy,” or “successes out of

opportunities,” then it would not be acceptable for the prescribed data collection method to record “level of prompt.” (p. 14)

Pfadt and Wheeler (2006) reported that collection of systematic data has been lacking in clinical practice despite its indication as a necessary component for the proper evaluation of pharmacological interventions (Kalachnik, 1988; Madrid et al., 2000). In a review of psychotropic medication use in the Hawaiian community, Bisconer et al. (1996) found that only 17% of clients reviewed had behaviors measured. Holden and Gitlesen (2004) had a similar finding noted in one Norwegian county. Among 110 participants receiving psychotropic medication, only 15.5% had data recorded to evaluate effects on symptoms and behaviors of at least one medication. Interestingly, when measuring attitudes about data collection, staff reported that this was important and feasible (Bays & King, 1988; Christian et al., 1999). Breuning and Ackles (1985) noted that, while direct behavioral observation is optimal, many trials do not use this method due to the cost and difficulty gathering it in the natural environment. Instead, many still rely on other measures such as rating scales, self-reports, global impressions, measures of learning and performance, standardized tests, and automated devices. While global impressions are the most used measure of change, they do not capture day-to-day variability, are too general, and have poor reliability.

Even when available, collection of objective behavioral data does not guarantee data use in making decisions related to psychotropic medication changes. Singh and Winton (1984) evaluated the impact of thioridazine, chlorpromazine, carbamazepine, and an overcorrection procedure on the frequency of self-injurious behavior displayed by a 15-year-old adolescent. Within this study, the authors tried different dosages of the

medication with the treating physician and nurses responsible for making changes as needed. Upon examination of the prescribing pattern, it did not appear objective data were used to make medication change decisions. One way to make objective behavioral data more functional is to integrate them with other sources and provide within a graph for ease of review (Barnhill, 2006; Pfadt & Wheeler, 2006). Researchers must account for reliability and validity, despite the sense of control that objective behavioral data provide.

Studies have examined reliability, and, in particular, inter-observer agreement in the context of efficacy studies for quite some time (Jacob, Tennenbaum, & Krahn, 1987; Repp, Neiminen, Olinger, & Busca, 1988; Sprague & Werry, 1971). While inter-observer agreement is typically the most referenced form of reliability, Jacob et al. noted others that include percentage agreement (used in inter-observer reliability), Kappa, which takes into account chance, and the correlation method that is used to determine how much of the variance between two “things” is accounted for. Less well understood, and possibly of greater concern when evaluating the impact of treatment, is accuracy. Validity in data collection pertains to the collection of accurate information. Repp et al. have identified seven factors that may impact accuracy. These include reactivity or change in the behavior due to being observed, observer drift, which is a shift in response definition over time that can lead to inconsistent recording, errors associated with recording procedures, the location of the observation and monitoring during data recording, observer expectancy and feedback may produce intentional or unintentional bias in recording, and the complexity of the behavior and/or setting.

Reactivity occurs when people change their behavior in response to the observation (Jacob et al., 1987; Harris & Lahey, 1982). Those observed can form their

own beliefs about why they are being observed. Researchers have measured reactivity by assessing behavior over time. The response of this phenomenon is a change in behavior (Jacob et al.; Spano, 2005). In a study on observer bias, Spano determined that reactivity during police observation changes with length of exposure. One strategy used to try and reduce reactivity is use of participant observers who are already in the person's environment. While this should theoretically reduce reactivity, Hay, Nelson, and Hay (1980) found this is not necessarily the case. In a study examining the impact of observations on reactivity among eight teachers and 32 male elementary students, the authors found that teachers provided more prompts to students they were observing; thus, impacting their behavior.

Steps that can be taken to increase accuracy of data being recorded include having well trained observers, use of uncomplicated codes, use of both male and female observers, having observers naïve to the experimental hypotheses, avoiding contact between the observers, use of unobtrusive observers, conducting checks of accuracy against criteria and use of permanent products such as video when possible (Repp et al., 1988). Reid (1982) has also noted that observer training should include a manual, observation forms and devices, and use of analogue coding such as films or videotapes when available. Further, feedback provided during training allows observers to improve.

To determine whether a prescribed psychotropic medication is effective in addressing a behavioral or psychiatric condition, Poling et al. (1991) proposed the following components:

- (a) Medication must be administered according to the treatment plan, (b) drug effects must be adequately measured, (c) data analysis must be adequate to detect

clinically important changes in behavior, and (d) conditions must be arranged so that observed changes in behavior can be attributed with confidence to the drug.

(p. 23)

Further, measures should be reliable, valid, and sensitive enough to identify changes in the behaviors and symptoms. Poling et al. noted that, while self-reports and global clinical impressions are frequently used, objective direct observation really should be considered. The result would be objective, clear, and complete behavioral definitions.

While collection of data is necessary based on both federal and state regulations and also clinical consensus, this is not sufficient for determining the efficacy of any particular medication prescribed (Breuning & Ackles, 1985; Poling et al., 1991). Cited by many as the standard of practice, Sprague and Werry (1971) noted the following six criteria for the study of pharmacological interventions: (a) placebo control, (b) double-blind, (c) standardized doses, (d) standardized evaluations, (e) appropriate statistical analysis, and (f) random assignment of subjects. Research has established a void of controlled research on the effects of psychotropic medication in this population (Baumeister & Sevin, 1990; Poling et al.; Singh et al., 2005). Poling et al. further recommended use of an A-B-A single subject design, though they noted the potential ethical issues involved with discontinuing a medication that has a perceived benefit. With use of only an A-B design with comparison to baseline rates prior to initiation of a medication, one is never confident that other variables did not contribute to the change in behavior if one is noted. They further stated that a double-blind and placebo controlled design is really the only way to truly be confident in the results.

Clinical Practice

While there is a high prevalence of psychotropic medication use for suppression of disruptive and dangerous behaviors displayed by persons with mental retardation, there is limited support for this practice. A number of authors believe this marginal support is associated with methodological flaws noted in pharmacological studies (Baumeister & Sevin, 1990). After a very thorough review of the literature, Baumeister and colleagues (Baumeister & Sevin; Baumeister et al., 1993) noted the limited use of double-blind and placebo controls, random assignment for between-group designs, adequate baseline and reversal phases for single-subject designs, and use of direct observations when evaluating efficacy of the treatment condition. Consistent with the limited use of double-blind and placebo controls, most medication efficacy studies within this population are open-label and do not provide the controls necessary to rule out other variables that may have contributed to any noted change in data being gathered (Madrid et al., 2000). Madrid et al. recommended a thorough diagnostic evaluation with use of behavioral rating scales, identification and careful assessment of behavioral response, and systematic changes to medication as steps to increase the integrity of study designs when evaluating psychotropic medication use.

In a recent study designed to determine the efficacy of antipsychotic medication for controlling aggression in adults with intellectual disabilities, Tyrer et al. (2008) examined 80 patients living in one of 10 centers in England and Australia. This study incorporated a placebo-controlled design comparing effects of risperidone and haloperidol. The authors found that aggression decreased within four weeks in both the medication and placebo groups. Of interest was that the placebo group had the greatest

change from pre-treatment rates. While methodological flaws have limited generalizability of some findings and studies have not been very supportive of this treatment option for persons with mental retardation, not all studies have had negative findings.

Within a study designed to examine the benefits of risperidone for treatment of psychopathology and challenging behaviors, Singh et al. (2005) completed a comprehensive literature review on studies related to risperidone use. Based on their criteria used, the authors found 47 experimental studies conducted with persons primarily diagnosed with mental retardation. Of these, 19 met the initial methodological criteria, and finally, only seven employed use of placebo and double-blind procedures. Of these, only six met all methodological criteria specified for this review. Of these six, results appeared to support use of risperidone as a treatment option for individuals with mental retardation who display dangerous or disruptive behaviors. Common side effects noted in this review included weight gain and sedation. The studies reviewed tended to rely more on global assessment measures to evaluate medication effects. As with this study, research notes clear improvement in adaptive behavior following discontinuation of antipsychotic medication (Smith et al., 2002). Smith et al. were unable to find significant improvement in a study examining the impact that reductions and discontinuation of antipsychotic medication have on measures of adaptive behavior and observations of responsiveness to staff interactions. While not well supported when psychotropic medications are appropriately used, Sovner (1988) reported that many continue to have the belief that, “psychotropic drug therapy always decreases cognitive functioning and prosocial behavior” (p. 31).

In an earlier study, Singh and Winton (1984) had mixed results when comparing use of psychotropic medication in the reduction of self-injurious behavior displayed by a 15-year-old adolescent diagnosed with profound mental retardation. These authors examined daily rates of self-injurious behavior during the administration of thioridazine, carbamazepine, chlorpromazine, and an overcorrection behavioral strategy alone and then carbamazepine in combination with the overcorrection. Results indicated that thioridazine at 300 mg a day was the only medication regimen to reduce self-injurious behavior. Further, the problem behavior decreased the most with implementation of the behavioral strategy alone. Of particular interest related to this particular study was the lack of reference to objective data used when physicians and nurses were making medication change decisions.

This diagnostic uncertainty and use for behavioral suppression are two criticisms related to psychotropic medication use with persons with mental retardation. There also appears to be significant variance in the care standards by setting. Bisconer et al. (1996) examined the patterns of psychotropic medication use among persons with mental retardation residing in the community settings of Hawaii. Of the 151 surveys on psychotropic medication use that the authors circulated, they received 97 back. Concerning findings included the lack of psychiatric diagnosis for 62% of those evaluated, having no psychological or psychiatric examination documented in the record for 31% of the cases, and only noting medication reduction plans for 5% of the cases reviewed. Further, while 85% of the cases displayed some form of challenging behavior, only 7% had a formal behavior intervention program. Finally, clinicians did not measure behaviors to determine the benefits of the psychotropic medication in 83% of the cases.

The majority of physicians prescribing the medication to this sample were general practitioners with psychiatrists prescribing in only 42.9% of the cases. Holden and Gitlesen (2004) reported on prescription patterns within a county of Norway. As with the Bisconer et al. study, the majority of physicians providing prescription and oversight were overwhelmingly general practitioners (62.3%). Of note in this study was the more stringent guidelines utilized by psychiatrists when they were involved. This included an increased reliance on collected data with 25.6% of psychiatrists compared with only 9% of general practitioners utilizing objective data when making decisions about medication efficacy. Further, 66.7% of psychiatrists used alternate assessments and environmental strategies before prescribing a medication. This is in contrast to only 10.6% of the general practitioners following this same strategy. Finally, 49.1% of psychiatrists, compared with 7.4% of general practitioners, tried behavioral interventions before prescribing a psychotropic medication.

While pharmacological intervention use to reduce problem behaviors is common, Baumeister et al. (1993) have noted the concomitant suppression of adaptive skills as well due to the low specificity of psychotropic medication. Because of this, the authors indicated the need to monitor potential side effects associated with this group of medications more closely. Limited side effect recognition is a problem noted by other researchers as well (King, 2002). Risks related to psychotropic medication use has led to the practice of making planned medication reductions while seeking what has been referred to as the Minimal Effective Dose (Kalachnik, 1988). This is associated with the lowest dosage that is effective in reducing the target symptoms.

Perception

With long-term side effects, misuse of medication and professional rivalry, Aman and Singh (1986) have documented a general negative attitude towards use of psychotropic medication with persons diagnosed with mental retardation. This has led some to believe that psychotropic medication is a second line intervention following psychosocial interventions (Sovner, 1988). Another issue mentioned was suppression of cognitive functioning measures, such as those measured with intellectual assessments and reinforcement based strategies.

Provider. In an attempt to measure attitudes related to caregiver perceptions of psychotropic medication, Aman et al. (1987) administered a questionnaire to 227 direct caregivers in two residential centers providing services to individuals with mental retardation located in New Zealand. Upon review of the data, direct care staff perceived aggressive, destructive, and self-injurious behavior as appropriate for use of psychotropic medication. Further, caregivers reportedly favored more objective measures of behavioral change while uses of subjective measures occurred more frequently. Christian et al. (1999) utilized the same survey to measure the opinions of direct contact staff for medication use outside of residential settings. Within this study, authors received 363 surveys out of a total of 1130 sent out. Out of these, 334 were complete and analyzed as part of this study. Results indicated that as many as 83.5% of respondents felt drug therapy was acceptable with a high percentage indicating likely use associated with self-injurious behavior (72.9%), delusions/hallucinations (72.8%), and aggression (67.0%). One interesting finding was that fewer participants believed medication was appropriate for individuals who could not choose the treatment for themselves (44.0%). Finally,

73.1% of those responding reported that behavioral observations were the most preferred form of data collection. This is also consistent with the results found by Aman et al..

Of providers, Christian et al. (1999) found that direct care providers perceived psychiatrists and other physicians as most influential in making decisions related to use of psychotropic medication. In fact, caregivers reported they are the least influential in decisions either to initiate or discontinue medication. In an attempt to acquire consensus about use of medication for management of behavioral issues in adults with mental retardation, Unwin and Deb (2008) surveyed a group of psychiatrists noted on the mailing list of the Royal College of Psychiatrists' Learning Disability Faculty in the United Kingdom. Of the 258 members, 108 complete questionnaires were available for analysis. Items assessed included order of preference, preferred daily dosages, preferences for polyprescribing, circumstances for the use of medication, and comparisons between aggression and self-injurious behavior (SIB). There was a strong preference for non-medication forms of intervention for both physical aggression (86.1%) and SIB (88.0%). When psychotropic medication is used for treatment of aggression, 80% of psychiatrists prefer to use antipsychotic drugs as first choice. After this, mood stabilizers such as anticonvulsants are second choice medications in 40.7% and antidepressants in 25.0%. Further, psychiatrists prefer to use risperidone for both aggression (78.7%) and SIB (74.1%) significantly more than other medications. Participants in this study reported a belief that psychotropic medication was appropriate when non-drug interventions failed (61.1% of respondents) and also when the behavior posed a risk of injury to the patient or others around. Further, while 6.5% of psychiatrists in this study reported drug treatment as an option when desired by patients and

caregivers, other studies on direct to consumer advertising have identified more significant concurrence with patient requests for specific medication (Gilbody, Wilson, & Watt, 2004).

Patient. Direct to consumer advertising accounts for \$2.5 billion per year of pharmaceutical marketing (Gilbody et al., 2004). In a recent article, Gilbody et al. reviewed the pros and cons related to advertising targeted directly to the consumer. Benefits reported by the pharmaceutical companies are primarily associated with increased flow of information and also an increase in positive attitudes towards receiving mental health support. Direct to consumer advertising has led to discussion of many psychotropic medications in the home. Critics of DTCA report the communication of biased information to the public. This is associated with the aim of advertising, which is to raise market share. Another criticism is associated with physician need to clarify pharmacological practice that may impact the patient-doctor relationship. If physicians prescribe the requested medication, the result may be poor practice and control of symptoms at the expense of other more appropriate interventions. Further, consumers exposed to DTCA are more likely to characterize their perceived problems in a way that is consistent with advertisements (Lacasse & Leo, 2006). When comparing prescription patterns to those in Canada, there is a significant correlation between patients requesting advertised medication and physician prescriptions in the United States (Frank et al., 2005). At least one factor appears to be direct to consumer advertising as this is not allowed in Canada (Gilbody et al.).

Studies have also documented the perception that groups have about the benefits that they will receive from taking psychotropic medication. Krell, Leuchter, Morgan,

Cook, and Abrams (2004) sought to examine the impact that expectancies have on patients' response to a novel antidepressant medication. These authors found that, prior to treatment, 10 out of 25 participants in their study believed the medication they were going to receive was going to be very effective. The remaining 15 indicated that it would be somewhat effective; thus, leaving no participants who perceived the medication they were going to receive as not beneficial at all. As many as 80% of psychotic persons receiving antipsychotic medication have side effects (Castle et al., 2002). Even with noted side effects, patients from the Australian Low Prevalence (Psychosis) Study database overwhelmingly reported perceived benefit from their medication. While this was less for those with low insight, psychotic patients reported medication to be either helpful or very helpful in 86.8 - 93.0% of the cases.

When alternate therapeutic approaches are included in the study, there continues to be a strong desire for these strategies. Biancosino et al. (2004) examined the perceived benefits of varying therapeutic strategies available for use within a residential setting. While medication was helpful, talking to a doctor, and periods of increased ability to move about freely were reported to be most beneficial. Other components that were noted to be beneficial included visitors, making friends with patients, and the increased structure. The least valuable items reported had to do with group activities. Of note, this study excluded individuals diagnosed with mental retardation.

Public. Public attitude in Germany was more negative prior to the introduction of newer antipsychotic medication in the 1990s (Angermeyer & Matschinger, 2004). With the insertion of medications such as risperidone, olanzapine, amisulprid, and quetiapine in the market, Angermeyer and Matschinger sought to measure change in public attitude

towards use of psychotropic medication. The authors selected participants through a random selection of interview participants in both East and West Germany. In all, an impressive 5025 interviews occurred with subsequent selection of 2529 participants used to measure perceptions about psychotropic medications. Upon examination of data from 1990 and 2001, there was an increase in positive attitude towards use of this class of medication. This included a shift in the following areas: (a) drug treatment is the best way of treating mental illness, (b) drug treatment is the most reliable way of preventing relapse, (c) the benefit brought about by drug treatment far outweighs the risk associated with it, (d) drug treatment is the treatment most likely to bring about rapid improvement, and (e) in severe mental illness drug treatment is the only proper treatment. However, over half of those completing the survey (range from 50.0 - 68.6%) reported persistent concern related to side effects and potential dependency. Further, the authors noted that, while there was a shift in a more positive direction from 1990 to 2001, there remained a more prevalent disapproval of psychotropic medication in general.

Angermeyer, Breier, Dietrich, Kenzine, and Matschinger (2005) explored public attitudes towards psychiatric treatment between those living in Bratislava of the Slovak Republic, Novosibirsk in Russia, and a group out of Germany. The authors intended to explore the varying attitudes across countries at differing stages of mental health reform with Germany considered advanced. Angermeyer et al. used a structured interview identical to that of Angermeyer and Matschinger (2004). Participants provided recommendations for seeking help, treatment, labeling, perceived cause, and anticipated prognosis after exposure to a vignette describing an undiagnosed psychiatric case. Across all countries, participants reported they would seek assistance for depression primarily

from a confidante. When the vignette portrayed a patient with schizophrenia, participants from Germany reported greatest interest in receiving assistance from a psychiatrist, while those in both Novosibirsk and Bratislava again noted they would primarily turn to a confidante. Further, people from the German cities were least willing to seek help from sources outside of the health care field. Across all three countries, psychotherapy was favored as a treatment option followed by psychotropic medication.

Expectancies

Parmley (2006) included aspects of beliefs and hypotheses when discussing expectancies. Experimenter effects can lead to expectations of some future event (Rosenthal, 1977). Rosenthal (2002) further subdivided experimenter effects into interactional or expectancy effects and non-interactional or observer effects. Observational effects do not directly impact the subject, but instead surface during periods of observation and recording of data collection (Rosenthal, 1980). Both interactional and non-interactional effects are associated with perceptual bias that translates to decreases in both validity and reliability of recorded data. Reliability pertains to consistency while validity has to do with truth (Harris & Lahey, 1982). If raters were biased in the same direction, this would lead to measures of high reliability, but potentially low accuracy if measures deviate from the designated criteria.

Barber and Silver (1968) set out to examine 31 studies that investigated experimenter bias effect in an attempt to replicate earlier studies by Rosenthal (1977). Within these studies, they defined this as investigators inadvertently influencing subjects to behave in a particular way based on their expectancies, hypotheses, and biases. Of the 31 studies, Barber and Silver determined that 19 did not clearly demonstrate the bias

effect. Within these studies, factors included not having positive results or not having clear conclusions due to misuse of particular statistical procedures to analyze the data. Upon examination of the remaining 12 studies that did demonstrate experimenter bias effect, two primary ways they influenced the results were (a) through no impact on subject behavior (e.g., misjudge, misreport, or fabricate data), and (b) through intentional and unintentional cues that may alter the responses of those being observed.

Consumer expectancies play a clear role in direct to consumer advertising (Gilbody et al., 2004). With more than \$2.5 billion dollars spent on DTCA per year (IMS Health., 2005), pharmaceutical companies report they are trying to provide quality patient information to the public. With a Canadian ban on DTCA, research comparing prescription patterns in Canada with that of the United States demonstrates that DTCA is associated with both expectancies related to particular drugs and increased requests for advertised medications. Gilbody et al. noted that physicians have to disabuse patients and risk losing them to another health care provider that is willing to go along with their expectations.

Expectations about treatment benefits have also been shown to correlate with better outcomes for psychotropic medication (Kumar et al., 2007; Turner et al., 2002). In a double-blind randomized placebo-controlled study examining the effects of expectancies related to use of amitriptyline for control of pain, Turner et al. were able to show a significant effect. While the investigational nurses were higher, both nurses and patients reported significantly higher expectations about pain reduction with amitriptyline than with placebo. In those who received amitriptyline, patients' expectations of benefits were significantly associated with greater response. The authors did not replicate this

finding in the placebo group. In a factor analytic study examining variables that are associated with medication expectancies, Kumar et al. surveyed 344 respondents and found that the constructs of effectiveness, side effects, and convenience surfaced. The authors were able to demonstrate significant main effects for expectations of medication effectiveness and experience. Not surprising, patients who had negative experience and expectations gave the lowest satisfaction scores.

Placebo Effect

When not included in clinical trials, placebo is a term typically used to describe substandard practices, ethically flawed, or fraudulent practice (Hart, 1999). Positive expectancies related to initiation of a medical procedure or treatment have been associated with placebo effects in clinical studies. In fact, the archetypal placebo event involves a medical setting and improvement in a patient's health because of the belief that some pill was an active and effective treatment of their symptoms (Stewart-Williams & Podd, 2004). These agents are physically inactive, while maintaining a psychological effect. Based on the expectancy theory, the placebo leads to a response because the patient wants it to. Within this model, placebos function to manipulate or induce expectancies. Stewart-Williams and Podd also note that advertising may lead to more powerful effects. With as much as \$193 million spent on DTCA in 2004 for antidepressant medication alone (Frank et al., 2005), it is not a surprise that placebo effects have been noted to account for as much as 33% of a response to medication (Ernst, 2007; Sandler & Bodfish, 2000).

In a study examining the presence of the placebo effect, Breuning et al. (1980) found strong evidence that staff recorded increased incidents of maladaptive behavior

based on expectancies of medication condition. Ten participants receiving antipsychotic medication were randomly assigned to one of six conditions: (a) received the drugs, no changes; (b) staff told that the medication was a placebo – it was really the active drug; (c) residents were off the medication but given a placebo – staff were told it was a placebo; (d) residents off the drugs and not receiving a placebo – staff told a new drug used that is given by food; (e) off drugs and both knew it; (f) both blind – placebo and staff believed still on drugs. Results indicated that in the double-blind condition (i.e., both resident and rater blind to the fact that the resident was receiving a placebo), staff rated the residents as having the fewest maladaptive behaviors (average of 16.3 incidents). Under the condition where staff believed that the resident was receiving a placebo, they recorded slightly higher rates of maladaptive behaviors than the condition in which the medication was discontinued (average of 43 behaviors compared with 42.1).

Kenna and Wood (2008) have used the term pharmacological optimism to examine factors that increase one's risk of misusing licit drugs. Following a factor analysis of a number of items related to expectancies and beliefs, the following five factors appear to characterize this phenomenon. These were (a) autonomic and tension reduction, (b) euphoria, (c) instrumentality and performance enhancement, (d) somatic domains, which would include pain relief, and (e) beliefs of side effects.

Hart (1999) noted spontaneous improvement, variability of symptoms, regression to the mean, confounds associated with other treatments, improved medical care through participation in a drug study, and bias through use of subjective outcomes as extraneous variables that may complicate the study of medication efficacy. Researchers have also proposed therapist-patient interaction as another factor that may contribute to the

perception of a response to a medication when in fact no relation exists (Ernst, 2007; Ankarberg & Falkenstrom, 2008). Hart proposed three models for which placebos function, (a) through release of endorphins, (b) as a learned response to medical intervention (conditioning model), and (c) through the expectancy model. While release of endorphins associated with an infusion may have been associated with the placebo response to secretin in autism (Sandler, 2005), the debate between the conditioning and expectancy models has been more contested (Stewart-Williams & Podd, 2004). Because the classical conditioning approach indicates conditioned responses mediate the placebo effect, this can account for unconscious aspects of non-cognitively mediated learning. While this study found equivocal responses between the placebo and medication, others have found an even higher response to the placebo.

Through an examination of risperidone's efficacy for treatment of behavioral issues in persons with mental retardation, Tyrer et al. (2008) investigated the reduction of aggression across groups treated with risperidone, haloperidol, and placebo. They found that of the 80 patients examined, all groups had significant reductions in the outcome measure. Of interest here was that the group with the greatest absolute change were those receiving placebo. The results of this study demonstrate the strong effects of placebo and expectancies and also the questionable benefits of antipsychotic medication for this population.

In a study designed to examine the effects of secretin on reductions of autistic symptoms in children diagnosed with that condition, Sandler and Bodfish (2000) and later Sandler (2005) found no benefit over that of placebo. According to parent and teacher reports, 30% of both the secretin and placebo group showed significant

improvement after infusion. One factor noted for the placebo effect was the heightened positive expectancy conveyed to the public through the media attention. Another possible contributing factor was the sensory experience associated with the intravenous injection. The authors further noted that expectations of improvement may lead parents and teachers to misinterpret normal symptom variability. Within this study, 75% of parents continued to believe in the potential benefits of secretin even after results of the study were shared with them.

One significant limitation associated with many placebo-controlled studies is the potential for investigators or patients to identify the form of medication administered. Turner et al. (2002) found that, for the amitriptyline group, 70% of patients and 73% of nurses were able to identify use of the active medication correctly. For the placebo group, 55% of patients and 75% of nurses were correct. In a similar study examining the validity of the double-blind procedure for investigation of fenfluramine, Brownell and Stunkard (1982) were able to demonstrate that 70% of subjects and physicians were able to determine which condition they were in. The authors believed the informed consent process, which provided information on both potential benefits and side effects of the medication, compromised the blind nature of the study.

Expectancy Effects

Rosenthal has examined experimenter and expectancy effects since the 1970s (Rosenthal, 1977, 1980, 1994, 2002; Rosenthal & Rubin, 1978). In some of his earlier work, Rosenthal (1977, 1980) noted a number of factors that may lead to some interaction between experimenter and subject. These included biosocial effects such as gender, age, and race, psychosocial effects such as personality characteristics, situational

effects such as experimenter experience, modeling effects associated with prior experience or exposure to the experimental condition, and expectancy effects in which the experimenters' expectancies alter their behavior in a way that impacts the behavior of those being investigated.

Researchers commonly use perceptual tasks to evaluate expectancy effects in settings that include laboratories, classrooms and college campuses. Further, Rosenthal (1994) indicated the primary focus related to interpersonal expectancy effects is the investigation of variables that moderate and mediate the effects. Mediation of the expectancy effect pertains to the communication of expectancies from investigator to subject (Rosenthal; Harris & Rosenthal, 1985). In a review of 135 studies on mediation, Harris and Rosenthal found 31 behavioral categories with 10 examined in 13 or more studies. In order of number of studies, these included praise, frequency of interactions, ask questions, positive climate, criticism, input, negative climate, accept ideas, eye contact, and ignore students. Of these, input, negative climate, and accepts students' ideas had the largest effect sizes. Interestingly, criticism and praise had a much lower effect. The authors concluded that it is not enough to demonstrate the presence of these mediating variables. Beyond this, research must document that mediating variables lead to changes in student behavior as well. Of the outcome measures, Harris and Rosenthal noted the most common are student achievement, student attitudes and observers' ratings of the student's behavior.

With the increase in studies on expectancy effects in the 1970s, Rosenthal and Rubin (1978) examined 345 studies on the topic. In addition to perceptual tasks, other areas of research included reaction time, inkblot tests, animal learning, laboratory

interviews, learning and ability, and everyday situations. Of note was the significant increase in studies on every day events after 1969 (11 before and 101 after).

Rosenthal (1977, 1994) proposed four primary areas where experimenters change their behavior based on expectancies. These include (a) climate, which pertains to socio-emotional environment which is typically warmer for particular subjects; (b) feedback, which is differentially provided; (c) input, pertains to the overall volume and difficulty of the material; and (d) output, which pertains to differential opportunities to respond. When these variables are differentially impacted by teacher expectancies about student performance, a self-fulfilling prophecy may be the result. Further, a characteristic of the expectancy effect is that subjects are more likely to respond in a way that supports the investigator's hypothesis or expectation (Rosenthal, 1980). Support for Rosenthal's four-factor theory comes from Harris and Rosenthal (1985) in their review of behavioral categories that mediate the expectancy effect.

In nursing home settings, researchers have found expectancy effects to be associated with a number of positive outcomes. Learman, Avorn, Everitt, and Rosenthal (1990) assigned patients at random to either an "average-expectancy" or "high-expectancy" condition. For those in the later condition, Learman et al. found high expectations about above average rehabilitation to be associated with greater relief of depressive symptoms (1.94 times more improvement than the control group) and significant decrease in hospital admissions. Further, this group performed better on measures of mental status. Another term for this finding has been the Pygmalion effect (Reynolds, 2007; Rosenthal, 1977). While studies discussed so far have pertained to positive expectancies, Reynolds examined what has been coined the Golem effect. The

Golem effect pertains to the opposite of the Pygmalion effect, or change in behavior or recorded data due to the inducement of negative expectancies. The authors examined this through a study on the performance of 351 business-school undergraduate students following delivery of an instructor's verbalized expectancies on particular tasks. Results support the presence of the Golem effect through degradation of performance on cognitively based tasks. Replication for non-cognitively based tasks did not occur. Finally, participants reported significantly higher scores under positive treatment conditions and significantly lower scores within the negatively induced condition.

Not all studies have found evidence of expectancy effects as readily. In the study conducted by Barber, Forgione, Chaves, Calverley, McPeake, and Bowen (1969), 51 student experimenters evaluated 501 student subjects on a perceptual task. Results did not support the presence of expectancy effects. The authors stated the variable findings might have been associated with the student relationships. Expectancies can alter the interaction between the observers and observed with the observed altering his or her behavior due to some change in the observer's behavior that serves to communicate expectancy. When this happens, an expectancy effect has occurred. However, research has shown that much of the perceived expectancy effects is accounted for by observer error (Barber & Silver, 1968; Johnson & Ryan, 1976).

Observer Effects

Observer effects are non-interactional and lead to variability between raters or between a rater and a designated criterion. Hoyt and Kerns (1999) and Markin and Kivlighan (2007) found variance between two scores to be attributed to one of two forms of rater bias: (a) different interpretation of the same rating scale, and (b) different

evaluations of the same target. These factors can account for as much as 37% of the variance (Hoyt & Kerns). The authors note that the greatest chances of error are associated with use of non-overlapping observers and impressions and meaning systems that are unique. Through an examination of 27 psychotherapists, each rating two to three clients, Markin and Kivlighan found that rater bias appeared to be a significant source of error in the evaluation of transference and insight. Upon examination of a selected 21 experiments from 1939 to 1976, Rosenthal (1980) found that there were 993 errors made from 314 observers. While the number is small in relation to the overall comparisons that were 138,986, the potential for erroneous research findings remains significant.

Balzer (1986) examined the impact of two biasing factors upon employee performance rating. In particular, the author hypothesized that both initial impressions, termed the “halo effect,” and rating task centrality would impact an appraisal task. Within this study, Balzer exposed 80 students to videotaped lectures to generate initial teacher impression. The author emphasized the importance of data recording for half of the participants. The intent of this exercise was to evaluate the task centrality or the impact of limited resources on the accuracy of their rating. Results indicated that first impressions can generate expectancies which produce significantly different appraisals. The authors note this to be similar in construct to a confirmatory bias as the later appraisal was in line with impressions. On the other hand, results did not support differences in appraisal as a function of task centrality.

Inaccurately coded behavior could also be a result of recording system bias that is associated with expectancies (Harris & Lahey, 1982). Expectancies can lead an investigator to influence coders or observers to alter their data collection to confirm their

expectancy. Research has referred to this in the literature as confirmatory bias. Confirmation bias is the tendency of evaluators to perceive things consistent with their expectations while conducting either scientific or clinical research (Marsh & Hanlon, 2007). In a study of the presence and impact of this bias, Marsh and Hanlon induced different expectancies related to aggression in male and female red-backed salamanders. After inducement of expectancies based on gender, student observers did appear to bias observations, but only to a small degree. The authors noted the presence of bias even in data gathered through direct observation. In nine of the 10 behaviors measured, the observations were in the direction of the induced expectancy. Confirmation bias accounted for more than 13% of the observed variation in behavior. The authors calculated magnitude of error variance through use of additional trained and naïve observers measuring behaviors from videotaped trials. Harris and Lahey also indicated the risk of increased bias for more ambiguously observed behaviors. Further, alternate sources of potential bias include expectancies, observer drift, and consensual observer drift, coding complexity, influence of external cues, behavioral valence, differential coder training, observer cheating, observational media, and differences between coders (Harris & Lahey).

Labels impact the accuracy of teacher evaluations. While diagnostic labels are required to receive particular services, Fogel and Nelson (1983) set out to demonstrate an unintended effect on student evaluation independent of actual condition. The authors randomly assigned 30 teachers to one of four diagnostic groups that included mental retardation, emotional disturbance, normal, or not provided a label. Because behavioral observations were made of a videotaped child, all groups evaluated the same behaviors.

Results indicated expectancy labels impacted checklists, while labels did not impact less ambiguous behavioral observations and grading of academic work. Parmley (2006) further examined the impact of initial diagnostic impressions on processing of contradictory information presented at a later time. The author recruited 102 participants from psychology listservs. Further, 62 clinicians participated in the initial phase of the experiment, but not the second. Following provision of a diagnostic label, Parmley later provided new data intended to debias the raters. Results indicated that clinicians evinced the confirmation bias 33% of the time.

While investigating 345 studies on the topic of expectancy effects, Rosenthal and Rubin (1978) noted that 43 of the studies included special controls to minimize cheating and observer errors. Johnson and Ryan (1976) conducted four experiments to determine the impact that observer/recorder error has on experimental results in the presence of expectancies. Within this study, the authors hypothesized that systematic recorder bias would only occur when the investigator induces expectancy. In the first experiment, Johnson and Ryan evaluated the impact of expectancies on subjects. Within 12 observers, it was determined that only six had established expectancies. In later experiments, the authors attempted to alter the subject responses. On a word association task, experimenters' errors were in the direction of expectancies. Johnson and Ryan noted that successful induction of expectancies is a necessary condition for examining recorder bias associated with expectancies.

Over a series of 12 experiments with 192 subjects, Johnson and Adair (1970) examined latency to respond on a word association task and to determine if expectancies were associated with greater observer/recorder error. The authors used regular visits by

the principle investigator to investigate the impact on expectancy development. Results indicated there was a significant expectancy effect but no effect by investigator induction. During a second word association study conducted by Johnson and Adair (1972), the authors separated 12 experimenters and 144 subjects based on induced expectancy. The authors found a significant main effect of induced expectancies on observer/recorder error. That is, induced expectancies were associated with observer/recorder error. An interesting finding of this study was that female experimenters produced significantly greater errors during periods of tape-recorder use. Further, females tended to show more overall observer/recorder error than the male experimenters.

Observer error is evident in more natural settings such as observations of police behavior (Spano, 2005). Spano examined the potential for reactivity, going native, and burnout to bias observations by investigating 37 observers accompanying patrol officers during 729 shifts. While going native involved losing objectivity, burnout pertained to later decreases in accuracy due to the physically and mentally draining nature of data collection. Results of this study supported the presence of reactivity and its impact on data recording ($p < .001$) but not on burnout.

Control for Expectancies

Things that have been found effective to control for rater bias include raters observing the same behavior or observer overlap, having similar meaning, and a consistent approach to rating (Hoyt & Kerns, 1999). When evaluating moderator variables of rater bias, Hoyt and Kerns found that the most salient factor was the nature of the measure with ratings of observable behavior and other explicit attributes being associated with negligible variance in ratings. Other variables that impacted bias included

hours of training and rating experience, overlap of raters, and knowledge of the rated subject. Harris and Lahey (1982) further noted use of agreement checks, effective coder training and review, use of very specific behavioral definitions, and training in settings similar to the natural environment as ways to further control expectation bias. Repp et al. (1988) also suggested observers be naïve to the experimental hypothesis.

While some studies on reactivity have found evidence even with participant observers (Hay, Nelson, & Hay, 1980), use of trained staff within the natural environment appears to reduce other sources of error (Towns et al., 1984). To control for reactivity, Repp et al. (1988) proposed use of well-trained observers, use of unobtrusive observer, uncomplicated codes, and both male and female observers if possible. In an attempt to increase the ecological validity and generalizability of the findings, Jacob et al. (1987) suggested careful attention to the observational environment is necessary.

Poling et al. (1991) noted the need to use placebo control when evaluating medication efficacy. Further, they reported that the overall effect of psychotropic medication is the combination of the intended pharmacological effect of the drug and any placebo effect it produces. Other supports that can be used to reduce the impact of expectancies include use of direct observation of objective (specifies observable events), clear (unambiguously describes the physical form), and complete (delineates the boundaries for inclusion and noninclusion behaviors) definitions (Poling et al). Fogel and Nelson (1983) have found decreased risk of bias with use of behavioral observations and objective grading procedures. This was not the case for more ambiguous checklist scores. In addition to use of direct observational data, Reid (1982) recommended use of sufficient training and monitoring of observers. He suggested use of a manual and also

analogue coding system if possible (e.g., videotapes). Further, periodic drills, retraining, and use of incentives for reliability and accuracy may also be necessary.

Direct observation does not eliminate risk to the reliability of a study. Trait labels can lead to confirmatory bias (Fogel & Nelson, 1983). Following induction of a false impression, accurate and objective data are not always effective in changing one's impression (Shuller, 1978). In an attempt to test strategies to facilitate appropriate shift in impression, Shuller utilized normative data and a credible source as two distinct attitude inductions. The author randomly assigned subjects to an expectancy group (emotionally disturbed, normal expectancy, and non expectancy) and also to one of four treatment groups (normative data treatment group, credible source treatment, norms plus credible source treatment, and no treatment). Results indicated significant findings for the expectancy and credible source variable, but not the norm group. Once again, with norms comprised of accurate data, shift in impression did not significantly occur. The authors stated that subjects tended to believe the norms only when they were consistent with their prior attitudes.

Among measures to reduce expectancy effects, experts have recommended the use of placebo and double-blind controls when evaluating the effectiveness of pharmacological interventions (Baumeister & Sevin, 1990; Sprague & Werry, 1971). Researchers have also found that when more objective behavioral measures are used, single-blind procedures may be sufficient to control observational bias (Townes et al. 1984). Without such controls, expectancy effects may influence collected information on psychiatric symptoms.

To examine the difference between single- and double-blind studies in the control of expectancies, Towns et al. (1984) had experimenters observe six girls with mental retardation under different conditions. Two of the observers were blind to the experimental study while two were knowledgeable about the placebo condition. The authors varied the intervention between those receiving methylphenidate and those receiving placebo. During the study, the 12 observed behaviors included both appropriate and problematic behaviors. While more subjective, the authors of this study also acquired global impressions. The results indicated that the informed group scored significantly more “other” stereotypic behavior and less body rocking. Towns et al. did not find any significant differences in their reliability. The authors concluded, when objective behavioral measures are used, single-blind procedures are as effective as double-blind procedures for evaluating medication effects. This is not consistent with other studies investigating the impact that preexisting knowledge of drug conditions has on experimenter bias (e.g., Breuning et al., 1980). This study included a training session, which focused both on accuracy and reliability of behavioral observations. To properly evaluate the efficacy and side effects of psychotropic medication, Poling et al. (1991) suggested drug studies meet the following four minimal requirements:

- (a) Medication must be administered according to the treatment plan, (b) drug effects must be adequately measured, (c) data analysis must be adequate to detect clinically important changes in behavior, and (d) conditions must be arranged so that observed changes in behavior can be attributed with confidence to the drug.

(p. 23)

To address this last point, the treatment design should include a period of baseline data collection at minimum with a reversal component (e.g., A-B-A) if feasible. A reversal design can control for misattribution of the medication effect in the presence of extraneous variables.

Researchers rarely use double-blind placebo designs in the everyday evaluation of psychotropic medication (Poling et al., 1991). Further, they are not sufficient to differentiate medication effects from expectancy/placebo effects (Rohsenow & Marlatt, 1981). Another weakness of typical placebo controlled studies is the limited credibility assessment of the placebo. Without this, subjects may be able to determine if they are receiving the placebo or active medication and thus compromise the results of the study. Rohsenow and Marlatt proposed using a balanced placebo design with steps to increase the credibility of the expectancy manipulation when examining medication efficacy.

Conclusion

Even with strategies to control for their effects, expectancies can endanger validity and reliability of medication efficacy data gathered. Because use of data is required to evaluate such interventions (U. S. Department of Health and Human Services, 2004), one must consider use of methodological designs that increase the confidence of such interpretations. These designs include single- and double-blind placebo controlled and also reversal designs (e.g., A-B-A). While single-blind studies can control for expectancies when objective behavioral data are used (Towns et al., 1984), researchers still prefer the double-blind placebo approach (Poling et al., 1991). However, studies have shown that even with use of the double-blind procedure, patients and clinicians are able to determine which medication is being delivered in most cases (Brownell &

Stunkard, 1982; Turner et al., 2002). Further, because most medication evaluations in clinical settings are open-label, they do not provide the controls necessary to rule out other variables (Madrid et al., 2000).

It is for these reasons that we must first seek to understand the presence and also the impact of expectancies on data recording. With the increase in direct to consumer advertising of psychotropic medications to the public and increased insurance coverage for drugs there continues to be a growing perception among many that psychotropic medication is not only appropriate but necessary for the treatment of mental illness. Because persons with developmental disabilities have seen excessive use of psychotropic medication for control of disruptive and dangerous behaviors (Baumeister & Sevin, 1990; Baumeister et al., 1993), and caregivers strongly believe that self-injurious behavior and physical aggression are indicators for use of psychotropic medication (Aman et al., 1987; Christian et al., 1999; Unwin & Deb, 2008), it is likely that expectancies will be prevalent when investigating these agents. Further, it was hypothesized that the presence of these expectancies also impacts the accuracy of data being recorded by caregivers either through the mechanisms of expectancy or observer effects.

CHAPTER III

METHODOLOGY

Introduction

Researchers (Holden & Gitlesen, 2004) and agencies providing regulatory oversight for organizations serving persons with mental retardation (U. S. Department of Health and Human Services, 2004) have noted excessive use of psychotropic medication, particularly in the area of general behavioral suppression (Baumeister et al, 1993). This has led to guidelines requiring evaluation of medication effects with an emphasis on reductions (U. S. Department of Health and Human Services; U. S. Department of Justice, 2006b). Objective, reliable, and accurate data are required to evaluate medication effects.

Expectancies have been shown to alter the accuracy and reliability of information being gathered within both clinical and experimental conditions. Expectancy effects involve an alteration in the investigator's behavior that impacts the behavior of those being investigated (Rosenthal, 2002). Along with expectancy effects, observer error associated with alteration in data recording practice (Harris & Lahey, 1982) provides limitations to the evaluation of treatment change.

Studies have documented the presence and impact of the placebo effect when initiating psychotropic medication in persons with mental retardation (Tyrer et al., 2008), along with expectations of deterioration associated with discontinuation of this group of medications (Breuning et al., 1980). With the mandate to reduce psychotropic medication

use within this population (U. S. Department of Health and Human Services, 2004), the presence and impact of expectancies for medication reductions must also be evaluated.

To accomplish this, this study sought to answer the following questions:

1. What are the expectancies of direct support staff regarding behavioral changes concurrent with psychotropic medication reductions in a residential facility for persons with mental retardation?

H₀: Direct support staff will not disproportionately expect a worsening in an individual's behaviors or psychiatric symptoms following a psychotropic medication reduction.

2. What relationship exists between reported expectancies and data recording behavior if expectancies vary with psychotropic medication reductions?

H₀: Following the medication reduction, there will be no difference in data recorded between staff who expect deterioration and those who do not.

3. What effect does informing direct care staff of planned psychotropic medication changes have on data recording practice in a residential facility for persons with mental retardation?

H₀: Staff who are informed of upcoming medication reductions will not record post-reduction data with greater frequency than those who have not been informed.

Research Design

This study was carried out in two phases with Phase I focusing on identification and examination of expectancies that direct support staff have about medication reductions to determine if differences existed (Question/H₀ 1), and then through the

examination of data recording behavior to note inconsistencies in practice based on expectations of deterioration (Question/H₀ 2). Within Phase II, the impact that preexisting knowledge of a planned medication reduction had on data recording practice was explored to determine if this knowledge was associated with a relative increase in post-reduction data (Question/H₀ 3). To answer Question 1 and test the associated null hypothesis, a memo was utilized to ascertain staff expectancies related to behavioral changes following reductions to individuals' psychotropic medication. This allowed for the determination of whether direct support staff believed that individuals would get worse, have no change, or get better following each reduction. Expectancy identification was then analyzed to determine distribution and also identify significant differences across expectancy condition for both problem behaviors and psychiatric symptoms.

Following the identification of expectancies related to medication reductions, Question 2 was answered and the second null hypothesis tested by examining the pre-reduction and post-reduction data for behaviors and psychiatric symptoms across expectancy condition. For testing of the second hypothesis, the most frequent problem behavior and also the most frequent psychiatric symptom were utilized. While psychotropic medications were designed for use with psychiatric conditions, they have been frequently used for general behavioral suppression for persons with mental retardation (Baumeister & Sevin, 1990; Baumeister et al., 1993). Through use of mixed methods, differences between expectancies and behaviors/symptoms along with group changes over time were examined.

With the limited use of single- or double-blind or placebo controlled studies in clinical settings such as the one included in this investigation, examination of conditions

that approximate these controls is warranted. One way to examine these conditions was to look for differences in staff reporting practice associated with policies related to informing staff of upcoming medication reductions. If differences existed in expectancies of behavioral change following medication reductions, variability in reporting behavior for those who are aware of upcoming reductions when compared to those who are “blind” to such changes may occur. Question 3 examined these differences. To answer this question and test the related null hypothesis, pre- reduction and post-reduction data were gathered before and after such a policy of informing direct support staff of upcoming reductions was in place. Through inclusion of cases in which reductions did not occur, comparisons across reduction and information conditions were conducted.

Population

Medication reductions occurred within a population of individuals residing at one of nine Illinois State Operated Developmental Centers (SODC). As of June 30, 2009, 526 adults diagnosed with mental retardation were in residence at the center where this study was conducted. Of these individuals, 173 were female and 353 male. The average age of residents was 53.57 years, with a range from 22.02 to 98.22. The average length of stay at this center was 21.80 years, with a range from seven days to 74.08 years. The average estimated IQ score was 22.84 with a range from 1 to 70. For those who reside at this center, 420 (79.8%) currently display either problem behaviors or psychiatric symptoms severe enough to warrant use of a behavior intervention program, with 206 (39.2%) receiving psychotropic medication as one form of treatment. There are a number of psychiatric conditions diagnosed within the population with the primary clinical condition being a mood disorder for 126 residents. Other noted conditions include

pervasive developmental disorders ($n = 76$), psychosis ($n = 61$), anxiety ($n = 10$), impulse control disorder ($n = 6$), or another condition such as an unspecified mental disorder ($n = 5$).

Within this setting, direct support staff have the primary responsibility to provide services and gather information. These staff have at least a high school equivalent education. The staff work one of three shifts, the AM, PM, and night shift. For each shift, every individual in residence at the center has been assigned a group leader from among all the direct support staff. The group leader works with the residents across an eight hour period with an alternate group leader (i.e., alternate) assigned to work with the individual on the primary leader's days off. Therefore, at any given time, a resident has six staff (three group leaders, and three alternates) assigned to work with them. During the initial stages of this study, AM and PM shifts were sampled equally (both at 42.1% of the 145 memos being obtained), with night staff comprising the remaining 15.8%.

Phase I

Selection of participants within Phase I occurred through convenience sampling from all individuals scheduled to have a psychotropic medication reduction within the first six months of the 2009 calendar year defining the subject pool. Further, group leaders and alternates assigned to work with these individuals were also considered participants due to their data recording duties.

During this stage of the study, 145 memos were collected for 56 (38.6%) female and 89 (61.4%) male residents. The ethnic breakdown included the following: Caucasians (72.4%), African-Americans (16.6%), and Hispanics (11.0%). The average age for the residents included in this portion of the study was 55.7 ($SD = 10.7$) with a range from 22-

years to 78-years-old. Although some participants had been at the facility for just one month, the average length of stay was 23.8 years ($SD = 10.6$). Further, participant residents averaged an IQ score of 23.1 ($SD = 15.0$) with a range from 4 to 70.

Residents received an average of 1.4 drugs ($SD = 0.7$) with a range from one to three. Antipsychotics were the most frequently used at 53.1% followed by anticonvulsants (29.0%) for all medications prescribed to the residents. Risperidone was the medication used with greatest frequency (22.1%). For detailed information related to all prescribed psychotropic medications, see Table 1.

Table 1
Psychotropic Medications Prescribed

Medication	Class	<i>n</i>	%
Risperidone	Antipsychotic	32	22.1
Divalproex	Anticonvulsant	28	19.3
Olanzapine	Antipsychotic	15	10.3
Oxcarbazepine	Anticonvulsant	14	9.7
Quetiapine	Antipsychotic	12	8.3
Chlorpromazine	Antipsychotic	9	6.2
Propranolol	Antihypertensive	8	5.5
Clonazepam	Anxiolytic	6	4.1
Lorazepam	Anxiolytic	5	3.4
Venlafaxine	Antidepressant	5	3.4
Ziprasidone	Antipsychotic	5	3.4
Aripiprazole	Antipsychotic	3	2.1
Fluoxetine	Antidepressant	2	1.4
Thioridazine	Antipsychotic	1	0.7

The majority of participants were diagnosed with a mood disorder (63.4%) with agitation and irritability reported as the most prevalent symptoms treated (32.4% and 22.1% respectively). Finally, verbal aggression (24.8%), self-injurious behavior (22.8%), and physical aggression (14.5%) were noted as the most frequently observed behaviors being targeted for reduction. For detailed information related to diagnoses, psychiatric symptoms, and target behaviors, refer to Tables 2 and 3.

Table 2
Diagnostic Information

Clinical Diagnoses (AXIS I)	<i>n</i>	%
Mood Disorder	92	63.4
Pervasive Developmental Disorder	17	11.7
Psychotic Disorder	14	9.7
Deferred Axis I Condition	6	4.1
Impulse Control Disorder	6	4.1
No Condition	6	4.1
Mental Disorder	4	2.8

Phase II

Participants for this part of the study were selected according to their information (i.e., informed of reduction or not informed of reduction) and reduction conditions (i.e., reduced or not reduced).

Group 1. All individuals receiving a reduction in psychotropic medication in the first six months of the 2000 calendar year were included in this study. This year was selected because it was the year prior to initiation of a policy of informing direct support

Table 3
Most Frequent Psychiatric Symptoms and Target Behaviors

Symptoms	<i>n</i>	%
Agitation	47	32.4
Irritability	32	22.1
Psychotic Symptoms	14	9.7
No Symptoms Noted	13	9.0
Stereotypic Behavior	11	7.6
Rapid Pressured Speech	10	6.9
Anxious Verbalizations	5	3.4
Disruptive Speech	5	3.4
Social Withdrawal	5	3.4
Mood Symptoms	2	1.4
Crying	1	0.7
Behaviors	<i>n</i>	%
Verbal Aggression	36	24.8
Self-Injurious Behavior	33	22.8
Physical Aggression	21	14.5
Noncompliance	13	9.0
Mouthing	11	7.6
Property Destruction	9	6.2
Inappropriate Sexual Behavior	7	4.8
Leaving Designated Area	6	4.1
No Behaviors Noted	5	3.4
Inappropriate Dining Behavior	2	1.4
Teasing	2	1.4

staff of medication changes. This would then closely resemble a single-blind methodology because the staff were unaware that the medication had been reduced. From this group, 60 cases were randomly selected to form Group 1.

Group 2. All individuals who were not scheduled to receive a psychotropic medication reduction during the second six months of calendar year 2000 were identified. Group 2 consisted of 60 randomly selected individuals from this group.

Group 3. All individuals receiving a reduction in psychotropic medication in the first half of the 2009 calendar year were identified in Phase I. Of these, 60 cases were randomly selected for inclusion in Group 3.

Group 4. All individuals not receiving a psychotropic medication reduction during the second six months of the 2008 calendar year were identified. Group 4 was comprised of 60 randomly selected cases from these individuals.

Exclusion Criteria. For groups 1 and 3, individuals were excluded if the medication reduction resulted in discontinuation of a psychotropic medication because this would be a replication of the study conducted by Breuning et al. (1980). Individuals were also excluded if there was a change in another psychotropic medication during the period of 30 days before and after the reduction under investigation. This was required to isolate staff expectancies to the specific medication reduced as part of this study.

One way analyses of variance (ANOVAS) were conducted to explore heterogeneity across groups for age, duration at the center, IQ score, and number of medications, while a series of $r \times 4$ chi square tests were conducted for the variables of gender, race, clinical diagnoses, medication class, and specific prescribed psychotropic medication. For demographic variables, no significant difference was found for IQ score,

gender, or ethnicity. However, a significant difference was found for duration at the center, $F(3, 236) = 9.5, p < .001$. A Tukey HSD test showed those in the 2008 reduction group (informed and reduced) were at the facility for a significantly longer period of time than those in the 2000 reduction and non-reduction groups (both at the $p < .001$ level). A significant difference was also found for age, $F(3, 236) = 3.9, p < .05$, with the Tukey HSD test showing those in the 2008 reduction group being significantly older than those in the 2000 reduction and non-reduction groups (both at the $p < .05$ level).

Upon examination of clinical information, subjects were not significantly different across groups for number of psychotropic medications (please refer to Table 4) or clinical diagnoses (please refer to Table 5). However, the groups were significantly different in drug class, psychotropic medication reduced as part of this study (please refer to Tables 4 - 6).

Data Collection

For this study, all information was gathered from direct support staff. These staff were primarily responsible for both the care of the individuals and the data collection of any noted problem behaviors or psychiatric symptoms over a 24-hour period. With three shifts (AM, PM, and night) and a group leader and alternate across each shift, there was a potential for six data recorders associated with every medication reduction.

Behavioral Data

For all individuals included in the study, frequency or interval data were recorded for specific psychiatric symptoms and also for behaviors being targeted for reduction through other means such as applied behavior analysis with structured data collection forms and procedures (Appendix B). Specifically, data for 30 days prior to the

Table 4

Demographic Information

Variable	Group 1		Group 2		Group 3		Group 4		F^a
	M	SD	M	SD	M	SD	M	SD	
Age	47.2	11.5	47.2	11.3	52.8	10.2	51.0	11.5	3.9*
IQ score	27.8	16.1	24.7	16.9	26.4	17.0	28.2	17.6	0.5
During at Facility	14.8	8.5	15.3	8.1	22.8	10.8	19.1	9.7	9.5**
Number of Medications	1.4	0.6	1.2	0.4	1.4	0.5	1.4	0.5	2.5
Variable	n	%	n	%	n	%	n	%	X^2
Gender ^b									4.1
Male	37.0	61.7	43.0	71.7	42.0	70.0	47.0	78.3	
Female	23.0	38.3	17.0	28.3	18.0	30.0	13.0	21.7	
Race ^c									9.0
Caucasion	50.0	83.3	43.0	71.7	44.0	73.3	44.0	73.3	
African American	10.0	16.7	15.0	25.0	10.0	16.7	13.0	21.7	
Hispanic	0.0	0.0	2.0	3.3	6.0	10.0	3.0	5.0	

^a $df = 3, 236$.^b $df = 3$.^c $df = 6$.* $p < .05$.** $p < .001$.

Table 5

Clinical Information by Group Affiliation

Variable	Group 1		Group 2		Group 3		Group 4		X^2
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	
Disorder ^a									27.7
Anxiety	2	3.3	3	5.0	1	1.7	0	0.0	
Eating	0	0.0	0	0.0	1	1.7	0	0.0	
Impulse Control	0	0.0	1	1.7	2	3.3	1	1.7	
Mental	0	0.0	1	1.7	2	3.3	4	6.7	
Mood	37	61.7	36	60.0	32	53.3	34	56.7	
PDD	6	10.0	6	10.0	10	16.7	3	5.0	
Psychotic	13	21.7	12	20.0	10	16.7	17	28.3	
Deferred	0	0.0	0	0.0	2	3.3	0	0.0	
No Disorder	2	3.3	1	1.7	0	0.0	1	1.7	
Drug Class Reduced ^b									14.0*
Antipsychotic	22	36.7			35	58.3			
Anticonvulsant	12	20.0			14	23.3			
Lithium	11	18.3			3	5.0			
Antidepressant	10	16.7			2	3.3			
Anxiolytic	0	0.0			1	1.7			
Other	5	8.3			5	8.3			

^a *df* = 24.^b *df* = 5.**p* < .05.

Table 6

Psychotropic Medication Reduced by Group Affiliation (Groups 1 and 3)

Variable	Group 1		Group 3		X^2
	<i>n</i>	%	<i>n</i>	%	
Psychotropic Medication ^a					41.8*
Aripiprazole	0	0.0	2	3.3	
Bupropion	0	0.0	1	1.7	
Carbamazepine	5	8.3	0	0.0	
Chlorpromazine	0	0.0	1	1.7	
Clomipramine	2	3.3	1	1.7	
Clonidine	2	3.3	0	0.0	
Divalproex	7	11.7	9	15.0	
Doxepine	1	1.7	0	0.0	
Fluoxamine	1	1.7	0	0.0	
Fluoxetine	3	5.0	0	0.0	
Haloperidol	1	1.7	0	0.0	
Lithium	11	18.3	3	5.0	
Nortriptyline	1	1.7	0	0.0	
Olanzapine	2	3.3	4	6.7	
Oxcarbazepine	0	0.0	4	6.7	
Propranolol	3	5.0	5	8.3	
Quetiapine	0	0.0	2	3.3	
Risperidone	14	23.3	22	36.7	
Sertraline	2	3.3	0	0.0	
Thioridazine	5	8.3	1	1.7	
Valproic Acid	0	0.0	1	1.7	
Venlafaxine	0	0.0	1	1.7	
Ziprasidone	0	0.0	3	5.0	

^a *df* = 22.**p* < .01.

medication change were compared with data for the 30 days following the change in dosage. As most cases included monitoring of multiple behaviors/symptoms, the behavior and psychiatric symptom with the highest rate prior to any changes in medication dosage was selected. This allowed for a percent change to be calculated providing an overall indication of change.

Expectancy Data

For all individuals scheduled to have a psychotropic medication change within the first six months of the 2009 calendar year, their group leaders and alternates were provided a memo stipulating the date that the medication change was to occur. To assess staff expectancies regarding the psychotropic medication change, two multiple-choice questions were inserted within the memo (Appendix A). These prompted staff to report whether they expected the person's behavior and psychiatric symptom to get better, have no change, or get worse.

Analytical Methods

In Phase I, both descriptive research and nonparametric statistics were utilized to explore staff expectancies. Examination of variables that included age, IQ score, number of psychotropics prescribed, and duration of services received at the center included use of one-way ANOVAs. Evaluation of categorical data such as diagnosed psychiatric condition and medication reduced included use of the chi square test (χ^2). To answer Question 1 and test the associated null hypothesis, the r x k chi-square (χ^2) test designed to compare observed frequencies of staff expectations with expected probabilities was used (Salkind, 2008).

To answer the second study question and test the related null hypothesis, comparison of pre-reduction and post-reduction data was conducted by analyzing data reported by the individual group leader or the alternate group leader. This then allowed for analysis of behavioral change across both expectancy conditions and between behaviors and psychiatric symptoms. Determination of significant differences occurred through use of a mixed-model analysis of variance (ANOVA), with a post hoc comparison of means.

To answer question three and test the final null hypothesis, Phase II was a quantitative analysis of variability in data related to staff reports of psychiatric issues. Consistent with an experimental design (Gay et al., 2006), this study utilized random assignment of subjects to different conditions. With two independent variables each being manipulated two ways (i.e., two informed conditions [informed of upcoming reduction; not informed], two medication change conditions [medication reduced; medication not reduced]), a 2 X 2 between-subjects factorial design was used. This allowed for analysis of both the main effects and interaction between the two variables. Application of this design determined the impact of medication changes under four distinct conditions. Again, examination of variables that included age, IQ score, diagnosed psychiatric condition, medication, and duration of services received at the center occurred. This included use of 2 x 2 chi-square (X^2) tests designed to compare observed frequencies of diagnosed psychiatric condition and medication (noted as categorical data) with expected probabilities (Salkind, 2008), and ANOVAs used to identify significant difference in age, IQ score and duration at the center across conditions.

Measure of Change

To generate a measure of change, the post-reduction data were divided by the pre-reduction data which was then multiplied by 100, resulting in a percent change over time. For example, if a person had 30 incidents of physical aggression prior to the reduction and 45 reported incidents after the reduction, this would result in a 150% change in physical aggression following the reduction ($45/30 \times 100 = 150$). This was necessary given the extreme variability of data ranges across individuals and the inclusion of both event and interval data. Further, if either the pre-reduction or post-reduction data were zero (0), a constant was added to both the pre-reduction and post-reduction frequencies to allow for this computation. For purposes of this study, this constant was one (1). For example, if a person had 4 reported incidents of self-injurious behavior prior to the reduction and 0 incidents after, this would indicate that the post-reduction rates were 20% of what the pre-reductions rates were ($1/5 \times 100 = 20$).

For the non-reduction groups, a random date was selected. This then allowed for a comparison of the 30 days prior, and 30 days after this date. Again, the procedures noted above were used to generate a percentage change over time.

Limitations

As with any study, a number of limitations surfaced. These limitations can be broadly grouped into the categories of setting and subjects, staff participants, and data collection and analysis.

Setting and Subjects

The center from which the data were collected for this study is one of nine state operated developmental centers in Illinois. The residents are those that cannot typically

be served in a less restrictive and more integrated setting due to the presence of significant and frequent problem behaviors. This is evidenced by the number of persons with behavior intervention programs and also the percentage of the population receiving psychotropic medication. This may limit the generalizability of the results to community settings.

There was a disproportionate number of male participants in this study. With the average IQ score of about 23, the majority of participants were functioning in the severe to profound range of mental retardation. Further, few younger residents were included with the average age of participant determined to be 55.7 years. Some variables serve to distinguish this center from other state operated residential facilities. These variables include conservative medication use and integration of behaviorally defined psychiatric symptoms.

The noted prevalence of 39.2% of residents receiving at least one psychotropic medication was well below the rates established in the literature for this type of setting (e.g., 56.5% noted by Valdovinos et al., 2003). Further, while the facility used in this study followed best practice models, which recommend the tracking of operationally defined behaviors and discrete psychiatric symptoms, this is not typical. Bisconer et al. (1996) found that only 17% of clients reviewed had behaviors measured in a previously reported study. Generalization of the present findings to settings without these controls may be limited.

Staff Participants

With the limited number of staff reporting an expectancy that individual behaviors or psychiatric symptoms would improve following a reduction, this category

was combined with the “Have No Change” group when analyzing differences in data recording behavior based on expectancy condition. Therefore, the analysis included a 2 X 2 X 2 mixed-method ANOVA (instead of 3 X 2 X 2) in which those who expected the person to get worse were compared against those who did not expect the person to get worse (i.e., those who thought they would get better and those who thought there would be no change).

The time group leaders and alternates spent with each subject was not recorded. It is possible that group leaders and alternates who spend more time with the individual would have different expectations than those who were less familiar with the individual. Further, given the non-confidential nature of the memos (part of facility practice which allows for follow-up), it is possible that staff reports of expectancies provided as part of this study were biased by their awareness that others would be evaluating their responses.

Finally, while staff were not informed in writing of medication reductions during the 2000 time period used to test the final null hypothesis, it is possible that they were aware of medication reductions. This awareness would most likely come following the reduction, potentially confounding the “blind” nature of this condition.

Data Collection and Analysis

There is no assurance that the data recorded were an accurate reflection of behaviors and symptoms given reliability or validity were not collected. However, we would assume a degree of unreliability exists given the nature of this study, expectancy effects and observer error. Return rates for the memos were not high. With 68 medication reductions that met the specified criteria over the first 6 months of 2009, a maximum return rate of 408 memos was predicted (one group leader and one alternate for each the

AM, PM, and Night Shift). Instead, 145 memos were received for 42 individuals. The lower number of individuals may have been a result of the IRB approval process which was not complete until February of 2009. Another reason may have been the recent revision to the format of the memo which pertained to the gathering of staff expectancies.

To answer the third research question and test the associated null hypothesis, it was required to add a constant to rates reported (pre-reduction and post-reduction). Without the inclusion of a constant, it would not be possible to calculate a percent change over time. In turn, this artificially inflated the affected pre-reduction and post-reduction rates by one. Further, there was occasion in which the pre-reduction rates were zero (0) for all behaviors and psychiatric symptoms. In these cases, the behavior and symptom were selected based on the order listed on the graphical representation of data.

CHAPTER IV

FINDINGS AND CONCLUSIONS

Introduction

This study was conducted to provide evidence for the impact of expectancy associated with psychotropic medication reductions in persons with mental retardation. This chapter reexamined the research questions and null hypotheses and provided a discussion and interpretation of the results. Finally, clinical and research implications were examined and recommendations for future research were included.

Psychotropic medications are prescribed at a higher rate for those with mental retardation than for those who do not have an intellectual disability (Holden & Gitlesen, 2004). This is particularly the case within intermediate care facilities that provide services to those diagnosed with mental retardation (Nøttestad & Linaker, 2003). Valdovinos et al. (2003) found the overall psychotropic medication use to be 56.5% in persons residing in residential facilities. Further, these medications are frequently used for control of behaviors instead of for stabilization of psychiatric conditions (Baumeister et al., 1993). This pattern of psychotropic medication overuse for persons with mental retardation has led regulatory bodies to take legal measures, as well as providing additional oversight for intermediate care facilities.

One such step in oversight was the Patient Freedom from Restraint Act (2000), requiring appropriate use of psychotropic medication that does not interfere with individual services such as treatment or habilitation. The U. S. Department of Justice has

conducted investigations into the restrictions of civil rights for those individuals living in residential care facilities. Lanterman Developmental Center in California (U. S. Department of Justice, 2006a) and Nebraska's Beatrice State Developmental Center (U. S. Department of Justice, 2008b) were cited for excessive use of psychotropic medication. Another example of regulation comes from the Centers for Medicare and Medicaid Services (CMS) stating, "A gradual withdrawal occurs annually or sooner if warranted by progress to the criteria for reduction established in the individual program plan, by the particular drug which is being used, or the specific condition for which the drug is being prescribed" (U.S. Department of Health and Human Services, 2004, p. 25). These reductions must occur unless a clinical contraindication such as decompensation of a person's clinical condition has been noted and supported by objective information.

Even with a mandate to collect data, which "yield accurate measurement of the criteria stated in the individual's IPP objectives" (U.S. Department of Health and Human Services, 2004, p. 14), Pfadt and Wheeler (2006) reported collection of such systematic data has been lacking in clinical practice. Further, for those agencies that do collect data, many do not include direct behavioral observation which is seen as the preferred method for collection (Breuning & Ackles, 1985). Even when available, data may not be used to make decisions (Singh & Winton, 1984) or the data may have questionable empirical integrity. One threat to the integrity of the data being collected may reflect expectancy effects.

Expectancies were noted as one form of experimenter effects which are the product of interactions between the subject and experimenter (Rosenthal, 1977, 1980, 2002). Expectancies may influence what has been termed the placebo effect in which a

person believes that an inert medication was effective (Stewart-Williams & Podd, 2004). While expectancies of improvement have been associated with the placebo effect, other research has noted expectations of deterioration following medication discontinuation in persons with mental retardation (Breuning et al., 1980).

For persons with mental retardation, evaluation of psychotropic medication and the relationship with expectancy effects should be understood and limited. The purpose of the present study was to evaluate both the presence of staff expectations related to psychotropic medication reductions for persons with mental retardation and the impact that these expectations have on the recording variability of behavioral data. The specific focus of this paper was to identify fluctuations that were associated with either observer error or expectancy effects independent of treatment change. This study investigated the following research questions:

1. What are the expectancies of direct support staff regarding behavioral changes concurrent with psychotropic medication reductions in a residential facility for persons with mental retardation?

H₀: Direct support staff will not disproportionately expect a worsening in an individual's behaviors or psychiatric symptoms following a psychotropic medication reduction.

2. What relationship exists between reported expectancies and data recording behavior if expectancies vary with psychotropic medication reductions?

H₀: Following the medication reduction, there will be no difference in data recorded between staff who expect deterioration and those who do not.

3. What effect does informing direct care staff of planned psychotropic medication changes have on data recording practice in a residential facility for persons with mental retardation?

H₀: Staff who are informed of upcoming medication reductions will not record post-reduction data with greater frequency than those who have not been informed.

This study was carried out in two phases. Phase I was designed to answer the first two study questions. Direct care staff familiar with the individuals scheduled to have a medication reduction were provided memos that included the medication that was scheduled to be reduced along with the date this was to occur. At the same time, they were provided a question that requested information about their expectations related to changes in both target behaviors and also psychiatric symptoms in response to the upcoming reduction. Specifically, staff were asked to report whether they believed the person's behaviors and psychiatric symptoms would *get better, have no change, or get worse*. Following this, an examination of data related to the individual's clinical condition was explored by comparing the data collected 30 days prior to the reduction to that collected 30 days after the reduction. This also allowed for an examination of changes in recording behavior among staff based on their expectations of clinical change.

Once staff expectancies related to reductions in psychotropic medication were made known, analyses across groups were conducted to determine if there were any factors that were associated with specific expectancies. Further, pre-reduction and post-reduction data by expectancy condition were analyzed using a mixed-model ANOVA to determine if these expectancies were associated with fluctuations in data recording.

Given the noted expectancies, Phase II of this study was intended to measure the impact of a policy drafted to inform direct support staff of upcoming medication reductions. The present study sought to determine if data recording prior to this written policy varied significantly with that following its initiation. This provided the opportunity to test the functional nature of a single-blind approach to reduce the impact of bias associated with psychotropic medication reductions in persons with mental retardation. Analysis of this portion of the study primarily consisted of a factorial ANOVA, which allowed for comparison of both main effects (i.e., information and reduction conditions) along with any interaction that may have been associated with the variables.

Findings

Staff Expectancies

In order to examine staff expectancies related to psychotropic medication reductions, staff were asked to report whether they believed the person would *get better, have no change, or get worse* following the reduction. It was hypothesized that direct support staff would disproportionally expect a worsening in an individual's behavior or psychiatric symptoms following this reduction. The study found that the null hypothesis was rejected at a significant level.

A chi square test was computed to compare the distribution of expectancies following a reduction in psychotropic medication. The test showed a significant difference between expectancy conditions, $X^2(2) = 113.1, p < .001$, for target behaviors, and also for psychiatric symptoms, $X^2(2) = 106.2, p < .001$. For the specific distribution across conditions and behaviors/symptoms, please see Table 7.

Table 7
Staff Expectancies Following Medication Reductions

Expectancy	Behaviors		Symptoms	
	<i>n</i>	%	<i>n</i>	%
Better	2	1.4	3	2.1
No Change	38	26.2	39	26.9
Worse	105	72.4	103	71.0

In order to investigate differences across groups that may have contributed to this distribution, one-way ANOVAs were conducted on the variables of age, duration at the facility, and IQ score across both expectancy variables (i.e., behaviors and psychiatric symptoms). For behavioral expectancies, no significant demographic differences were found across any of the expectancy conditions (Age: $F(2, 142) = 0.06$; Duration at Facility: $F(2, 142) = 2.83$; IQ score: $F(2, 142) = 0.03$). When examining symptom expectancies, no significant differences were found for age, $F(2, 142) = 0.86$, or for IQ score, $F(2, 142) = 0.06$. However, a significant difference was found for years at the facility between those who expected no change ($M = 19.4, SD = 11.1$) and those who expected the person to get worse ($M = 25.6, SD = 9.9$), $F(2, 142) = 5.20, p < .01$.

When considering group differences on clinical factors, no differences were found on either the number of medications (Behavioral Expectancies: $F(2, 142) = 1.07$; Symptom Expectancies: $F(2, 142) = 0.61$) or the specific psychotropic medication that was reduced (Behavioral Expectancies: $X^2(26) = 31.2$; Symptom Expectancies: $X^2(26) = 28.3$). As can be seen from Table 8, a significant difference was found across behavioral

expectancy groups for diagnosed psychiatric condition. However, the same was not found for psychiatric symptoms, $X^2(20) = 23.8$.

Table 8
Diagnoses by Behavioral Expectancy Groups

Variable	Better		No Change		Worse		X^2
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	
Disorder ^a							28.6*
Impulse Control	0	0.0	1	2.6	5	4.8	
Mental	0	0.0	3	7.9	1	1.0	
Mood	1	50.0	19	50.0	72	68.6	
PDD	0	0.0	2	5.3	15	14.3	
Psychotic	0	0.0	8	21.1	6	5.7	
Deferred	0	0.0	3	7.9	3	2.9	
No Disorder	1	50.0	2	5.3	3	2.9	

^a $df = 12$.

* $p < .01$.

Relationship between Expectancies and Data Collection

Significant variability was found for both behavioral and symptom expectancies and an examination of associated data recording practices was warranted. It was hypothesized that, following the medication reduction, there would be differences in data recorded between staff who expect deterioration and those who did not. For this analysis, comparison of pre-reduction and post-reduction data was completed by analyzing data reported by individual staff. By examining recording practice by expectancy condition, this allowed further exploration of changes in recording practice by staff expectancy.

Two mixed-model ANOVAs were conducted to examine both the between-group differences for those who expected deterioration and those who did not, along with the within-subject change from the pre-reduction to post-reduction period. For the behavioral expectations, there was a significant difference between expectancy group, $F(1, 138) = 7.5, p < .01$, and a significant interaction between the two variables, $F(1, 138) = 6.5, p < .05$. The main effect for data recorded over time was not significant, $F(1, 138) = 2.2$. For detailed information related to behavioral expectancies and pre-reduction and post-reduction data, please see Table 9. To follow-up the interaction effect, two one-way ANOVAs were conducted. While the pre-reduction data trended towards significance, $F(1, 138) = 3.5$, a significant difference was found for the post-reduction data by expectancy group, $F(1, 138) = 8.6, p < .01$.

Table 9

Data Fluctuation by Behavioral Expectancy

Variable	Pre-Reduction		Post-Reduction	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
No Deterioration	1.8	1.3	0.8	2.1
Deterioration	4.5	0.8	8.1	1.3

For symptom expectancy, a significant difference in data recording behavior across expectancy condition was found, $F(1, 130) = 10.8, p < .01$. Follow-up one-way ANOVAs were conducted to explore the significant difference found across expectancy condition, resulting in determination of a significant difference for both the pre-, $F(1, 130) = 7.3, p < .01$, and post-reduction data, $F(1, 130) = 10.2, p < .01$, across groups. No significant differences were found from time one to time two, $F(1, 130) = 0.2$. Further,

there was no significant interaction effect noted, $F(1, 130) = 0.8$. For specific rates of data across condition, please refer to Table 10.

Table 10
Data Fluctuation by Symptom Expectancy

Variable	Pre-Reduction		Post-Reduction	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
No Deterioration	0.9	3.2	0.3	3.5
Deterioration	11.5	2.2	13.9	2.4

Policy Evaluation

At the facility under investigation, policy changes that took place in 2001 included initiation of a form that informed direct support staff of upcoming changes in psychotropic medication for the individual. With a significant number of staff expecting deterioration following a reduction in psychotropic medication (see Table 7), it was hypothesized that staff awareness of upcoming reductions would contribute to fluctuation in data recording behavior.

To examine this, a 2 X 2 factorial ANOVA was conducted to compare both reduction conditions (i.e., those that received a reduction and those that did not) and also information condition (i.e., before initiation of the 2001 policy and those after which were informed in writing of upcoming reductions). No significant difference was found between the two information conditions, $F(1, 236) = 0.02$, nor for the interaction between information and reduction conditions, $F(1, 236) = 0.14$. However, a significant main effect for reduction condition was found, $F(1, 236) = 9.77, p < .01$. Upon examination of the descriptive information, those who had their psychotropic medication

reduced had post-reduction rates that were 188.4% of the pre-reduction levels. A negligible change in reporting (107.1%) occurred for those who did not have a reduction.

Conclusions

Use of psychotropic medication has been reported at higher rates for those who have developmental disabilities than for those who do not (Aman & Singh, 1986; Holden & Gitlesen, 2004). When examining prevalence of psychotropic medication use within residential facilities, overall rates have been found to be over 55% (Valdovinos et al., 2003). Of the total population at the state operated residential center included in this study, 39.2% received at least one psychotropic medication which represents a conservative prevalence compared to that noted by Valdovinos et al. This lower prevalence may be attributed to regulations designed to reduce overall use of pharmacological interventions in response to federal investigations (Prigmore & Davis, 1973; U. S. Department of Justice, 2006a, 2008b).

Regulations have been instituted by the U. S. Department of Health and Human Services (2004) which require that a reduction in an individual's psychotropic medication occur at least annually, unless clinically contraindicated. Researchers have also noted the benefits of reducing psychotropic medication to a level in which side effects are minimized while clinical benefits are preserved (Kalachnik, 1988). While some have noted the clear ability to reduce the rates of psychotropic medication use for persons with mental retardation (Janowsky et al., 2006; Hancock et al., 1991), use continues to be high. This is likely associated with the continued perception that psychotropic medications are appropriate interventions for both behaviors and psychiatric symptoms (Christian et al., 1999; Unwin & Deb, 2008).

Perceived benefits from use of placebo have been noted to occur in as many as 33% of cases (Ernst, 2007; Sandler & Bodfish, 2000). When examining expectancies related to medication discontinuation in persons with mental retardation, Breuning et al. (1980) found that 70 of 74 staff reportedly expected deterioration following discontinuation. With regulations and best practice indicating the need to reduce psychotropic medications, an examination of staff expectancies was necessary.

Expectancies

This study found that direct support staff working at a residential facility for adults with mental retardation expected decompensation in a person's clinical condition following a reduction in their psychotropic medication. The results indicated that less than 3% of staff believed a person would get better following this change, while over 70% of staff participants expected a worsening of both target behaviors and also psychiatric symptoms. This evidence is sufficient to reject the first null hypothesis (H_0 : Direct support staff will not disproportionately expect a worsening in an individual's behaviors or psychiatric symptoms following a psychotropic medication reduction).

While expectancy groups were found to be statistically equivalent on variables such as age and IQ score, a significant difference was found for length of residence across symptom expectancy groups. Individuals who were expected to get worse had an average length of stay of 25.6 years compared to an average of only 19.4 years for those who were expected to have no change. Upon examination of clinical variables, the expectancy groups were not found to be significantly different in regards to number of medications prescribed or specific medication reduced. There was however a significant difference across diagnosed condition with a greater prevalence of both mood and

pervasive developmental disorders (PDD) and a lower prevalence of psychotic disorders in residents for whom staff expected behaviors to get worse following the reduction. This result was not found for symptom expectancies which may be consistent with previous research noting the prominent use of psychotropic medication to control behaviors such as physical aggression and self-injurious behavior (Baumeister & Sevin, 1990; Baumeister et al., 1993).

Impact of Expectations on Data Collection

Previous research has found that expectancies of improvement were correlated with perceived clinical benefit of psychotropic medication (Kumar et al., 2007; Turner et al., 2002). With the noted negative expectancies found in this study, the intention of this portion of the study was to explore whether this translated to variability in data based on expectancy condition. If this was the case, this would provide evidence that expectancies may be one factor that limits both the reliability and validity of data being collected on target behaviors and psychiatric symptoms alike.

The results did show that expectancy condition was associated with frequency of data recorded. The findings are unclear whether this variability is independent of true clinical change, or if staff who expected a person to get worse following a medication reduction recorded a greater frequency of both target behaviors and psychiatric symptoms than those staff who did not expect deterioration. The results from both Table 9 and Table 10 show that not only were behaviors/symptoms recorded with greater frequency for those who expected worsening following the reduction, but the change from pre-reduction to post-reduction data trended in the expected direction as well. This was noted

by the post-reduction rates being elevated for the *get worse* expectancy group, as opposed to the decrease noted for the other group that did not expect deterioration.

One unexpected result was the difference in pre-reduction data across the two expectancy conditions for both behaviors and symptoms. This indicated that staff who are recording lower rates of behaviors and symptoms in general (i.e., independent of medication changes) were more likely not to expect a worsening of a person's condition following the reduction. While the cause and effect of this relationship is unclear, there continues to be strong evidence of a relationship between expectancies and data recording behavior.

At this point, what is unclear is whether this variability in data recording by expectancy is due to an interactional expectancy effect where the individuals' behavior was actually elevated for the *worse* expectancy group, or if it was due to observer error which biased staff recording in the direction of their expectancies. However, with the difference noted in data recording across expectancy condition, we can confidently reject the second null hypothesis (H_0 : Following the medication reduction, there will be no difference in data recorded between staff who expect deterioration and those who do not).

Informed Reductions

One way to control for bias would be not to inform the subjects or researchers of the research conditions. For evaluation of psychotropic medication efficacy, it has been suggested that placebo control and double-blind strategies be used to properly evaluate treatment changes for persons with mental retardation (Singh et al., 2005; Sprague & Werry, 1971). However, even with double-blind procedures, both patients and clinicians

can determine whether they are receiving a placebo or the active agent with some accuracy (Brownell & Stunkard, 1982; Turner et al., 2002).

By informing direct support staff of upcoming planned reductions, it is likely that any preexisting expectancies would bias the evaluation of the treatment change. A policy change at the facility creating a form for this very purpose provided for an evaluation of this potential confounder. Subjects were grouped based on their assignment to one of four conditions based on the year (pre-policy and post-policy implementation) and also whether they received a reduction or not. This then allowed for a comparison of both main and interaction effects to determine if staff expectancies translate to variability only when formally informed of the planned change. Without this pre-reduction information, the procedure resembled a single-blind design.

When compared with the 30-day period prior to the reduction, individuals who received a medication reduction had a significantly greater increase in data recording during the 30 days following the reduction. In fact, the post-reduction number was 188.4% of what the pre-reduction number had been. For those who did not receive a reduction in their psychotropic medication, the number remained virtually unchanged (i.e., 107.1% of the pre-reduction rates). This provided evidence that, either the individuals had a decompensation in their clinical condition following their reduction, or that staff expectancies related to the upcoming reduction impacted the rate that data were being recorded.

By examining the information condition (2000 before the policy was in place, 2008 after the policy was in place) it was believed that the data during 2000 would approximate a single-blind study and reduce the control for potential staff expectancies.

However, with no significant difference found for either the information condition or the interaction between the information or reduction variables, the change in reporting practice cannot be attributed to the written communication (i.e., policy change). For this reason, the third null hypothesis was unable to be rejected (H_0 : Staff who are informed of upcoming medication reductions will not record post-reduction data with greater frequency than those who have not been informed). With the involvement of the team, a probable cause for this finding was that reductions in 2000 were still communicated to direct support staff, just not in the form of a written document.

One unexpected finding was the significant difference found between the 2008 reduction group (informed and reduced) and the 2000 reduction and non-reduction group (both groups uninformed). Further, a similar difference was found for age across the 2008 reduction group and both of the 2000 groups. As can be seen from Table 4, the average age of those in the 2008 reduction condition was 5.6 years greater than the 2000 conditions with the average length of stay for the 2008 reduction group being 7.5 to 8 years greater than the 2000 groups. With the average length of stay over 14 years, it is likely that this difference can be attributed to the discrepancy in years that the subjects were selected from (i.e., 2000 versus 2008).

Implications and Recommendations

Expectancies are known to reduce the objective evaluation of treatment. One example of this phenomenon is the placebo effect in which a client perceives benefit following the administration of an inert agent (Ernst, 2007; Stewart-Williams & Podd, 2004) which has also been referred to by Kenna and Wood (2008) as pharmacological optimism. With strong expectancy conditions such as that seen with the trial use of

secretin for children with autism, objective evidence to the contrary may not be sufficient to ameliorate some from these erroneous views (Sandler & Bodfish, 2000).

Expectancies have also been noted to lead to changes in client behavior (or the observed) which appear mediated through what Rosenthal has termed expectancy effects (Rosenthal, 1977, 1980, 1994, 2002; Rosenthal & Rubin, 1978). Expectancy effects manifest themselves through an alteration in observer/experimenter behavior such as frequency of interactions, eye contact, and positive praise (Harris & Rosenthal, 1985). This change in behavior then translates to modifications in the subjects' behaviors being observed. Observer effects, which can be perceived as rater bias, can also lead to differences in evaluations of the same targets. This non-interactional effect of expectancies has been shown to impact the accuracy of recorded behavior (Harris & Lahey, 1982). This risk becomes greater the more ambiguous the observed behavior is. Expectancies and their effects have been found associated with psychotropic medication use for persons with developmental disabilities.

Expectancies have been noted in studies pertaining to the initiation of treatment in the form of placebo effects (Sandler & Bodfish, 2000; Tyrer et al., 2008), and also discontinuation of medication, which has been associated with expectations of deterioration (Breuning et al., 1980). The results from the present study also document the presence of expectancies associated with reductions in psychotropic medication for individuals residing in a state operated developmental center. Specifically, over 70% of staff participants reported an expectation that the individual would get worse following the reduction. With the noted impact that expectancies have on the accuracy of data being collected, the present results are problematic for the accurate evaluation of

pharmacological interventions within this population. Through an examination of variability in data recording practice for both target behaviors and psychiatric symptoms, this study further strengthens this concern.

With staff who expect decompensation recording behavior and psychiatric symptoms with significantly greater frequency, the expectancies found in the first part of this study appear in fact to be negatively impacting the reliability and likely the validity of the data. This is of particular concern given the non-benign nature of pharmacological interventions (Castle et al., 2002). Without an accurate evaluation of changes to psychotropic medication schedules, individuals may be exposed to unjustified side effects without the noted clinical benefits. Even though federal, state, and facility policies related to medication reductions are followed (e.g., McDonald, 1988; Patient Freedom from Restraint Act, 2000; U. S. Department of Health and Human Services, 2004), the data used to justify the dosage of medication may be erroneous. If expectancies impact treatment evaluation, it is advantageous to understand what those expectancies might be and how they may be controlled.

Pharmaceutical companies spend an exceptionally large amount of money on advertising that is targeted directly to the consumers (DTCA). In 2001, almost \$18 billion was spent on marketing this group of medications, with \$193 million being spent on DTCA in 2004 for antidepressant medication alone. It is perhaps possible that advertising, coupled with attitudes towards individuals with mental illness, account for the perceived appropriateness that providers hold for use of pharmacological interventions for psychiatric symptoms along with inappropriate behaviors (Aman et al., 1987; Christian et al., 1999; Unwin & Deb, 2008). It appears that a growing positive

attitude towards use of psychotropic medication exists (Angermeyer & Matschinger, 2004; Angermeyer et al., 2005).

Given their potential for confounding treatment evaluation, a number of measures have been proposed to control expectancies. These include use of consistent approaches to rating, training, overlap of raters, and knowledge of the rated subject (Hoyt & Kerns, 1999) along with use of direct observation (Fogel & Nelson, 1983; Poling et al., 1991). For pharmacological interventions, placebo and double-blind controls have been suggested (Baumeister & Sevin, 1990; Poling et al., 1991; Sprague & Werry, 1971). However, with use of more objective behavioral measures, single-blind procedures have also been noted to control for expectancies (Towns et al., 1984). Through an examination of data reporting practice before and after the initiation of a policy of providing written notification to direct support staff of upcoming reductions, one aspect of this study included an approximate evaluation of such a single-blind procedure.

Without a significant difference across information conditions (i.e., before and after initiation of a policy of written notification of upcoming reductions), it may be that staff during the earlier years were able to obtain information of the upcoming reduction in other ways. This is likely given the presence of the IDT process that includes group decision-making (Natvig, 1991). This along with the ability of staff and patients to determine placebo conditions at a high rate (Brownell & Stunkard, 1982; Turner et al., 2002) appear to leave some doubt about the controlled nature of placebo studies. Along with the apparent inability to control for flow of information at the facility under investigation, some additional limitations surfaced following the analysis and interpretation of results. In addition to the transmittal of expectancies that may have

occurred for the earlier groups, the interval between information groups may have also led to the addition of other extraneous variables. There were undoubtedly numerous clinical and policy changes that could have taken place over this eight-year period.

Overall, this study did serve to extend our knowledge on expectancies related to medication reductions that occur at a residential facility for persons with mental retardation. There is support for both the presence and impact of expectancies on data recording behavior. Without the apparent ability to control information about treatment changes, there remain a number of areas where research and clinical practice can expand.

To better differentiate changes in data associated with staff expectancies from that of true clinical change, it is recommended that some exploration of data beyond the 30-day period following a reduction take place. Subsequent return to pre-reduction rates may be further evidence of the presence and impact of expectancies for this population. Results from such an evaluation would have implications about returning reduced medication to its previous dosage.

This study clearly documented the strong negative expectancies associated with medication reductions. It is suggested that further investigation take place for other medication changes such as initiation and increases. While initiations may be more associated with the presence of a placebo effect, increases in psychotropic medication may or may not produce similar expectancies. Further, it would be interesting to note whether expectancies following increases are inversely related to those of decreases or if some other relationship exists. The presence and impact of expectancies related to increases would have further implications for treatment integrity.

It would be beneficial to understand factors associated with the negative expectancies that most staff reported. This could be conducted through follow-up interviews or surveys related to treatment change and their expectations. With multiple variables gathered, regression analyses would allow for determination of factors that are predictive of expectancy condition. This information would also provide insight into steps that could be taken to alter or at least minimize the formation of expectancies.

One area that this study did not address was that of patient or consumer expectancies associated with medication changes. It is suggested that further exploration take place in this area to determine whether consumer expectancies follow the same trajectory as staff expectancies. Further, knowledge of treatment change is readily available to the consumers given they are the ones who are taking their medication. Control of this knowledge may require trials of placebo methodology.

A number of undocumented changes may have taken place between the 2000 and 2008 that could have been a factor in negating a significant difference between information conditions. For this reason, it is suggested that data from 2002 be gathered and compared with that from 2000 in a similar manner done within this study. While the evaluation periods would continue to be opposite the year the policy of written communication was instituted, the shorter interval should reduce extraneous variables that may have been injected during later years.

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APPENDIX A

Psychotropic Medication Increase / Decrease / Initiation

INDIVIDUAL: _____ DATE: _____

PURPOSE: Group Leaders and Alternates spend the most direct contact time with those individuals whom reside at Shapiro. It is for this reason that input from these staff is both invaluable and necessary to provide good care. This is one of those times.

Please take a moment and tell me about your feelings or beliefs about the medication change referenced on the attached form (SC#450). ***It is important to provide accurate information on this form. The information gathered will only be used for research and quality enhancement purposes.***

Please answer both questions.

Following this medication change, I believe the person's target behavior (e.g., physical aggression, self-injurious behavior, property destruction, etc.) will: (please circle one)

Get Better

Have No Change

Get Worse

Following this medication change, I believe the person's OBC/psychiatric symptoms (e.g., hallucinations, psychomotor agitation, crying, etc.) will: (please circle one)

Get Better

Have No Change

Get Worse

Group Leader/Alternate Initials: _____ Shift: _____

*Once completed, please tear off and provide to the **Unit Psychologist/Behavior Analyst**. Thank you in advance for your input and all the work you do here at Shapiro Center.

APPENDIX B

Shapiro Center Data Recording Forms

SHAPIRO CENTER
Momentary Time Sampling Recording Form (443-M)

Name: _____ ID#: _____ Living Area: _____ Monday's Date: _____

INSTRUCTIONS: Every hour **on the hour** (as indicated by the time) observe the individual. If he or she is engaging in the behavior/OBC(s) indicated on data sheet, (1) record this by placing a mark in the box that corresponds to that behavior/OBC(s), (2) indicate the intervention that was provided following the occurrence of that specific behavior/OBC, and (3) initial the box for staff initials. If no behavior is observed, please do not check a box for behavior/OBC or intervention, but ensure that you initial the box to indicate you made an observation during

Example Mark:

Monday

Time	BEHAVIOR/OBC					INTERVENTIONS					Staff Initials
	Behavior/OBC 1	Behavior/OBC 2	Behavior/OBC 3	Behavior/OBC 4	Behavior/OBC 5	Intervention 1	Intervention 2	Intervention 3	Intervention 4	Intervention 5	
7:00am											
8:00											
9:00											
10:00											
11:00											
12:00pm											
1:00											
2:00											
3:00											
4:00											
5:00											
6:00											
7:00											
8:00											
9:00											
10:00											

Tuesday

Time	BEHAVIOR/OBC					INTERVENTIONS					Staff Initials
	Behavior/OBC 1	Behavior/OBC 2	Behavior/OBC 3	Behavior/OBC 4	Behavior/OBC 5	Intervention 1	Intervention 2	Intervention 3	Intervention 4	Intervention 5	
7:00am											
8:00											
9:00											
10:00											
11:00											
12:00pm											
1:00											
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10:00											