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THE EFFECTS OF A NEUROLEPTIC DRUG ON ADAPTIVE AND DISRUPTIVE BEHAVIOR OF RETARDED ADULTS

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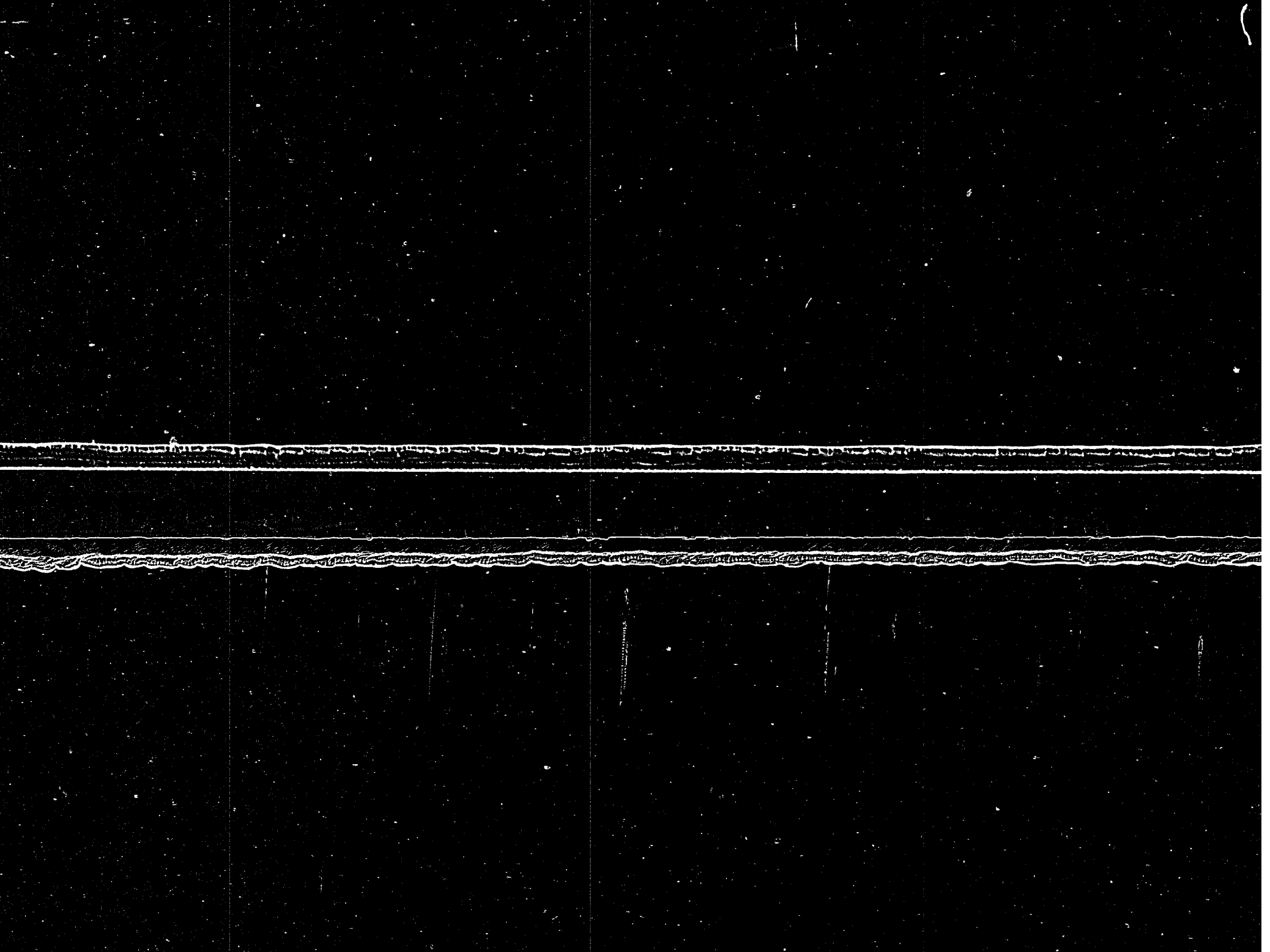

THE EFFECTS OF A NEUROLEPTIC DRUG ON ADAPTIVE AND DISRUPTIVE BEHAVIOR OF RETARDED ADULTS

by

Laurie Anne Westlake

A Dissertation Submitted to the Faculty of the

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As members of the Final Examination Committee, we certify that we have read the dissertation prepared by Laurie Anne Westlake entitled THE EFFECTS OF A NEUROLEPTIC DRUG ON ADAPTIVE AND DISRUPTIVE BEHAVIOR OF RETARDED ADULTS and recommend that it be accepted as fulfilling the dissertation requirement for the Degree of Doctor of Philosophy.

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Final approval and acceptance of this dissertation is contingent upon the candidate's submission of the final copy of the dissertation to the Graduate College.

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SIGNED: Laurie Anne Westlake

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ABSTRACT

Single subject research procedures were used to evaluate the following effects of Mellaril, a neuroleptic, on adaptive and disruptive behaviors of three institutionalized retarded people: 1) documentation of social interactions, activity level, vocational performance, repetitive motoric behavior, disruptive incidents, and possible tardive dyskinesia to determine which behaviors changed during drug and placebo conditions, and 2) individualized clinical evaluation to determine whether drug therapy decreased disruptive behavior and increased or interfered with adaptive functioning.

Each subject received individualized Mellaril dosages and served as his/her own control in reversal designs. All subjects were abruptly withdrawn from the drug. One subject (125 mg.) underwent B-A-B phases while two subjects (60 mg., 250 mg.) underwent B-A-B-A phases, where B indicated the drug condition and A indicated the placebo condition. Each phase lasted approximately one month. A fourth subject underwent B-A phases and was dropped from the study due to an epileptic convulsion. Pharmacotherapy for this disorder confounded Mellaril-behavior relationships.

A trained observer recorded occurrence of behavior on weekdays within the institution including 15 minutes per subject in residential settings and five minutes per subject in vocational settings. Institutional staff documented daily frequencies of incidents including

aggression and property destruction. Institutional staff, the trained observer, and the subjects were not told the timing of drug/placebo changes.

The results indicated that the following behaviors increased following drug withdrawal: vocational performance, talking, looking at and proximity to others, and talking/laughing to self. Activity level decreased upon drug withdrawal. The following patterns of disruptive behavior were subject-unique: one subject (250 mg.) clearly showed the most incidents while on-drug; one subject (60 mg.) did not show changes during the first drug withdrawal, but showed increases during the second; and the third subject (125 mg.) engaged in incidents at steadily increasing rates during all conditions.

The applicability of single subject designs to applied behavioral pharmacology is discussed. Variables within an applied setting which potentially obfuscate drug-behavior relationships are identified. Suggestions for future research are offered.

CHAPTER 1

INTRODUCTION

The use of drugs common to psychiatric practice has become programmatic for a large percentage of the institutionalized retarded. The most frequently prescribed psychiatric drugs are those of the neuroleptic category which produce changes in the behavioral expression of emotion. Neuroleptics typically suppress range of affect and contribute to a general disinterest in the environment (Baldessarini, 1981). Workers in the field of retardation have referred to the neuroleptics as "behavior control" drugs and have used them to suppress disruptive behavior among retarded people.

The prevalence of neuroleptic drug prescription for the retarded has been documented by several surveys conducted within the last 12 years. In 1970, Lipman sent questionnaires to every state institution for the retarded in the United States and reported that 51.1% of the residents were receiving behavior control drugs. In a more recent study, Sprague (1977) surveyed a large state institution in the midwest and concluded that 59.9% of the retarded were behavior control drug recipients. Other studies have obtained similar findings and have indicated that two prototype neuroleptics, Thorazine and Mellaril, were the most commonly used drugs (DiMascio, 1975; Silva, 1979). Although the trend in drug prescription may vary across institutions, drug

treatment of behavior problems among the retarded has steadily increased since the 1955 discovery and the subsequent widespread use of neuroleptics in psychiatric populations (Sprague and Baxley, 1978).

The increase in drug prescription has been a major concern of groups involved in applied research, legal rights, and service delivery in the field of retardation. Interested workers are faced with integrating information pertinent to all three issues in order to make decisions regarding habilitative and rehabilitative care for the retarded. The research findings have summarized the efficacy of the neuroleptics as instrumental in managing behavior problems and have indicated untoward somatic and behavioral effects. Drug prescription for legally incompetent retarded recipients has raised ethical issues due to the absence of informed consent for drug therapy and the presence of untoward medication effects. The quality of service delivery during drug therapy has been examined and questioned since the worker must often weigh the benefits of drug therapy against potential harmful effects.

The three issues will be presented apart from the others in an effort to summarize the main points of each. This review is followed by a description of the methods of an applied behavior analysis which were used to address the complexity of the issues involved in behavior control drug prescription for the retarded.

Research Findings

The growing trend towards drug treatment has not been reflected in an increase in clinical studies investigating drug therapeutic

efficacy among the retarded. In fact, a recent literature review compared the number of studies prior to 1967 to those published since that date and concluded that there has been an alarming decrease in such studies over the previous decade (Lipton et al., 1978). There is a paucity of available literature addressing behavior control drug treatment among the retarded or the establishment of reliable clinical measures to ascertain their usefulness (Sprague, 1973; Sprague and Baxley, 1978; Sprague and Ullmann, 1981; Sprague and Werry, 1971; Werry, 1977).

A review of the literature has indicated that the most common problem behaviors treated with drugs included aggression, property destruction, self-injurious behavior, and repetitive motoric responses such as rocking. The clinical effectiveness of the neuroleptics as measured by nonstandardized behavior checklists and global ratings has been equivocal across studies. Thorazine produced improvement in aggression, self-injurious behavior, and hyperactivity compared to placebo in 18 retarded people (Hunter and Stephensen, 1963), but no evidence of change in "disturbed behavior" of 21 retarded people receiving active (Thorazine) or inert drug syrup was reported (Weir, Kernohan, and MacKay, 1968).

In another study, Thorazine compared to placebo produced positive changes in social behavior of 11 destructive and hyperactive retarded subjects, although its impact on the problem behaviors was negligible (Craft, 1957). Both placebo and Thorazine contributed to "improved behavior" in retarded people who engaged in aggression, self-mutilation, and repetitive motoric behavior (Adamson et al., 1958).

Mellaril, the other most commonly used neuroleptic, has similarly produced equivocal findings with respect to clinical gains. Drug therapy produced some changes in manageability, hostility, overactivity, appetite, and sleep in 59 retarded subjects who received either Mellaril or placebo (LeVann, 1970). Similarly, Mellaril compared to placebo produced changes in desired directions on behavioral ratings of hyperkinesis, concentration, aggression, mood, and class standing (Alexandris and Lundell, 1968). In another study Mellaril reduced repetitive motoric behavior but other motor behaviors were not affected (Davis, Sprague, and Werry, 1969).

Notably, this last study was the only one which provided operational definitions for the behavior under study. The other early studies should be reviewed with caution due to questionable methodologies including lack of consistent operational definitions and interobserver reliability measures for the behaviors which were evaluated.

The early studies reported results according to group averages which could not, of course, be generalized to the behavior of an individual drug recipient and did not address the issue of idiosyncratic drug-related responses. Marholin and Phillips (1976, p. 480) criticized global statements claiming clinical improvement based on a decrease in problem behavior by noting the price paid by one patient receiving Thorazine: "Sitting or lying, the patient is motionless in his bed, often pale and with his eyes lowered. He remains silent most of the time. If he is questioned, he answers slowly and deliberately in a monotonous, indifferent voice; he expresses himself in a few words and becomes silent."

In addition to their sedating effects on the central nervous system, the neuroleptics have modified other bodily functions (Gadow, 1979; Baldessarini, 1981). They can affect the autonomic nervous system by producing blurred vision, dizziness, decreased sweating and salivation, nasal stuffiness, constipation, and inhibition of penile ejaculation without interfering with erection. The neuroleptics can cause low blood pressure which may result in fainting particularly if the recipient quickly rises from a sitting or prone position. The endocrine system can also be affected in that changes in release of gonadotropic hormones may cause discharge from the nipples in females as well as males.

The most disconcerting effects of neuroleptics have been the four extrapyramidal syndromes which have involved certain motor areas of the brain (Gadow, 1979). Nerve fibers located in the extrapyramidal system are believed to coordinate motor activities such as posture, muscle tone, walking, and patterns of movement. Neuroleptics can cause skeletal muscle spasms, changes in body posture, strange movement of limbs, and paucity of facial expression.

Parkinsonian syndrome is one type of disorder of the extrapyramidal system associated with neuroleptics. Spontaneous movements are depressed and the face may take on a blank, mask-like expression. Other problems include tremors, drooling, and a shuffling walk. The affected person may show hand and finger movements which look like he/she is rolling a pill (or other small object) between the fingers (called "pill-rolling").

Akathisia and dystonic reactions are two additional extrapyramidal disorders. Akathisia includes motor restlessness. The neuroleptic recipient cannot sit still and appears agitated. Acute dystonic reactions include any of the following: facial grimacing, rolled eyes such that the gaze is fixed upward, and strange posturing of the head due to contraction of neck muscles.

These three extrapyramidal tract disorders have differed from the fourth disorder, tardive dyskinesia, in that the symptoms listed above are ameliorated through neuroleptic drug dosage reduction or the addition of drug treatment for these adverse effects (Baldessarini, 1981). Tardive dyskinesia has included rapid sucking and chewing, restless fingers (called "piano-playing"), and jerky body movements which have not been amenable to any medical treatment (Kobayashi, 1977). This disorder is believed to result from long-term neuroleptic therapy and often has not presented until drug withdrawal (McAndrew, Case, and Treffert, 1972; Paulson, Rizvi, and Crane, 1975; Polizos and Engelhardt, 1978; Polizos et al., 1973).

The advantages of drug treatment in the form of decreased problem behavior should be determined within the larger context of its impact on an entire behavioral repertoire before meaningful clinical gains can be claimed. An analysis of this sort requires measurement of operationally defined desirable and undesirable behaviors as well as possible adverse drug-behavior effects. In addition to the adverse effects already listed, the neuroleptics have produced impaired social interaction and social learning (Rassidakis, Kondakis, and

Papanastassion, 1970; Paul, Tobias, and Holly, 1972); impaired performance on intelligence tests (Breuning and Davidson, 1979); and impaired learning performance (Sprague and Baxley, 1978; Sprague and Berger, 1980; Sprague and Sleator, 1976; Werry, 1977).

Ethical Issues

A review of the research findings has indicated that the neuroleptics have sometimes been effective as disruptive behavior suppressants. Unfortunately, the findings have also indicated that desirable behaviors may also be impaired during this therapy. The use of neuroleptics has presented a dilemma to workers in retardation since legal standards have required that treatment programs be implemented in response to the individual's entire repertoire including psychological, social, educational, and medical needs. Legally, a neuroleptic can be included as part of the treatment program as long as it does not interfere with the possibility of other treatment gains.

The most significant legal development regarding behavior control drug prescription among the retarded has been the court's acceptance of a developmental model of retardation stipulating client's rights to habilitation (Sprague and Baxley, 1978). The constitutional right to treatment for institutionalized retarded persons was enforced through the Wyatt v. Stickney (1972) decision which, among many issues, stated that: 1) residents shall have a right to be free of unnecessary or excessive medications; 2) medication shall not be used as punishment, for the convenience of staff, as a substitute for a habilitation program, or in quantities that interfere with the resident's habilitation

program; and 3) progress under the drug regimen must be reviewed regularly.

Similarly, other cases have been decided in support of the retarded person's rights to habilitation programs without excessive medication (Nelson v. Heyne, 1974; Gary W. v. Louisiana, 1976). In summary, legal decisions have called for documentation that institutionalized retarded persons are receiving habilitation and rehabilitation services and that behavior control drug treatment has been consistent with these approaches.

Consistent behavioral monitoring of the clinical effectiveness of neuroleptics has not been the general practice despite the prevalence of this therapy. Sprague (1977) reviewed medical records and procedures in 35 institutions and concluded that, at best, vague anecdotal statements with respect to the progress of drug therapy were logged on an infrequent basis. Rarely were the problem behaviors that warranted drug treatment specified or referenced throughout the duration of treatment.

Sprague concluded that "chaos reigns" in clinical practice and the evaluation of drug treatment among the retarded. By comparison, recent behavioral programs put forth to improve skill levels among the retarded have utilized rigorous treatment evaluation techniques. Likewise, according to Sprague, the burden of proof regarding the therapeutic efficacy of drug prescription remains with the advocates of neuroleptic treatment to provide evidence that drugs are being used in a manner consistent with modern theories and practices of habilitation and rehabilitation programs.

Service Delivery

Habilitative and rehabilitative program development for the retarded includes strategies to increase adaptive behaviors and decrease problematic or disruptive behaviors. The skills of every day living such as proper grooming, dressing, language, social interactions, and when age-appropriate, application of basic academic and vocational skills are adaptive behaviors (Grossman, 1973). Recently, the trend in program development has been towards individualization of the retarded client's treatment plan (Bijou, 1977; 1980). Habilitative and rehabilitative programs are designed to enhance the individual's adaptive skill level based on behavioral checklists which summarize his/her specific adaptive behavioral strengths and deficits.

The program developer is responsible for reviewing all available treatment options in order to provide the client with adequate and individualized programs (Cleland, 1978; Garrard and Richmond, 1978a). The use of neuroleptic treatment requires a drug-behavior analysis of its potential advantages and disadvantages for each individual client. The former include a decrease in disruptive behaviors while the disadvantages may include interference with progress during programs to promote social and cognitive adaptive behaviors.

The program developer is presented with an additional problem in that research findings, as already indicated, have typically presented drug behavioral effects in terms of group averages. The applicability of these findings to the individual client has presented problems due to the fact that many of the retarded have responded in an

idiosyncratic manner to neuroleptic treatment (Sprague and Baxley, 1978).

Since all programs, including drug treatment, must be individualized for each client, special procedures are necessary to evaluate the most effective methods of service delivery. These procedures must be sufficiently sensitive to show adaptive behavioral change in response to the various treatment alternatives.

Applied Behavior Analysis

Applied behavior analysis has been used extensively in applied settings such as school systems, state hospitals, and institutions for the retarded (Kazdin, 1978; Wahler and Fox, 1981). The approach offers the following procedures for empirical documentation of adaptive behaviors of individual retarded clients in the institutional setting. Frequency counts or other similar measures are used to quantify the occurrence of commonplace and socially relevant behaviors such as talking, proximity to others, time involved in activities, and the like. Once the relevant behaviors have been operationally defined, a lengthy account called a baseline includes a time series record of behavioral rates before any intervention is introduced to change behavior. Throughout the baseline, documentation of behavior rate during the same activity and in the same location occurs on a near daily basis.

An adequate behavioral monitoring system of neuroleptic treatment with the institutionalized retarded should provide information regarding which behaviors change under what environmental conditions, e.g., setting, staff behavior, other behavioral programming, etc., and

when, e.g., drug dosage, time of drug-related behavior, etc. Obtaining data in response to these questions would raise drug evaluation standards to those in practice for other rehabilitative efforts and applied research practices.

These methodological dimensions of applied behavior analysis are presented as techniques to provide data in response to the above questions: 1) process and outcome evaluation; 2) identification of behaviors which are relevant to the individual; 3) identification of numerous environmental influences which impact on these relevant behaviors; and 4) inductive versus deductive procedures to identify determinants of behavior change relevant to the individual's behavior.

A process-oriented evaluation provides valuable information about the timing of behavior change and the conditions under which the change occurs as well as the overall value of the ultimate clinical outcome (Hersen and Barlow, 1976; Azrin, 1977). An initial baseline period consists of no less than five data points obtained on five sequential occasions reflecting the occurrence of behavior in quantified terms prior to experimental manipulations or the introduction of the intervention. Measurement of the behavioral rate and trend over time provides information on relative occurrence within the context of possible observation session to observation session behavioral fluctuations (Sidman, 1960).

The following example illustrates the value of monitoring behavior over time. An aggressive client observed over five days may aggress accordingly: day 1--6 incidents; day 2--0 incidents; day 3--1

incident; day 4--0 incidents; and day 5--2 incidents. The pretreatment data would take on a different meaning if any of the five days was removed from the context of the entire baseline period. Additionally, the point will be stressed later that response variability may be due to environmental conditions which could potentially confound conclusions regarding drug-behavior relationships. An assessment of drug treatment necessitates the establishment of some reliable frame of reference to which drug-related behaviors can be compared (Sprague and Baxley, 1978).

Following baseline, intervention through introduction of independent variables occurs systematically; that is, one change at a time is introduced within an adequate time frame to measure its impact. Monitoring behavior change in a time series fashion provides an overall behavioral trend that can be compared to the baseline trend. This approach allows the investigator to observe changes in behavioral patterns and pinpoint precisely when behavioral changes occur. Conceivably, behavioral monitoring over time provides an opportunity for early identification of adverse drug effects that bear upon the client's welfare and the outcome of the study.

Applied behavior analysis uses single subject experimental designs which allow individualized selection and assessment of a wide range of adaptive and problem behaviors relevant to the drug treatment outcome for the individual (Martin, 1971; Marholin and Phillips, 1976). Different clients may present with different problem behaviors with varying behavioral expectations regarding clinical outcome.

Proponents of behavioral programs have mandated specification of behavioral alternatives to problem behaviors and the procedures for

their implementation as required in program development (Azrin, 1977; Hersen and Barlow, 1976; Kazdin, 1978). Initiation and evaluation of drug treatment can proceed in accordance with the standards set for other rehabilitative efforts when individualized target behaviors are defined and measured before initiation of drug therapy and/or throughout its duration.

Behavioral monitoring based on time series procedures allows an evaluation of the relative contributions of numerous environmental influences while these interact with drug-related behavior (Marholin and Phillips, 1976; Martin, 1971). Numerous components of behavior programs (and absence of programs) usually manifested in staff behavior may potentially confound an evaluation of drug effects when these components remain unidentified. For example, variability in reinforcement techniques in the form of rewards available for performance made a significant difference in on-drug versus on-placebo performance on the Wechsler Intelligence Scale for Children subtest scores among the retarded (Bruening and Davidson, 1979).

Since the occurrence of problem behaviors and other behaviors relevant to the drug-behavior assessment may vary according to staff behavior and/or setting, behavioral monitoring can occur across settings and can include staff behavior. Session-to-session fluctuations in behavior rate can be correlated with idiopathic environmental events within the institution. Aggressive incidents, fire drills, staff turnover, and the like may impose session-specific changes in client behavior.

The final dimension of applied behavior analysis includes a comparison of inductive and deductive procedures in an evaluation of drug therapeutic efficacy. The investigator who proceeds according to deductive principles must assume a relatively homogeneous population who will respond to the drug in a uniform and predictable way in order to prove the null hypothesis false. A group design with a large "N" is used to ensure the validity of statistical significance. The involvement of many subjects plus the assessment time required necessarily calls for a minimum of dependent measures. The investigator must select a few relevant clinical behaviors which will be the most applicable to the most subjects. Response variability due to events beyond the investigator's control is removed statistically, and individual scores are combined in a group average. A study may conceivably yield non-significant statistical results if the average reflects dramatic changes in one direction on the part of half the group but change in the opposite direction among the rest of the group. The results of the study reflect "on the average" results which can be generalized to a similar population.

The following problems with these procedures limit their usefulness when applied to clinical evaluation of drug treatment among the retarded. First, there is little evidence that indicates homogeneity of the retarded population (Garrard and Richmond, 1978a; 1978b). Second, the retarded considered collectively may present a variety of relevant behaviors that extend beyond the scope of selected dependent measures. Third, the design can provide outcome information on whether

behavior change occurred, but it cannot monitor behavior and provide an account of how behavior has changed as influenced by numerous day-to-day environmental events. Finally, and perhaps most importantly in terms of the applicability of the findings, the program developer is usually most interested in specific treatment procedures which can be generalized to the individual.

In selecting a research design, the investigator prioritizes relevant research questions and proceeds according to those methods which can provide the most meaningful answers. Similarly, the program developer articulates questions regarding the efficacy of certain treatment options among the retarded. Acturarial questions necessitate large group designs because the "answers" include documentation of the overall group tendency. As the numbers within the group increase, the ability to generalize to a larger population also increases. Measuring the responses of many, however, has limited relevance for the individual who may not present with problems which respond in the predicted "on the average" manner to drug treatment.

This point is made not to undermine the overall value of group research as these methods have provided needed information including average dose-response curves, dosage in proportion to body weight, identification of the specific drugs which have provided the greatest tendency to ameliorate certain problems, etc. Without this information, there would be no data upon which to base initiation of drug treatment. Given the average findings, however, the investigator or the program developer is faced with questions regarding titration of dosage that will maximize clinical benefits for the client.

In sum, applied behavior analysis offers useful methods to the applied researcher and/or to the program developer who share an interest in evaluating behavior control drug prescription according to a data base. Single subject experimental designs offer an individualized assessment of operationally defined behaviors which are observed throughout the duration of drug therapy. Drug-behavior relationships are identified through a comparison of baseline behavioral rates to post-intervention behavioral rates. These data can be used to make individualized drug prescription decisions. Single subject design data are generalizable to other individuals with similar adaptive behavioral functioning (Hersen and Barlow, 1976; Kratchowill, 1978).

A recent study used the procedures of applied behavior analysis to measure the behavior of five chronic Thorazine recipients during drug withdrawal (Marholin, Touchette, and Stewart, 1979). All subjects were male residents in an institution for the retarded, and their ages ranged from 27 to 53 years old. Each client served as his own control in a double blind single subject B-A-B design (phases: B--on-drug; A--on placebo; B--on drug).

All clients were receiving Thorazine on a daily basis at the onset of the study. Four of the clients received 200 mg. and one client received 800 mg. All clients had been receiving a neuroleptic for six or more years, and all were abruptly withdrawn from the drug during the study.

Trained observers recorded individual client behavior on a daily basis in residential and vocational settings within the institution.

Social behaviors, activity level, talking or laughing to self, and repetitive motoric behavior were recorded in the residence for ten minutes during each daily observation session. The vocational behaviors recorded during ten minutes included compliant responses to come to work, the number of nuts and bolts correctly sorted, and the amount of time spent on the task.

The results indicated that abrupt drug withdrawal produced different changes in the observed behaviors which varied across subjects. For example, three clients showed more social behaviors while on-drug while two clients showed more social behaviors while on-placebo. Four clients had the highest activity level while on-placebo, but one client was more active while on-drug. Three clients talked to themselves the most while on-placebo while two clients talked to themselves more when on-drug compared to placebo. One client engaged in more repetitive rocking while on-drug, one client engaged in more such rocking while on-placebo, and three clients showed no repetitive motoric behavior at all during the study. In general, all clients were more compliant to instructions in the vocational area and were better able to sort nuts and bolts accurately while on-placebo.

The results from this study have clearly indicated that idiosyncratic drug-behavior relationships are common among the retarded. Additionally, daily fluctuations in behavior were recorded throughout the study such that individual patterns of responses during the phases emerged. The authors found that any category of behavior that had not changed within the first 48 hours following drug manipulation did not

change in subsequent observation sessions. These results provided suggestive methodological information regarding the timing required in measuring drug-related behavioral changes. In sum, the importance of measuring clinically relevant behaviors for the individual over time periods of sufficient length to compare on-drug and on-placebo behavior was clearly established.

Present Study

The aim of the present study was an application of behavior analysis to determine the effects of the neuroleptic, Mellaril, on adaptive and disruptive behavior of institutionalized retarded persons. The methods of the Marholin et al. (1979) study were approximated in that similar social, activity level, repetitive motor, and vocational adaptive behaviors were recorded. Additionally, the present study included observations of mouth and tongue movement as an indicator of possible tardive dyskinesia, and disruptive behaviors such as aggression, destruction of property, and self-abusive biting and/or hitting.

Four clients were selected for the study, and each served as his/her own control in a sequence of on-drug, on-placebo phases which were designed for an individual drug-behavior assessment. Two clients participated in a double reversal with a sequence of on-drug, on-placebo, on-drug, on placebo phases. One client participated in a reversal with a sequence of on-drug, on-placebo, on-drug phases. One client participated only in initial on-drug, on-placebo phases before his involvement was terminated due to an epileptic seizure and subsequent regimen of an anticonvulsant drug. All clients who participated in the study were not

receiving a daily regimen of any other psychoactive drug besides Mellaril.

The comparison of on-drug behavioral rates with on-placebo behavioral rates addressed two objectives: 1) specific behaviors were identified as sensitive to changes in rates of occurrence in response to drug change when the observations of all clients were combined; and 2) each client's pattern of behavioral rates for each behavior were elucidated as a means to individualize the drug-behavior assessment.

CHAPTER 2

METHOD

Subjects

Four severely retarded adults in residence at the Arizona Training Program at Tucson (ATPT) were selected to serve as subjects. The selection criteria included ongoing prescription of only one neuroleptic and the absence of other drugs which affected the central nervous system. It was desirable to have all subjects receive the same neuroleptic so that only one drug was implicated as the primary pharmacological change agent during the study. Twenty-five clients in residence at ATPT were receiving neuroleptics, but only six clients were receiving the same neuroleptic, Mellaril, as the only central nervous system drug. One of the six clients was blind, and one showed moderate motoric impairments. These two clients were not selected due to the presence of obvious biomedical abnormalities which could affect drug absorption, metabolism, and subsequent drug-behavior relationships. The four selected clients showed no obvious biomedical abnormalities, and the cause of their retardation was unknown. All four clients were receiving Mellaril for disruptive behavior which had been problematic for at least two or more years.

The clients were already receiving Mellaril at the time of selection, and all had been receiving Mellaril or a drug of the same

pharmacological class for at least two years. Due to the loss of institutional records, it was impossible to discern the exact length of time that the clients had been receiving a neuroleptic. The medication dosages had been adjusted within a 25 to 50 mg. range during the year before the study started. No dosage changes had occurred in the three months before the client was selected. The following profiles summarize drug dosage, adaptive behavioral functioning level, and disruptive behaviors for each client.

Ricky

This 49 year old male was receiving 125 mg. of Mellaril per day. According to the American Association on Mental Deficiency (AAMD) category of retardation level (Grossman, 1973), he was placed in the severe range. He had been in residence at this institution for two and one-half years before which he had been transferred from another state institution. He was semi-independent with regard to self-help skills in that he was told when to get dressed, when and how to groom, etc. He was able to follow instructions on his own once he was told what to do. He was capable of following simple two-step instructions such as "go to your room and get your coat."

He was dependent with respect to vocational skills in that he worked only when given a simple task, and he required additional reminders approximately every five minutes to remain on-task. At the onset of the study his vocational task consisted of removing masking tape from a rubber scrub tub.

He made simple one-word utterances such as "yes," "no," "here," etc. and he used gestures frequently to indicate his needs. He spent a large percentage of his time within close proximity to staff members watching them but rarely talking or otherwise interacting with them in a socially appropriate manner.

Ricky had presented behavior problems throughout the entire two and one-half years that he had been in residence at ATPT. It was likely that he came to the institution with behavior problems since he was receiving neuroleptics when he was transferred. He engaged in many anti-social acts such as pinching, poking, slapping, kicking, and hitting.

Louise

This 29 year old female was receiving 250 mg. of Mellaril per day. Her AAMD classification was in the severe retardation range. She had been in residence at ATPT for one and one-half years before which she had been transferred from another state residential institution. She required constant instructions and physical guidance with all self-help activities. She was inconsistent in her compliance with instructions such that at times she ignored them, at times she followed instructions well, but sometimes she did the opposite of what she was told. For these reasons, her retardation was accentuated by lack of compliance with habilitation strategies.

Her vocational skill performance was similarly inconsistent in that she often ignored her work and staff member instructions while she paced around the room. At the onset of the study her vocational task consisted of putting 1" to 1 1/2" wooden beads on a large string. She

worked on this task when she was placed behind a work table with barriers which inhibited escape. It was necessary for the staff member to give her instructions to do her work approximately every minute.

She demonstrated no verbal language or gestures throughout the study, but she did reach for food or other items that she wanted. She was aloof from staff members and peers in that she rarely approached anybody. Most of her time was spent alone engaged in pacing from one end of the room to the other.

Louise had presented behavior problems throughout the entire one and one-half years that she had been in residence at ATPT. Like Ricky, she was receiving neuroleptics when she was transferred so it was likely that she had presented behavior problems for several years. She engaged in a behavior called "head-butting" which consisted of forcefully pushing her head into other's stomachs. She also slapped and hit others as well as slapping and biting herself. Her other problem behaviors consisted of screaming and putting her head in the toilet.

Mary

This 30 year old female was receiving 60 mg. of Mellaril per day. Her AAMD classification was in the severe retardation range. She had been in residence at ATPT for longer than five years before which she had been living with her mother. She was almost completely independent with regard to self-help skills although she did require assistance with skills such as choosing appropriate clothes for the weather. She did require some reminders on the appropriate times to get dressed or

groomed. She was capable of following complex instructions such as "unload the dishwasher and put everything away properly."

In the vocational setting she was capable of complex work activities. At the onset of the study her vocational task consisted of putting papers in envelopes, stamping the mailing address, and stamping the return address. Although she could complete her work with few errors, she did require occasional reminders to remain on-task.

She used three to approximately six word utterances in social conversation as well as in letting her needs be known. In response to a question such as "what did you have for lunch?" that was given following the meal, she could answer appropriately. She spent a large percentage of her time watching everyone around her, and she did initiate social interactions with others, especially staff members, by approaching, smiling, and sometimes initiating conversation.

Mary had been receiving neuroleptics for aggressive problem behavior for more than five years. She engaged in hitting, biting, slapping, and/or kicking others. In the three years prior to the onset of the study, her problem behaviors had been decreasing in frequency as well as the magnitude of injury to others. Her drug dosage had been closely monitored and slowly decreased. Her inclusion in the study and her withdrawal from medication was desirable according to ATPT staff members since she had been showing signs of tardive dyskinesia. This neurological disorder consisted of lip smacking and tongue writhing, and it was believed to be a long term effect of her neuroleptic regimen.

Karl

This 28 year old male was receiving 325 mg. of Mellaril per day. His AAMD classification was in the severe retardation range. He had been in residence at ATPT for ten years before which he had been living with his parents. He was almost completely independent with regard to self-help skills although he did require reminders as to the appropriate times to engage in grooming and the like. He was capable of following complex instructions and initiating complex behavioral sequences. For example, upon the author's initial observation, Karl was preparing his own afternoon snack. He gathered bread, butter, and utensils from their respective storage places, and he made buttered toast. He found a can of juice and a glass, and then he opened the can pouring the juice into the glass. Following consumption of his snack, he cleaned up after himself including washing his own dishes.

He was similarly capable of complex vocational work activities including the use of a welder. He did require instructions to start a task once he had completed the work that had been placed in front of him. His behavior problems which will be summarized shortly precluded his involvement with intricate or potentially dangerous work materials for safety reasons.

He used no verbal language although he did whine and scream in resistance to following instructions. He had several signs such as "eat" and "work" in his repertoire. He readily used gestures and/or physically guided others to indicate his needs. He was quite aloof from most people although he did single out a couple of staff members

who he followed after by walking. In the absence of these special staff, he remained alone.

Karl had been engaging in problem behaviors and receiving neuroleptics throughout his entire ten year stay at the institution. Occasionally, he slapped or hit others as well as himself. His most frequent problem behaviors, however, consisted of ripping his clothes and his mattress as well as breaking objects such as dishes and light fixtures. These behaviors had occurred in sufficient frequencies and intensities such that he destroyed entire wardrobes and mattresses in as little as a one week time period.

Karl was included in the present study for only the first two months of the entire four month evaluation. He had a major motor epileptic seizure and was placed on a regimen of anticonvulsant drugs. The addition of a drug that affected the central nervous system and, consequently, behavior, made it impossible to continue a behavioral evaluation of Mellaril. His participation in the study was terminated before firm conclusions could be made regarding the effects of Mellaril on his behavior.

Dependent Measures

Table 1 summarizes the specific adaptive behaviors and respective operational definitions which were observed for all clients. Social interactions, activity level, and vocational performance constituted the adaptive behavioral categories. Observational settings and procedures are explained in the next section.

Table 1. Adaptive behaviors and operational definitions

Behavior	Operational Definition
Looking	The client's gaze is focused on staff or peer for at least two seconds.
Talking to staff or peer	An audible word, sound, or sign is directed at staff or peer as a greeting or attempt at conversation.
Approach	The client initiates an interaction with staff by turning toward him/her. The client must be within three feet of the staff and make eye contact.
Touch	The client's hand comes in contact with a peer or staff member in the form of a handshake, light brush, etc.
Proximity	The client is located within three feet of a staff or peer for at least ten seconds.
Walking	The client's feet are on the floor, and he/she must move at least 12 inches during the ten second interval.
Off-feet	The client's feet are off the floor, and his/her weight is supported by a chair, bed, or the floor.
Vocational sorting task	The client places the electrical parts in the corresponding correct bins.

Table 2 summarizes specific maladaptive and disruptive behaviors which were defined and observed for specific clients based on institutional records. Although data collection emphasized specifity of the disruptive behaviors, the frequencies were tallied as "aggressive and self-abusive" incidents for Louise, and "aggressive" incidents for Ricky and Mary. Disruptive behaviors including aggression, self-abuse, and property destruction were recorded by institutional staff and the research assistant employed by the experimenter. Observational settings and procedures are explained in the next section.

Observational Settings and Data Collection

All observations were conducted on the grounds of ATPT in respective residential and vocational settings. Ricky lived in one residence while both Louise and Mary lived in another setting. Likewise, Ricky attended one vocational workshop while both Louise and Mary attended a different one.

Residential Observations

The residential facilities housed 20 to 25 clients in each setting. The residence was a large self-contained unit comprised of a kitchen, laundry room, living room, restrooms, and bedrooms. A research assistant observed each client individually during an unstructured leisure time. The clients were allowed to wander freely throughout the residence and outside while the observations took place. Although there were no planned activities directed by staff, the opportunities available to all clients during leisure time included watching television,

Table 2. Maladaptive and disruptive behaviors for specific clients

Client	Maladaptive Behavior	Disruptive Behavior*
Ricky	talking/laughing to self mouth and tongue movement repetitive motor: body rocking self-abuse	hitting eye-poking pushing kicking slapping hairpulling pinching teasing property destruction
Louise	talking/laughing to self mouth and tongue movement repetitive motor: body rocking body twirling moving furniture foodstealing self-abuse* clothes stripping* throwing work materials*	hitting slapping head-butting property destruction
Mary	talking/laughing to self mouth and tongue movement repetitive motor: rocking self-abuse	hitting slapping biting kicking hairpulling property destruction

*Institutional staff recorded the frequency

listening to music, sitting on the patio, and sitting with peers and staff.

Each observation for each client was 15 minutes. Observations were always conducted between 3:30 and 4:30 p.m. which was the time period immediately following the clients' return from respective workshops. Observation sessions occurred only on weekdays with approximately 4-5 sessions per week.

The occurrence of behaviors listed in Table 1 and those listed in Table 2 was recorded by the research assistant using ten-second interval recording. A small timing device which fit into the ear and clicked every ten seconds was used, and the record reflected whether each behavior had occurred during the ten-second interval. The observation session was made up of 90 sequential ten-second intervals. The observational data that were collected for behaviors listed in Table 1 were expressed in terms of the percent of intervals scored for each behavior during each observation session. The percent figure was interpreted as the amount of time that the behavior occurred. The disruptive behaviors listed in Table 2 were expressed as a frequency per session.

Data Collection Training

The research assistant was a female undergraduate student in psychology who underwent six hours of training in ten-second interval data collection techniques. Videotape of a retarded ATPT client who was not included in the study was used during the training sessions. The client was depicted during an unstructured leisure time activity in an ATPT residence, and the research assistant recorded the behaviors

listed in Tables 1 and 2. The videotape was 45 minutes in duration, and the data were collected during 15 minute time blocks to simulate the length of actual observation sessions required during the study. The experimenter monitored all training sessions and participated in inter-observer reliability checks.

Interobserver Reliability

Phi was used to calculate a coefficient for the agreements and disagreements for the occurrence of each behavior observed by both the research assistant and the experimenter. The formula for phi is:

$$\frac{BC - AD}{\sqrt{(A+B)(C+D)(A+C)(B+D)}}$$

A = the frequency of occurrences recorded by observer$_1$ but not by observer$_2$; B = the frequency of occurrences agreed upon by both observers; C = the frequency of nonoccurrences agreed upon by both observers; and D = the frequency of occurrences recorded by observer$_2$ but not by observer$_1$.

The training was completed for the research assistant when all coefficients for all behaviors were $\geq$.60 which is the acceptable level for phi. Interobserver reliability coefficients were calculated throughout the study for each client and for each observed behavior once during the first phase, and twice during each on-drug and on-placebo phase therafter. The reliability checks occurred during sessions which immediately followed the onset of the phase and during the

last sessions prior to drug manipulation. All coefficients for all clients and respective behaviors were within the acceptable range, and the average coefficient per client when all figures for all behaviors were considered was as follows: Ricky, .96; Louise, .98; and Mary, .97.

Vocational Observations

The clients attended a day program in a workshop from 9:00 a.m. to 3:00 p.m. Monday through Friday. Typically, 15 to 20 clients were assigned to each workshop, and the work activities varied according to client adaptive functioning level and work availability. The institution contracted with outside agencies for work which dictated the work that was available. Consequently, the client's work routine in all workshops varied from week to week. The variability in work activities precluded naturalistic observations in the vocational setting since it would have been impossible to relate changes in client performance to drug changes as opposed to change in work activity. A work sample task that consisted of sorting small electrical components was developed to be a constant daily activity throughout the study.

The sorting task entailed placing electrical parts in respective bins for five minutes. Each client was given a task that was designed to meet his/her capability level regarding color and shape discrimination. Ricky and Louise were both given a three piece task that consisted of a 2" x 3 3/4" silver metal plate, a 2" x 1/2" x 1/2" gold metal piece, and a 1" x 1/2" x 1/2" red and black plastic piece. Mary was given a five piece task that consisted of a 2" x 1" x 1" silver

metal piece, a 1 1/2" x 1 1/2" x 1" black and silver metal piece, a 1" x 1" x 1/2" black-red-silver metal piece, a 1 1/2" metal prong with a red plastic top, and a small 3/4" silver metal piece.

The same research assistant who conducted residential observations also administered the sorting task and collected the data. Each client was given the task individually in his/her usual workshop setting between 2:00 and 3:00 p.m. Monday through Thursday. There were approximately 3-4 sessions per week.

During each session the research assistant used the same task administration procedures including the same verbal instructions, demonstration of the task by sorting each piece once, and verbalization of praise to the client upon task initiation and completion. The research assistant then excused the client and counted the number of pieces that were correctly sorted and the number of pieces that were incorrectly sorted (errors).

Training in Task Implementation

The experimenter trained the research assistant in task administration procedures during four daily sessions in one week. On the first day the experimenter worked with each client and demonstrated the procedures. For the remaining three days, the research assistant implemented the task with each client under the verbal guidance of the experimenter. For the first six weeks of the study, the research assistant collected self-observation frequency data as a means to monitor that the same verbal instructions, demonstration, and frequency of praise occurred during each session. The experimenter observed the research assistant

with each client once every three weeks thereafter to monitor consistency of procedures.

Institutional Staff Data Collection

ATPT staff members were ordinarily responsible for keeping 24 hour continuous frequency counts on the occurrence of disruptive incidents. For purposes of the study, staff members assigned to respective residential and vocational settings of the clients included in the study were asked to keep specific frequency counts for each client and the behaviors listed in Table 2.

Staff members were given a simple data form designed for each client which consisted of a blank to enter the date and blanks to check next to a preprinted list of client behaviors. The experimenter instructed staff members in observational techniques and the use of the data forms. Supervisory personnel employed by the institution monitored staff compliance with data collection through verbal reminders as well as verbal praise and notes when the data forms were properly used.

Monitoring Reliability of Staff-Report Data

Interobserver reliability coefficients were not computed and there were no data to summarize the accuracy of staff reports. The reliability and consistency of staff data collection were monitored through observations by supervisory personnel at ATPT and the experimenter. The consistency and accuracy of frequency counts were compared with those entered in a logbook that the staff customarily used to record disruptive incidents. If incidents were logged in the book but

not entered on the data form, the supervisor brought this to the attention of the staff member who then entered the incident on the client's data form.

The frequency that staff members had reported for the day was compared with the research assistant's frequency which was recorded during the observation session. A problem with accuracy of data collection was identified when the staff-reported frequency was less than that of the research assistant since the observation period for the latter was only 15 minutes. Inaccuracies in the staff-reported data were always brought to the attention of supervisory personnel and the staff members by the experimenter so that staff members received additional reminders to collect accurate data.

Consistency of Institutional Staff Behavior during Client Programs

Staff interactions with clients were observed before the study began and throughout its duration to reduce the possibility that staff behavior affected the occurrence of the behaviors under observation. Two types of client programs, Skill Plans and Behavior Plans, dictated staff behavior with clients, and these were reviewed by the experimenter and institutional staff prior to the onset of the study.

Skill Plans delineated the techniques for the staff members to use in training the clients in specific adaptive behaviors. Those relevant to behaviors under observation included programs to promote social behaviors such as approaching and talking with others. Program procedures were implemented by staff members through strategies called

"incidental teaching." Staff members did not conduct structured teaching activities for social interaction; instead, they encouraged the clients to interact with them and their peers during the normal flow of activities conducted within the area routine. For example, during leisure time, a staff member might suggest to one client to sit next to another client while listening to music.

During the observation session the experimenter and/or the research assistant instructed all staff members not to initiate or direct any interactions with the client under observation during the 15 minute leisure time activity. Control of staff behavior in this manner allowed the research assistant to collect data on client behavior that was minimally influenced by staff-client interactions. Other behaviors as summarized in Table 1 were likewise minimally altered by the day-to-day fluctuation in staff behavior.

Behavior Plans delineated specific staff member behaviors when intervening during incidents of disruptive behavior. The Plans were implemented whenever a disruptive incident occurred including the 15 minute observation period. In accordance with the philosophy of the institution, all Plans were individualized for each client according to his/her adaptive functioning level. The clients who served as the subjects were included in Plans which had been developed based on specific behaviors that the client presented and the client's response to staff intervention techniques.

The function of the review of Plans throughout the study by the experimenter and institutional staff was to ensure that all staff

members consistently implemented procedures in accordance with Plans. No changes in procedures which affected the behaviors under observation were scheduled once the study had begun.

Medication Manipulations

The clients received the same Mellaril dosage at the onset of the study that the institutional psychiatrist had been prescribing for the previous three months. The dosage had been determined according to individual client needs. All clients were abruptly withdrawn from their Mellaril dosage as it was changed the same day that the phase changed.

The clients received the same Mellaril dosage as they had been previously when the drug was re-introduced. The dosage was increased slowly to prevent temporary sedation which has been associated with the initiation of Mellaril. The respective dosages for Louise and Mary were increased by thirds over a three day period such that by day three both received their full dosages. Ricky's dosage was increased more slowly due to his extreme sensitivity to any sudden changes in his life which typically resulted in escalation of disruptive incidents. His dosage increases occurred as follows: days 1 and 2--50 mg.; days 3 and 4--75 mg.; day 5--100 mg.; and day 6--125 mg.

The clients received only Mellaril throughout the study as they were not receiving a regimen of any other psychoactive drugs. Ricky did receive 500 mg. of chloral hydrate for five days during the third week following his drug withdrawal to ameliorate insomnia.

All clients received placebos upon drug withdrawal which had been provided by Sandoz, the same pharmaceutical company that produced

Mellaril. The placebos were the exact color and size as their Mellaril counterparts. The research assistant and the clients were not told when the medication was changed. Supervisory personnel and institutional staff members were also kept "blind" with respect to these changes. The nursing personnel, the psychiatrist, and the experimenter did not participate in data collection and were aware of the timing as well as nature of drug changes.

The length of the on-drug phases and the placebo phases was determined by the experimenter and the psychiatrist prior to the onset of the study, and each phase was predicted to last 4-5 weeks. This time period was based on the psychiatrist's opinion that neuroleptics typically require 3-6 weeks to completely leave the body following drug withdrawal.

Ricky's phases were slightly longer at six weeks each due to his trend of behavioral disruptions occurring during each phase. It was necessary to wait until his incidents stabilized to a relatively constant rate from day to day. In the absence of this stability, the effects of drug withdrawal or administration could not be separated from other extraneous variables which might have had an influence on the occurrence of disruptive incidents, e.g., staff behavior while implementing Skill Plans and Behavior Plans.

Experimental Design

Each client served as his/her own control in a single subject experimental design. Table 3 summarizes drug dosage for each phase and length of time for each phase according to client. Ricky underwent a

Table 3. Drug dosage and the number of weeks per phase for each client

Client	B_1 On-Drug	A_1 On-Placebo	B_2 On-Drug	A_2 On-Placebo
Ricky				
125 mg.	6.1	7.3	6	not applicable
Louise				
250 mg.	4.8	4.2	4.1	4.1
Mary				
60 mg.	4.8	4.2	4.1	4.1

B-A-B reversal while both Louise and Mary underwent a B-A-B-A reversal where in all cases the B phases referred to on-drug and the A phases referred to on-placebo.

Table 4 summarizes the number of observation sessions that occurred during each phase for each client. The residential and vocational observations refer to those conducted by the research assistant.

Table 4. Number of observation sessions conducted in residential and vocational settings for each client

Client	On-Drug Res.	On-Drug Voc.	On-Placebo Res.	On-Placebo Voc.	On-Drug Res.	On-Drug Voc.	On-Placebo Res.	On-Placebo Voc.
Ricky	28	20	28	24	24	18	not applicable	
Louise	22	17	18	17	18	15	18	15
Mary	23	17	21	17	18	15	18	15

Data Analysis

Descriptive Terminology and Computations

The data were depicted through tabular and graphic presentation. Questions regarding the clinical significance of drug withdrawal and administration in terms of behavior change were answered through visual inspection of the data.

A reversal in behavioral levels and/or trends was apparent when the occurrence of behavior during B phases differed from the occurrence of behavior during A phases indicating that the change in behavior was most likely due to the change in drug administration. For example, the occurrence of behavior was high rate during phase B, low rate during phase A, and again, high rate when the phase B conditions were introduced for the second time, and low rate if the phase A conditions were replicated. In sum, during both B phases the behavior occurred at a

high rate and during both A phases the behavior occurred at a low rate such that the change in the independent variable reversed the behavioral rate.

The behavioral level was used to describe the average daily response that occurred during the phase. Each behavior that was observed using ten-second interval recording yielded a behavioral level. The level was computed by adding all the daily figures for the percentage of intervals scored during each phase and dividing this figure by the total number of observation sessions during that phase.

The behavioral level for the disruptive incidents that were reported by institutional staff was calculated according to two different methods to depict the average daily response and to depict total phase frequency. The average was determined by summing the total frequency of incidents for each phase and dividing this figure by the total number of calendar days during that phase. The total phase frequency of disruptive incidents for Louise and Mary was expressed as the actual raw frequency that had been recorded. The figures were relatively comparable across phases since the number of calendar days was fairly equal across phases. In Ricky's case the number of calendar days that data were reported by the staff varied across phases such that it was necessary to adjust the total phase frequencies to make them comparable. The following formula was used to adjust the data:

$$\text{frequency} \times \frac{\text{standard length (days)}}{\text{actual length (days)}}$$

The frequency was the total number of incidents that had been reported during the phase. The actual length was the number of days that data had been reported. The actual lengths for the three respective phases were 28 days, 42 days, and 32 days. The standard length was computed as the average of the three actual lengths.

The behavioral trend was used to describe the observation session-to-session pattern of specific behavioral responses during each phase as compared to patterns of the other phases. For example, a downward trend is reflected by an initially high frequency of responses during the early part of the phase followed by steady decreases in responses by the end of the phase. A downward trend could be replicated thus indicating reversal of trend when it appeared in both A phases but not in B phases. Trend was determined for each behavior through visual inspection of graphic presentation where the behavior rate was presented for each observation session or calendar day.

Comparison of On-Drug Versus On-Placebo Behavioral Levels

Graphic data presentation was used to summarize the sensitivity of specific behaviors to drug withdrawal and administration through depiction of a comparison of behavioral levels during on-drug versus on-placebo phases. The data which were collected during all observations for all clients were summed with respect to occurrence of specific behaviors during on-drug phases (both B phases) and with respect to occurrence during on-placebo phases (both A phases). The sum of the occurrence of the behavior during both same phases was divided by the

total number of observation sessions during both same phases to yield average daily responses for respective on-drug and on-placebo phases.

The behavioral categories and classes which were depicted in this on-drug versus on-placebo comparison included: social behavior (average of the total of proximity, looking, talking to staff or peers, approaching staff, and appropriate touching); activity level (average of the respective totals for off-feet, walking); talking/laughing to self (average of the total of talking and laughing, and respective averages for talking, laughing); vocational performance (average number of pieces correctly sorted and the average number of errors); and disruptive incidents (average of the total of staff-reported aggressive and self-abusive incidents).

There was a total of 238 observations which were conducted utilizing the ten-second interval recording. The on-drug phases included 133 observations and the on-placebo phases included 105 observations. There was a total of 190 observations which were conducted during the vocational sorting task. The on-drug phases included 102 observations, and the on-placebo phases included 88 observations. The institutional staff reported data for a total of 223 days. The on-drug phases included 123 days, and the on-placebo phases included 100 days.

Within Client Comparison

All data for the three clients were presented in tabular and graphic form according to individual client and specific behaviors for each. Behavioral levels and trends were identified in terms of presence across phases.

CHAPTER 3

RESULTS

On-Drug and On-Placebo Behavioral Levels

The combined observational data are presented in Figures 1, 2, and 3, and the bar graphs depict a comparison of behavioral levels. The data for all three clients were combined to compute average daily responses according to specific behaviors during Mellaril and placebo phases.

Figure 1 summarizes the data that were collected during residential observations. The social behavior category showed the most change with a 44.1% increase from the Mellaril to the placebo phases. The behaviors included in the social category were talking, looking, and being three feet proximal to others. The behaviors that constituted activity level were next in terms of the amount of change that occurred. In general, the clients were less active while receiving placebo. There was a 12.7 difference in the occurrence of walking and a 15.5 difference in off-feet when these average daily responses for Mellaril and placebo phases were compared.

The behavioral levels for talking and laughing to self are depicted in Figure 1 as the total occurrence for both behaviors and by talking, laughing respectively. The total difference was a 2.7%

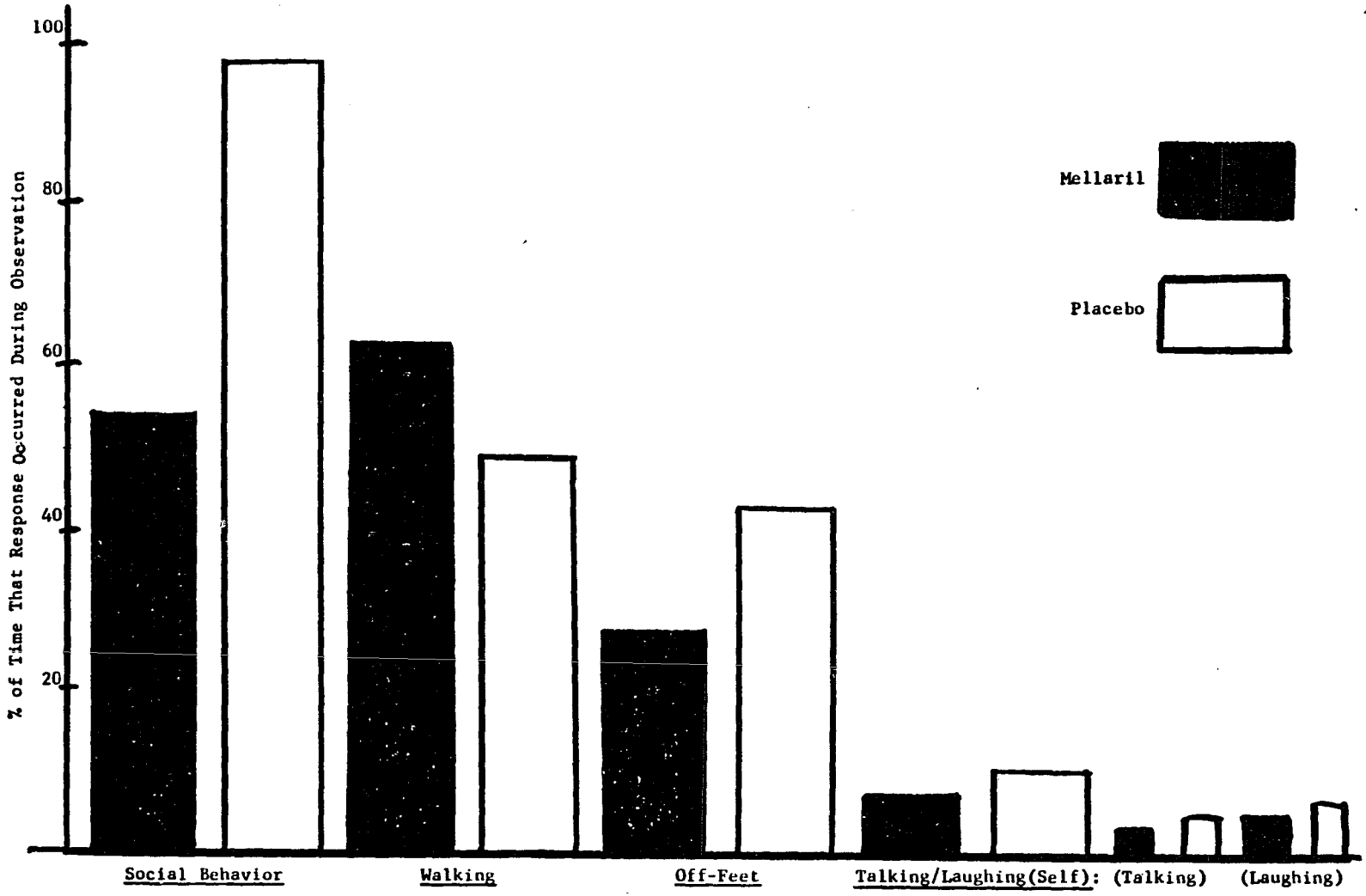


Figure 1. Average daily responses of residential observations based on combined data during Mellaril and placebo phases

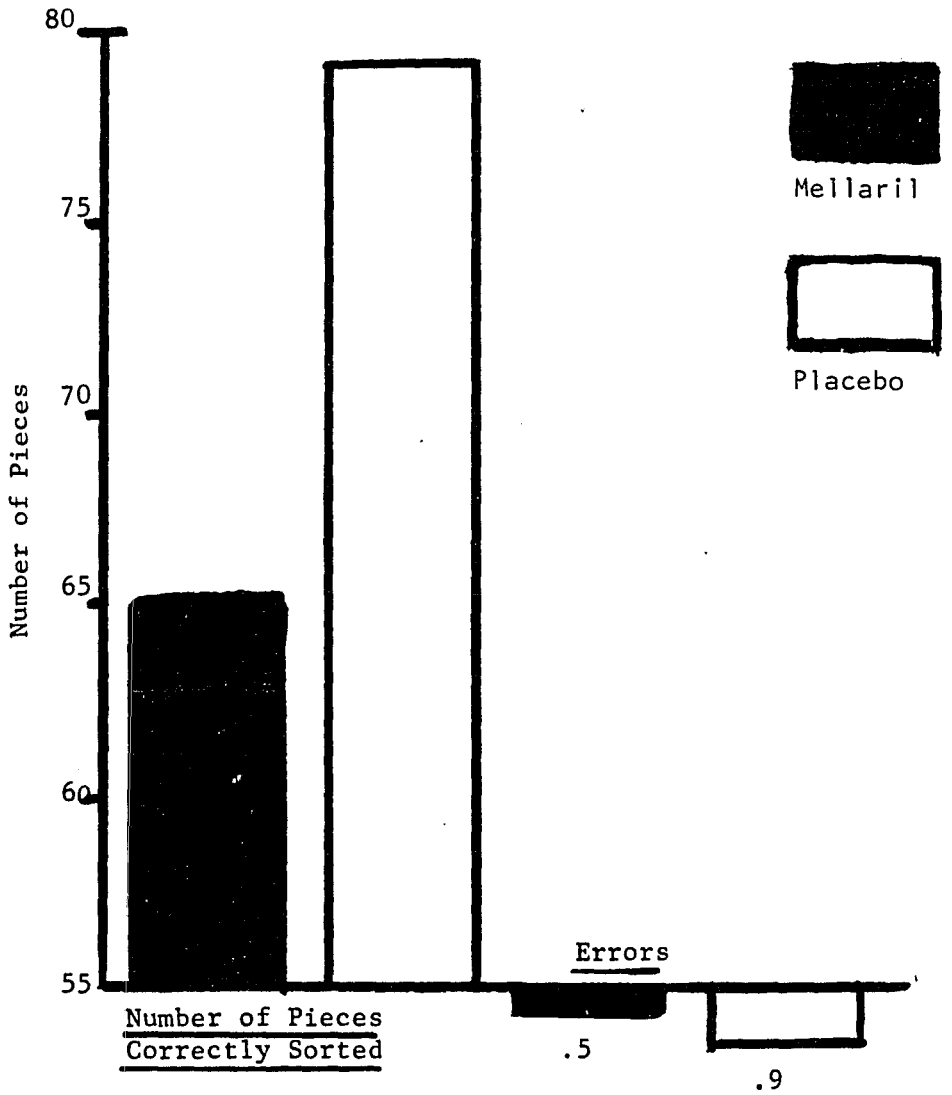


Figure 2. Average number of pieces correctly sorted and errors per day based on combined observations during Mellaril and placebo phases

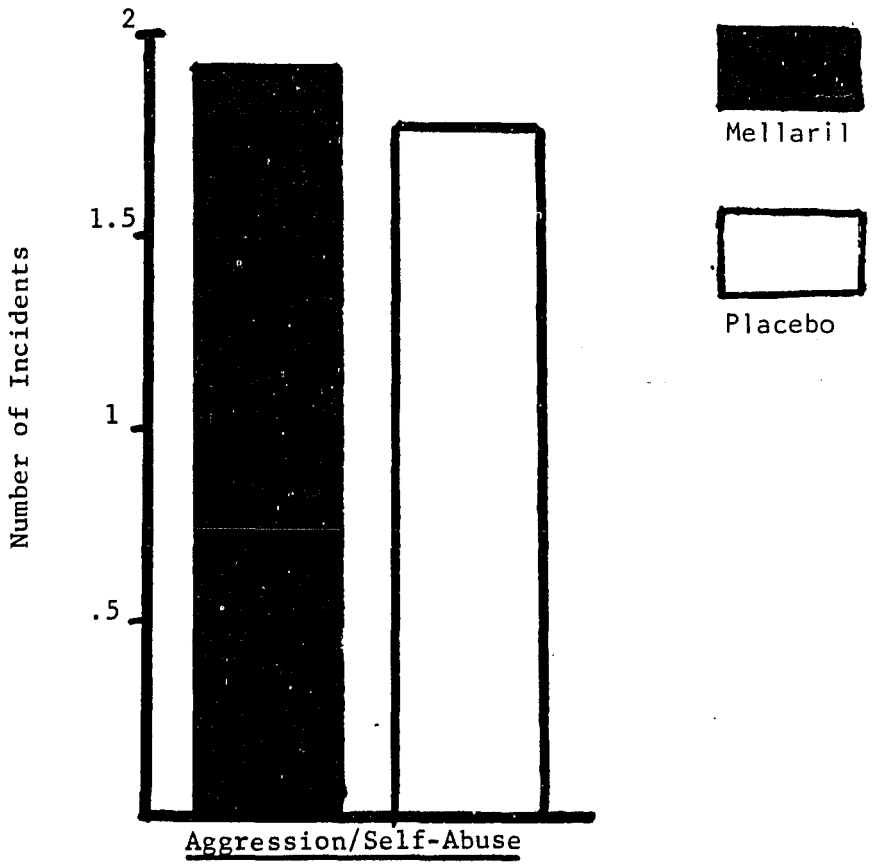


Figure 3. Average number of aggressive/self-abusive incidents per day during Mellaril and placebo phases

increase during the Mellaril phases which was made up of a 1.7% increase in talking to self and a 1% increase in laughing to self.

Presentation of the occurrence of several behaviors has been deleted from the figure due to negligible changes across phases. Approach, touch, repetitive motoric behaviors, mouth and tongue movements, and the trained observer's record of disruptive behaviors did not show notable changes when the data were combined for these behavioral categories.

Figure 2 depicts the data that were collected during the vocational sorting task. There was a 13.7 difference in the average number of pieces sorted per day between Mellaril and placebo phases. More pieces were correctly sorted during the placebo phases. The difference in the average numbers of errors was only .4.

Figure 3 summarizes the average number of incidents of aggression and self-abuse that was reported daily by institutional staff. There was a negligible .1 difference between Mellaril and placebo phases.

Individual Patterns of Behavior

Reversal of Behavioral Levels

Table 5 presents a summary of the specific behaviors and the direction of change which occurred for each client. Only those behaviors which showed consistent level reversals are included in this table. A level reversal occurred when the occurrence of behavior changed consistently following both drug withdrawals for Louise and Mary or when

Table 5. Reversal of client behavioral levels during Mellaril withdrawal

Behavior	Reversal of Level	Direction of Behavior Change
Proximity	Ricky	increase
	Louise	increase
	Mary	increase
Looking	Ricky	increase
	Louise	increase
	Mary	increase
Talking	Ricky	increase
	Mary	increase
Approach	Ricky	increase
Touch	Ricky	increase
Walking	Ricky	decrease
Off-feet	Ricky	increase
	Mary	increase
Mouth and Tongue Movement	Ricky	decrease
	Mary	increase
Talk/Laugh (self)	Mary	increase
Sorting Task	Ricky	increase
	Louise	increase
	Mary	increase
Disruptive Incidents	Louise	decrease

Ricky's behavior returned to a similar on-drug level following his drug withdrawal. The direction of behavior change indicates whether occurrence increased or decreased as a result of drug withdrawal.

Three behaviors that consistently increased for all clients following drug withdrawal were looking and being three feet proximal to others, and the number of pieces correctly sorted during the vocational task. The occurrence of talking to others also increased for Ricky and Mary who were the only two subjects with a verbal repertoire. The other behaviors listed in the table showed level reversals that occurred only for the client noted.

Client Profiles of Behavioral Levels

Appendix A presents respective individual levels of specific behaviors by phase for Ricky, Louise, and Mary. All behaviors that were observed during the study are presented as average daily responses or phase frequencies as noted on the tables.

Ricky's behaviors are depicted in Table A-1. He showed an increase in the occurrence of social behaviors during the placebo phase as compared to the on-drug phases. All classes of social behavior reflected a reversal in level across all phases. These behaviors included talking, looking, approaching, appropriately touching, and being three feet proximal to others.

Ricky's overall activity level was lower during the placebo phase in that he walked less and sat more during this time period compared to behavioral rates during the on-drug phases. The two behaviors

which constituted activity level, walking and off-feet, showed level reversals across all phases.

Mouth and tongue movement reflected a level reversal that indicated that Ricky's behavior increased during the on-drug phases. No other repetitive motor behaviors were recorded during the study.

Ricky's performance on the vocational sorting task showed a reversal in level across all phases in terms of the average number of pieces that he sorted per day. He was able to sort more pieces while on the placebo as compared to Mellaril. His errors during the task did not change significantly across phases.

Several classes of Ricky's behavior steadily increased in occurrence throughout the entire study regardless of phases. These included talking/laughing to self, teasing others, and aggressive incidents as reported by institutional staff.

Louise's behavior are depicted in Table A-2. She increased the amount of time that she spent looking at others and being three feet proximal to others while she was on-placebo compared to on-drug, but her other social behaviors showed little change. The two classes of social behavior which showed the increases in occurrence reflected consistent level reversals across the double drug withdrawal phases. The occurrence of approaching others showed only a weak reversal in that the level changed significantly from the first on-drug phase to the first on-placebo phase but showed only a small change during the second drug withdrawal.

Louise's activity level decreased following the first drug withdrawal but not during the second. Walking decreased during the

first placebo phase as compared to the occurrence of this behavior during the first on-drug phase, but this change was not reflected in the data when the second on-drug and on-placebo phases were compared. Similarly, off-feet increased during the first drug withdrawal, but not during the second.

Performance on the vocational sorting task showed a reversal in level across all phases in terms of the average number of pieces that Louise sorted per day. She correctly sorted more pieces while on-placebo. Her errors during the task did not change significantly across phases.

The occurrences of foodstealing and the total number of staff-reported disruptive incidents increased during on-drug phases as compared to the placebo phases. These classes of behavior showed reversals in levels across all phases.

Mary's behaviors are depicted in Table A-3. Talking, looking, and being three feet proximal to others increased during the placebo phases as compared to the on-drug phases. These three classes of social behavior showed consistent level reversals across the double drug withdrawal phases.

The two behaviors which constituted activity level, walking and off-feet, showed only small differences across phases in the respective rates of occurrence. Mouth and tongue movement, however, showed a reversal in levels across all phases which indicated increases in this behavior during the placebo phases.

Mary's performance on the vocational sorting task showed only a weak reversal across all phases in that the number of correctly sorted

pieces increased only slightly during the placebo phases as compared to the on-drug phases. Her errors during the task did not change significantly across phases.

The only class of inappropriate behavior that showed a consistent level reversal across all phases was talking/laughing to self in that the behavior increased during the placebo phases. The total number of staff-reported disruptive incidents showed no change in rate of occurrence during the first drug withdrawal, but the incidents decreased when Mellaril was re-introduced and they increased during the second drug withdrawal.

Changes in Behavioral Trends

Although individual clients differed in the degree to which behavioral levels changed, there were similarities among the clients with respect to changes in behavioral trends. The configuration of data points within a phase in comparison to other phases is referred to as the trend and is an indicator of the pattern of behavior change that occurs from observation session-to-session. The term variability is used to describe the numerical range of the data points, and the phase trend is more variable than its predecessor when the numerical differences between the highest and lowest data points within the phase are greater and occur more frequently. Trends in individual client behavior patterns are presented in Figures 4, 5, 6, 7, and 8 which depict the occurrence of behavior by observation session according to client.

The first drug withdrawal introduced more variable social behavior than the second withdrawal, and social behavior declined the most

Figure 4. Occurrence of three-feet proximity to others by observation session for Louise, Mary, and Ricky

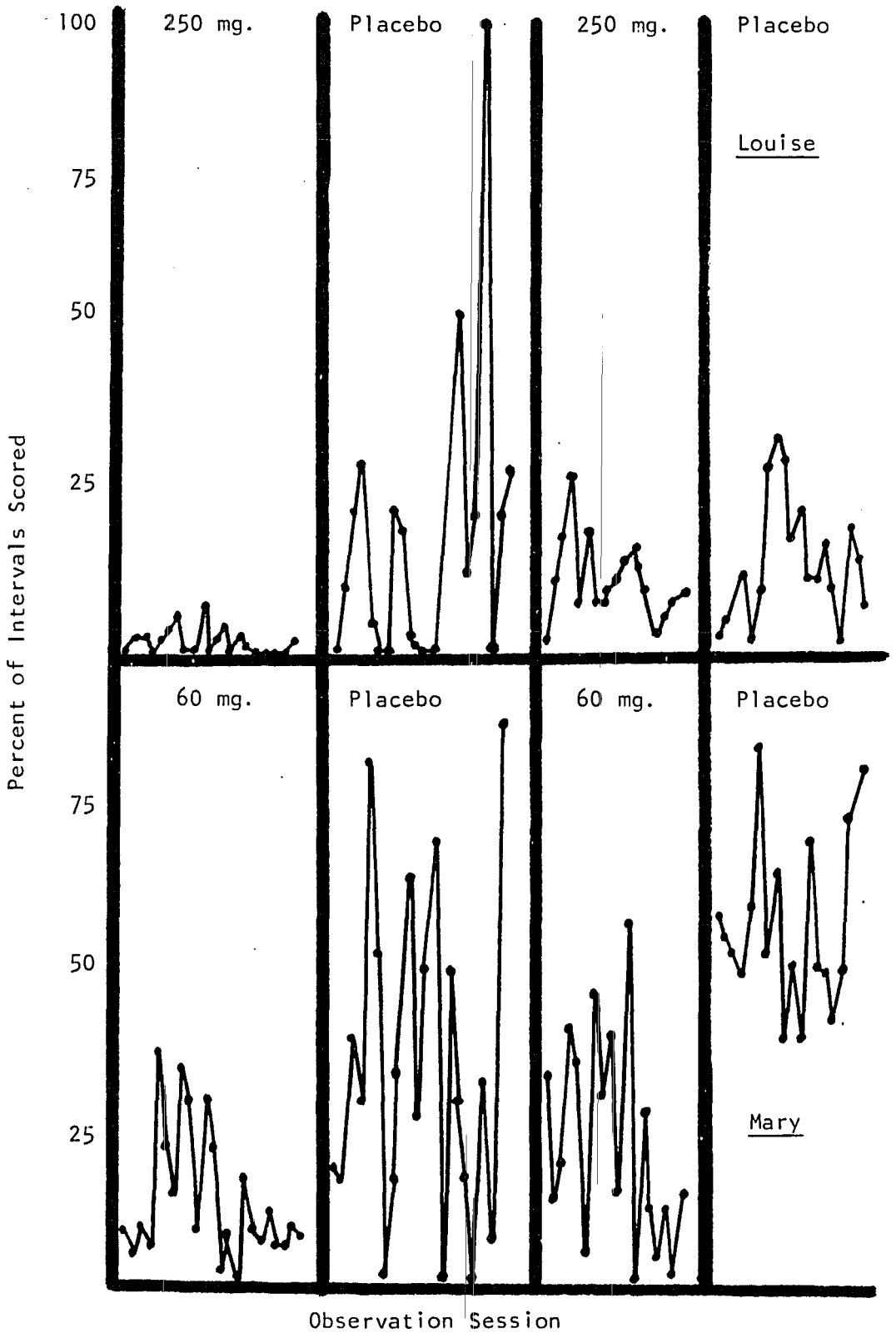
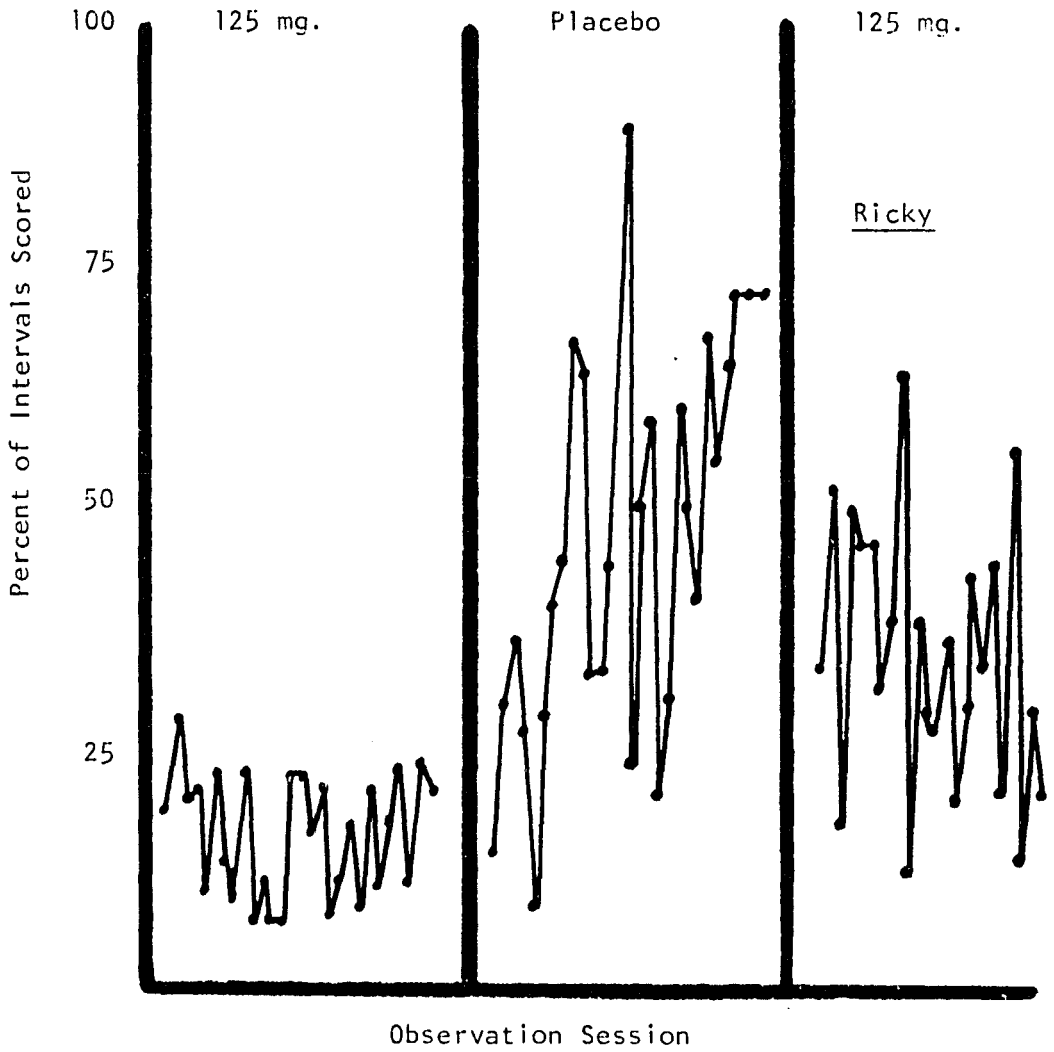

100
75
50
25
250 mg.
Placebo
250 mg.
Placebo
Louise
60 mg.
Placebo
60 mg.
Placebo
Mary
Percent of Intervals Scored
Observation Session

Figure 4, continued


100
75
50
25
125 mg.
Placebo
125 mg.
Ricky
Percent of Intervals Scored
Observation Session

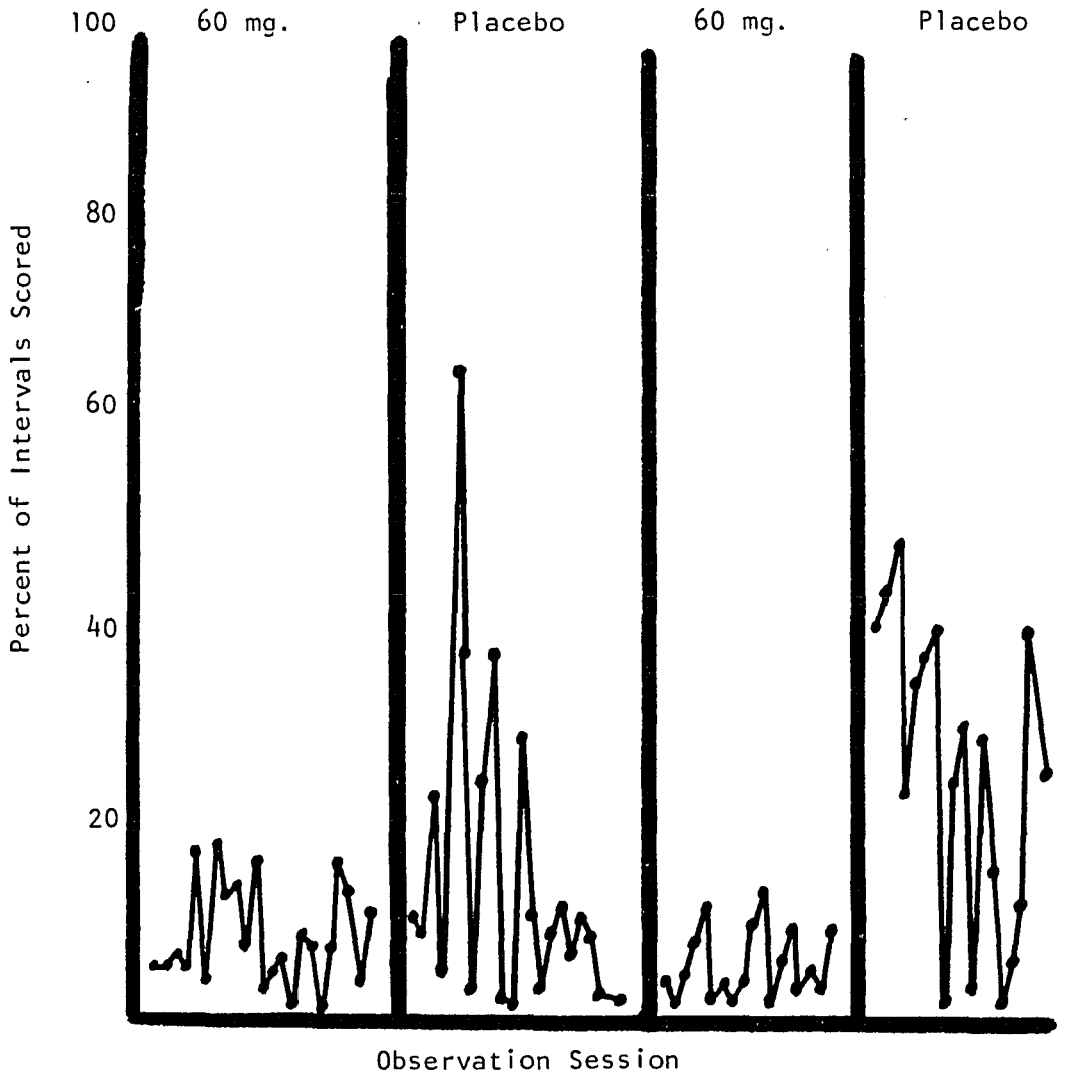


Figure 5. Occurrence of talking to others by observation session for Mary

Figure 6. Occurrence of walking by observation session for Louise, Mary, and Ricky

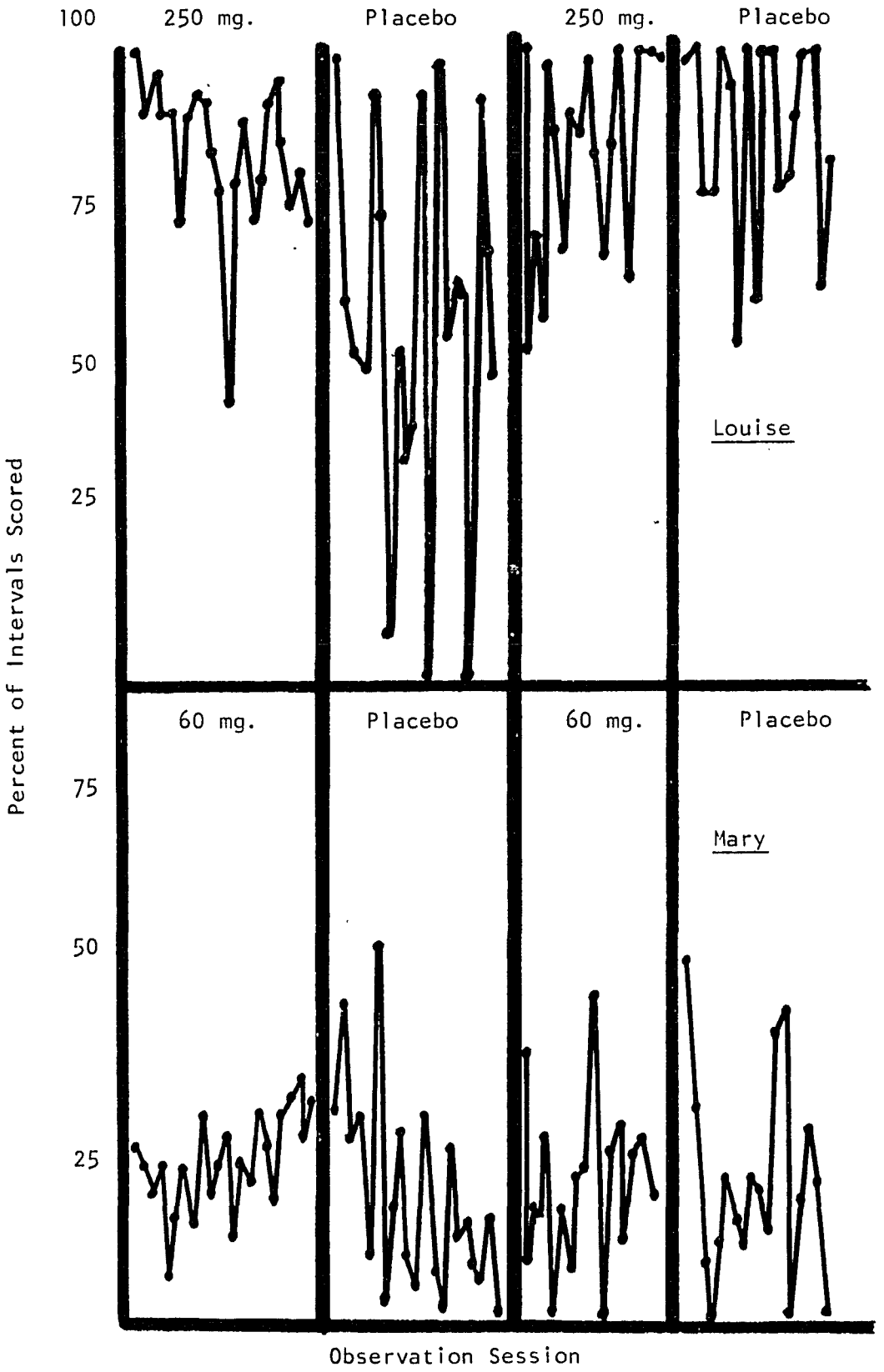

100
250 mg.
Placebo
250 mg.
Placebo
75
50
25
Louise
60 mg.
Placebo
60 mg.
Placebo
75
50
25
Mary
Percent of Intervals Scored
Observation Session

Figure 6, continued

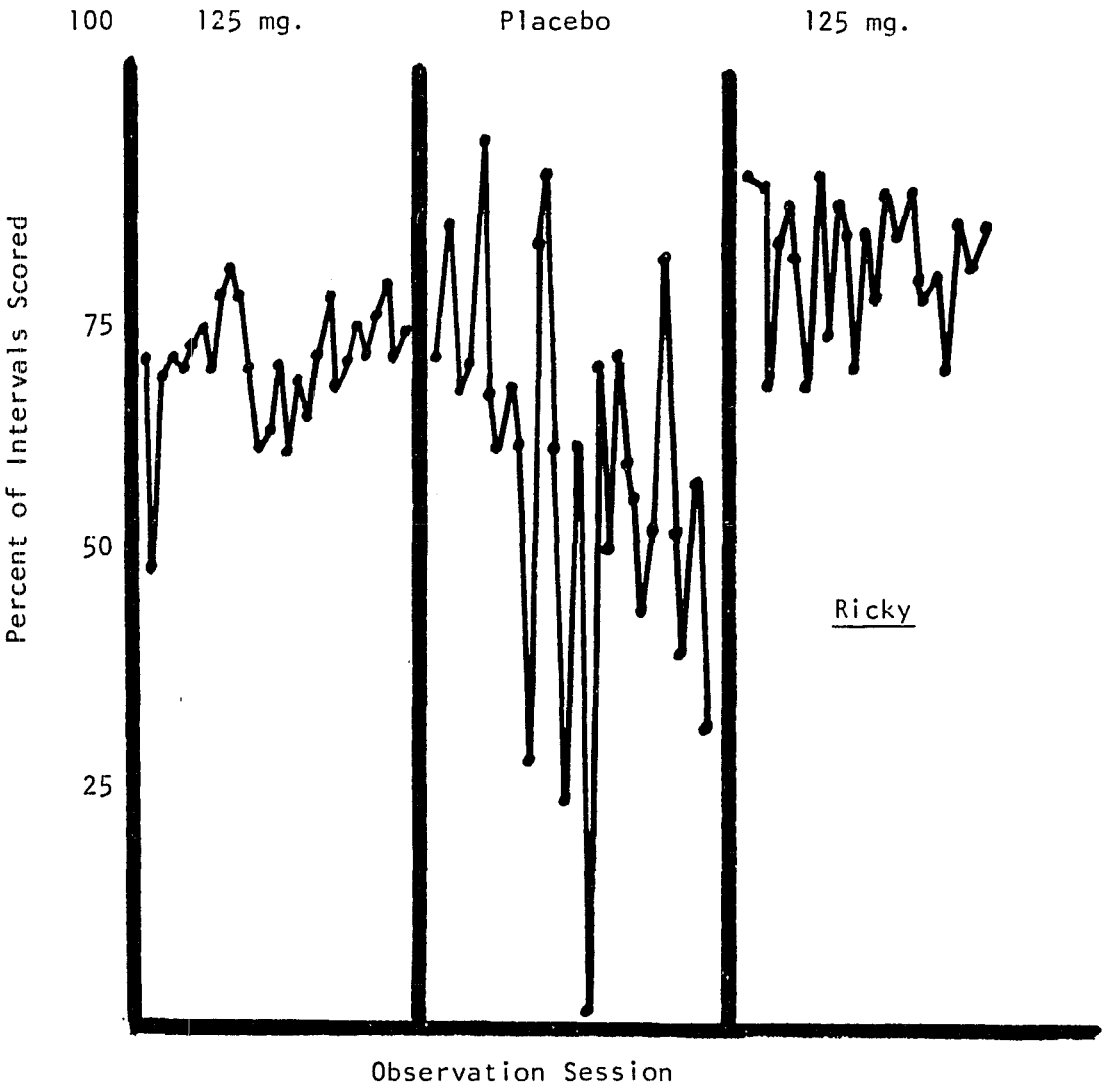

100
125 mg.
Placebo
125 mg.
Percent of Intervals Scored
75
50
25
Ricky
Observation Session

Figure 7. Number of pieces correctly sorted on the vocational task by session for Louise, Mary, and Ricky

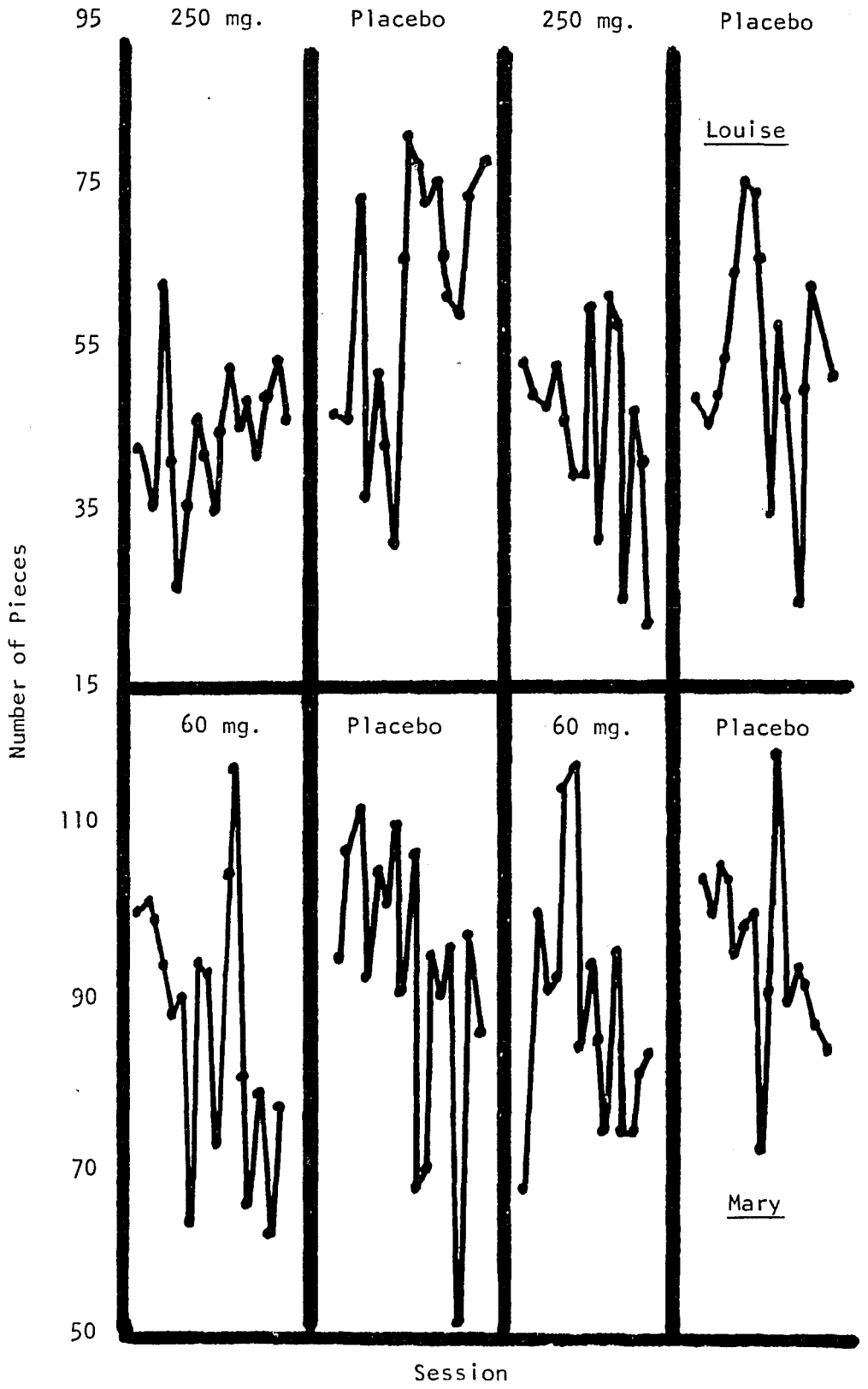
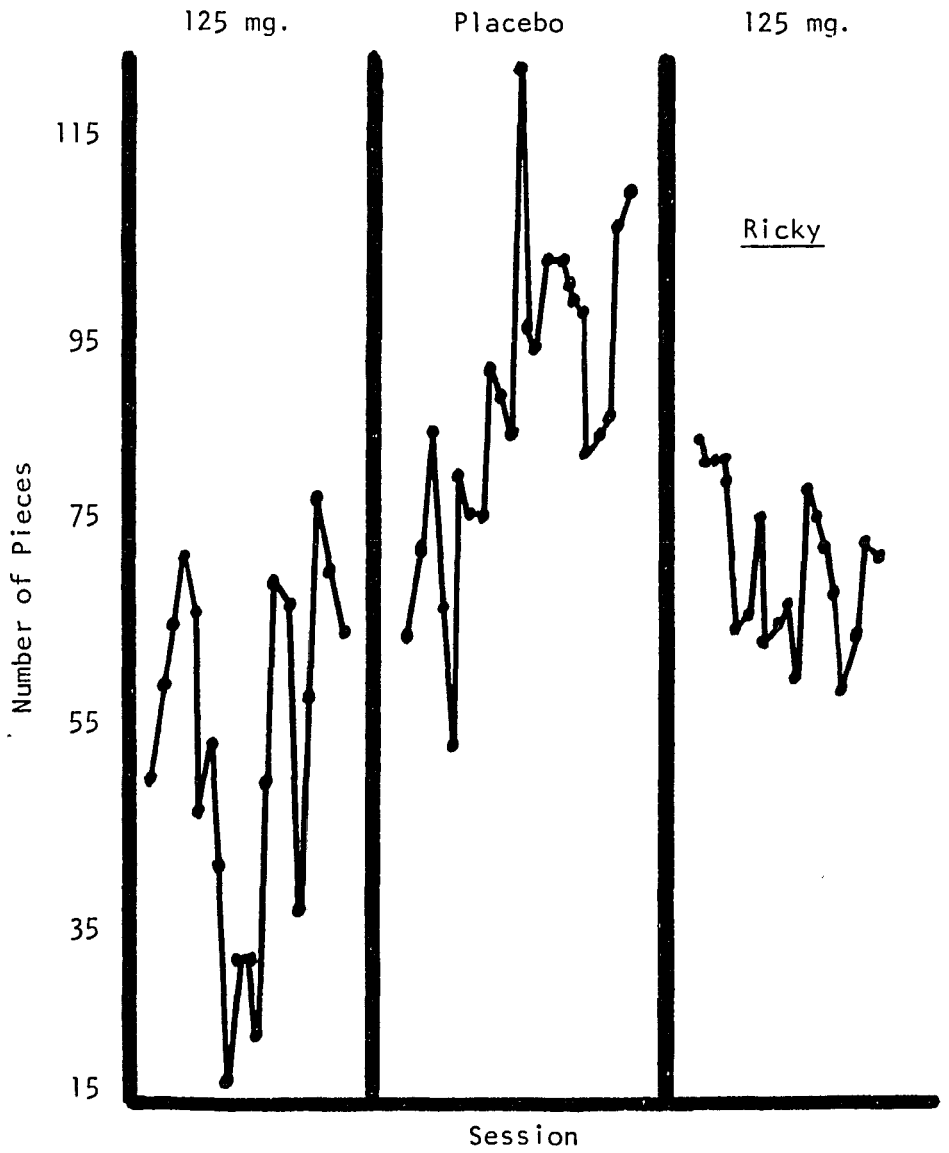

95
75
55
35
15
110
90
70
50
250 mg.
Placebo
250 mg.
Placebo
Louise
60 mg.
Placebo
60 mg.
Placebo
Mary
Number of Pieces
Session

Figure 7, continued


125 mg.
Placebo
125 mg.
Ricky
115
95
75
55
35
15
Number of Pieces
Session

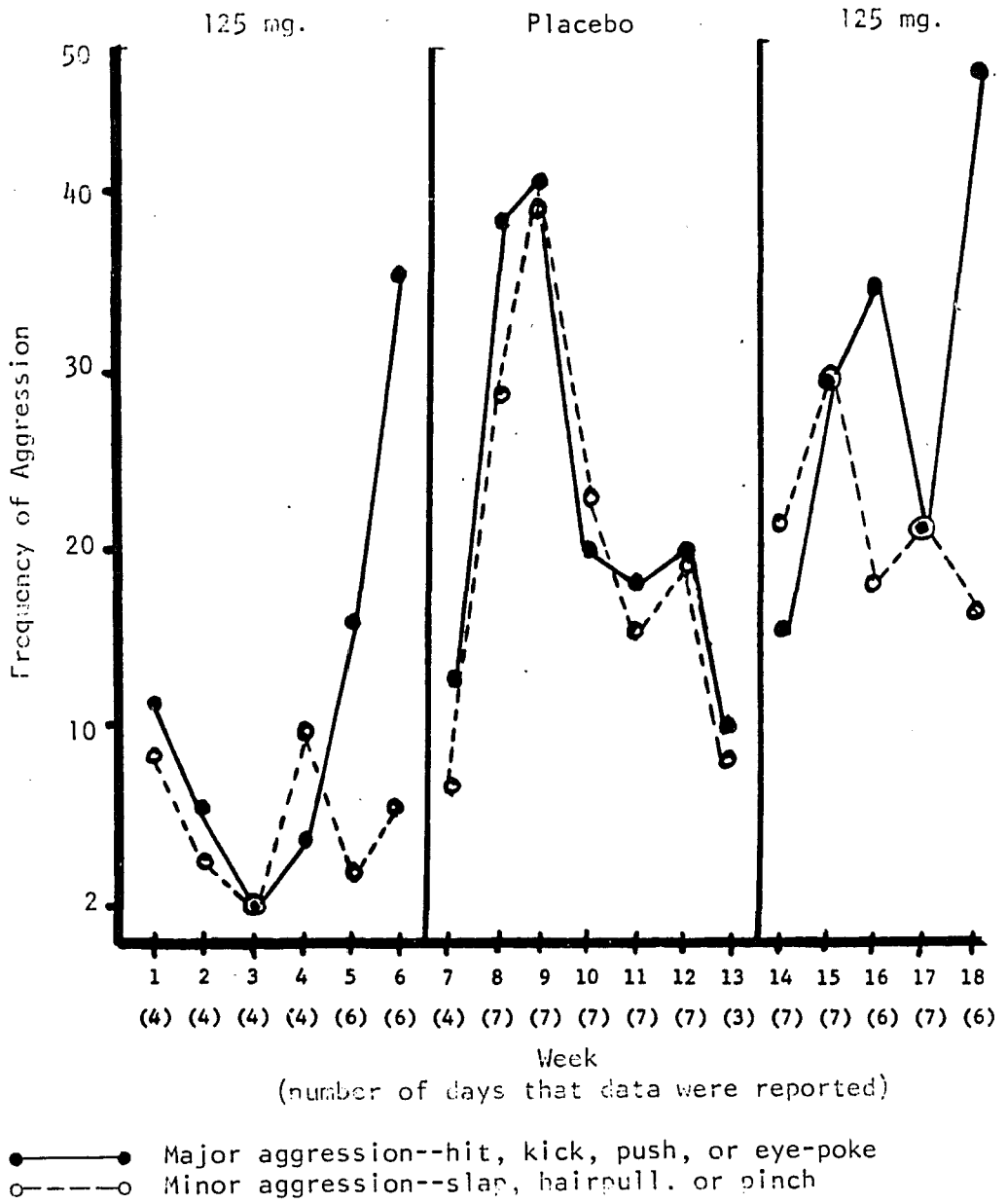


Figure 8. Frequency of major and minor aggressive incidents by week for Ricky

dramatically during the second drug phases. The occurrence of the average daily response for the social behavior of being three feet proximal to others is depicted in Figure 4 for Louise, Mary, and Ricky, and the changes in behavioral trends are representative of similar changes in other classes of social behavior. The trend reflected in the first placebo phases showed much greater variability than those of the first on-drug phases. Notably, the differences in variability between the second on-drug and on-placebo phases was not near as great as the differences depicted during the initial drug withdrawal. All three clients showed a downward behavioral trend during the second on-drug phases.

An exception to these trends appeared in the behavioral patterns that Mary displayed in talking with others. Mary had the most developed verbal repertoire compared to the other two clients since she initiated social interactions and had a wider vocabulary. The average daily response for the percentage of time that Mary spent talking with others during each observation session is depicted in Figure 5. Although her data did reflect increases in variability during the placebo phases as compared to the on-drug phases, she showed downward trends during the placebo phases. Her overall behavioral rates showed increases following drug withdrawals, but the downward trends indicated instability of the initial increases in the behavior.

Initial drug withdrawal produced greater variability in activity levels which was reduced upon re-introduction of the Mellaril. This trend was not repeated during the second drug withdrawal. The

occurrence of the average daily response for percentage of time spent walking is depicted in Figure 6 for Louise, Mary, and Ricky. The first placebo phases showed greater variability than the first on-drug phases, and again, the differences in variability were not replicated during the second drug withdrawal. Variability did decrease during the second on-drug phases upon re-introduction of Mellaril.

All three clients showed a reversal of the existing trend in walking behavior upon initial drug withdrawal. Louise showed a downward trend during the initial on-drug phase which became more variable during the next placebo phase. Mary and Ricky both showed respective upward trends during the initial on-drug phases which were reversed during the initial drug withdrawal.

The average number of pieces sorted per day during the vocational task is depicted in Figure 7 for Louise, Mary, and Ricky. Both Louise and Ricky showed upward trends during the initial on-drug phases which were accentuated by the initial drug withdrawal. Both also showed reversals of these existing trends when Mellaril was re-introduced in that both showed a decrease in the number of pieces sorted when they began to receive Mellaril again. Mary showed consistent decreases in behavioral rates and downward trends across all four phases. She did show an initial increase in the number of pieces sorted during the first day of the drug withdrawal phases as compared to her performance while on-drug. The initial increase in her behavior, however, was not stable as her performance declined throughout the phases.

The three clients presented idiosyncratic patterns of disruptive behavior throughout the study. As presented previously in Table A-2,

Louise clearly became more aggressive when she was receiving Mellaril as compared to placebo. Mary, as indicated in Table A-3, did not show a difference in the frequency of incidents during her first drug withdrawal, but she did show an increase following her second drug withdrawal. Ricky presented a consistent increase in the frequency of disruptive incidents across all phases.

Figure 8 depicts the occurrence of Ricky's incidents of major and minor aggression according to week. Major aggression included incidents of hitting, eye-poking, pushing, and kicking, while incidents of minor aggression included slapping, hairpulling, and pinching. The number that appears in parentheses beneath the number denoting the week indicates the number of days that data were reported by institutional staff during that week and as such can be interpreted as an index of data collection consistency.

Incidents of major aggression increased in frequency and showed an upward trend during the first on-drug phase. At this time, incidents of minor aggression occurred at a stable rate. During the placebo phase, both major and minor incidents initially escalated before decreasing in frequency to show a downward trend. The occurrences of major incidents increased during the second on-drug phase showing an upward trend while minor incidents showed an increase in frequency, and thus, level, but the upward trend appeared to be moving downward.

CHAPTER 4

DISCUSSION

In general, the combined observational data indicated that social behavior showed the most increases following Mellaril withdrawal. These findings were consistent with those of Rassidakis et al. (1970) and Paul et al. (1972). Other behaviors which changed following Mellaril withdrawal included improvement in vocational performance and decreased activity level. Behaviors which showed only slight increases included talking and laughing to self. Repetitive motoric behavior and disruptive incidents showed little change in response to the drug withdrawal. Failure to document a difference between on-drug and on-placebo disruptive incidents was consistent with another study which included 25 retarded women who were withdrawn from a neuroleptic (McConahey, Thompson, and Zimmerman, 1977).

Some changes in levels of individual client behaviors were consistent with those reflected by combined data, but some individual levels were also unique. These findings were consistent with those of Marholin et al. (1979) in that idiosyncratic patterns following neuroleptic withdrawal from retarded people were more prevalent than general patterns.

All three clients showed increases in looking and being three feet proximal to others as well as vocational performance following

Mellaril withdrawal. The two verbal clients likewise showed similar increases in talking to others. The clients showed idiosyncratic changes in behavioral levels for approach, touch, walking, off-feet, mouth and tongue movement, talking/laughing to self, repetitive motoric behavior, and disruptive incidents.

Observations of mouth and tongue movement were conducted as a means to measure possible tardive dyskinesia. The clients responded idiosyncratically following drug withdrawal. Louise had no mouth and tongue movement regardless of phase while Ricky and Mary showed opposite changes in behavior. Ricky's mouth and tongue movement increased while on-drug, but Mary's behavior increased while on-placebo. Mouth and tongue movement following neuroleptic withdrawal has been indicative of tardive dyskinesia in some drug recipients, and this disorder has resulted from long-term neuroleptic prescription (Baldessarini, 1978, 1981; McAndrew et al., 1972; Polizos and Engelhardt, 1978; Smith and Leelavathi, 1978).

Observations aside from those included in data collection suggested that several clients underwent withdrawal reactions when Mellaril was abruptly stopped. Karl, the client who did not complete the study, and Ricky both showed nighttime restlessness and insomnia within eight days to three weeks following Mellaril withdrawal. Louise did not show immediate signs of insomnia, however, she did develop sleeping problems two months following Mellaril withdrawal after the final phase. Louise did show immediate signs of discomfort in that one week following her first Mellaril withdrawal she became listless and spent the majority of

her daytime lying on the couch. Mary did not have sleeping problems, although her tardive dyskinesia worsened upon drug withdrawal.

Abrupt neuroleptic withdrawal has produced depressed locomotor activity (Luchens, Freed, and Wyatt, 1980), as well as insomnia, headaches, nausea, and vomiting (Lacoursiere, Spohn, and Thompson, 1976). Typically, these symptoms have appeared within several days to two weeks following abrupt neuroleptic withdrawal, but the data generated thus far have not correlated their occurrence with predictive variables such as prewithdrawal dosage or duration of drug therapy (Gardos, Cole, and Tarsky, 1978).

Overall, the combined observational data have been a helpful indicator of general behavioral sensitivity to Mellaril withdrawal. In some cases, however, individual client behaviors changed in ways which were unique for that individual. The relationship between the behavioral levels depicted in the combined data and those of individual's data is similar to the relationship between group averages in group research designs and the individual scores which make up the group average. The combined data (group average) yielded a general picture of the tendency for certain behaviors to change in response to Mellaril manipulation. A group average included individual scores in the computation, but the group average number is not the same as the individuals' scores.

Idiosyncratic behavior patterns are important to consider during an evaluation of drug prescription when these patterns differ from the general pattern. For example, the combined data reflected little change in disruptive incidents as a result of drug withdrawal, but Louise's

data depicted nearly a twofold increase in incidents when she was receiving Mellaril as compared to placebo. The general pattern suggested that drug versus placebo made little difference in frequency of disruptive incidents such that drug prescription decisions might be somewhat unaffected by these findings. A decision for Louise, however, should be based on her individual pattern of behavior and must take into account the obvious escalation of disruptive incidents while she was receiving Mellaril.

Combined data or group averages can assist the applied researcher or program developer in selecting behaviors that correspond with a greater likelihood of sensitivity to drug change. This selection of behaviors is a necessary first step in any applied research or program evaluation endeavor. Conclusions about individual behavior change and subsequent drug prescription will be more likely to be accurate when his/her own behavior pattern is used as the baseline. The prevalence of individual changes has suggested that the most sensitive clinical method of drug-behavior assessment should be tailored to record individual client behaviors over the time course of drug therapy. Habilitative and rehabilitative strategies can then be based on individual client response to drug intervention.

The findings of the present study have raised issues and have offered methods to applied researchers and program developers who are interested in the assessment of behavior control drug prescription for the retarded. Applied research and program development may be inseparable in that both include a careful selection of behaviors with

proposed sensitivity to the drug intervention and both must exert reasonable control over influences which may obfuscate relationships between a drug and its behavioral effects.

The present study was conducted in an applied setting, a large institution for the retarded, and the working process necessary to produce the data elucidated many potential influences on client behavior besides drug manipulation. Although the present findings reflected drug-behavior relationships for some clients and some behaviors, questions have remained regarding the determinants of some behavioral changes. For example, some behaviors changed during the first drug withdrawal, but not during the second. This could have been due to differences in the Mellaril dosages and related blood levels in that the clients had been receiving drugs for several years prior to the initial withdrawal whereas they had only been receiving Mellaril for one month prior to the second withdrawal. The changes in behavior, however, could also have been due to changes in environmental events surrounding the clients.

An applied setting requires a careful analysis of potential extraneous influences on behavior to ensure the success of an applied research endeavor or program evaluation in pinpointing the determinants of behavior change. The role of environmental influences in applied behavior pharmacology is of crucial importance to the identification of events which may require experimental control during a drug-behavior assessment.

Drug-Behavior-Environment Interactions

The primary objective of research in behavior pharmacology is an elucidation of drug-behavior relationships. Variation in drug dosage, as an independent variable, should prove to be responsible for behavior change. Drug-behavior relationships can be difficult to detect, however, due to the presence of other variables which interact with the drug to produce behavior change. Behavioral pharmacologists have accumulated data which indicate that a drug affects behavior through modifying responses to immediate environmental events (Iversen and Iversen, 1975; Seiden and Dykstra, 1977).

The neuroleptics have typically produced apathy in response to environmental events especially those of an emotional or social nature (Baldessarini, 1981). Data collected during the present study reflected several trends in response variability which were possibly influenced by environmental factors. The ranges in behavioral rates when on-placebo phases were compared to on-drug phases increased dramatically following the first drug withdrawal but not following the second for the occurrence of three feet proximity to others (Figure 4) and walking (Figure 6). Increases in ranges in behavioral rates occurred following both drug withdrawals for the occurrence of vocational performance (Figure 7, Louise) and talking (Figure 5). Perhaps these findings indicated an increased interest and sensitivity to environmental events upon drug withdrawal, and the response variability was due in part to the range of events which occurred during the phases.

The reliability of an empirical account of drug-behavior relationships depends on whether relevant environmental events have been

identified and properly controlled throughout the study. Ideally, relevant events are defined and manipulated to ensure that no changes occur during the time period that drug-related behavioral effects are measured. Stabilization of environmental influences in this manner is necessary to control their potential confounding effects. Drug-behavior-environment relationships are elucidated through measurement of behavior change under specified drug dosages within the context of constant environmental conditions.

All classes of Ricky's social behavior reflected increases in ranges of behavioral rates when the second on-drug phases were compared to the first on-drug phases as represented by the occurrence of three feet proximity to others (Figure 4). In Ricky's case it appeared as though increases in social behavior which were gained following the first drug withdrawal were not completely reversed following reintroduction of Mellaril. Similar changes were also observed in levels of two classes of social behavior including looking and being three feet proximal to others as depicted in Table A-1. Social behavior occurs during interactions with others in an environmental context such that Ricky's changes could have been partially due to changes in environmental opportunities for social interaction.

A study conducted by environmental psychologists in a psychiatric institution illustrated the important effects of certain environmental features on behavior (Ittelson, Proshansky, and Rivlin, 1970). The investigators selected one ward and conducted observations including a description of the setting and the behavior of the patients. The ward

had a long corridor which separated a nurse's station and an overheated, poorly furnished recreation room. Observations revealed that patients tended to stand in isolation in the corridor or around the nurse's station. The authors changed the recreation room by placing comfortable furnishings in patterns to encourage social interactions. The change in environmental format produced a decrease in time that the patients spent in isolation and an increase in social behavior in the recreation room.

Environmental features in an institutional setting which may mediate behavior include those changed in the previous study such as floor plan and furniture. Many other events may also affect the occurrence of behavior including the roles that staff play in staff-client interactions, the location and the availability of staff, the nature and availability of client-oriented activities, the frequency and nature of client-client interactions, and idiopathic institutional occurrences such as fire drills. A drug-behavior analysis should take these features and events into account since a drug affects behavior through modifying responses to immediate environmental events.

Environmental Events in an Applied Setting

The complexities of a study designed to elucidate drug-behavior relationships in an applied setting such as an institution are obvious due to an infinite number of potentially confounding environmental events. Necessary experimental control of such events in the present facility for the retarded included four interdependent categories: 1) consistency in area routine activities; 2) consistency in staff behavior

while teaching skills to the retarded clients (Skill Plans); 3) consistency in staff behavior while managing disruptive incidents (Behavior Plans).

Observations during the daily residential routine at ATPT indicated that a client made many different responses. He/she woke up in the morning, got out of bed, participated in grooming activities, ate breakfast, engaged in opportunities for social interactions, and so forth. This routine was a consistent sequence of events occurring from day to day which provided the client with many learning opportunities to become more self-sufficient.

Typically, institutional staff members used teaching strategies to ensure that the client acquired important skills of everyday living. Sometimes it was necessary to announce that an activity was occurring and to give instructions for desirable behavior during the activity. Feedback to the client in the form of verbal and/or physical praise was used to let the client know that his/her behavior was appropriate. Sometimes it was necessary for the staff to redirect disruptive behavior by verbally describing and/or physically demonstrating proper alternatives.

Throughout the daily routine the staff members used such strategies to increase prosocial behaviors. During observations for the present study, the staff were instructed not to initiate any interactions with the subjects due to the likelihood that these would introduce uncontrolled variability to drug-behavior relationships. Social behaviors such as talking, approaching, looking, appropriately touching, and being

three feet proximal to others were possibly sensitive to change due to staff-client interactions.

All three clients showed an increase in one or more social behaviors immediately following Mellaril withdrawal. In Mary's case (Figure 5) however, the increase in occurrence of talking to others was not sustained across the placebo phases in that the frequency of talking decreased to rates lower than those during the Mellaril phases by the end of the placebo phases. Mary showed initial increases in social behavior related to drug withdrawal, but her behavior was not reinforced through interactions with staff members since staff did not interact with her during the observation session.

A downward behavioral trend reflected by decreases in the occurrence of the response is called extinction when the withdrawal of a positive reinforcer precedes this trend. The absence of staff interactions as plausible positive reinforcers resulted in extinction of Mary's social behavior. The behavioral gains acquired through drug withdrawal were not sustained due to the absence of environmental events (staff behavior) which functioned as discriminative and reinforcing stimuli for the behavior.

Institutional staff were responsible for intervening during all disruptive episodes that occurred throughout the daily routine. The clients engaged in many behaviors which were in discord with appropriate social practices such as aggressing on other clients and staff, self-abuse, destroying institutional property and the like. These behaviors were dealt with through individualized Behavior Plans which usually

consisted of removing the disruptive client from the area and placing him/her outside, and/or withholding social attention or a treasured item until the behavior became acceptable.

In the following example, the drug-behavior assessment included a comparison of disruptive incidents during on-drug and on-placebo conditions. Consistency in staff behavior while implementing the Behavior Plan was necessary in order to draw firm conclusions from the assessment. Ricky who was receiving 125 mg. of Mellaril averaged five incidents of hitting, kicking, and/or hairpulling on a daily basis at the onset of the study. Staff members were instructed to adhere consistently to Ricky's Behavior Plan for aggressive behavior throughout the entire study. The plan consisted of attention to his victim in that immediately following the attack, Ricky's victim was given a hug and led from the scene. Ricky was ignored during this part of the procedure but one to two minutes later staff were supposed to talk to him and give him social attention if he had been quiet with no further incidents of aggression.

As already indicated, Ricky's average daily incident rate was five during the first on-drug phase. When he was on-placebo the incidents increased to an average of seven, and during the second on-drug phase the incidents further increased to an average of ten daily (Table A-1). Across all phases staff members were not consistent in implementing the plan for aggressive behavior. Sometimes staff yelled at Ricky to stop and/or pulled him away from his victim. Most of the time the staff correctly implemented the attention to the victim but failed to pay attention to Ricky when he had become quiet.

The inconsistencies in staff behavior obscured possible relationships among drug and Behavior Plan effects on the occurrence of Ricky's aggression. It was not possible to conclude that the drug was exerting behavior control, but it could not be completely ruled out. According to principles of operant conditioning, it was more likely that inconsistent staff behavior was responsible for failure of the plan to control Ricky's aggression. Consistent consequences contingent on specified behaviors must be rigorously implemented in order to change behavior (Gelfand and Hartmann, 1975).

In Ricky's case the staff had emotionally-based beliefs that the drug was instrumental in controlling his aggression, and they were rather "hostile" throughout the study. This hostility took the form of verbally protesting the study, failing to fill out the necessary data forms, and blaming Ricky's aggression on the experimenter for withdrawing the drug. Staff comportment might have also affected the rate of Ricky's aggression due to how they treated him since staff behavior included intermittent avoidance of Ricky, intermittent attention to him for aggression, and reconciliatory demands for more drugs. The occurrence of these events strayed far from the consistency required to successfully implement a plan for aggressive behavior and/or a drug-behavior assessment.

Future Research in Applied Behavioral Pharmacology

The experimental evidence summarized thus far has emphasized the importance of identification and control of environmental variables in an effort to elucidate drug-behavior relationships. In an

institutional setting relevent environmental features have included the ways in which teaching strategies and Behavior Plans were implemented during the daily routine. A drug-behavior assessment cannot be conducted in an applied setting simply by manipulating drug dosage and measuring behavior change. Events within the environmental context must be defined and stabilized to increase the likelihood that drug manipulation can be identified as a major determinant of behavior change.

An appropriate closing for this discussion is a description of an elaborate study which offered methods that can be incorporated into future research. The behavioral effects of Thorazine on 25 women were measured within the context of an entire ward in an institution for retarded people (McConahey et al., 1977). Before the onset of the study, the experimenters implemented an extensive ward token system to train the women in everyday living skills such as proper dress, grooming, use of utensils during meals, appropriate social interaction, etc.

The token system also functioned as a means to stabilize the staff-implemented schedule of reinforcement. Tokens, as positive reinforcers, were administered contingent on behaviors which occurred at proper times during the morning routine, and were cashed in at a regularly scheduled store where the women purchased trinkets and food items.

Notably, the token system was in effect only during half the day. The experimenters compared client performance under the conditions of stimulus control offered by the tokens during the morning routine to lack of specified stimulus control in effect during the afternoon routine. This analysis was relevent to an evaluation of the behavioral

effects of Thorazine during both conditions. The women participated in four successive phases each of one month duration: on-drug; on-placebo; on-drug; and on-placebo.

Statistically significant results indicated that the women achieved the highest performance rates on skills of everyday living while on-placebo and while under the stimulus control of the token program. Response to the token economy was hindered during the on-drug conditions. There were no differences in performance when these were compared between on-drug and on-placebo phases during the afternoon in the absence of the token program. The data comprised of aggressive incidents indicated a lack of statistical significance when those of the on-drug phases were compared to those of on-placebo phases. There were significantly more aggressive incidents in the absence of the token program compared to those which occurred during the program regardless of drug phase.

Despite the complexities inherent in an applied setting such as an institution, these findings offered techniques to begin to unravel the relative contributions of environmental contingencies and drug effects on behavior. Environmental events such as strategies to teach everyday living skills were properly controlled through a token system which offered a consistent format for staff behavior. The token system also stabilized client performance through a consistent routine and schedule of reinforcement that provided predictable consequences for behavior.

Future research in applied behavioral pharmacology should include techniques for total environmental engineering. Control of environmental events which impact on client behavior is essential to a drug-behavior assessment conducted in an applied setting since a drug affects behavior through modifying responses to immediate environmental events.

APPENDIX A

LEVELS OF BEHAVIORS BY PHASE FOR RICKY, LOUISE, AND MARY

Table A-1. Ricky--levels of behaviors by phase

Behavior	I-125 mg.	II-Placebo	III-125 mg.
Observational Data % of time behavior occurred--ave./day	Mellaril	Placebo	Mellaril
R Proximity (3 feet)	16	46	35
R Walking	70	58	80
R Off-feet	14	31	15
R Approach	8	14	5
R Touch	7	13	3
R Talk to staff, peers	9	18	9
R Looking	26	56	42
R Mouth-tongue movement	65	44	59
Repetitive motor	0 record	0 record	0 record
Talk or laugh to self (T)	7	13	15
Talk	2	4	7
Laugh	5	9	8
Teasing (total frequency*)	95	204	252
Self-abuse (total frequency*)	8	1	2

Staff Report Adj. freq.*/ave./day	Mellaril Freq.	 $\bar{X}$/Day	Placebo Freq.	 $\bar{X}$/Day	Mellaril Freq.	 $\bar{X}$/Day
Aggression--Res.	129	5	247	6	307	10
Aggression--Voc.	?	?	11	.4	9	.3

Vocational-Sorting Task	Mellaril	Placebo	Mellaril
# of pieces sort--ave.	52	89	71
Errors--ave./day	.8	.9	1.3
R Aggression during task (weak)	5	0	1
Throwing during task	12	2	1

*Adjusted frequency--adjustment for difference in number of days that data were reported across phases

R = Reversal--the data suggest that Mellaril affected the behavior

Table A-2. Louise--levels of behaviors by phase

Behavior		I-250 mg.	II-Placebo	III-250 mg.	IV-Placebo
Observational Data % of time behavior occurred--ave./day		Mellaril	Placebo	Mellaril	Placebo
R	Proximity (3 feet)	2	17	11	15
	Walking	83	57	83	85
(weak)R	Off-feet	3	39	5	8
(weak)R	Approach (*Frequency)	2	21	11	14
	Touch	1	2	4	2
	Talk to staff, peers	0	0	0	0
R	Looking	8	23	13	22
	Repetitive motor (total)	15	21	32	26
	Mouth-tongue movement	.09	0	0	0
	Twirling	8	12	15	16
	Move furniture	6	7	15	10
	Rocking	2	2	2	1
Observational Data Frequency					
R	Food stealing	7	4	7	1
	Self-abuse	0	0	0	0
	Aggression	1	0	0	1

Table A-2, continued

Behavior	I-250 mg.	II-Placebo	III-250 mg.	IV-Placebo
Staff Report Frequency	Mellaril	Placebo	Mellaril	Placebo
R Aggression or self-abuse (Residential)	8	6	17	7
Aggression (Vocational)	3	3	4	3
Stripping (Vocational)	4	1	3	3
R Throwing work material (Vocational)	9	3	4	3
Total	24	13	28	16
Vocational Sorting Task Average per session	Mellaril	Placebo	Mellaril	Placebo
R # of pieces sorted	45	62	46	53
Errors	.3	.8	.5	.4

R = Reversal--the data suggest that Mellaril affected the behavior

Table A-3. Mary--levels of behaviors by phase

Behavior	I-60 mg.	II-Placebo	III-60 mg.	IV-Placebo
Observational Data % of time behavior occurred--ave./day	Mellaril	Placebo	Mellaril	Placebo
R Proximity (3 feet)	14	35	23	58
(weak)R Walking	25	19	26	23
(weak)R Off-feet	58	65	63	67
Approach	3	3	2	1
Touch	3	4	1	.9
R Talk to staff, peers	7	14	4	24
R Looking	45	54	40	68
Repetitive motor	0 recorded	0 recorded	0 recorded	0 recorded
R Mouth-tongue movement	12	17	9	33
R Talk or laugh to self (T)	4	10	.9	5
Talk	.7	6	.3	4
Laugh	3	5	.6	1
Self-abuse	0	0	0	0
Aggression (frequency*)	1	1	0	8
Staff Report Frequency	Mellaril	Placebo	Mellaril	Placebo
Aggression--Residential	16	17	12	22
Aggression--Vocational	3	2	2	4
Total	19	19	14	26

Table A-3, continued

Behavior	I-60 mg.	II-Placebo	III-60 mg.	IV-Placebo
Vocational Sorting Task Average per session	Mellaril	Placebo	Mellaril	Placebo
(weak)R # of pieces sorted	89	94	89	97
Errors	1.4	.4	.9	.2

R = Reversal--the data suggest that Mellaril affected the behavior

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