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Behavioral Treatments for Drug Abuse and Dependence

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Contents

Behavioral Treatments for Drug Abuse and Dependence: Progress, Potential, and Promise

Lisa Simon Onken, Jack D. Blaine, and John J. Boren

This monograph is a product of a National Institute on Drug Abuse technical review meeting, "Behavioral Treatments for Drug Abuse and Dependence," held in Bethesda, Maryland, on September 1 and 2, 1992. The meeting was chaired by the editors of this monograph. The participants included Drs. Thomas D. Borkovec, Anna Rose Childress, John Grabowski, Scott W. Henggeler, Stephen T. Higgins, Kenneth I. Howard, Marsha M. Linehan, G. Alan Marlatt, William R. Miller, Karla Moras, Charles R. Schuster, Maxine Stitzer, and Fred Wright.

In the past decade, behavioral treatment researchers have explored the efficacy of numerous behavioral interventions for drug dependent individuals and have made considerable progress. Research studies on behavioral treatments for drug dependence were presented by scientists who do state-of-the-art research in this area: Drs. Stitzer, Childress, Grabowski, and Higgins. In her presentation and in the chapter she wrote with Drs. Iguchi, Kildorf, and Bigelow, Dr. Stitzer reviewed the research on the use of positive versus negative contingencies with methadone maintenance patients and presented the advantages of using positive incentives. Cognitive therapy for substance abuse was clearly described by Dr. Wright at the technical review and again in the chapter written by Drs. Wright, Beck, Newman, and Liese. Dr. Childress reviewed the work she has done on cue exposure with opiate and cocaine addicts. In her chapter, she and her coauthors, Drs. Hole, Ehrman, Robbins, McLellan, and O'Brien, alert the field to the need for providing patients with active strategies for managing their drug problems in addition to the passive cue exposure strategies used in the laboratory. Dr. Grabowski pointed out that even when clinics do not define them as such, all clinics use clinicwide behavioral interventions, commonly thought of as the rules of the clinic. Dr. Grabowski and his coauthors, Drs. Rhoades, Elk, Schmitz, and Creson, reviewed the ways in which these clinicwide and individualized contingencies can impact

positively on drug dependence treatment. Dr. Higgins showed how community reinforcement, an approach that controls and utilizes reinforcers in multiple aspects of the cocaine-dependent individual's life, can increase the ability to achieve and maintain cocaine abstinence. Dr. Higgins' approach, described in the chapter by Drs. Higgins and Budney and originally developed by Hunt and Azrin (1973) for use with alcoholics, holds great promise for the treatment of cocaine addiction. The work of the fine behavioral treatment researchers at the technical review has, in many ways, set the standard for behavioral drug dependence treatment research.

Significant progress has been made in the past 20 years in alcoholism treatment. As Dr. Higgins has shown, some of the treatments known to work well for alcoholics may work well for persons addicted to other drugs. Familiarity with the literature on behavioral treatments for alcohol dependence can greatly improve our ability to develop effective treatments for drug dependence. The research on behavioral treatments for alcohol dependence has been comprehensively reviewed by Dr. Miller and is a significant contribution to this monograph. In the same spirit, Dr. Marlatt and his colleagues, who are alcoholism behavioral treatment researchers, have written a piece on harm reduction. Their perspective challenges the conventional wisdom regarding drug dependence treatment (i.e., that anything short of complete drug abstinence is a failure). Whether or not one agrees, unconventional perspectives may provide an impetus for framing a problem in a different way, ultimately leading to new approaches toward solving problems. The editors hope and believe that the contributions made to this monograph will spark new ideas regarding the behavioral treatment of drug dependence.

Dr. Henggeler presented his research findings on the treatment of antisocial adolescents with multisystemic therapy. Dr. Linehan has developed dialectical behavior therapy for parasuicidal individuals who meet criteria for borderline personality disorder. Both Dr. Henggeler's and Dr. Linehan's populations are well known for being difficult to treat. Both populations are also well known for their substantial comorbid drug dependence problems. The treatments that Drs. Henggeler and Linehan have developed for their respective populations are truly remarkable. The editors believe that they will

provide invaluable insights into the treatment of the drug dependent individual.

Methodological issues were highlighted at the technical review by Drs. Borkovec, Moras, and Howard. In this monograph, Dr. Borkovec explicates methodological and design guidelines for between-group behavioral treatment research. One of the difficulties in doing good behavioral drug dependence treatment research is obtaining valid and reliable measurements of outcome. Dr. Moras has clearly described strategies that may be used to maximize the ability to do this. Dr. Howard, in his inimitable way, maintains that although clinical researchers routinely design studies to determine main effects, they typically end up rummaging through the data when main effects do not appear looking for information (interactions) to explain the results. Did the men respond to treatment and the women not? Did the people who had spouses do well and the people without them poorly? In their contribution to this monograph, Drs. Howard, Krause, and Lyons have provided straightforward before-the-fact strategies to enable researchers to disaggregate the data after the fact. The points that these fine methodologists have made are well taken, and the editors of this publication are confident that they will serve to enhance the quality of behavioral drug dependence treatment research.

Dr. Schuster provided insights as to why behavioral treatments are not more readily utilized outside of research settings. In their contribution to the monograph, Drs. Schuster and Silverman have enumerated concrete suggestions to facilitate the utilization of behavioral treatment methods in drug dependence treatment settings. Dr. Miller, with a combination of incisive thinking and humor, provided a commentary on the points that were made at the meeting. As is strikingly apparent in his second chapter and the final chapter to this monograph, he is able to cut to the heart of problems, making the complicated and muddled appear obvious and clear. The insights of Drs. Schuster and Miller are greatly appreciated and, the editors are sure, will make invaluable contributions to this field.

The editors of this monograph would like to extend our thanks to Drs. Harry Haverkos and Robert Battjes, Director and Deputy Director of the Division of Clinical Research, respectively, who made the technical review that sparked this monograph possible. We also would

like to thank the fine group of technical review participants who contributed to this monograph. Finally, we would like to inform the field of NIDA's dedication to supporting research in this area. NIDA has launched a major initiative in this area, the Behavioral Therapies Initiative, that affirms a continuing interest in expanding the support of fine research on behavioral treatments for drug dependence.

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Advancing the Application of Behavioral Treatment Approaches for Drug Dependence

Charles R. Schuster and Kenneth Silverman

Over the past 30 years, a range of behavioral interventions for drug dependence have been found effective in diminishing drug use (Childress et al. 1985; Stitzer et al. 1985, 1989); unfortunately, those interventions have not been widely adopted by treatment providers. The purpose of this chapter is to discuss methods that might facilitate the widespread applications of behavioral treatment interventions that have been shown to be efficacious in controlled studies. This topic, which has been referred to as knowledge utilization, is not a problem confined to the drug abuse treatment field but rather is an issue that is common to all science-based applied activities, from engineering to medicine. This is basically a problem of how behavioral change can be best achieved, not in clients seeking treatment but rather in treatment practitioners and in the researchers who are developing, evaluating, and disseminating the new treatment approaches.

Why is this area of importance to both researchers and practitioners? First, utilization of new behavioral interventions could result in significant improvement in the success of prevention or treatment practitioners. In addition, the public, the legislatures, and the insurance companies that pay for treatment increasingly are demanding accountability, asking, "Does it work? Are there more cost-effective procedures?" It is also of importance to researchers, whose support ultimately rests on the perception of society, and especially Congress, that research does have some practical value. It is true that fundamental research is of importance for knowledge generation in its own right; humans are unique in their inquisitiveness about how the world works, and societies should support scientists whose work allows us all to vicariously express this need. However, it is also a fact that society is increasingly demanding accountability, asking,

"What are we getting for our expenditures?" This means that scientists must be increasingly cognizant of the relevance of their work to applied fields.

IMPEDIMENTS TO THE APPLICATION OF RESEARCH FINDINGS

What are some of the impediments to the application of behavioral treatment research? First, this problem must be addressed with the appropriate humility about what research can do for treatment practitioners and with an appropriate respect for what they are currently doing. It must be recognized that most frontline treatment practitioners are not educated in the principles underlying behavioral treatment approaches or in the jargon of treatment research. Further, frontline treatment practitioners often deal with cases that would be excluded from research studies. How many research studies reject participation by those who are illiterate, have no fixed address, are polydrug abusers, or have other psychiatric or other medical complications? In addition, those in the trenches of the "drug war" are underpaid, overworked, and often demoralized (Ball and Ross 1991; Gustafson 1991). with little time or energy to read about the latest treatment research findings in *NIDA Notes,* let alone apply them to their own clinical activities. Furthermore, some of the frontline treatment providers in drug abuse clinics are recovering addicts who are emotionally tied to the approaches that they believe are responsible for their successful rehabilitation. It is a small wonder, therefore, that treatment practitioners are not using procedures that were described a few months ago in a professional journal!

There are additional impediments to the acceptance of behavioral procedures that are unique to this treatment approach. First, behavioral approaches, if not fully explained and understood, sound mechanistic and inhumane. To say, for example, the goal of treatment is to "control the behavior of clients" sounds to most like an Orwellian state with Big Brother watching. In addition, behavioral approaches are met with skepticism by those who believe that addiction involves a disordered brain that can only be reordered by a medication. According to this view, behavioral interventions are inadequate because they only affect symptoms and do not address the underlying causes of

drug abuse. Further, behavioral treatment programs may be expensive to implement and require financial and staffing resources that are not available to the average drug abuse treatment clinic. For example, behavioral interventions often are evaluated in research clinics that have client-to-staff ratios that are considerably greater than those in the average clinic. Finally, behavioral approaches can be complex and require a considerable amount of training to be properly applied. Given these impediments, it is obvious that, if researchers are interested in having new treatments applied, more must be done than simply publishing data in professional journals or giving lectures at professional conferences.

RESEARCH WITH THE GOAL OF WIDESPREAD APPLICATION

Ideally, research progresses in a stepwise fashion from the laboratory, in which basic principles are explored, to controlled studies, in which those laboratory-derived principles are applied in the form of new procedures to solve real problems, to widespread application under real-world conditions, in which the empirically derived principles and procedures are evaluated for their real-world utility. Behavioral treatment interventions can readily follow this progression. Behavioral approaches are firmly rooted in an extensive body of laboratory research that has shown that drug self-administration in animals and humans can be diminished by systematic manipulations of the environment (Goldberg 1976; Griffiths et al. 1980; Johanson and Schuster 1981; Pickens et al. 1978). The principles and procedures that have proven effective in modulating drug-taking behavior in the laboratory have served as the basis for the behavioral drug abuse interventions that currently are being applied and evaluated in controlled clinical research settings. This powerful tradition will no doubt continue; behavioral researchers will continue to adapt laboratory-derived principles and procedures to develop new and effective behavioral treatments. At this point in the development of behavioral approaches to drug abuse treatment, it is essential to focus special attention on the final goal of widespread application. This focus may help shape the development of new behavioral approaches in ways that may facilitate their subsequent application.

In recent years, behavioral drug abuse treatments have been developed and evaluated under relatively controlled circumstances in the context of small-scale research programs funded largely by the National Institute on Drug Abuse (NIDA). Many of these programs have proven effective in reducing drug abuse (Childress et al. 1985; Stitzer et al. 1985, 1989), and some programs have produced effects that have not been equaled by other pharmacological or nonpharmacological approaches (e.g., Higgins et al. 1991, in press). Although considerable advances have been made by researchers developing and evaluating behavioral interventions for drug abuse, this effort could benefit considerably by a systematic and coordinated research program similar to the NIDA Medications Development Program. A program of this type could help focus the behavioral treatment research by developing specific goals, including goals that might facilitate subsequent large-scale application of behavioral treatments across the United States. In fact, a NIDA Behavioral Therapies Development Program already has been suggested by Dr. Snyder (personal communication), and NIDA has formed a Workgroup to develop and implement the program.

The NIDA Behavioral Therapies Development Program could facilitate the large-scale application of behavioral treatments by outlining a number of specific objectives. First, it could encourage the development of low-cost interventions that would use available resources and that could be applied with minimal training of counselors and other clinic staff professionals. Contingency management programs in methadone maintenance clinics that provide take-home methadone doses contingent on drug abstinence (as verified by urinalysis) are good examples of low-cost, easily implemented interventions of proven efficacy (Stitzer et al. 1984). These programs are being refined and ultimately could be studied on a large-scale basis in methadone clinics across the country to determine their general utility.

Experience suggests that these low-cost programs will likely have limitations. Contingency management programs, for example, have been effective in reducing drug use as long as they are in effect, but they have not had long-term effects. In addition, powerful reinforcers like methadone may not be readily available to treatment providers outside of methadone clinics, further limiting their general applicability. Also, outside of research settings, the Federal methadone

regulations do not allow total flexibility for contingent take-home methadone doses. Even if improved, these contingency management programs probably will have to be considered as important elements in comprehensive treatment programs designed to develop client behaviors (lifestyles) that support drug abstinence and that are incompatible with drug use. Those comprehensive programs are likely to be costly and complex and to require extensive staff training to implement. Research on this type of program is clearly necessary, and the NIDA Behavioral Therapies Development Program could encourage it. In addition, with a focus on eventual large-scale application, the NIDA Behavioral Therapies Development Program could encourage several other important activities. First, researchers could be encouraged to create manuals and training procedures so that the behavioral interventions could be taught to the staff in nonresearch clinics. Second, studies analogous to labeling studies for pharmacological treatments could be funded to examine whether the behavioral interventions can be properly administered by staff in nonresearch clinics, given the materials and training procedures prescribed by the originators of the treatment. Third, efforts to replicate the results of successful behavioral treatments could be encouraged. Finally, researchers could be encouraged to conduct economic analyses to determine if the treatments are cost-effective, considering not only the actual costs of the treatment but also the savings to society in terms of reductions in crime, the spread of human immunodeficiency virus infection, etc. This type of analysis is essential to be able to get funding sources to increase the amount of money available for each treatment slot.

Effective drug abuse treatment interventions that can be packaged and accurately and reliably taught to nonresearch treatment staff should be evaluated in large-scale demonstration projects that involve a number of nonresearch treatment clinics, preferably in more than one geographical area. This research should evaluate process variables to determine if the treatment approach is implemented adequately and outcome variables to determine if the treatment is effective in reducing drug abuse. The Center for Substance Abuse Treatment (CSAT), a part of the Substance Abuse and Mental Health Services Administration (SAMHSA), might fund such large-scale demonstration projects and in this way support an important step in a focused effort to disseminate new and effective behavioral treatments. By providing

special funding opportunities for research that is focused on ultimate large-scale evaluation and application, the Behavioral Therapies Development Program within NIDA, along with SAMHSA's CSAT, could facilitate the development of effective behavioral treatments for drug abuse that have widespread applicability.

NIDA ENDORSEMENT OF EFFECTIVE AND EXPORTABLE PROGRAMS

Interpretation of research is a time-consuming and complex matter. Even if behavioral treatment approaches are thoroughly evaluated from the laboratory to large-scale demonstration projects, it may be difficult or impossible for frontline treatment providers to wade through all of the relevant publications to identify the most suitable program for their needs. To aid in the identification of effective and applicable behavioral drug abuse treatment approaches, NIDA could establish an independent committee or consensus group in which experts would periodically review the current research and recommend treatment approaches for adoption by the treatment community. This committee could establish criteria and procedures for evaluating behavioral treatment approaches similar to the criteria and procedures developed by the Federal Drug Administration to evaluate new treatment medications, but without the regulatory authority. Behavioral treatment approaches that are recognized as effective and appropriate for large-scale application could be announced to treatment providers in marketing campaigns along with information about whom to contact for aid in the implementation of the newly endorsed programs.

REINFORCEMENT CONTINGENCIES FOR PROVIDING EFFECTIVE TREATMENT

A fundamental tenet of behavior analysis is that behavior is, to a large degree, controlled by its consequences. This suggests that the problem of application of research findings can be analyzed by identifying the consequences of maintaining the behavior of researchers and practitioners and employing these consequences to maximize the effective utilization of research findings by practitioners. It is clear that there are some natural reinforcers for the behavior of both

researchers and practitioners that support effective utilization of research findings. There is no question that effectively preventing drug abuse in the target population of adolescents or successfully treating a drug-abusing client is highly rewarding to practitioners. In postinterviews, attendees at a recent NIDA Technology Transfer Conference expressed a need for training in the use of prevention and treatment evaluation methods (Backer 1991). Similarly, researchers at this conference who could see that the products of their work might be successfully applied to prevention or treatment were gratified and indicated their willingness to participate in future conferences where practitioners and researchers could get together. However, as discussed above, there are major impediments to the operation of these natural reinforcement contingencies in shaping and maintaining the behaviors of researchers and practitioners over the long term. It may be necessary, therefore, to supplement these natural reinforcers with systems that provide other reinforcers to maintain the behavior of researchers and practitioners.

Some of the suggestions described above involve arranging reinforcement contingencies for the behavior of researchers to develop programs that are suitable for large-scale application. The funding opportunities that will be offered by the NIDA Behavioral Therapies Development Program for the development and evaluation of behavioral treatment programs that are designed and suitable for large-scale application may help shape and maintain research activities that are focused on large-scale application. The opportunity to conduct large-scale demonstration projects with funding by SAMHSA's CSAT might have two effects. First, it might encourage NIDA-funded researchers to develop programs that appear suitable for widespread application so that those programs could be evaluated in large-scale demonstration projects funded by CSAT. Second, the funding opportunities to conduct large-scale demonstration projects should generate a substantial amount of behavior. Finally, recognition of the efficacy and general utility of a particular treatment approach by a NIDA body of experts also might function as a reinforcer for the researchers who designed and evaluated the recognized treatment approach, particularly if that recognition is useful to those researchers in obtaining future NIDA grants and grants from CSAT.

One of two types of reinforcement contingencies could be arranged for the behavior of treatment practitioners. First, reinforcement contingencies could be arranged for adopting and utilizing treatment approaches that have been proven effective through research. Although this approach may have some appeal, it is probably impractical. Treatment approaches can be implemented with varying degrees of skill and accuracy. The same treatment approach can be implemented by one clinic or one counselor properly and with great effectiveness while another clinic or counselor may implement the approach poorly, retaining its basic fonn while loosing much of its function. Determining whether or not a clinic or a counselor is properly implementing the treatment approach so that the reinforcers can be applied would be very difficult in many situations.

Alternatively, reinforcement contingencies could be arranged for providing effective drug abuse treatment. Reinforcement contingencies of this type should function to increase the effectiveness of the treatment provided; in addition, those reinforcement contingencies might increase the likelihood that treatment programs and treatment practitioners would seek out and adopt new interventions that have been determined to be effective through research. Unlike many types of treatment, the effectiveness of drug abuse treatment can be objectively and reliably determined through regular urinalysis. Using urine results, reinforcement contingencies could be arranged at the level of the treatment program as well as at the level of the individual treatment provider. Currently, State and Federal funds to treatment programs are provided for those programs for complying with structural requirements. To increase treatment effectiveness and to increase the likelihood that treatment programs would adopt new and effective behavioral treatments, States and the Federal Government could make funding decisions based on the demonstrated effectiveness of treatment programs. This could be accomplished by providing more funds to programs that are effective relative to other ongoing programs in retaining patients in treatment, reducing drug use, and producing long-term effects. Similar contingencies could be arranged for the individual treatment providers. Counselors, for example, could receive benefits for retaining their patients in treatment, reducing drug use, and producing long-term effects in their patients (cf., McCaul and Svikis 1991). The effectiveness of these contingencies should increase as a function of the magnitude of the reinforcement contingencies,

suggesting that substantial monetary consequences will be most effective; however, given existing funding limitations, it may be necessary to provide consequences that are probably weaker but available to treatment programs such as flexible working hours, decreased caseloads, parking spaces, reduced paperwork requirements, and opportunities to attend conferences.

Reinforcement contingencies cannot be arranged for effective treatment unless adequate systems are in place to evaluate treatment effectiveness. Such systems necessarily will include regular urinalysis testing and regular monitoring of that testing by an independent agent. No doubt, contingencies on effectiveness would have a number of effects, some of which may be undesirable (e.g., accepting into treatment only patients who are likely to succeed). Therefore, the precise delineation of the guidelines and controls for implementing reinforcement contingencies for treatment effectiveness will require careful planning. Furthermore, although the recommendations to reinforce effective treatment by treatment programs and by individual treatment providers are reasonable and are based on an extensive body of literature on the effects of similar reinforcement contingencies on human behavior in other treatment situations (e.g., Iwata et al. 1976; Greene et al. 1978), reinforcement contingencies of this type have not been studied in the administration of drug abuse treatment and would be important subjects of future research.

TRAINING TREATMENT PRACTITIONERS

The majority of practitioners in the drug abuse field today are not skilled in behavioral treatment approaches, and some practitioners are philosophically opposed to such interventions, or at least are skilled in approaches that are antithetical to behavioral approaches. It seems reasonable that new behavioral treatments will be most appealing and most easily taught to practitioners with prior training in behavioral approaches. Therefore, efforts must be made to increase the number of counselors, psychologists, and psychiatrists receiving training in behavioral approaches. Currently, CSAT (through the Substance Abuse Counselor Training Program) provides training in drug abuse counseling to people entering the drug abuse treatment field. Advances in the application of effective behavioral treatments could be

made if NIDA researchers who develop new and effective behavioral treatment interventions were encouraged to contribute to this training program. Increasing the number of college and university programs for counselors, psychologists, and psychiatrists that provide training in behavioral approaches would further prepare the treatment community to accept and effectively utilize new behavioral interventions.

CONCLUSION

Five steps have been proposed to facilitate the widespread application of behavioral drug abuse treatment approaches: (1) the funding by NIDA's Behavioral Therapies Development Program of research efforts designed to facilitate widespread application of behavioral treatments, (2) the funding of large-scale demonstration projects by SAMHSA's CSAT to evaluate the widespread applicability of behavioral treatment approaches that have been found effective and reproducible in the smaller and more controlled NIDA-funded projects, (3) the creation by NIDA of a committee or consensus conference of experts that periodically would review behavioral treatment research and endorse and market to treatment providers the approaches recognized as effective, (4) the administration of State and Federal funds to treatment programs contingent on providing effective treatment relative to similar treatment programs and the arrangement of reinforcement contingencies for individual treatment practitioners for providing effective treatment, and (5) an increased focus on providing training in behavioral approaches to drug abuse counselors in CSAT's Substance Abuse Counselor Training Program as well as to counselors, psychologists, and psychiatrists in college and university programs.

The success of efforts to apply behavioral treatments will also depend on the reaction and cooperation of the communities in which the drug abusers live. Clearly, behavioral treatments, which often focus on the development of behaviors that compete with drug abuse, will be most likely to succeed in communities that support those efforts, for example, by providing jobs and recreational opportunities to people in drug abuse treatment. Although some of this community involvement can be recruited by treatment practitioners, community support also

can be encouraged through public education campaigns that prepare communities to accept the view that drug abuse can be treated by strategically molding and enriching the environments of drug abusers.

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Contingency Management in Methadone Treatment: The Case for Positive Incentives

Maxine L. Stitzer, Martin Y. Iguchi, Michael Kidorf, and George E. Bigelow

INTRODUCTION

Methadone maintenance has been widely and effectively implemented for nearly 30 years as a treatment for opiate dependence. During methadone treatment, heroin use is suppressed through pharmacological satiation and cross-tolerance. However, methadone does not directly address the full array of substance abuse problems that patients often bring to the treatment setting. In particular, the continued use and abuse of drugs from nonopiate pharmacological classes is recognized as a significant clinical problem in contemporary methadone programs. Cocaine use is widespread among methadone patients (Kosten et al. 1986; Hanbury et al. 1986; Condelli et al. 1991), and benzodiazepine tranquilizers also still are abused by a subset of patients (Stitzer et al. 1982; Iguchi et al., in press). Aversive contingencies involving treatment termination are readily available and widely employed by counseling staff in an effort to promote behavior change among their patients, including cessation of supplemental drug use. Typically, a contract is negotiated with the patient in which parameters of improved performance are specified that must be achieved within a delineated timeframe, with the consequence of nonperformance being gradual dose-tapering and ultimately treatment termination. Previous studies have indicated that clearly specified aversive contingencies involving the threat of dose reduction or treatment termination can be effective for promoting improved treatment outcomes (Dolan et al. 1985; McCarthy and Borders 1985; Stitzer et al. 1986). However, the disadvantage of this approach is that poorly performing patients, who are often the neediest and most severely drug-dependent individuals, are likely to be terminated from treatment (Iguchi et al. 1988; Stitzer et al. 1986).

Positive incentives also are available in the context of methadone clinic operation that can be used to influence abuse of nonopiate drugs during methadone treatment. Specifically, clients can be offered tangible rewards or incentives contingent upon objective urinalysis evidence that they have complied with program requirements or have recently abstained from the supplemental drugs typically used. Previous studies have shown that the methadone medication take-home privilege, whereby clients can miss a day of clinic reporting and ingest their daily medication dose at home, is desirable to clients (Stitzer and Bigelow 1978) and effective as an incentive for use in contingency management programs. An early study by Stitzer and colleagues (1982) and a more recent study by Iguchi and colleagues (1988) both offered medication take-home privileges based on drug-free urines and demonstrated that 40 to 50 percent of the benzodiazepine-abusing methadone patients enrolled as subjects reduced or eliminated their supplemental benzodiazepine use during intervention trials lasting from 12 to 20 weeks. Magura and colleagues (1988) found that l-month contracting for contingent take-homes produced a favorable response (i.e., drug abstinence) in 34 percent of their polydrug-abusing subjects, while Milby and colleagues (1978) found a similar percentage of clients responding to a take-home incentive program with increased numbers of consecutive drug-free urines, as required by the intervention.

Most of these early studies focused on selected groups of identified polydrug-abusers and used within-subjects designs to evaluate effectiveness of contingent take-home programs. A more recent study, which will be described below, used a controlled clinical trials design to evaluate the extent to which contingent take-home privileges would influence drug abuse outcomes of an unselected group of new intakes to methadone maintenance treatment (Stitzer et al. 1992). It should be noted that these studies of methadone take-home privileges have particular clinical relevance because they emphasize the use of take-home privileges in a flexible and responsive manner to motivate periods of abstinence from drug use in polydmg-abusing patients. This is in contrast to the way that take-home privileges often are used as awards only to patients with long-standing histories of abstinence from all illicit drugs.

CONTINGENT TAKE-HOME STUDY: METHODS

Subjects

Study participants in the recently conducted clinical trials study were 53 patients newly admitted to methadone maintenance treatment. Demographic profile was typical for a lower income methadone maintenance population: average age was 34 years (±6.7 yrs), 72 percent were male, 66 percent were white (the remainder being black), 34 percent were employed, and 23 percent were married at treatment entry. Forty percent had no current involvement with the criminal justice system, the remainder were either on probation (38 percent) or free pending trial (22 percent). There were no statistically significant differences between the study groups on any of the demographic variables.

Baseline Drug Use

Drug use was detected in 64 percent of urines collected during the first 3 months following treatment enrollment, which constituted the baseline evaluation phase. This high overall rate of drug-positive urine samples probably reflects both a sampling bias in patients admitted to treatment, since the authors' clinic has a reputation for accepting polydrug abusers, and also may be due to the very intensive urinalysis testing schedule employed that was designed to maximize detection of drug use. Cocaine and benzodiazepines were detected in urine testing with approximately equal frequency (cocaine in 32 percent of samples positive, and benzodiazepines in 38 percent). There were no significant differences between the groups in rates or patterns of baseline drug use. Individual subjects usually displayed clear biases in selecting their supplemental drugs. Of the 53 subjects included in the data analysis, urine testing indicated that 22 (41.5 percent) primarily used benzodiazepines alone or benzodiazepines and opiates, while another 20 (37.7 percent) primarily used cocaine alone or cocaine and opiates, and 3 primarily used opiates alone. Four had both cocaine and benzodiazepines in more than 50 percent of their urines, and four could not be assigned a primary drug of abuse due to low frequency of detection of any drug.

Clinic Procedures

During the study, subjects reported to the clinic every day to ingest their methadone dose in a cherry syrup vehicle under nursing supervision (unless they previously had been assigned to receive a take-home dose of methadone for that day). Average methadone dose was 51.4 mg/day (range = 30 to 60 mg; mode = 50). Subjects also were expected to participate in weekly drug abuse counseling and an intensive urine monitoring schedule. Urines collected during the study were tested for opiates, cocaine, and benzodiazepines using a sensitive and selective immunoassay procedure (Enzyme Multiplied Immunoassay Test [EMIT]) and tested using thin-layer chromatography (TLC) for the broad array of sedative and stimulant drugs that can be detected with this procedure. Contingencies in this study were based on all drugs that could be detected by either of these methods.

Study Condition Assignment

Subjects were stabilized for 12 weeks following treatment admission; this served as baseline for the random assignment study. At this point, subjects were stratified on gender and race and randomly assigned to one of two conditions: contingent (n = 26) or noncontingent (n = 27) opportunity to receive methadone take-homes. Subjects continued on the assigned protocol for 6 months, at which time the noncontingent study subjects still in treatment (n = 18) were switched to the contingent protocol.

Take-Home Procedures

Subjects in the noncontingent condition were assigned randomly at the beginning of each calendar month to receive zero, one, two, or three take-home doses of methadone per week for the month. These take-home doses were delivered independent of urine test results.

Under the contingent protocol, subjects could earn a maximum of three take-home doses per week (Tuesday, Thursday, and Saturday). The first (Tuesday) take-home privilege was assigned after six consecutive drug-free urines (2 weeks) had been observed. An additional take-home day (Thursday, then Saturday) was authorized following each additional successive 2-week drug-free period. Thus, six

consecutive drug-free weeks (18 consecutive urines) were required to earn the maximum number of take-homes. One take-home dose was forfeited for each drug-positive urine sample detected either by EMIT or by TLC analysis within a given 2-week block. Following a reduction or cancellation of take-home privileges, 2 full weeks of drug-free urinalysis results were required to earn back each take-home day. The rationale for the 2-week requirement of drug-free urines was that this represents a clinically meaningful period of drug abstinence that at the same time can be an achievable goal for the population of chronic supplemental users of cocaine or benzodiazepines.

CONTINGENT TAKE-HOME STUDY: RESULTS

Retention

Mean retention duration during the intervention period was 23 weeks, with no difference between the groups. Overall, about 30 percent of originally assigned subjects dropped out of treatment before the end of the 6-month evaluation. Early dropouts exhibited more polydrug abuse during baseline than did those who stayed in treatment.

Urine Testing Outcomes: Conditional Probabilities of Change

In order to give equal weight to urine results of early dropouts and those retained throughout the evaluation, data analysis was based on the overall percentage of positive urine samples given by each subject during baseline and during the portion of the intervention evaluation in which he or she participated. In this way, data from each subject contributed equally to the analysis whether or not the subject stayed through the entire intervention period. The primary focus of data analysis was an examination of the conditional probabilities of change (i.e., the probability that patients who could improve would improve and patients who could worsen would worsen during intervention as compared to baseline). Subjects who could improve were defined as those whose baseline rate of drug-free urines was 90 percent or less; these patients (n = 25 contingent, 25 noncontingent) were classified as improving if their rate of drug-free urines increased by 10 percent or more during the intervention. Subjects who could worsen were

defined as those whose baseline drug-free urine rate was 10 percent or more; these patients (n = 20 contingent, 21 noncontingent) were classified as worsening if their rate of drug-free urines decreased by 10 percent or more during the intervention. The ±10 percent criterion for defining change was selected to eliminate from consideration small changes in urine test results based on chance fluctuations.

As shown in figure 1, 32 percent (8 of 25) of contingent subjects who could improve did improve their drug-free urine test rate by 10 percent or more. In the noncontingent group, only 12 percent (3 of 25) who could improve did improve. Thus, the chances of improving were 2.5-fold greater for contingent than for noncontingent subjects. In the contingent group, 35 percent (7 of 20) of contingent subjects who could worsen showed a decline of 10 percent or greater in percentage of drug-free urines. In the noncontingent group, 62 percent (13 of 21) who could worsen did worsen. Thus, there was twice the chance of worsening in the noncontingent as compared with the contingent condition.

Clinical Improvement Criteria

In order to apply a more stringent definition of clinical improvement, subjects were required to improve their drug-free urine test rate by 10 percent or more and to have in addition at least 4 consecutive weeks (12 consecutive samples) of drug-free urines during the intervention period. The requirement for 4 consecutive weeks of abstinence is consistent with criteria recently utilized by the Food and Drug Administration (FDA) in evaluating the efficacy of medications used as cessation aids in tobacco dependence treatment. All the subjects in the contingent group who improved their urine test results also met the 4-week abstinence criterion, but one subject in the noncontingent group failed to meet the additional criterion. The groups differed significantly on percentage of patients meeting this criterion of improvement (32 percent versus 8 percent; $z = 2.12$, $p<.05$).

Magnitude of Change

Subjects in the contingent group who improved during the study submitted on average 42 percent drug-free urines during baseline and

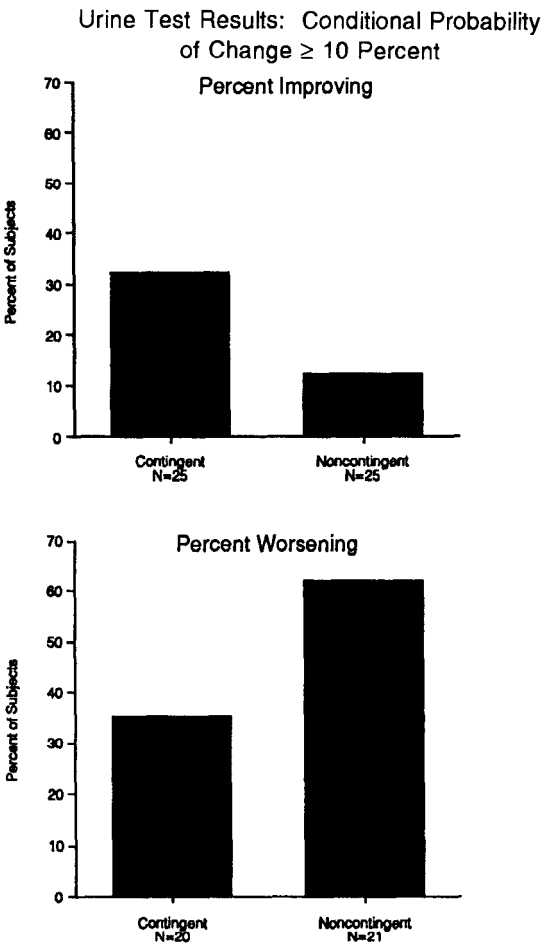

FIGURE 1. *The percentage of subjects who improved urine test results by 10 percent or more from baseline to intervention periods is shown in the upper panel for contingent (n=25) and noncontingent (n=25) subjects who could improve. The percentage of subjects whose urine test results worsened from baseline to intervention periods is shown in the lower panel for the contingent (n=20) and noncontingent (n=21) subjects who could worsen.*

70 percent drug-free urines during the intervention. Thus, while the criteria required a 10-percent improvement, these subjects were actually improving their urine drug-free test rate by nearly 30 percent on average. Further, these patients remained continuously abstinent for 9.4 weeks on average, although the criteria required only 4 weeks (range = 5.3-15.3 weeks) during the intervention. A final point to be made about treatment outcome is that subjects who improved were equally likely to be cocaine or benzodiazepine abusers. This fails to support a previous suggestion that cocaine abuse may be harder to treat than other forms of drug abuse (Magma et al. 1988).

Replication In Noncontingent Patients

The noncontingent patients (n = 18) who switched to the contingent protocol later in treatment were evaluated using the same improvement criteria described above for the contingent group in the main study. Of those who were able to improve (n = 16), 28 percent met the stringent criteria of clinical improvement, including at least 4 weeks of continuous abstinence during the evaluation period. Thus, this partial crossover feature of the study provided a within-subject replication of the main study findings.

Prediction of Positive Treatment Response

A strong predictor of positive response was baseline rate of drug-free urines, as illustrated in figure 2. All contingent subjects who improved their rate of drug use and earned take-homes during the treatment intervention had a 33-percent or better drug-free urine rate during baseline. In other words, these patients had submitted on average one or more drug-free urine samples per week under the 3-times-per-week testing schedule, suggesting a sporadic rather than continuous pattern of supplemental drug use. In contrast, there were no treatment responders among the subset of contingent intervention patients (n = 10) who submitted a very high proportion of drug-positive urines during baseline. The same relationship between baseline urine test results and subsequent treatment response was noted for the noncontingent patients who switched to the contingent protocol later in their treatment (right panel). Further, a similar relationship was noted with regard to multiple drug use (data not shown); treatment

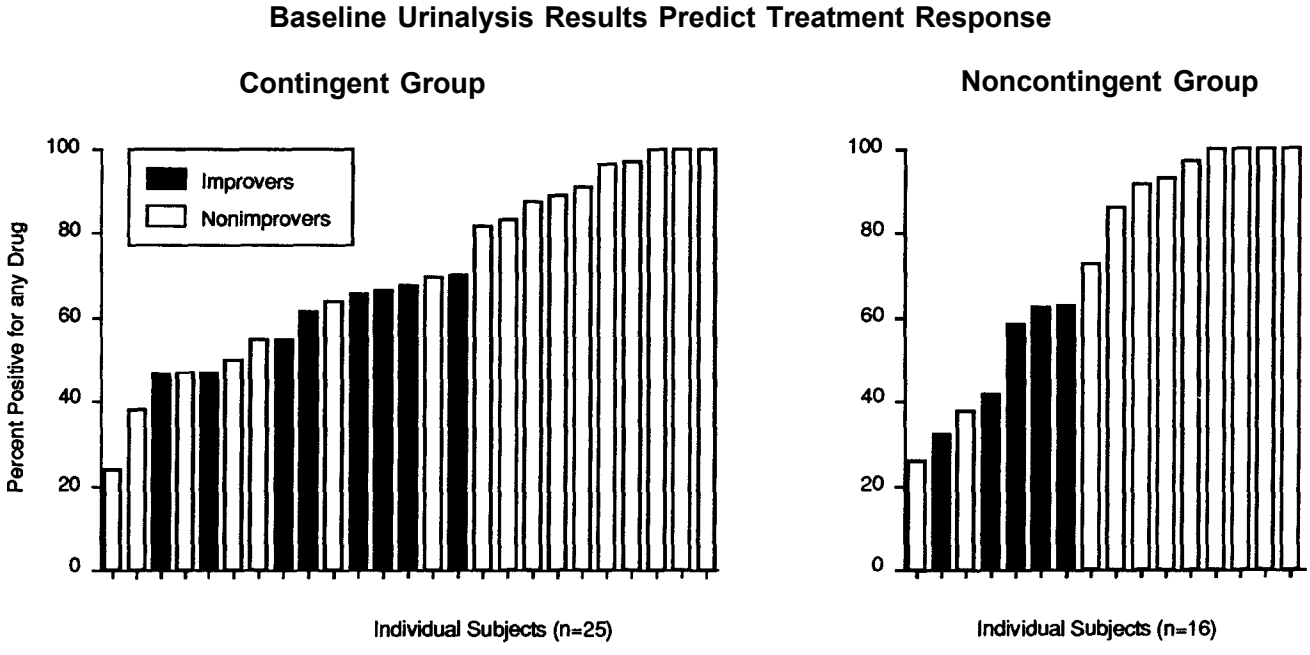

FIGURE 2. *Characteristics of baseline drug use are shown for individual study participants who were able to improve their urine test results. Subjects from the original contingent group (n=25) are shown in the left panel while those from the delayed-exposure partial crossover group (n=16) are shown in the right panel. Data for each subject are the percent of baseline urines testing positive for any illicit drug. Filled bars represent individual subjects who met the criteria for clinical improvement during the intervention (10 percent or greater improvement in percentage of drug-free urine tests and submission of at least 12 consecutive drug-free urine samples).*

responders tended to submit relatively few urines containing more than one drug of abuse, while treatment failures were more likely to show evidence of polydrug supplementation.

Study Summary

Thus, the controlled random assignment study showed that a subset of new treatment intakes responded favorably to a contingent take-home intervention that offered a desirable and practical clinic privilege (take-home medication) as an immediate incentive for objective evidence of supplemental drug abstinence. In contrast, the most likely outcome for subjects given noncontingent access to the take-home privilege was a worsening of treatment outcome vis-a-vis supplemental drug use. The 30-percent treatment response rate was replicated when noncontingent subjects were switched to the contingent protocol in a partial crossover. Further, no adverse effects of the take-home privilege were detected in terms of treatment retention or patterns of cessation and relapse. Finally, positive therapeutic response to the contingent take-home intervention was associated with lower rates of drug-positive urines submitted during baseline.

CONTINGENT TAKE-HOMES AS ROUTINE CARE

Subsequent to completion of the contingent take-home study, the methadone maintenance research clinic where the study had been conducted adopted the policy of offering take-home privileges to all entering clients based on drug-free urine test results. Initially, following FDA guidelines, patients had to wait 3 months after enrolling in treatment before take-home privileges could be earned. Following approval of an FDA exemption from the 90-day requirement, take-homes were offered after 1 month of treatment enrollment. The protocol for take-home earning and loss was identical to that described for the controlled study, following the 2-week rule. Among patients entering treatment during a 1-year period (n = 84), it was observed that 24 percent achieved the maximum number of take-home days (i.e., 3 days per week) during their first year of eligibility for take-home privileges, indicating that they had achieved at least 6 weeks of continuous abstinence from supplemental drugs. The mean number of take-homes earned was 57 (range = 11-144), with the

minimum number of take-homes representing about 8 drug-free weeks. The success rate observed in this clinical treatment sample closely paralleled the success rate seen during the controlled study and adds further credence to the effectiveness of the incentive program for motivating drug abstinence among methadone maintenance patients.

Predictors of positive treatment response for the clinic sample included lower baseline rates of drug-free urines, as previously seen in the controlled study. However, take-home earners in the clinic treatment sample were also much more likely to be employed and much less likely to have a drug-abusing sexual partner than patients who failed to earn take-homes during treatment. Thus, additional prognostic variables were identified in this sample.

GENERAL DISCUSSION

Research fmdings suggest that several structured incentive protocols are effective in promoting improved treatment outcomes among polydrug-supplementing methadone maintenance patients. To date, the incentives examined have been those that are implemented readily within the context of a treatment program that dispenses daily methadone. The interventions include contingent take-home incentives (Magura et al. 1988; Stitzer et al. 1992), contingent dose-change incentives (Stitzer et al. 1986), and treatment termination contracting (Dolan et al. 1985). In general, these structured incentive approaches have promoted improved outcomes in the range of 25 to 50 percent of patients. There is no evidence to suggest that one type of incentive program or combination of incentives is more effective than another. The foregoing observations suggest that incentive programs appear to be a good place to start for making inroads into the chronic supplemental drug use of methadone patients. Take-home incentive, altered-dose incentive, and treatment termination contracting protocols are implemented easily within the context of a drug abuse treatment clinic that dispenses methadone. All contingent incentive strategies provide structure and clearly defined expectations for the patient treatment plan and can be effective with a subset of patients. How can clinics choose among these specific intervention strategies?

The positive findings from the random assignment study as well as medical and ethical concerns support a recommendation that contingent take-home incentives be used as the primary routine care intervention in methadone clinics to promote improved treatment outcomes for polydrug-abusing patients. The program is consistent with known principles of effective behavioral management. By offering a reward for the beginning steps of change (i.e., 2 weeks of drug-free urines), the program defines a reachable short-term goal that can provide the basis for longer term improvement. The use of positive incentives that give patients something to gain but nothing to lose can provide a refreshing change from the coercive tactics often employed in drug treatment programs. Positive incentives also eliminate the ethical dilemma of forced early treatment termination for the more highly drug-dependent and impaired patients. Although contingent dose increases may have a role in treatment, interventions that involve contingent methadone dose reductions violate the medical precepts of treatment because an adequate and stable methadone dose is imperative for successful methadone maintenance. Further, since patients assigned to interventions involving dose reduction tend to drop out of treatment (Stitzer et al. 1986; Iguchi et al. 1988), the impact of withdrawing treatment needs to be considered if such interventions are employed as disciplinary actions. To this end, it would be useful to define more clearly the characteristics of patients who perform poorly in standard methadone treatment and to determine for this group the specific health, longevity, drug use, and psychosocial benefits associated with continuing long-term treatment involvement versus return to the community through treatment dropout or disciplinary termination.

Contingent incentive programs have received a considerable amount of attention in controlled research, perhaps because these are readily available and convenient to implement in routine clinical care. Thus, for example, the controlled study described in this chapter demonstrated that the methadone take-home privilege awarded after 2 consecutive weeks of drug-free urines was effective in promoting abstinence from cocaine and benzodiazepines used during methadone maintenance treatment. The probability of improvement in drug use outcome was 2.5-fold greater for patients who received their take-homes contingent on urine test results than for patients who received take-homes independent of urine test results, while the probability of worsening on the objective drug use measure was twice as great for

noncontingent than for contingent treatment patients. Further, 32 percent of contingent patients achieved sustained periods of abstinence from supplemental drugs. The conclusion of clinical effectiveness for the take-home incentive protocol was supported further when research findings were translated into routine clinical practice, where it was observed that 24 percent of new treatment intakes successfully earned take-homes when the contingent procedure subsequently was implemented as routine care. These data also are consistent with global impressions of clinical staff that patients enrolled in the contingent take-home intervention were trying to discontinue illicit drug use, while patients in the noncontingent condition tended to be "out of control" with respect to drug use.

Previous studies have shown that collection of urine test data has little benefit in and of itself unless the data are put to some use (Goldstein et al. 1977; Havassy and Hall 1981; Milby et al. 1980). The research on contingent take-homes provides the basis for a rational use of urine test results to shape behavior and promote improved clinical outcomes for methadone patients. Practicality of the intervention may rest in part on the ability of programs to implement frequent urine testing programs. With short-acting drugs like cocaine as the target of intervention, urine testing two or three times per week would be advantageous, while randomized testing once weekly would appear to be a minimum requirement. One strategy that might be considered for efficient use of urine testing resources would be to test intensively those patients who are attempting to achieve drug abstinence and earn incentives while placing other patients on a minimal testing regimen. This strategy reflects the rationale that urine testing is much more useful for confirming drug abstinence than for confirming ongoing drug use.

To put the research findings into proper perspective, it must be acknowledged that in fact the majority of methadone maintenance patients have not responded to contingent incentive interventions with therapeutic improvement. Thus, it appears that treatment modifications are needed to impact on a larger proportion of patients. One possible avenue is to require less behavior change so that more patients can experience success and receive the incentives being offered (i.e., a "shaping" strategy). Thus, for example, take-homes could be offered for a single drug-free urine or even for evidence of reduced use

obtained through quantitative urine testing methods. A second avenue would be to develop more potent incentives. The incentives available at the clinic, including take-home doses, could be supplemented with material incentives (i.e., goods and services) available in the community, using as a model the "voucher" system recently described by Higgins and colleagues (1993) for the treatment of primary cocaine abusers. This approach has the advantage of providing more individualized incentives, since patients earn vouchers with a cash value for improved performance but can select their own specific rewards in exchange for the vouchers.

Another possible avenue to developing more potent incentives might lie in combining the positive incentive approach with a structured aversive contingency involving treatment termination. This would be worth evaluating, since the threat of treatment termination is employed so widely in methadone clinics and since both positive and aversive interventions have some demonstrated efficacy. Thus, it might be possible to achieve additive effects through their combined use, particularly if different patient subgroups responded to negative versus positive incentive approaches. However, two previous small-sample studies from this laboratory have suggested that the combined approach would not be particularly fruitful. Stitzer and colleagues (1986) compared drug abuse treatment outcomes for patients (n = 10) who could receive gradual methadone dose raises (up to 30 mg higher than their 50 mg baseline dose) if they provided drug-free urines versus outcomes for patients (n = 10) who received gradual dose reductions (down to 30 mg below their 50 mg baseline dose) as a consequence of providing drug-positive urines. Interestingly, the same percentage of patients in each group (50 percent) responded by providing drug-free urines during the 18-week trial. A more direct test of the combined treatment idea was provided by Iguchi and colleagues (1988). In this experiment, all study patients could earn take-homes by submitting drug-free urines, while half the patients (n = 8) received an additional dose-reduction contingency leading eventually to a 0 mg methadone dose if they continued to provide drug-positive urines. Surprisingly, the percentage of patients responding with drug-free urines during the intervention was the same for the two treatment groups (38 percent), suggesting that the two interventions did not produce an additive effect on patient response. It is nevertheless plausible that different patients would respond to programs offering different specific incentives, and

additional research characterizing treatment responders versus nonresponders as a function of the type of contingent incentive program implemented would be useful.

It is important in general to identify patient characteristics associated with good versus poor treatment response in order to select appropriate available treatments, to more effectively channel treatment resources, and to develop rational treatment interventions for patient subgroups. Baseline rate of drug-free urines has been identified as an important predictor of treatment response, with lighter users who occasionally submit drug-free urines being more likely to succeed in a take-home incentive program (Stitzer et al. 1992) or a treatment termination contracting program (Dolan et al. 1986) compared with heavier users who rarely submit a drug-free urine. Social stability, including employment and living with a partner who does not abuse drugs, was also an important predictor in the clinical sample exposed to take-home incentives. Interestingly, within the contingent treatment group of the random assignment study, there were additional patients who had a good outcome prognosis based on urine profile (i.e., they submitted 20 to 60 percent drug-positive urines during baseline; figure 2) but who did not respond to the take-home intervention by further reducing their drug use. One strategy for effective use of counseling resources would be to target these better prognosis individuals for additional intensive therapy in order to discover and eliminate barriers to abstinence. Intensified counseling for better as opposed to poorer prognosis patients might be a more efficient use of therapeutic resources, since at present there is little information about what strategies are effective with the poorest prognosis patients.

Research findings support the recommendation that structured incentive protocols, particularly those involving contingent take-home privileges, can and should be incorporated, along with adequate supportive counseling, for the routine treatment of methadone maintenance patients who supplement with cocaine or benzodiazepines during treatment. A positive response, with improved outcome on drug use measures, can be expected in one-quarter to one-half of these patients. The task that remains for researchers and clinicians is to design more potent interventions that can impact the ongoing supplemental drug use of patients who fail to respond to available positive incentive programs such as contingent take-homes. These interventions most likely will

involve offering more potent incentives for evidence of recent abstinence, employing principles of shaping to encourage small changes leading to drug abstinence, and addressing lifestyle factors and skills deficits that may act as impediments to abstinence.

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Clinicwide and Individualized Behavioral Interventions in Drug Dependence Treatment

John Grabowski, Howard Rhoades, Ronith Elk, Joy Schmitz, and Daniel Creson

INTRODUCTION

Behavioral Approaches

Behavioral interventions for treatment of drug dependence have been developed over the last three decades. They involve systematic manipulation of a broad range of treatment conditions and are important for both understanding and treating features of these disorders. Their utility resides in the focus on drug-seeking and drug-taking, collection of specific data on individual patterns of drug dependence and abuse, and adapting the elements of treatment to the patients' needs. Behavioral approaches also emphasize strategies that actively extend to the patients' everyday life, thereby assuring that behavioral change will endure after treatment ends. This is best represented by the work of Higgins and Budney (1993).

The terms "behavioral intervention," "behavior modification," "behavior therapy," and "behavioral treatment" often are used interchangeably and describe a variety of therapeutic elements. Each originally emphasized some concepts over others. While cognitive therapies presume that changing speech and "thinking" changes behavior, behavioral approaches focus on more tangible representations of behavior. All derive from the underlying framework that assumes that altering relationships between behavior and its environmental determinants is critical to change. Thus, for example, Childress and colleagues (1993) focus on behavior following a model originally proposed for application to drug abuse by Wikler (1948) and O'Brien (1977, 1991). Changes in responses are presumed to contribute to change in other behaviors such as drug-seeking and drug-taking. Hunt

and Azrin (1973), Stitzer et al. (1985), Bigelow et al. (1984), Higgins and coworkers (1992), Higgins and Budney (1993), and others focused on operant, or instrumental, behavior based on a model explicated by Skinner (1953). Modification of the behaviors of drug-seeking and drug-taking is presumed to alter physiological and cognitive correlates. Each approach emphasizes specific techniques and is derived from observations and assumptions about determinants of drug abuse. The unifying strategy is detailed analyses of specific events surrounding drug abuse and application through regimens designed to alter measurable behavior.

Within this framework, drugs of abuse are considered to serve as reinforcers, and in that regard they share many of the same characteristics of other events sustaining behavior. Drug-taking is considered to be an orderly behavior that results from the interaction of fundamental biologic and behavioral processes. These perspectives have fostered innovative treatment interventions that focus on the interplay of environmental, behavioral, and pharmacological factors and have been the focus of other National Institute on Drug Abuse (NIDA) reviews (e.g., Krasnegor 1979; Thompson and Johanson 1981; Grabowski et al. 1984; Ray 1988). A critical feature of these efforts is the focus on the relationship between drug-taking and its consequences and, in turn, on establishing a similarly persistent relationship between treatment-oriented behavior and its consequences and ensuring that behavioral change endures.

Explicit application of behavioral approaches has made only limited inroads in traditional treatment environments (e.g., Thompson et al. 1984; Schuster and Silverman 1993), despite extensive research and positive findings indicating unique contributions. Unfortunately, to the extent that behavioral interventions have been acknowledged, they often are linked to the elimination of "problem behaviors," while other therapeutic strategies are proposed to form the basis for developing positive behaviors. For example, Woody and colleagues (1984) described behavioral interventions in terms of loitering, gun toting, and drug dealing, while psychotherapy was viewed as the intervention of choice for achieving positive goals, The work of Crowley (1984) and, more recently, of Higgins and Budney (1993) points to use of a spectrum of combined therapeutic elements to develop adaptive behaviors.

All Clinics Have Contingencies

Many clinicians do not refer to their techniques as behavioral interventions, while others simply ignore or eschew behavioral approaches. However, the very character and framing of therapy dictates that the principles are used, labeled or not.

Behavior therapists often refer to "contingencies for reinforcement." These specify the relationship between behavior and consequences. Thus, in every clinic, certain behaviors have consequences even if that reaction is punishment or inaction. Typically, contingencies are not recognized or manipulated in a systematic fashion directed at enhancing treatment. The authors' thesis is that these often-unspecified contingencies should be made explicit and consistent with treatment goals, then systematically applied. The point of application may range from a single behavior of an individual to an entire treatment system (Thompson et al. 1984).

This chapter illustrates first that common elements of standard treatment settings can be addressed readily from a behavioral perspective rather than being ignored or considered annoyances of clinical systems. The behavioral-environmental features of studies described here were designed, in part, to explicate interventions in the context of standard clinic procedures. The chapter also describes successive levels of increasingly specific and individualized applications of behavioral approaches. Studies will be summarized with reference to data on clinic function, take-home doses of medications, group contingencies, and, finally, individualized interventions for specific behavioral problems. A major goal of this chapter is to describe strategies that permit standard drug abuse treatment clinics to operate more effectively (also see Elk et al., in press-*a*).

GOALS AND IMPLEMENTATION

The goal of implementing clinicwide contingencies is to provide a systemic and systematic foundation for maintenance of treatment-oriented behavior while reducing problems considered endemic and integral to clinics, drug abuse treatment, and the patient population.

Global fixed contingencies for reinforcement and punishment of a variety of behaviors, both adaptive and maladaptive, can be implemented. Thus, for example, many clinics have provisions for gun toting, loitering, and drug dealing, but they should not be the foremost considerations of treatment. In fact, they can be framed as clinicwide contingencies sustaining adaptive behaviors. These treatment-oriented behaviors include arriving on time, remaining only for necessary activities, complying with the regimen(s), completing necessary paperwork, providing blood and urine samples when required, and generally using the clinic as a treatment site. This goal is dependent on the clarity of the contingencies and the consistency of their application and requires no more effort than implementation of traditional systems.

Implementation of manipulated contingencies common to a group of patients similarly requires little more effort than other commonly used formulae. An example is the use of take-home doses of methadone provided contingent on opiate- or cocaine-free urine samples to modify behavior. A patient who does not use other opiates in one week may receive a specified number of take-home doses in the next week. Conversely, use of opiates during a week when take-home doses of methadone are available produces a requirement for daily visits (no take-home doses) in the subsequent week. This contingency for all patients receiving methadone can be expected to produce behavioral change in some members of the larger group when systematically applied. Lack of change in behavior of other patients dictates the need for additional or alternative strategies similarly implemented for a subset of patients. The advantage of this dynamic approach resides in systematic collection of information that then determines modifications of the treatment contingent on specific patient behaviors. Surprisingly, these techniques are commonly thought to be the unique province of research-oriented clinics. Yet they can be readily applied, and their absence in standard treatment clinics may reduce treatment efficacy.

The next level of individualized contingencies in treatment has two stages that may be viewed as fixed contingencies applied to the behavior of individuals or as more refined variable-shaping procedures that are adjusted repeatedly based on one or more individual behavioral patterns. These may be more labor-intensive interventions, but they are no different from the development of detailed individualized

treatment plans. Based on intake data, individualized elements of treatment can be prescribed. This orientation provides for sequential implementation of the elements of treatment. For example, elimination of cocaine use in a pregnant, drug-abusing female may be achieved by providing reinforcers for each successive day for which quantitative or semiquantitative urine screens indicate reduced cocaine use. Compliance with a rigorous medication regimen for a tuberculosis- (TB-) positive male and concurrent reduction in cocaine use may be similarly tailored on an individual basis.

The procedures can be implemented sequentially or concurrently. Patients first may be exposed to the general requirements and successively to the specific approaches. Alternatively, all levels may be introduced within days of intake.

IMPLEMENTATION OF CLINICWIDE CONDITIONS OF TREATMENT

Basic "Rules"

In the authors' clinic, which primarily treats cocaine and opiate dependent patients, the basic contingencies are defined clearly as an integral part of treatment and treatment research (see table 1). Details described in this table permit improved strategies for providing treatment as well as conducting research. Potential subject-patients participate in an initial telephone screening interview. All procedures are implemented as they might be at any high-quality health care facility, and patients are treated accordingly. Meeting the basic criteria leads to an immediately specified appointment for intake procedures.

The intake process is carefully scheduled and links elements important to inclusion or exclusion. This assures that less-costly elements are carried out first so that false positives are screened out early. This saves patient and staff time as well as money. An initial interview is followed by a general medical evaluation. The intake process leads to group assignment and medication dispensing for opiate or cocaine dependence at the earliest time, often the same day but always within 24 hours.

TABLE 1. *This table lists issues and behaviors that emerge in most drug dependence treatment clinics, although which problems are most frequent is population dependent. Focus on these issues often interferes with service delivery. Generic provisions can be added or eliminated as needed. Positive ("+") and negative ("-") consequences must be clearly stated and systematically applied. The goal is specification of positive consequences for which the absence of that consequence is itself unpleasant. Failure to comply with items 9 and 10 has the consequences of warnings and potential discharge. Some issues, such as discussion of accuracy of laboratory drug screen results, have neither positive nor negative consequences; they are not open for discussion, just as blood pressure readings are medical test results generally accepted and not points for contention.*

Examples of Fixed Clinicwide Contingencies for Patients and the Nature of Consequences

1. Regular attendance for continued treatment+/-
2. Maintain appointment time for counseling+/-
3. Maintain appointment time for medication+/-
4. Complete data and information update forms+/-
5. Return of medication bottles+/-
6. Provide urine samples for drug screens as scheduled+/-
7. Arrive and depart in reasonable time ("no loitering")-
8. Maintain clean air ("no smoking")-
9. Contribute to a physically healthy clinic ("no weapons")-
10. Support the clinic as the sole vendor ("no drug dealing")-
11. Responsiveness to chemistry laboratory findings ("no arguing")o

Patients are provided with medication time options from three 1-hour periods scheduled daily–early morning, midday, or early evening. Similarly, a fixed counseling time is determined in consultation with the patient. All data and information collection activities are scheduled to reduce inconvenience for the patient. The basic requirements are described in both the intake and consent procedures and in the first counseling session. Urine screens, routinely collected under observation, are described to the patient as essential medical evaluations for treatment and research. The difficulties of this process have been eased by using a video recording system with tapes reviewed daily by nurses rather than using a live micturition monitor. Finally, there is an inclusive and clearly stated contingency surrounding treatment; it is that 75 percent of all specified data collection points and visits must be met for the patient to be considered to be "in treatment." This provides the patient some leeway, assures that there is contact with the provisions of treatment, provides certainty with respect to sufficient data, and assures a clear criterion for dropout.

The result of clearly specified contingencies for basic clinic- and treatment-oriented behavior is that only 5 (of over 700) patients have been discharged in the last 4 years of operation due to the serious problems more common in other clinics. The relatively high rate of compliance independent of individualized treatment contingencies, in part, may be related to a decent and positive environment in which treatment is provided. In brief, clearly labeled, systematically applied contingencies for participation in treatment appear to have a palliative effect in provision of treatment, even in what is construed to be a difficult population.

Large-N Studies With Fixed Group Conditions

The goal of the authors' primary studies has been to examine specific components of real treatment. The focus of the research is the joint action of behavioral and pharmacological elements. In a series of studies, the first step was to examine fixed treatment requirements involving visit frequency. The question was whether being required to visit the clinic more frequently (5 days per week) or less frequently (2 days per week) affected outcome. These requirements meet the criterion of contingencies for reinforcement to the extent that a

patient's behavior determines whether or not he or she will be maintained in treatment. They are characteristic of standard treatments that typically require a fixed number of visits per week to preclude discharge. Identifying optimal visit frequency is an important issue for cost and effectiveness.

Two large studies have addressed the role of take-home dose frequency or visit frequency as a condition of treatment in relation to medication doses (Grabowski et al. 1992*a*, 19926; Rhoades et al. 1992*a*). The importance of medication dose is clear, and medication dose can be expected to interact with other features of treatment. The impetus for examination of take-home dose or visit frequency derives from two sources. In part, it emanates from findings in behaviorally based studies indicating that contingent take-home doses can be an effective reinforcer (e.g., Bigelow et al. 1984). Beyond potential reinforcing value, this variable was of considerable interest for two pragmatic reasons. First, it may affect retention, and ultimately success, in treatment independent of manipulating its frequency in a contingent manner. Second, and obviously important, the number of visits per unit time determines the number of patients who can be served by a clinic within available resources.

In one ongoing study of primary opiate dependent patients (Rhoades et al. 1992a, two doses of methadone (50 and 80 mg) were examined in relation to two take-home conditions. Patients received either 2 or 5 take-home doses of methadone each week. Conversely, they were required to visit the clinic either 5 or 2 days per week. Special dispensation was obtained from the Food and Drug Administration and Drug Enforcement Agency to conduct these studies in which take-home requirements other than those provided for by regulation could be implemented; thus, patients were permitted to have take-home doses from the beginning of treatment (Rhoades et al. 1992*a*). In a second parallel study with primary cocaine-dependent patients (Grabowski et al. 1992*a*, submitted), three medication conditions–two fluoxetine doses (20 mg and 40 mg) and placebo–also were examined in relation to two visit conditions–two or five per week. While there was no manipulation of conditions during treatment, the underlying contingencies for reinforcement prevailed as they do in any clinic. These studies emulate the conditions of traditional clinics, in which failure to comply with the requirements could produce discharge or

dropout status. Conditions were specified clearly and consistently implemented. The major independent variables were medication dose and take-home frequency, while the major dependent measures were retention and illicit drug use.

The preliminary interim results for retention with primary opiate dependent patients are presented in figure 1. Methadone take-home frequency (and hence clinic visit frequency) was clearly a determinant of retention. Patients receiving more take-home doses remained in treatment for longer periods. Opiate-positive urine results did not differ as a function of frequency within groups at the same methadone dose, but they did differ across the two dosage levels. Opiate-positive urine screens were less frequent, occurring at a rate of about 10 percent, in patients receiving the higher methadone medication dose; the higher dose had the expected effect of greater reductions in illicit opiate use. One of the main results of this study addresses the question raised by Childress and coworkers (1991) regarding minimum required conditions in methadone maintenance. In this case, within identical counseling, drug screen, and other treatment elements, take-home frequency and dose determined retention. Minimum required conditions are driven, in part, by patient characteristics and goals, but it is clear that visit frequency can have pronounced effects.

The retention results for the study with primary cocaine dependent patients are presented in figure 2 and also indicate the importance of general visit requirements. Clinic visit frequency was a determinant of retention. Cocaine-positive urine screens did not differ significantly across groups regardless of fluoxetine dose or visit frequency (Grabowski et al., submitted).

Framed as either clinic visits or take-home frequency, this variable is a major and important feature of treatment. It was codified in methadone regulations and also is typically an issue of discussion with respect to cocaine-dependent patients. However, it must be noted with respect to methadone regulations that the requirements are imprecise, are not optimal, and were not substantially data based. Specifically, the low (50 mg) and high (80 mg) doses of methadone combined with high-frequency take-home dose produced the best results with respect to retention. High-frequency take-home doses and, thus, fewer clinic

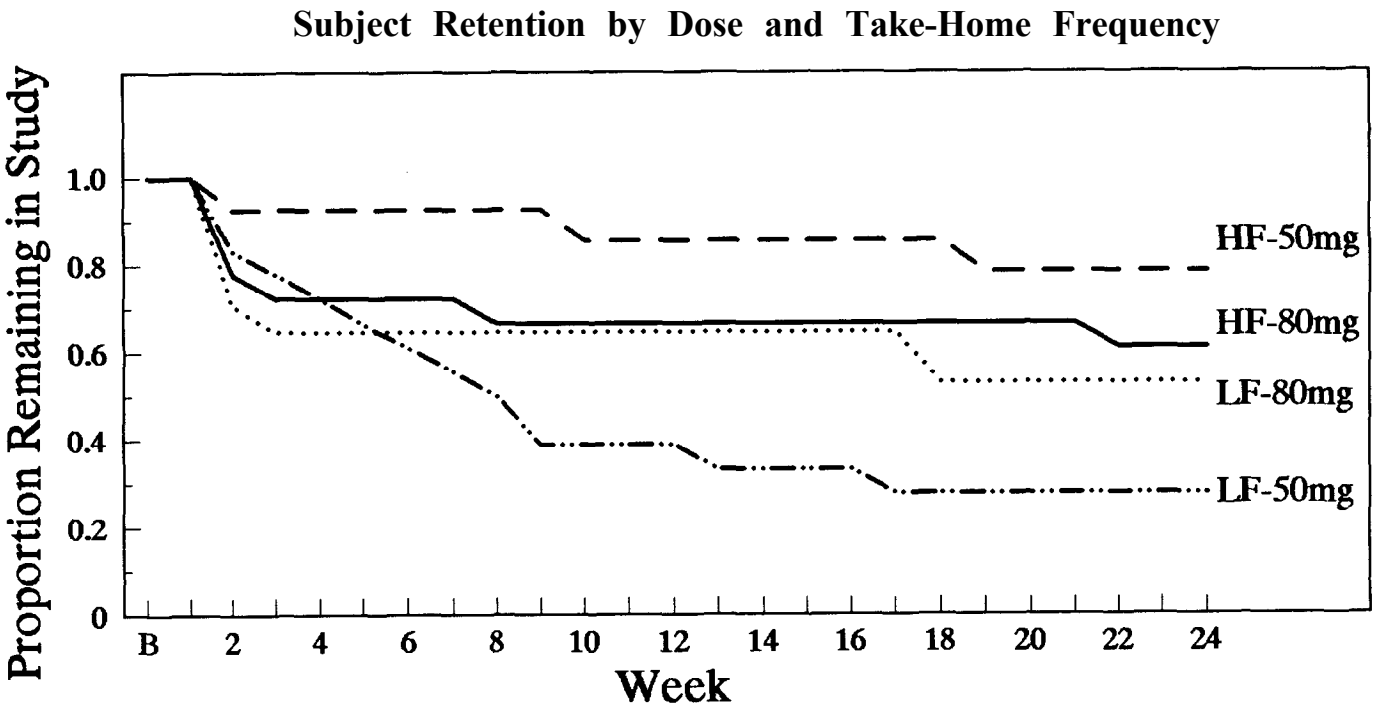

FIGURE 1. *Patients received low- (2/wk) or high- (5/wk) frequency take-home doses of methadone and visited the clinic either 5 or 2 days/week. Patients in these groups received either 50 mg or 80 mg of methadone. Retention data are presented as a function of these four conditions.*

KEY: HF=high frequency; LF=low frequency; B=baseline

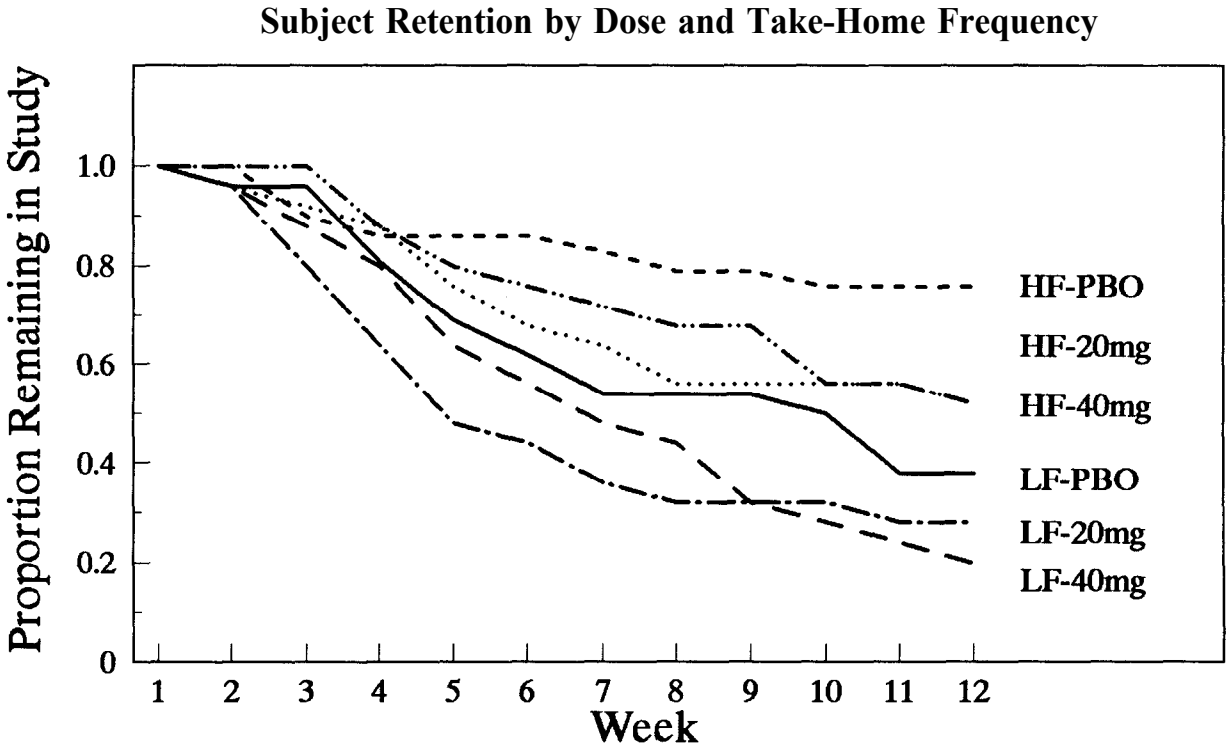

FIGURE 2. *Patients received low- (2/wk) or high- (5/wk) frequency take-home doses of methadone and visited the clinic either 5 or 2 days/week. Patients in these groups received either 20 mg or 40 mg of fluoxetine or placebo. Retention data are presented as a function of these six conditions.*

KEY: HF=high frequency; LF=low frequency; PBO=placebo

visits also had no untoward or differential effects in cocaine-dependent patients in terms of retention.

There are complexities to the data relevant to treatment. A clinically important collateral finding emerged with the higher dose of methadone. While opiate-positive urine screens were less frequent, cocaine-positive urine screens were more frequent, and this difference was statistically significant. This does not argue against the use of higher doses of methadone, which contributes to reduced human immunodeficiency virus (HIV) transmission risk, but it does indicate the need for explicit manipulation of contingencies surrounding cocaine use or, at least, careful adjustment of methadone dosing to reach an optimal balance (Grabowski et al. 1993).

Placebo was more effective than either dose of fluoxetine within the take-home condition (Grabowski et al., submitted). An important, but not surprising, collateral finding (Grabowski et al. 1992*a*) was that benzylecgonine-free urine samples at intake were correlated positively with less drug use during treatment, and, conversely, metabolite-containing urines at intake were correlated with more drug use during treatment as a function of take-home condition. Specifically, cocaine-dependent patients with positive drug screens at intake did less well (i.e., had more cocaine-positive drug screens) than patients who had negative drug screens at intake when required to visit less frequently. This suggests that required level of intervention can be predicted at intake, and this addresses a patient matching issue. A behavioral perspective stipulates that consideration be given to fine-tuning and individualizing the provisions of treatment, with some patients requiring more visits to the clinic and others fewer.

In combination, it is evident that take-home dose frequency is an important factor in retention independent of refined systematic manipulation. Thus, clinicwide contingencies requiring frequent clinic visits (e.g., 5 or 7 days per week) are arguably less efficacious in terms of generating long-term treatment-oriented behavior.

MANIPULATION OF CONTINGENCIES FOR GROUPS OF PATIENTS

The clinicwide provisions for contingencies governing consequences provide a broad-brush approach to increasing the probability of positive, treatment-oriented behavior. As addressed by the work of Iguchi and coworkers (1988), contingencies with positive consequences for drug-free urine screens may have advantages over aversive consequences in terms of retention. Further, the work described above and implementation of effective clinic procedures described by Elk and colleagues (in press-*b*) suggest that a generally favorable or positive clinic environment contributes to treatment-oriented behavior. Stitzer and Kirby (1991) reviewed behavioral approaches for reducing illicit drug use among methadone patients. This augments an extensive literature that points to the ease of inclusion of behavioral interventions in any clinic. Beyond global conditions or contingencies in treatment, manipulation of contingencies and individualized approaches can be implemented.

Progressing through the levels of intervention, the authors have implemented other studies in a manner emulating standard clinic conditions. For example, the effect of contingent take-home doses of methadone was examined (Rhoades et al. 19923). This A-B-A design study examined the effects of (A) two different baseline conditions (high- and low-frequency take-home) alone for 8 weeks, (B) then contingent consequences dependent on drug screen results for 12 weeks, and (A) return to the baseline condition for 4 weeks. With the exception of the return to baseline, this was not unlike the circumstances that might prevail in a standard clinic attempting to implement behavioral procedures. That is, patients enter treatment, are stabilized during the first 8 weeks, and then are placed under an active behavior-dependent contingency.

Thirty patients were assigned randomly to one of two groups and received 70 mg of methadone as a maintenance dose. Patients in one group initially received five take-home doses per week, while the other group of patients received two take-home doses per week. After 8 weeks, patients were reminded that take-home doses would be dependent on results of the twice-weekly drug screens in weeks 9-20. Drug-free urine screens led to high-frequency take-home doses for the

following week. Patients were compliant with the basic requirements of treatment during the first weeks of treatment. They provided data, attended counseling sessions, and attended the clinic according to the requirements of their take-home dose regimen. The contingent arrangement between urine screen results and take-home dose opportunities was, in this case, ineffective in reducing the number of drug- (typically cocaine) positive urine screens. This is reflected by the fact that, for any given week, approximately 80 to 90 percent of the patients in each of the groups failed to meet the drug-free criterion and were required to attend the clinic 5 days per week (figure 3). However, it is equally clear that this study supports the previously described fixed-condition methadone study in that an early regimen of frequent take-homes was effective.

Extensive analyses indicated that demographics and intake variables were not related to presence or absence of responsiveness to this contingency. Modifications of this procedure likely would have produced a better result. However, it is clear that the imposition of this basic contingency for a subgroup of patients did not have a substantial effect on collateral drug use. This strongly supports the need for further research to examine factors diminishing or enhancing effects of such contingencies and explain these results in light of the extensive manipulations with positive outcomes. While this particular study does not affirm the previous reports, it does support the view that contingencies can be implemented readily for large numbers of patients in the context of other ongoing treatments. This is important, since a common argument against the use of behavioral procedures is that they are unduly costly and time consuming. Another important feature of behaviorally based perspectives is that subsequent procedures are modified based on current results to identify the most effective combination of contingencies. The authors are conducting further work to elucidate determinants of effectiveness of behavioral interventions in implementing clinicwide procedures. One consideration is that much of the earlier work involved methadone patients dependent on benzodiazepines for whom the simple consequence of drug-screen-dependent take-home doses reduced collateral drug use. Many of the patients in the present study were cocaine-dependent, and this disorder may require modification of the original contingency management take-home strategy.

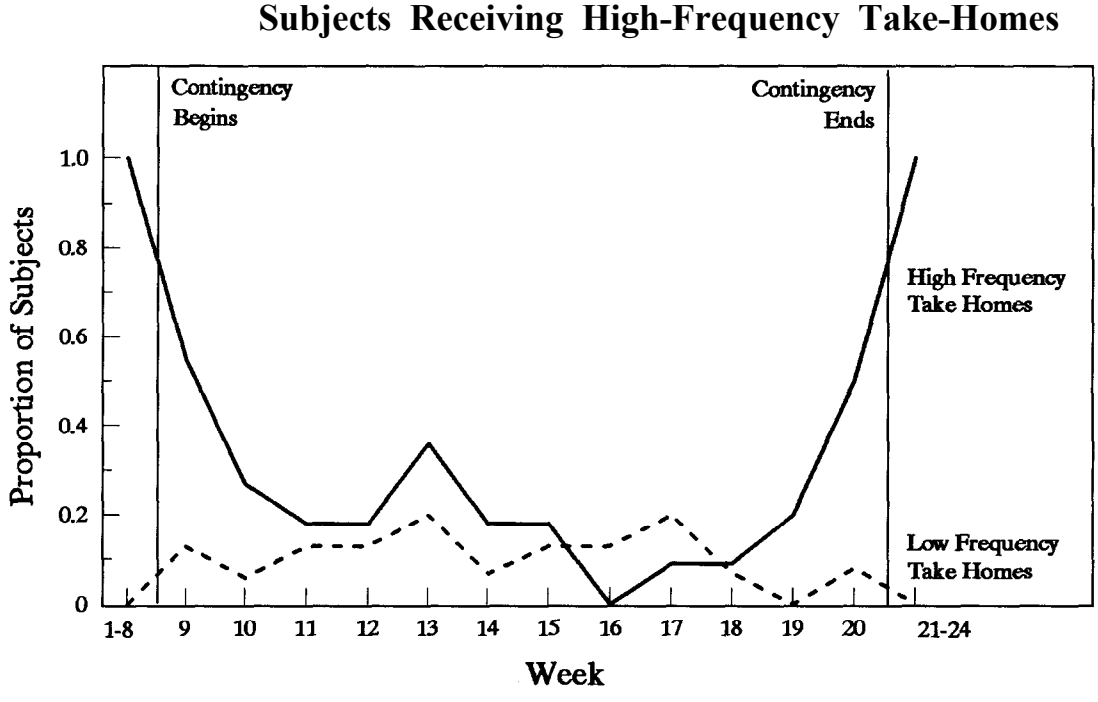

FIGURE 3. *In an A-B-A study, one group received low- (2/wk) or high- (5/wk) frequency take-home doses of methadone for 8 weeks. For 12 weeks, both were placed under a contingency for which negative urine screens produced the high-frequency take-home (HFTH) conditions in the next week, while positive urine screens produced the low-frequency take-home (LFTH) condition in the next week. During the last 4 weeks, the baseline condition was reinstated. Overall, approximately 10-15 percent of the patients in the baseline LFTH and HFTH conditions met the drug-free criterion during the contingency period.*

IMPLEMENTATION OF INDIVIDUALIZED CONTINGENCIES

Clinicwide conditions and manipulated contingencies for specific behaviors of groups of patients am initial applications that are implemented readily. The next step towards precision in treatment includes application of individualized contingencies, both fixed and adjustable (e.g., Bigelow et al. 1984; Pickens and Thompson 1984; Boudin 1972).

Like mutating micro-organisms that require variants on an antibiotic theme, drug dependence is not a unitary invariant problem. Changes have emerged in drug abuse, collateral disorders, and special populations that must be treated; these in turn require adjustments in intervention strategies. Over the past decade, multiple drug use has emerged describable as concurrent primary drug dependences (e.g., opiate and cocaine). Stitzer and Kirby (1991) have alluded to this in the context of behavioral interventions, and Dunteman and coworkers (1992) have described predictors of outcome in methadone-maintained patients who also use cocaine. Homeless patients have become more common in this population, providing a major challenge in the development of treatment. Infectious diseases have become intimately intertwined with drug abuse. HIV has vectors directly and indirectly related to drug abuse, including infection through dirty needles on one hand and transmission from drug-abusing partners to non-drug users on the other hand. TB has reemerged as a major problem, particularly among drug-using populations. Another major concern that has emerged is that of drug-abusing pregnant women whose general repertoire of health behaviors, if not their specific drug of dependence, may have unalterable detrimental effects on the fetus or their children. It can be expected that behavioral intervention strategies are well suited to application to specific problems of patients and that combined elements may be used to resolve coexisting problems (e.g., Higgins et al. 1992) in special populations.

Reinforcer Menus

Development of individualized contingencies requires assessment of a wide range of consequences that may serve to reinforce behavior as well as aversive consequences that may eliminate a specific behavior. Schmitz and Grabowski (1992) have used procedures previously

described by Stitzer and Bigelow (1978) in identification of potential reinforcers. This permits individualization of treatments at best or at a minimum provides an indication of the relative strength of those reinforcers that one can apply readily. Using the reinforcer menu approach, the authors have found that some of the readily available presumed reinforcers may, in fact, be of limited utility (figure 4).

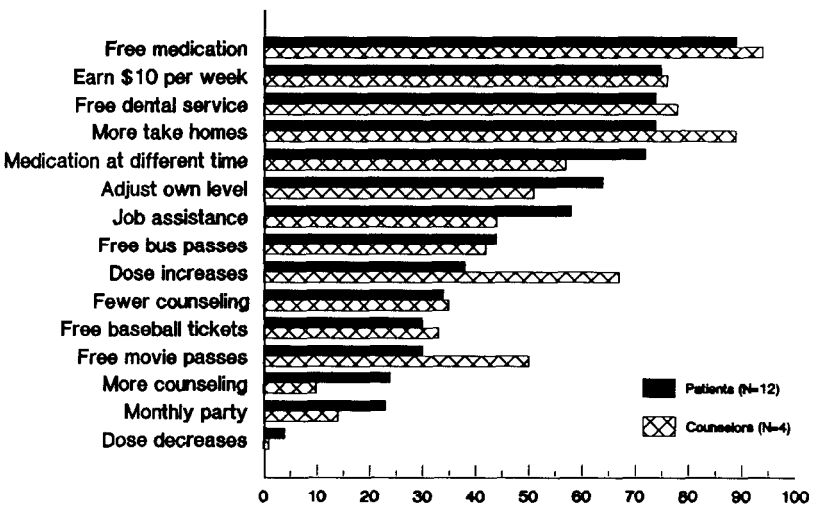

FIGURE 4. *Patients were provided with a list of 15 methadone treatment clinic privileges as potential reinforcers. Patient preferences were established using this paired comparisons method. Counselors were given the same list and asked to complete it with a view to patient preferences. The solid bar indicates patient preferences, and the lined bar indicates counselors' ratings of patient preferences. The plausible potential reinforcers were used in clinic programs.*

SOURCE: Schmitz et al. 1991

Other opportunities or tangibles have been identified that might be useful but are difficult to provide, In fact, one survey in which both counselors and patients were queried clearly suggests some discrepancies between treatment professionals' views and those of patients in terms of potential importance of reinforcers (Schmitz and Grabowski 1992).

The reinforcer menu approach has the obvious benefit of determining for whom and under what conditions the elements of treatment should be implemented. A simple determination of patient preferences readily could be achieved during the course of standard intake procedures at any clinic. This, in turn, could provide information to the staff guiding treatment. At the same time, it must be recognized that there may be disparities between tangibles and opportunities that are stated to be important and those that alter behavior when inserted into the tripartite statement of behavior-contingency-consequence. That is, as previously discussed, take-home doses of methadone may be powerful modulators of drug-taking under some but not all circumstances, although patients may report in an initial survey that they are important. Therefore, the therapist must approach the problems with a view to revision as needed based on patient goals, preferences, and observed results when procedures have been implemented.

The identification of a reinforcer is ultimately determined empirically in its application to a particular problem or the establishment of a new behavior. Two examples are found in work with patients entering treatment for drug abuse: those who are positive for TB and female patients who are pregnant.

TB-Positive Patient Study

Noncompliance often is viewed as a sine qua non of drug-dependent patients despite the pervasiveness of the problem across therapeutic disciplines. This is particularly true in the face of unpleasant or time-consuming treatment requirements. Ironically, strategies for enhancing compliance are an integral element of behavioral treatment for any disorder but are rarely labeled as such in research reports. It can be said that practitioners of behavioral approaches in drug abuse and other areas of behavior therapy and behavioral medicine have developed a specialty in treatment compliance as an integral part of their efforts.

The absence of explicit reference to this matter results in failure of the broader clinical community to appreciate this unique contribution.

TB has increased in prevalence both worldwide and in the United States, and it is specifically more prevalent in the drug-abusing population than the general population. This can be attributed to a variety of ancillary factors rather than drug abuse per se. Nevertheless, the disease presents special problems in the drug abuse treatment setting. In the authors' clinic, approximately 8 percent of the patients tested with the Mantoux procedure have been positive. In addition, four staff members have become TB positive over the last 3 years. A positive response requires subsequent chest x-rays and evaluation. In the absence of active TB, one of several medications must be administered for 6 months. All of these agents are potentially hepatotoxic and may have unpleasant side effects such as nausea and vomiting. A solution in some clinics is refusal at intake or discharge of patients found to be TB positive. Working with the Houston Department of Health and Centers for Disease Control and using NIDA funding for drug abuse treatment, the authors examined techniques for assuring compliance with the ioniazide (INH) regimen.

In the first of a series of studies, a fixed-contingency procedure was used to increase TB treatment compliance in opiate-dependent methadone patients (Elk et al., in press-*a*). TB treatment was provided within the drug abuse treatment clinic. The approach was extremely conservative and attempted to balance patient needs, staff concerns, hepatotoxicity, and drug interactions.

Additional consent procedures were presented explicitly addressing the problems of interaction of INH with alcohol and other drugs. Patients were stabilized on 70 mg of methadone for 2 weeks, and baseline data of drug use were obtained. Methadone was dispensed contingent on INH ingestion throughout. A contingency also was imposed for which drug-positive urine screens resulted in 5 mg decreases in methadone dose, while urine screens indicating no concurrent drug use permitted the patient to request dosing increases or decreases. The results indicated that the contingent provision of methadone was appropriate and effective in enhancing INH-taking behavior, and with one exception, all patients participated in this treatment regimen (figure 5). The unexpected high rate of concurrent drug (cocaine) use was

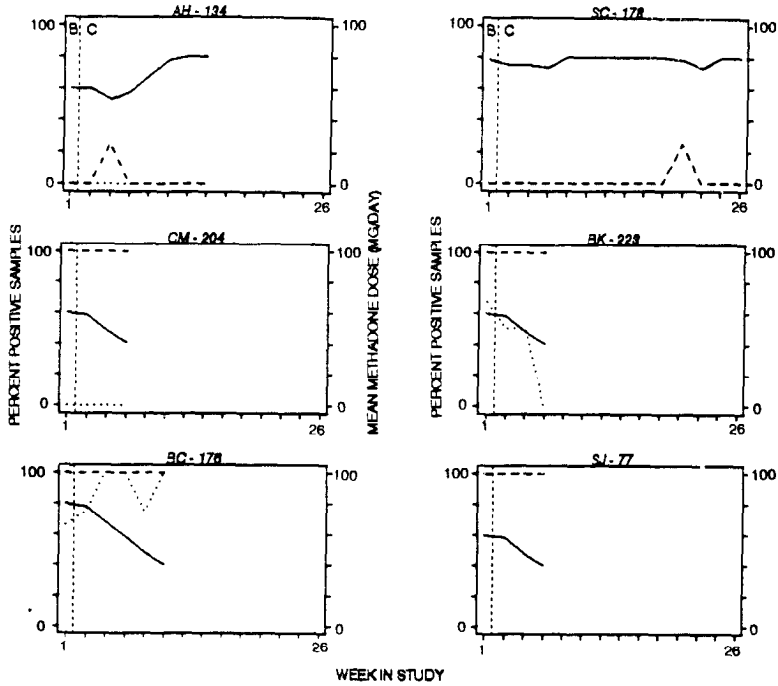

FIGURE 5. *Opiate-dependent patients with positive Mantoux tests were enrolled in a study where methadone dosing was contingent upon INH ingestion. Positive urine screens resulted in 5 mg methadone dose reductions, while negative urine screens produced the option of patient-controlled dose adjustment. The conservative contingency was used due to concerns of hepatotoxicity. The contingency produced INH ingestion, but the contingency did not sustain reductions in drug use or long-term treatment-oriented behavior. Data for 6 patients are presented; only one (top left panel) remained for the entire 6-month course of INH treatment. The others were discharged from this contingency due to collateral cocaine use.*

KEY: B=baseline; C=contingency. Solid line is methadone dose, dotted line is opiate use, and dashed line is cocaine use.

SOURCE: Modified from Elk et al. 1992

unaffected by the contingency. In effect, patients unable to comply established a self-imposed detoxification regimen through successive weeks of positive screens.

On this occasion, the defined intervention produced equivocal results. However, the careful attention to outcome and details of treatment inherent in behavioral approaches resulted in changing the basic contingency. The authors subsequently have intervened with a shaping procedure directed at systematically decreasing cocaine use by reinforcing sequential reductions as measured by quantitative benzyleconine-positive screens (figure 6). This has proven more successful in reducing risks of hepatotoxicity of INH by reducing illicit drug use.

Pregnancy Study

Another complex and difficult area is treatment of drug-dependent pregnant women. Much attention has focused on presumed drug-effect-related mechanisms of problems in fetuses and in newborns delivered by these women (e.g., Finnegan and Kandall 1992). Delineating mechanisms is ultimately of both scientific and clinical importance. However, the absence of clear data on the cause of problems need not deter implementation of behavioral interventions to reduce drug use and enhance healthful behaviors in this population.

Again, necessity was the mother of intervention. The University of Texas Health Science Center Department of Obstetrics requited assistance with cases of pregnant women who had been using drugs. Elk and colleagues (1993) developed strategies based in the behavioral framework. An interim report by Kirby and colleagues (1992) indicated that while some behavioral change resulted from simple contingency management procedures, behavior at times changed independent of contingencies and at other times was refractory to change (figure 7).

The goals and needs of intervention were multiple, as they were with TB-positive patients. Patients required prenatal care and information as well as treatment of drug dependence. The interesting finding indicated above was that some patients were compliant throughout when the treatment began, while others struggled with drug use,

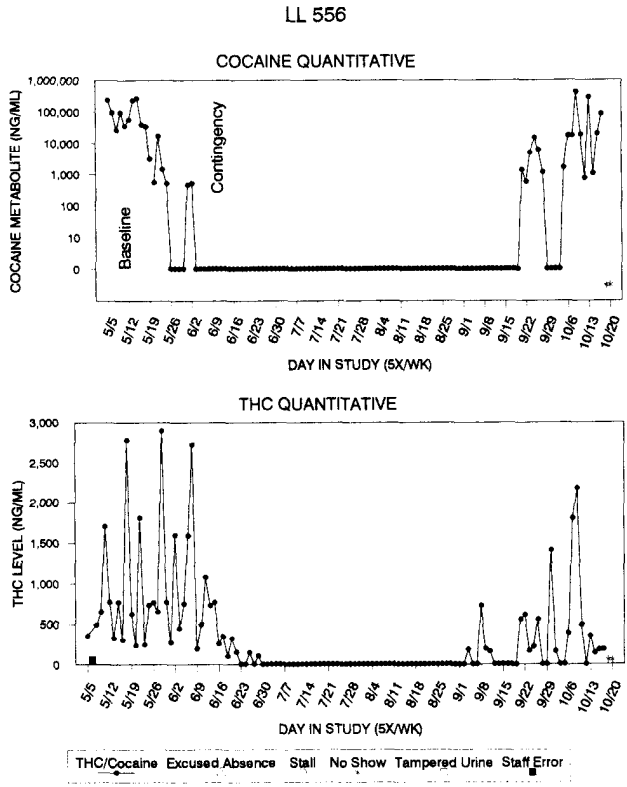

FIGURE 6. *Patients with positive Mantoux tests were enrolled. In these cases, sucessive reductions in cocaine use were shaped using a monetary reinforcer while sustaining the INH regimen. This graph shows data for one patient. These individualized contingencies emphasizing positive reinforcers were effective in sustaining treatment-oriented behavior and reducing drug use as reflected by the benzyleconine level.*

SOURCE: Elk et al., unpublished data

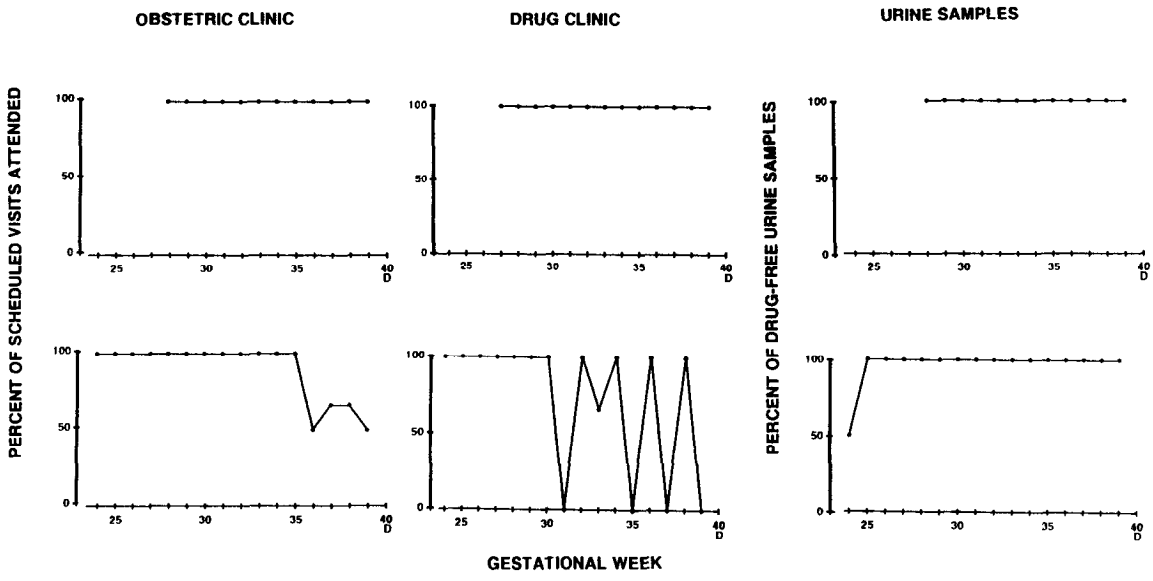

FIGURE 7. *Panels A and B represent two patterns of behavior of pregnent female patients in attendance of the obstetrics and drug clinic and urine screens. The top series (left to right) indicates compliance when contact was made. The bottom panel indicates good but deteriorating attendance for drug counseling and prenatal care sessions but continued attendance for urine screens indicating no drug use; patients received money for urine screens. Some patients quickly complied with all requirements, others were irregular, and others (not presented here) were dropped out quickly. Patients were enrolled at different times in gestation, and pregnancy periods differ, thus total weeks differ. A shaping procedure has since been implemented.*

SOURCE: Modified from Kirby et al. 1992

attendance at clinics, and other aspects of prenatal care. For some, pregnancy itself had a therapeutic effect in a manner similar to that described by Baile et al. (1982) in smoking cessation efforts with recent heart attack patients. The behavior of other patients was less influenced by early efforts with contingencies and presumed substantial reinforcers.

Elk and colleagues (in press-*a*) are currently examining specific interventions for these patients that might effectively override the behavioral control exerted by circumstances surrounding drug use. Shaping procedures to reduce cocaine use and enhance attendance in all elements of obstetric and drug abuse treatment are being implemented, and development of innovative procedures continues.

The cases of TB patients and pregnant women provide extreme examples at the individual level of detailed behavioral analysis, precision in intervention, and mixed results. They also provide examples of factors controlling behavior that are not accessed readily by behavioral or other psychotherapeutic approaches. Thus, for example, the state of pregnancy may alter the behavior of some women who use drugs and overwhelm the behavioral and pharmacological determinants inherent in drug use as controlling factors. Thus, they may simply stop using drugs as the result of complex experiential and social factors. However, pregnancy is no more a cure for drug abuse than heart attacks are cures for tobacco smoking. These changes are not magical reversals, and behavior is explicable. Like the cigarette smoking case, pregnant women may cease drug use during pregnancy only to resume postdelivery. Not uncommonly, a woman may stop using drugs but be generally noncompliant with other requirements of treatment such as prenatal care, with equally or more detrimental consequences. Overall, treatment failures can be as instructive as successes for identifying specific treatment components leading to eventual successful intervention and prevention of drug abuse, as has been the case in the examples of individualized drug abuse treatments for pregnant women and patients who are TB positive.

CONCLUSIONS AND DIRECTIONS

A rationale has been presented for explicit inclusion of behavioral intervention components in drug abuse treatment. The first goal of drug dependence treatment is to diminish and ultimately eliminate behavior sustained by the pharmacological agent and associated social environmental factors. Achieving initial behavioral change requires establishing the conditions for positive treatment-oriented behaviors. Thereafter, the process can be implemented at several levels of increasingly refined and specific interventions. Enduring change requires that circumstances be established that sustain behavior not only beyond the reach of the clinic but beyond the duration of active therapeutic intervention. It can be argued that a variety of other factors described, if not explained, by myriad theories and observations modulate drug-taking, and thus, necessarily, a range of factors determines the probability of success of any particular treatment regimen. Nevertheless, achieving behavioral change optimally requires systematic analysis of behavioral and environmental factors controlling drug-taking, precise implementation of therapeutic techniques based on these observations, and perpetuation of these effects. In the concluding paragraphs, consideration is given to concerns regarding practical implementation of behaviorally based contingency management approaches in both research and nonresearch treatments. The studies that the authors are conducting were not intended to provide guidelines for clinic management, but they have done so (Elk et al., in press-*b*), and the main variables provide important data for major elements of treatment. Thus, the results will be briefly considered from these perspectives.

As a pragmatic matter, there is a need for encouraging the view that clearly stated clinicwide contingencies be prescribed for staff members and patients. While these are assumed to exist (but may not) by mutual agreement in many traditional treatment environments, the history and current circumstances of drug abuse treatment appear to call for precision in specification of these contingencies, which typically are framed as clinic rules.

The nature of the consequences must be specified with an emphasis on the positive consequence, although a combination of positive and negative consequences may be inherent in any procedure. Certainly,

the common standard clinic provision, in which the first-line consequence is exclusion from treatment, is a self-defeating exercise akin to suspension of children from school who are in need of education. In one case, education cannot proceed, and in the other, the implications are lack of treatment, spread of HIV, and continuing societal and personal costs. Contriving positive consequences can be difficult, but it should be the goal. It necessarily begins with the view of positive behavioral goals rather than a list of "thou shall nots."

Clinicwide provisions must be institutionalized with little deviation. Deviations that do occur should be well documented and justified by both the patient and provider. Failure to meet an appointment time is rarely accommodated in other treatment or nontreatment settings, but it is much more commonly accepted in drug abuse treatment, not because of humanistic concerns, but rather because of the crisis-oriented provision of service and, perhaps, simple disorganization. If promptness by patients is not expected, it is not achieved, and patients who are prompt may be punished because of chaos elsewhere in the clinic. Where it exists, the lack of adherence to treatment requirements by patients may be defined in part by the lack of attention by staff members; the interaction is clear and reciprocal. Failure to implement the requirements of the clinic serves only to increase the lack of adherence by the patients.

Related to the preceding points is the requirement that the contingencies should be viewed as facilitating treatment compliance and success rather than as arbitrary rules to suppress unwanted problematic behaviors. The goal is not to regiment these patients unduly, nor is the treatment based on a belief that they require these steps while others do not; rather it is to provide a framework for treatment that is responsive and perhaps an advance over what most patients receive in health care settings. Further, it simply provides treatment in accord with other settings and indirectly provides valuable training to those patients who do not have basic skills such as promptness that they will need when applying for jobs, attending school, and engaging in social relationships. Adherence to a schedule is, for some patients, a notable achievement and should be reinforced and reciprocated.

A structure of hierarchical levels of interventions has been described. The rationale is twofold. First, it is a logical progression applicable to any such setting, and successive refinement in the intervention presumably can produce better results more frequently. Further, while all patients should expect a generally structured clinic operation, not all patients require the most refined steps in application.

The second issue is pragmatic: the merit and success evidenced by the data from intensive behavioral interventions with procedures such as those used by Higgins and Budney (1993) cannot be argued. Similarly, Thompson and coworkers (1984) provided a systematic plan for case management with patients having multiple disorders and deficiencies. Not all sites will be able to achieve these levels of intervention immediately due to the paucity of available resources. Arguments that there is long-term saving are logically meritorious but practically irrelevant if the immediate resources are not available. However, the argument of limited resources is insufficient to excuse failure to implement the most general level of contingencies. Thus, a hierarchical arrangement of interventions is a realistic initial strategy from which to begin. Furthermore, some procedures can be adjusted that would save money or permit redistribution of funds to more effective ends both within clinics and at the level of Federal regulations. There is no question that the treatment system can be enhanced through modifications in delivery based on the best available data, and methadone regulations provide an excellent example. For instance, patients are not provided with take-home doses for 90 days. Data from the authors' large fixed-condition study and the first phase of the contingent take-home study suggest that the prevailing regulations are counterproductive. These same seemingly conservative regulations require only eight urine samples per year; this is an obviously inadequate monitoring procedure. The need for appropriate alternatives in the form of more frequent screens with systematic contingencies is clear, and these ends can be achieved by enhancing the standard of care rather than adding regulation. Whenever possible, clinics should strive for the successive levels of implementation, with counseling sessions serving as the basis for behavioral data collection to the end of developing optimal interventions through as many levels as the clinic's resources permit.

With respect to the results of the authors' projects, a few noteworthy features will be mentioned. The data suggest that the context of clinicwide contingencies must be considered. For example, the effort to expand on those contingencies described in the literature over the years suggest that refinement of provisions such as contingencies based on take-home doses may be necessary, and several sources for these problems have been mentioned.

The data presented in this paper add information to respond to questions raised by Childress and colleagues (1991) regarding conditions of methadone treatment and those pointed to by McLellan and Alterman (1991) concerning patient matching and levels of treatment. In two studies, one with primary opiate-dependent patients and the other with primary cocaine-dependent patients, differences in retention in treatment were clearly evident as a function of visit frequency and as a function of intake urine screen results. The consequence of visit frequency itself appears to be "dose dependent"–that is, dependent on the dose of visits required or take-home opportunities permitted.

Attention to the diverse problems of patients and the encompassing treatments such as those described by Higgins et al. (1992) and Higgins and Budney (1993) is important. However, researchers must not lose sight of other factors more closely related to drug-taking and medications. This is exemplified by the finding that other drug-taking (e.g., cocaine use) must be closely monitored, since a valuable and important therapeutic remedy such as higher methadone dose may have untoward consequences in increased use of another drug. This requires attention to balancing interventions, as is true in all composite therapeutic regimens. This further strengthens the argument that creative and effective contingency management regimens must be developed.

The last of these points addresses the issue-perhaps the caution-that the strength of behavioral interventions resides in their continuing requirement of evaluation and reevaluation of treatment conditions and expected behavioral change. Thus, excessive claims about procedures can be damaging. For example, in the area of evaluation, reinforcer menus provide a patient's statement about preferences; patients in treatment for substance abuse disorders are likely to be no worse than

other patients in their self-report, but they certainly are no better. Thus, care must be used in application of self-report data. Further, improvement in data analysis capabilities is needed to determine the valid interpretations of such measures (e.g., Rhoades et al., in press). Caveats must accompany claims of utility, and variation in requirements may emanate from patient characteristics and treatment setting. Similarly, contingent take-home doses generally have been considered to be extremely effective reinforcers, but the authors' data suggest they are helpful but variable. That is, they are likely to be variable across time, setting, and form of implementation, while fixed conditions can have substantial effect but do not have the flexibility required to adapt to the needs of specific patients. Thus, the principles and procedures of behavioral interventions should be encouraged rather than an invariant set of prescriptions.

A final thought concerns divergence in the area of substance abuse disorders, which is perhaps no more or less than that in other areas of psychology and psychiatry. Behavior appears, after all, to be everyone's domain, and the number of theories and strategies for changing behavior often seems to approximate the number of practitioners. This makes communication difficult. The goal of standardizing the language and orientation of interventions is not predicated on presumed common etiology or sanctity of terms. Rather it is based in the assumption that progress in the development of efficacious treatment of substance abuse disorders is very much dependent on communication and replication. McLellan and Alterman (1991) have argued the need for prospective studies with common rules if the goal of identification of predictors is to lead to successful matching of patients to treatment. Similarly, the structure and processes of treatment should be described in common terms to permit ready comparison across interventions. The behavioral framework seems well suited to meeting this need. The need for research and application is clear.

The constellation of drug-seeking and drug-taking provides an example of a disorder characterized by interactions of physiological, behavioral and environmental elements. It thus seems appropriate that interventions rely heavily on systematic application of a behavioral framework that has been demonstrated to be efficacious in a spectrum of biobehavioral disorders.

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Cue Reactivity and Cue Reactivity Interventions in Drug Dependence

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INTRODUCTION

Jimmy* pulls out of the graveled driveway onto the smooth asphalt surface of the road. It feels so good to drive again after the long months in "rehab." No heroin use in over 6 months. "Not bad," he congratulates himself. But as he takes the exit into the old neighborhood, his bowels begin to growl. He breaks out in sweat, gripping the steering wheel and trying to ignore the raw, acid taste in the back of his throat. Yawning, eyes watering, he feels mounting panic, and the desire for drugs begins to burn in the pit of his stomach. "So much for good intentions," he mutters, turning toward a familiar alley and the drug that will make everything right again.

Dennis leaves his cocaine therapy group full of energy. "I've got 30 days clean, and now I'm going for 90!" he yells to a buddy as they enter their cars. As he leaves the parking lot, a familiar white sedan is pulling in-Diana's car; she probably is going to the next group session. Dennis' heart begins to pound-gripped by a flood of memories about the car, where he and Diana had shared so much cocaine. A wave of intense feeling rushes from the tip of his toes, up to his head, and back down again. Thoughts racing, desire coursing through his body, he turns away from the road home, into the night. As he approaches the familiar buying comer, he can taste the cocaine in the back of his throat. He is sweating heavily now, ears ringing. "Just a taste," he bargains with himself, "just a taste is all I'm going to buy."

*Patients' real names are not used.

Though different in some ways, these clinical anecdotes share an important common feature: certain cues that previously have signaled the arrival of drug (the sight of a certain neighborhood or car) seem to set off a host of feelings and reactions. Most commonly, these reactions include some feeling of arousal and a strong desire for the drug itself. These responses are of interest because they may prompt drug-seeking and drug use. This chapter presents a theoretical and practical approach to these problematic responses. It will focus on two behavioral strategies used in the authors' work with opiate and cocaine patients: passive cue exposure and, more recently, active strategies for coping with drug craving and arousal.

Relapse and Conditioned Cue Reactivity

Relapse, the return to drug use after a period of abstinence, is a frustrating problem for patients and clinicians alike. Patients detoxify and become drug-free but often return to drug use within days or weeks. How is it that drug-seeking behavior gets started up again after abstinence has been established, sometimes even for years? It is well recognized that abused drugs are rewarding (Wise 1988), but this fact alone does not seem a sufficient explanation for the phenomenon of relapse; after all, drugs always have their potential rewarding properties, but animals and people do not administer them all the time.

One possible reason for relapse is that drug-related cues may trigger strong craving and arousal as described in the clinical anecdotes at the opening of the chapter. In the authors' view, the cues may acquire the "triggering" properties through classical, or Pavlovian, conditioning (Pavlov 1927). In this type of learning, stimuli reliably signaling arrival of the drug could acquire the ability to later elicit special drug-related responses such as those described in the opening paragraphs. Just as Pavlov's dogs learned an association between the sound of a bell and the arrival of food, drug patients may have learned associations between a large number of stimuli and the effects of their drugs. If these drug-related responses to drug signals have motivational properties, they could act as a trigger for drug-seeking behavior when they are next encountered. Understanding these responses thus could help explain individuals' patterns of ongoing drug use, and controlling or reducing them might help prevent relapse in patients who manage to become drug-free. Of course, both drug use

and relapse are multidetermined, and factors such as the patient's psychiatric, social, and employment problems all may play a contributing role. A general goal of cue reactivity research is to determine the relative contribution of the responses to drug signals in setting off drug-seeking behavior.

HISTORICAL AND THEORETICAL NOTES

The study of conditioned cue reactivity began, appropriately, with Pavlov. He first described the ability of cues that had reliably signaled the injection of a drug, morphine, to later trigger drug-like responses that resembled the effects of morphine itself (Pavlov 1927). In the late 1940's, Wikler (1948) was the first to suggest that certain kinds of conditioned drug-related responses might play a clinical role in relapse to drug use. Wikler's work emphasized the possible role of drug-opposite, or "withdrawal-like," responses in opiate users, hypothesizing that the experience of these responses might prompt drug-seeking to alleviate withdrawal discomfort. Subsequent to Wikler, Siegel's work (1975, 1976, 1978, 1979) in animals also focused on conditioned drug-opposite (called by him "drug-compensatory") responses, some of which may play a role in the development of drug tolerance. Stewart and colleagues (Stewart et al. 1984; deWit and Stewart 1984; Eikelboom and Stewart 1982) have instead emphasized the potential of conditioned drug-like states in triggering drug use and relapse. Studies from these researchers have shown that stimuli likely to "remind" animal subjects of a previously self-administered drug (e.g., a small dose of a pharmacologically similar drug or a small "priming" dose of the drug itself) would lead to a rapid reinstatement of drug self-administration (deWit and Stewart 1984). In this view, drug-related cues trigger positive incentive states, "pulling" the user toward the anticipated drug reward.

Since the 1970's, the authors' group at the University of Pennsylvania has extensively studied cue-triggered responses in both animals and humans to both opiate- and cocaine-related cues (O'Brien 1975; O'Brien et al. 1977; Childress et al. 1986*a*, 1986*b*, 1988*a*, 1988*b*; Ehrman et al. 1991). The authors have observed both drug-opposite and drug-like responses in both patient populations, with the type of responses reported and measured varying somewhat across setting

(laboratory versus naturalistic), with perceived differences in drug availability, and between drug classes (e.g., cocaine patients never exhibit opiate withdrawal signs).

The responses observed by the authors and by others likely have been shaped not only by characteristics of the drugs studied but also by parameters of dose and the timing of response measurement. For example, though opiate drugs are sedating at higher doses, at lower doses they have stimulant effects, and these direct effects become conditioned (Vezina and Stewart 1984). When responses are measured in relation to signals for drug administration also can make a difference. Drug-like responses in opiate users, for example, often occur in the brief interval immediately following a "sham" injection ritual, but these responses are often both preceded and followed by withdrawal-like symptoms (Childress et al. 1988*b*).

Even in animal research, in which it is possible to control the conditioning history of the subject, to know precisely the nature of the signaling stimulus, and to control for factors that could confuse interpretation of results, controversies persist about the true nature of responding to drug signals (deWit and Stewart 1981). In the clinical situation, where most of these variable are unknowns and controls are difficult, disagreements about the true nature of the conditioned response are not surprising. Rather than asking whether responding to drug signals is drug-opposite or drug-like, it is probably more useful to ask under what set of conditions each type of responding is most likely to be seen.

Theoretical interests aside, both drug-opposite and drug-like conditioned responses could put a patient at risk for drug use. He or she may be pushed to seek relief from the discomfort of drug-opposite responses or pulled to seek the reward promised by drug-like responses. In both cases, movement is in the same direction: toward the drug and toward potential relapse.

WHEN IS A RESPONSE A CONDITIONED RESPONSE?

It is important to realize that reactivity to drug-related cues can occur for reasons other than conditioning. For example, drug cues (e.g., the sight of a needle in the injecting paraphernalia) could be more arousing than neutral cues, even for a non-drug user. Most studies of cue reactivity do not control for this possibility by assessing the response of non-drug users to their test cues. Additionally, what if drug users reacted nonspecifically to cues related to drugs other than the ones they had used? This possibility can be controlled for by testing subjects with drug cues unrelated to their drug use history, but it is rarely done. A recent review by Robbins and Ehrman (1991) fully describes the criteria for determining whether a response is conditioned in origin and the controls that are necessary, but often absent, from conditioning designs and cue reactivity assessments with naturalistic stimuli.

Most of the work reviewed below simply tested drug-related versus neutral cues in one type of drug user. Most researchers did not systematically test cues in non-drug-using controls, nor did they test identified drug users with cues from another drug class. Conservatively, the responses from these studies should be considered simply as reactivity without a conditioning connotation until well-controlled studies are done.

A pattern of reactivity easily consistent with a conditioning interpretation would entail a differential, enhanced responsivity by the drug user to cues relevant to drug use history (as compared to non-drug cues and to cues unrelated to his or her drug use history), with an absence of this pattern among a control group of non-drug users. A recently completed set of studies yielded this pattern of results, providing the strongest evidence thus far that much reactivity to drug-related cues is conditioned in origin (Ehrman et al. 1991). The physiological and subjective reactivity by cocaine patients (n = 15) to cocaine-related cues was shown to be specific (i.e., dependent upon the patient's particular drug use history). They did not react similarly to opiate cues, and naive non-drug using controls (n = 15) did not show differential increases in craving or arousal to cocaine-related cues as compared to non-drug (neutral) or opiate-related cues.

CUE REACTIVITY IN THE LABORATORY SETTING

Opiate Abusers

Much of the cue reactivity data for opiate abusers comes from laboratory assessments in which patients were shown both opiate-related and neutral stimuli and their responsivity then was compared (Childress et al. 1986*a*, 1986*b*, 1988*b*). Opiate-related stimuli featured a 10-minute video of simulated drug-buying, drug-selling, and heroin administration, followed by an opiate-related task in which patients conducted a mock "cook-up" ritual using a white powder resembling heroin. (Patients knew the powder was not real heroin and that no real drugs would be available.) Neutral stimuli consisted of a non-drug (nature) video equal in length to the drug video and a non-drug task, playing a computer video game. Physiological measures included peripheral skin temperature (TEMP), galvanic skin resistance (GSR), and heart rate (HR). Subjective measures were obtained by asking each patient to rate, on a 1-to-10 scale, the degree of subjective opiate high, craving, or withdrawal experienced under each set of stimulus conditions.

Physiological Responses. Methadone patients (n = 89) showed a differential responsivity to opiate-related versus neutral stimuli, with patients generally experiencing significantly greater decreases in TEMP and in GSR to the drug-related stimuli (Childress et al 1986*a*, 1988*b*). A subsample of detoxifying opiate inpatients showed a generally similar pattern of physiological reactivity (Childress et al 1988*b*). Abstinent opiate abusers (n = 15) who had just returned from a minimum 30-day inpatient stay also showed a differential responsivity to opiate-related versus neutral stimuli, again with significantly greater reductions in TEMP and in GSR to the opiate-related stimuli. HR changes to opiate-related versus neutral stimuli in opiate abusers were variable and generally fell short of statistical significance. The changes in TEMP and GSR are consistent with increases in physiological arousal to the drug-related stimuli. The degree of change in physiological responsivity to opiate-related cues often was striking, with occasional reductions in peripheral skin TEMP of more than 12°F.

Subjective Responses. Under laboratory conditions, methadone outpatients showed increased craving and an increased probability of withdrawal symptoms in response to opiate-related versus neutral stimuli (Childress et al. 1986*a*, 19883). Reports of withdrawal often were accompanied by yawning, tearing, sneezing, chills, and complaints of mild nausea or muscle aches. Detoxifying opiate inpatients had a similar pattern of subjective responsivity, except that these patients were even more likely (possibly due to the physiological liability associated with detoxification) than methadone patients to report withdrawal in response to opiate-related stimuli. Opiate abusers abstinent for 30 days also reported increased opiate craving to opiate-related versus neutral stimuli (Childress et al 1986*b*). The prevalence of increased craving to opiate-related stimuli in abstinent opioid users was 90 percent–a rate almost twice that observed in the methadone-maintained patient sample. Across the samples, opiate craving was the most commonly reported subjective response to opiate-related cues.

Reports of increased subjective high in response to opiate-related versus neutral cues were relatively uncommon. This pattern may reflect a bias of the testing situation, as high-like (placebo) responses to cues are most likely when the patient expects drug (O'Brien et al. 1986; Meyer and Mirin 1979). Patients in the laboratory situation were told that no real drugs would be involved. They may have been additionally concerned that reporting "high" responses would raise suspicion about recent drug use. Most of them, when asked, acknowledged having such experiences in their natural environment (see Cue Reactivity in the Natural Environment section).

In sum, opiate patients, whether on methadone, detoxifying, or abstinent, show a differential reactivity to opiate-related versus neutral cues. The response pattern usually is characterized by signs of increased autonomic arousal, signs of increased opiate craving, and, variably, by reports of withdrawal-like symptoms. This reactivity can be demonstrated for the majority of patients even in an artificial laboratory setting with standard (not individualized) stimuli. Further, a recently completed study shows non-drug users do not exhibit differential reactivity to opiate-related versus neutral cues (Ehrman et al. 1991).

Using Mood States as Cues. Most of the early work in opiate cue reactivity used simple external cues. However, it became apparent, both from the natural environment reports and from direct study, that internal cues such as mood state could both interact with external cues and act as powerful drug signals themselves (Childress et al. 1988*b*). In one of the earliest observations, an angry mood (resulting from confrontation with a security guard before the extinction session) was associated with full reinstatement of previously extinguished withdrawal symptoms. In a subsequent systematic study, hypnotically induced mood states, particularly depression and anger, were found to directly trigger opiate craving and, to a lesser extent, withdrawal-like symptoms in abstinent opiate abusers (McNair et al. 1971). The impact of negative moods on craving reliably occurred even before the addition of external opiate-related cues. Interestingly, most patients in the sample carried lifetime diagnoses of affective disorder, and thus they would have had ample opportunity (perhaps through attempts at self-medication) for depressed mood state to become a reliable signal for the arrival of drugs.

Cocaine Abusers

Assessments of reactivity to cocaine-related cues have used protocols very similar to that described for opiate cue reactivity, simply replacing opiate-related stimuli with cocaine-related videos and paraphernalia. The cocaine videos and paraphernalia are matched to the patient's dominant mode of administration (e.g., cocaine smoking versus injecting).

Physiological Responses. Assessments in a sample of 51 recently detoxified cocaine abusers showed a differential reactivity to cocaine-related versus neutral cues, with reliably greater decreases in skin TEMP and in GSR in response to the cocaine-related cues (Childress et al. 1988*a*, 1988*b*). HR changes were complex and interacted with the cue modality (video versus task). Interestingly, the reactivity to cocaine-related cues was equally evident in a subgroup of patients who had undergone a full 30-day rehabilitation prior to testing (Childress et al., submitted). The TEMP and GSR findings were replicated in a second study (Ehrman et al. 1991) that additionally found reliable increases in HR to cocaine-related versus neutral video stimuli. In a subsequent protocol, the findings for TEMP and GSR have remained

consistent (Ehrman et al., in preparation). The reduction in skin TEMP to cocaine-related cues can sometimes be dramatic, with decreases of 10°F or more below baseline levels.

Non-drug-using control subjects do not show these physiological responses to cocaine-related cues, suggesting the responses do reflect a history of cocaine use rather than some nonspecifically arousing or unsettling properties of the cues (Ehrman et al. 1991). The physiological responses also show a degree of specificity in that cocaine users do not show them in response to opiate-related cues (Ehrman et al. 1991).

Subjective *Responses.* Increased cocaine craving is by far the most common and robust response to cocaine-related versus neutral stimuli, and this finding now has been replicated in several protocols (Childress et al. 1988*a*, 1988*b*, submitted; Ehrman et al. 1991, in preparation).

Reports of cocaine craving sometimes are accompanied by the sensation of a cocaine taste in the back of the throat, a faint ringing in the ears, a feeling of excitement, or even sexual arousal. Interestingly, patients often will endorse these concrete drug-like symptoms more readily than "cocaine high." Despite education in the authors' program about reactions to cues, some patients insist they cannot feel high because they have not used any cocaine. Reports of cocaine withdrawal (increases in global self-ratings of cocaine "crash" or withdrawal on a 1-to-10 scale) to the authors' laboratory cues also are relatively uncommon, although some variable effects have been detected (Childress et al. 1988*b*, submitted).

In sum, cocaine patients show a differential reactivity to cocaine-related versus neutral cues on both physiological and subjective measures, and this response is both specific (not occurring to opiate-related stimuli) and linked to the patient's drug use history (the pattern does not occur in non-drug users). These responses were equally evident even in patients who had completed an intensive 30-day rehabilitation and usually would be considered "ready for the street." This reactivity emerged despite the use of relatively sterile cues, an artificial laboratory setting, and the patients' knowledge that real drugs would not be available. Reactivity evidenced in the laboratory is,

therefore, likely to be a conservative estimate of the response to similar cues in the natural environment.

CUE REACTIVITY IN THE NATURAL ENVIRONMENT

Opiate Abusers

In an early retrospective questionnaire given to 100 methadone patients, about 60 percent of the patients reported that day-to-day situations had provoked craving or withdrawal (O'Brien 1975). Another study based on retrospective interviews with active heroin users (McAuliffe 1982) reported a lower (27.5 percent) incidence of withdrawal response to naturally occurring cues. An 8-week prospective study of naturally occurring craving, withdrawal, and high-like episodes in a small sample of stabilized methadone patients found that 94 percent (16 of 17) reported episodes of drug craving attributed to cues. These episodes commonly were attributed to cues such as the sight of a drug-using friend, hearing drug talk, money, desire for euphoria, or the occurrence of a depressed mood. Sixteen of seventeen patients (94 percent) also experienced episodes of withdrawal-like feelings. Though methadone patients often attributed these withdrawal-like episodes to physical discomfort or "methadone-dose-not-holding," some of these episodes may have been triggered by cues because their occurrence was unrelated to the time since the last dose of methadone. Seventy-six percent of the methadone patients reported at least one episode of opiate high-like feelings in response to cues (Childress et al. 1988*b*). In a similar prospective study in a small sample of abstinent opiate abusers, all (8 of 8) had experienced episodes of opiate craving, averaging 11 episodes per patient for the 8-week period. In contrast to the frequency of craving episodes, reports of withdrawal and high-like episodes were relatively uncommon (Childress et al. 1988*b*).

Cocaine Abusers

In structured weekly interviews with a research assistant who also gathered urine samples, cocaine patients readily acknowledged craving episodes as occurring to cues in the natural environment but infrequently endorsed high or withdrawal symptoms (Childress 1991*a*).

This pattern may have been influenced by the patients' concern that high or withdrawal responses might be viewed as pharmacologic, rather than conditioned, in origin. In contrast, in detailed interviews with a clinical psychologist about real-life episodes of cocaine craving (Childress 1991*a*), cocaine patients produced extraordinarily consistent reports of drug-like responses, recounting symptoms of cocaine taste, ear ringing or buzzing, a hot/cold "rush," and a feeling of cocaine high. Thus, the way in which reports are gathered and the person to whom they are given may affect the nature of the responses reported by patients as occurring in the natural environment. Endorsements of craving are best viewed simply as a marker of subjective cue reactivity-the word may be used by the patient as a global description for a number of different concrete responses.

The factors that trigger cocaine craving episodes are very similar to those previously mentioned for opiate patients (Childress 1991*b*). The most commonly cited cues involved the sight of a drug-using friend, money, and depression or other uncomfortable internal state (Childress 1991b). The occurrence of such cue-related episodes also has been reported by Wallace (1989), who performed a microanalysis of relapse episodes in a sample of 35 crack cocaine smokers. This study found that 34 percent of relapse episodes involved exposure to cocaine-related cues (people, places, or things) and 11 percent were connected with handling money, which can act as a cue. Wallace's analysis noted that although most relapse episodes involved multiple determinants, environmental cues were among the top three contributors, ranking with "painful emotional states" and "failure to enter aftercare" as causes for return to cocaine use.

Summary

There now is accumulated evidence that cues that signal opiates or cocaine can trigger physiological reactivity, and particularly craving, in opiate or cocaine users. Although some responses to cues are very drug-specific (e.g., cocaine users never exhibit opiate withdrawal symptoms), there are also similarities in responsivity across drug classes. Many of the physiological responses are consistent with increased arousal, and craving usually is confined to the signaled drug. Additionally, there is evidence that negative affective states and other

internal cues have potency at least equal to external cues in both types of drug dependence.

That drug-related responses can be elicited reliably in artificial laboratory settings, where almost everything about the situation–especially the unavailability of drug-makes them less likely to occur, attests to their strength. Although most studies of cue reactivity have not been controlled stringently, some that have (Ehrman et al. 1991) suggest the origin of much cue reactivity is, indeed, classical conditioning.

Data from the natural environment (Childress 1991*a*, Wallace 1989) lend support to the notion that cue reactivity may be a contributor to relapse. Both opiate and cocaine patients report frequent episodes of craving in response to cues, and the responses to cues often are cited as contributors to relapse.

BEHAVIORAL STRATEGIES

If the reactivity to drug signals plays a role in relapse, then preventing or reducing this reactivity could be of potential clinical benefit. This section surveys several different approaches to the problem of drug-related cue reactivity, with emphasis upon the passive and active strategies used in the authors' own work.

Avoidance

Traditional treatment approaches acknowledge the dangers of drug-related cues for relapse (Washton 1988), generally warning avoidance of all people, places, and things associated with drug use. This approach hopes to prevent the craving and arousal triggered by avoidable external cues. While some cues are avoidable (e.g., a particular bar or drug-selling comer), many more, unfortunately, are not. In most urban environments, potential drug signals are everywhere-from empty crack vials in the street to the television report of a local drug raid on the evening news. Most patients are inundated by cues, and a complete avoidance strategy is probably unrealistic. Even if external cues could somehow be avoided, the

reviewed data suggest internal mood cues may be of equal importance, and they are not avoidable in the usual sense of that word.

Aversive Counterconditioning

Counterconditioning most often is encountered in the form of classical aversive conditioning, in which an aversive stimulus such as emetine nausea or shock is paired repeatedly with stimulus properties (smell or taste) of the abused drug or with actual drug administration (McLellan and Childress 1985). The goal is a conditioned aversion, such that stimuli (sight, taste, or smell) associated with the drug will trigger nausea or repulsion instead of craving or a desire to use.

Although aversive emetine conditioning has been used in the treatment of many alcoholic inpatients over the past four decades, controlled studies of its use in opiate and cocaine patients are not yet available. One study is now underway: Elkins (in press) and his research team are conducting a comparison of conditioned aversions produced by chemically induced nausea, by shock, and by hypnotically induced nausea. The outcome of groups receiving these treatments (in addition to standard inpatient treatment) will be compared against control groups receiving milieu therapy or milieu therapy plus relaxation training. It seems likely that aversive conditioning based on nausea will be more effective in an alcohol treatment sample than in cocaine patients: nausea is a consequence of biologic significance for consummatory behaviors, and it easily can become associated with the taste and smell cues related to ingestion (Garcia et al. 1966; Rozin 1969). It is unclear whether this same response can be attached to cues associated with cocaine, which is usually smoked or injected rather than ingested.

Passive Cue Exposure (Extinction)

If the reactivity to drug signals is based on classical condition, then presenting the signals not followed by drug should eventually lead to reduction of the reactivity through the process of extinction. Attempts to weaken the eliciting power of drug-related conditioned stimuli are also commonly referred to as cue exposure procedures. These techniques often are combined with other standard psychosocial treatments.

In Opiate Patients. In a large-scale treatment-outcome study of extinction in methadone patients (Childress et al. 1988*b*; McLellan et al. 1986), a fixed-trials format determined the number of exposures to each stimulus class (e.g., audio or video). Ten-minute exposures to eliciting stimuli were preceded by a brief psychotherapy session and followed by deep relaxation. Patients given up to 35 treatment sessions showed a significant reduction (extinction) of conditioned craving in response to the drug-related stimuli across sessions, but withdrawal symptoms often persisted. Both therapy and therapy plus extinction groups showed significantly greater clinical improvement at followup than the control group that received only extra drug counseling.

Other results from this study were less encouraging. Very few methadone patients chose to detoxify during the course of the study despite therapeutic support and small financial incentives, meaning that the impact of extinction upon relapse to drug use could not be assessed adequately. Moreover, the outpatient extinction procedure did not produce complete reduction of withdrawal symptoms, either because the amount of nonreinforced exposure was inadequate or, perhaps as likely, because the outpatients would sometimes engage in drug use, leading to reinstatement of the conditioned responses.

In Cocaine Patients. A recently completed random-assignment treatment-outcome study (n = 60 patients total, 9 were initial pilots, and 10 were additional nonrandom subjects) with detoxified cocaine patients tested the possible benefit of adding passive exposure to cocaine-related cues (extinction) to either psychotherapy or drug counseling (Childress et al. 1988*a*, 1988*b*, submitted). The interventions were begun postdetoxification, during a 2-week inpatient treatment phase, and continued for 8 weeks (2 months) beyond discharge. Patients who received passive exposure to cocaine-related cues showed better retention and more cocaine-free urines than control patients receiving like amounts of therapy or counseling but with control activities instead of passive cue exposure (Childress et al., submitted). Data from the cue exposure phase of this study showed that repeated exposure (more than 15 hour-long sessions over a 2-week period) led to a virtually complete reduction in reported cocaine craving to cocaine cues, but physiological arousal was more persistent. For example, although skin TEMP reductions to cocaine-related stimuli

were diminished after repeated exposure, TEMP still was reduced below baseline in response to cocaine signals. More disturbing, patients' weekly reports of craving episodes showed that they often still experienced craving in response to cues that could not be simulated easily in the passive cue exposure paradigm (e.g., sight of an undressed sexual partner is often a trigger for cocaine craving). These results indicated that passive cue exposure produced modest benefits but that generalization of this training to real world cues was incomplete.

In sum, passive cue exposure effects can be demonstrated, but the effects are modest and quickly undermined by concomitant drug use. Using these techniques in a setting where drugs are not available circumvents this problem but creates another-the problem of generalization to cues outside the treatment setting.

Active Strategies

The best role for passive cue exposure techniques may be as an adjunct to strategies that reduce the probability of drug use, even when drugs are available. Such techniques would permit extinction to occur by reducing the likelihood of reinstatement effects. Conversely, the occurrence of extinction might permit a more effective implementation of coping skills, sometimes undermined by strong cue reactivity. Positive and potentially synergistic clinical benefits might result.

In an ongoing study attempting this combined approach, cocaine patients are taught active strategies for reducing the craving and arousal often triggered by drug-related cues (Childress 1991*c*). Detoxified cocaine outpatients (current n = 16) are assigned randomly to one of two treatment groups in a 12-week protocol. The treatment groups combine weekly drug counseling with either active tools (deep relaxation, behavioral alternatives, negative/positive consequences, aversive/positive imagery, mastery imagery, and cognitive interventions) for reducing craving and arousal or with other control activities (videotapes about family relationships and addiction). Patients practice the active tools in the presence of a trained therapist, using them to reduce the craving triggered by recounting (in vivid sensory detail) a personal craving episode. This approach thus employs both active strategies and, by repeated use of the craving

episodes, an exposure component. Although final outcomes are not yet available, patients are able to learn these tools and to use them to reduce the craving triggered by recounting a recent craving episode (Childress 1991*c*).

OTHER APPLICATIONS OF CUE REACTIVITY ASSESSMENTS

To Screen Putative Anticraving Agents

The cocaine epidemic in the United States has prompted an intense search for medications with anticraving properties (Gawin et al. 1989). It seems reasonable to ask whether these agents might help block or reduce the craving and physiological reactivity triggered by drug-related cues. At least three separate research groups now are using cue reactivity paradigms to assess the impact of these drugs on cocaine craving (Ehrman et al., in preparation; Margolin et al. 1990; Kranzler and Bauer 1990). Thus far, assessments conducted with the putative anticraving agent amantadine show that craving was unaffected by the drug, but physiological arousal to cocaine-related cues actually was increased for patients on amantadine versus those on placebo (Ehrman et al., in preparation). Cocaine cue-reactivity assessments with carbamazepine, bromocriptine, and bupropion also are underway (Ehrman et al., in preparation; Margolin et al. 1990; Kranzler and Bauer 1990). Since most of the medications are used as part of a clinical trial, it will be possible to see whether the medication effects on cue reactivity parallel or predict clinical efficacy. Screening agents in a few patients with these procedures is far less expensive than a full-scale clinical trial and may provide some needed initial guidance in selecting agents that deserve further study.

It is of note that replacement therapies for opiates (methadone) and cigarette smoking (nicotine polacrilex gum) reduce withdrawal but leave craving quite intact (Henningfleld and Brown 1987). Whether specific anticraving pharmacotherapies can be developed remains to be demonstrated, but cue reactivity assessments could either facilitate this goal or reveal it to be overly optimistic.

To Study the Neurochemical Substrates of Conditioned States Related to Drug Use

A new and potentially exciting extension of the cue reactivity work is offered through the recent availability of in vivo brain-imaging technology. Newly initiated research (Childress 1991*a*) is attempting to visualize the neurochemical correlates of craving states induced by exposure to drug-related cues in cocaine abuse patients. With future development of radiotracers for multiple neurotransmitter systems, it should be possible to define the neurochemical and neuroanatomical substrates for different types of craving. This, in turn, would aid development of medications that could effectively modify the response to drug signals.

SUMMARY

Despite a venerable history dating back to Pavlov and countless testimonials from patients such as those in the opening paragraphs of this chapter, there is much that remains to be learned about drug signals and, particularly, about ways of reducing their adverse effects on human drug users. There is a substantial amount of data showing increased craving and signs of physiological arousal to drug-related versus neutral cues in drug users for both drug classes reviewed here. Additional controlled studies will be useful in refining which responses among those studied are, in fact, conditioned in origin and therefore can be subjected reasonably to learning-based interventions. Most attempts to modify cue responsivity for clinical benefit have met with only modest success, and there is ample mom for creative, but controlled, treatment-outcome studies.

In recent years, several other groups have joined in the effort to understand drug-related cue reactivity, extending the research area to alcohol and nicotine (Monti et al. 1987; Niaura et al. 1988, 1989; Cooney et al. 1984; Hodgson and Rankin 1982; Drummond 1990; Laberg 1990). The interested reader is referred to several additional reviews of cue reactivity and cue exposure research related to alcohol and nicotine (Niaura 1988; Drummond 1990; Laberg 1990), opiates (Powell 1990), opiates and cocaine (Childress et al. 1988*b*; O'Brien et al. 1990), and all the preceding areas (Rohsenow et al. 1991).

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Treatment of Cocaine Dependence Through the Principles of Behavior Analysis and Behavioral Pharmacology

Stephen T. Higgins and Alan J. Budney

INTRODUCTION

This report describes a series of prospective and retrospective studies conducted to examine the efficacy of an outpatient behavioral treatment for cocaine dependence (Budney et al. 1991; Higgins et al. 1991, 1993*a*, 1993*b*, in press-*a*). The treatment is based on the scientific principles and conceptual framework of behavior analysis and behavioral pharmacology. In that framework, use of abused drugs is considered a special case of operant behavior that is maintained by the reinforcing effects of the drugs involved. Scientific support for this behavioral approach to drug abuse stems from the reliable empirical observation that laboratory animals self-administer most of the same drugs that are abused by humans (Griffiths et al. 1980; Henningfield et al. 1986). Cocaine, amphetamines, opioids, sedatives, and ethanol are readily self-administered by laboratory animals (Young and Herling 1986). Neither a prior history of drug exposure nor physical dependence is necessary for these drugs to function as reinforcers and maintain an ongoing pattern of drug self-administration. Effects of alterations in drug availability, drug dose, response requirement, and other environmental factors on drug ingestion are orderly and have generality across a variety of species, including humans, and different types of drug dependence (Griffiths et al. 1980). Such commonalities across species and types of drug dependence support a position that the fundamental causes of drug self-administration and dependence lie at the level of basic biologic processes common across many species (Brady 1981; Griffiths et al. 1980; Stitzer et al. 1989).

This behavioral model of drug abuse has permitted researchers to effectively extrapolate and apply to drug dependence scientific principles already available from research on other types of operant behavior and has generated a great deal of empirical knowledge concerning the dynamic role played by environmental and pharmacological variables in the reinforcing effects of drugs (Goldberg and Stolerman 1986). That knowledge has important treatment implications that are applicable to the treatment of cocaine dependence.

The basic strategy is to rearrange the drug user's environment so that (1) drug use and abstinence are readily detected, (2) drug abstinence is positively reinforced, (3) drug use results in an immediate loss of reinforcement, and (4) the density of reinforcement derived from nondrug sources is increased to compete with the reinforcing effects of drugs.

A Behavioral Treatment for Cocaine Dependence

The behavioral treatment described in this report is 6 months in duration and implements the aforementioned strategy via contingency-management procedures (Bigelow et al. 1981; Stitzer et al. 1989) integrated with counseling from the Community Reinforcement Approach (CRA) (Sisson and Azrin 1989).

Detection of Drug Use. In order to detect cocaine use and abstinence, urine specimens are collected under staff observation according to a fixed monitoring schedule (e.g., Monday, Wednesday, and Friday). Specimens are screened immediately with an onsite Enzyme Multiplied Immunoassay Technique (EMIT) (Syva Corp., Palo Alto, CA). All specimens are tested within several minutes after collection and screened for benzoylecgonine, a cocaine metabolite. Failure to submit a scheduled specimen is treated as a cocaine-positive specimen. This fixed schedule of drug monitoring leaves little opportunity for undetected cocaine use. At least one randomly selected specimen each week also is screened for the presence of other abused drugs, and breath alcohol levels are assessed at the time urine specimens are collected.

Abstinence Is Reinforced. Contingency-management procedures are used to reinforce cocaine abstinence. Patients, therapists, and, when

possible, significant others are informed of urinalysis results immediately after testing. During weeks 1-12, specimens negative for benzoylecgonine earn points that are recorded on vouchers and given to patients. Points are worth approximately $0.25 each. The first negative specimen is worth 10 points, or $2.50. The value of vouchers for each subsequent consecutive negative specimen increases by 5 points (e.g., the second voucher is worth 15 points, the third, 20 points, etc.) To further increase the likelihood of continuous cocaine abstinence, the equivalent of a $10 bonus is earned for each three consecutive negative specimens. Submission of a cocaine-positive specimen or failure to submit a scheduled specimen resets the value of vouchers to the initial $2.50 value, from which they can escalate again. Submission of five consecutive cocaine-negative specimens following submission of a positive specimen returns the value of points to where they were prior to the reset. Points cannot be lost once earned.

Money Is Never Provided Directly to Patients. Instead, vouchers are used to purchase retail items in the community. A staff member makes all purchases. Items obtained using the vouchers are quite diverse and have included ski-lift passes, fishing licenses, gift certificates to local restaurants, camera equipment, bicycle equipment, and continuing education materials. Counselors retain veto power over all purchases. Purchases are approved only if, in the counselor's opinion, they are in concert with individual treatment goals of increasing drug-free prosocial activities. The voucher system is in effect during weeks 1-12 of treatment, while during weeks 13-24 the magnitude of the reinforcer is reduced to one Vermont State Lottery ticket for each cocaine-negative specimen.

Drug Use Results in the Loss of Positive Reinforcement, Vouchers, lottery tickets, and social reinforcement are withheld when urinalysis results indicate recent cocaine use.

Reinforcement Density From Nondrug Sources Increased. The voucher system is designed to increase reinforcement density from nondrug sources, and aspects of CRA also are used for that purpose. The CRA procedures are implemented in twice-weekly, 1-hour counseling sessions for 12 weeks and then once weekly during the subsequent 12 weeks.

Sessions Focus on Four General Issues. First, subjects with a spouse, friend, or relative who is not a drug abuser and is willing to participate in treatment receive reciprocal relationship counseling. This is a validated procedure for instructing dyads how to negotiate for positive changes in their relationship (Azrin et al. 1973). To integrate CRA and contingency-management procedures, significant others are telephoned immediately following each urinalysis test and informed of results. If the specimen was negative for cocaine, the significant other engages in agreed-upon activities with the patient. If the result was positive for cocaine use, the significant other refrains from the activities but offers assistance to the patient in dealing with difficulties in achieving abstinence. In recent trials, approximately 80 percent of patients have had a significant other participate in treatment at some point during the 6-month treatment period (Higgins et al. 1993a). Significant others have included spouses or other sexual partners, parents, siblings, in-laws, and friends. No empirical evidence exists to indicate that any one type of significant other is better than another.

Second, subjects are instructed how to recognize antecedents and consequences of their cocaine use. They are counseled to restructure their daily activities to minimize contact with known antecedents, find alternatives for the positive consequences derived from cocaine use, and make explicit the negative consequences of cocaine use. Skills training is provided to those with specific deficits (e.g., drug refusal, problem solving, or assertiveness). Patients exhibiting persistent evidence of depression are provided a behavioral treatment for depression that is easily integrated with this behavioral treatment for cocaine dependence. Other problems that may interfere with achieving cocaine abstinence (e.g., persistent insomnia) also are addressed through behavioral counseling. Acquired immunodeficiency syndrome (AIDS) prevention counseling is provided to all patients.

Third, unemployed patients are offered employment counseling (Azrin and Besalel 1980). Assistance also is provided for those interested in pursuing educational goals or job changes and those with miscellaneous practical needs such as financial counseling, alternative housing, or legal and social services.

Fourth, subjects are counseled to develop new recreational activities or to become reinvolved in those they pursued prior to beginning cocaine use. Counselors and subjects work together to identify these activities. This also provides an avenue for integration of the contingency-management and CRA components. Vouchers earned through cocaine-free urine specimens are used to support costs of initiating these activities.

Treatment is delivered by master's-level counselors specifically chosen because they are *not* trained in traditional approaches to drug and alcohol counseling. In the authors' experience, it is difficult to find master's-level counselors with experience in behavior therapy. To date, the authors have had success training rehabilitation counselors, general adult counselors, and graduate students in clinical psychology in this approach. Clinical supervision is provided by a doctoral-level behavioral psychologist at least once weekly, and such close supervision by someone experienced in the use of behavioral treatments for substance abuse is necessary for effective application of this treatment approach.

All patients who meet DSM III-R criteria for alcohol dependence or report that alcohol use causes problems in their attempts to achieve cocaine abstinence are offered disulfiram therapy. Disulfiram therapy is an integral part of the CRA treatment for alcoholism (Sisson and Azrin 1989). The dose is usually 250 mg/daily unless patients report being able to consume alcohol at that dose without a reaction. In this case, the daily dose is increased to 500 mg. Disulfiram ingestion is observed by clinic staff when patients come for urinalysis monitoring. Take-home doses are provided for the other days and, if possible, are ingested in the presence of a significant other in accordance with disulfiram assurance procedures designed to improve compliance (Sisson and Azrin 1989).

RESEARCH STUDIES

Behavioral Treatment Versus Drug Abuse Counseling

Nonrandomized Trial. The first study examining the efficacy of this behavioral treatment in establishing initial cocaine abstinence was

conducted with 13 consecutive admissions to an outpatient clinic (Higgins et al. 1991). Results were compared against data from a second group of 15 consecutive admissions who received standard outpatient drug and alcohol counseling from a disease-model orientation. This study focused on the first 12 weeks of treatment. Urines were collected on Saturdays in addition to the Monday, Wednesday, and Friday schedule described above. Because the disulfiram component of the treatment was just beginning, only one patient in the behavioral group received disulfiram therapy.

Those in the drug abuse counseling group participated in the same schedule of urine monitoring as those in the behavioral treatment, but results were not shared with patients or therapists; patients received $5 per specimen independent of results. The schedule of counseling was the same as in the behavioral group, but group therapy was emphasized consistent with the typical format in this approach. Patients were counseled that cocaine addiction was a treatable but incurable disease. They were requested to attend self-help meetings in addition to their regularly scheduled sessions. The regularly scheduled sessions consisted of both supportive and confrontive therapy, didactic lectures, and videos on cocaine dependence, AIDS, the disease model of addiction, and the self-help orientation. Patients were expected to identify a sponsor from a local self-help group by week 12. Counseling was delivered by master's-level counselors experienced in standard drug and alcohol counseling, and clinical supervision was provided by a master's-level person with extensive experience in delivering and supervising this type of treatment.

To participate in the study, subjects had to be 18 years of age or older and meet DSM III-R criteria for cocaine dependence. The groups differed significantly on only two subject characteristics. Subjects in the behavioral treatment reported ingesting more cocaine per week (10.2 ± 8.6 g/week versus 3.7 ± 3.8 g/week) prior to entering treatment and had a significantly greater proportion of intravenous cocaine users (69 percent versus 17 percent) than the standard counseling group.

Acceptability of the behavioral treatment and drug abuse counseling to patients was inferred from the number who failed to attend more than one therapy session in the two groups. All who were offered the behavioral treatment accepted it, while 12 of 15 (80 percent) accepted

12-step counseling. Treatment retention was significantly better in the behavioral treatment than drug abuse counseling ($p<0.05$). Eleven of the thirteen (85 percent) subjects in the behavioral treatment versus 5 of 12 (42 percent) in the drug and alcohol counseling group were retained for 12 weeks of counseling. Subjects from the behavioral treatment achieved significantly longer periods of continuous cocaine abstinence than subjects in the 12-step counseling group ($p<0.01$) (figure 1). For example, 78 percent of the subjects in the behavioral group achieved 4 or more weeks of continuous cocaine abstinence versus 25 percent of the subjects in the counseling group. No members of the counseling group achieved more than 7 weeks of continuous cocaine abstinence, while 46 percent of the subjects in the

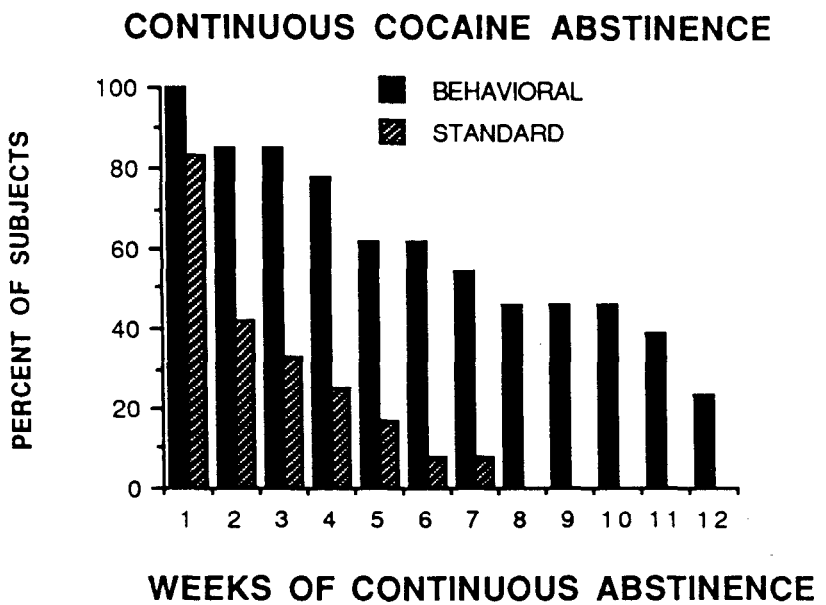

FIGURE 1. *Periods of continuous cocaine abstinence in patients receiving behavioral treatment and drug and alcohol counseling. The height of each bar represents the percentage of patients (y-axis) achieving a duration of documented cocaine abstinence greater than or equal to the number of weeks indicated (x-axis).*

SOURCE: Higgins et al. 1991

behavioral group achieved 8 or more weeks of continuous cocaine abstinence, and 23 percent achieved 12 weeks.

Randomized Trial. This initial trial comparing the behavioral treatment and standard drug and alcohol counseling was followed by a randomized trial comparing the same two treatments (Higgins et al. 1993a). Thirty-eight patients were randomly assigned to the two treatments (19 per group). Patient characteristics did not differ significantly across the two treatment groups. Treatment duration was 6 months in both groups. The main differences from the initial trial were that urine specimens were not collected on Saturdays, treatment duration was increased from 3 to 6 months, and disulfiram therapy was available to both treatment groups. Eight of the patients in the behavioral treatment group received disulfiram therapy at some point during the 24 weeks of treatment. Only one patient in the standard counseling group received disulfiram therapy, which is consistent with a common reluctance among traditionally trained drug abuse counselors to recommend disulfiram therapy.

One (5 percent) patient in the behavioral treatment versus eight (53 percent) in drug abuse counseling failed to attend more than one session ($p = 0.02$). Significantly more patients in the behavioral treatment than drug abuse counseling completed treatment ($p<0.01$). For example, 84 percent and 58 percent of those in the behavioral treatment completed 12 and 24 weeks of treatment, compared with 26 percent and 11 percent in drug abuse counseling. When cocaine abstinence was analyzed as a function of consecutive treatment weeks, significantly larger numbers of patients in the behavioral group were abstinent during weeks 3-24 ($p<0.05$, figure 2, upper panel). Importantly, the incentives in the behavioral treatment were decreased in magnitude from the vouchers to lottery tickets at the end of week 12 without a precipitous decrease in cocaine abstinence (figure 2, upper panel). Significant differences also were evident when continuous cocaine abstinence was compared ($p = 0.005$). For example, 68 percent and 42 percent of patients in the behavioral treatment achieved at least 8 and 16 weeks of documented continuous cocaine abstinence versus 11 percent and 5 percent in drug abuse counseling (figure 2, lower panel).

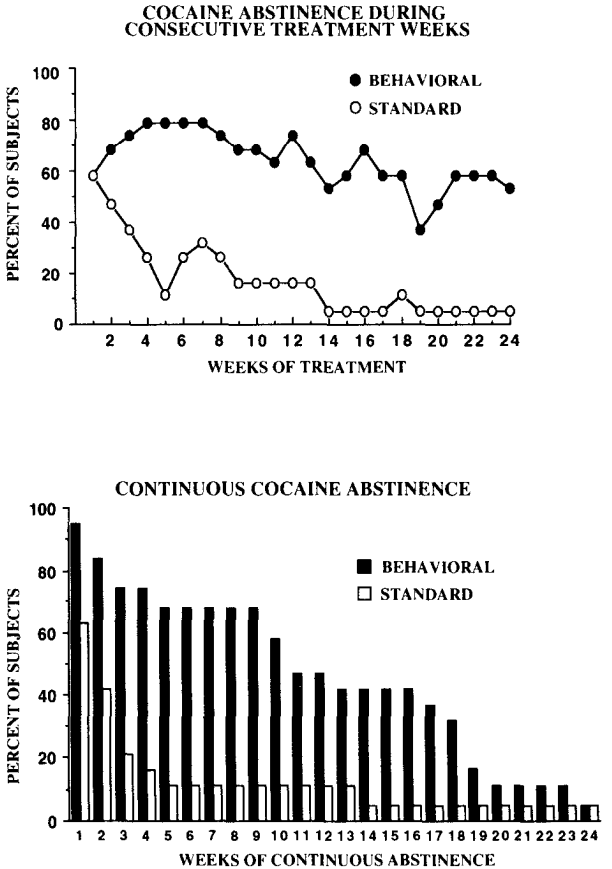

FIGURE 2. *Upper panel: Percentage of patients (y-axis) in behavioral treatment and drug abuse counseling in whom cocaine abstinence was documented during consecutive weeks of treatment (x-axis). Lower panel: Periods of continuous cocaine abstinence in patients receiving behavioral treatment and drug and alcohol counseling. The height of each bar represents the percentage of patients (y-axis) achieving a duration of documented cocaine abstinence greater than or equal to the number of weeks indicated (x-axis).*

SOURCE: Higgins et al. 1993*a*

This trial replicated the results from the nonrandomized trial, extended them to a longer treatment period, and demonstrated that treatment gains were maintained after the voucher system was discontinued. The consistency of the results observed across the two trials demonstrates the reliability of the effects of this behavioral treatment and strongly suggests that any outcome differences observed between this treatment and standard drug abuse counseling are not attributable to inadvertent differences in subject characteristics. It merits mention that the difference between the two treatments in this trial in the number of patients who received disulfiram therapy cannot account for the outcome differences observed, as similar differences were observed in the earlier trial in which only one patient in the behavioral treatment group received disulfiram therapy. As is reported below, disulfiram therapy is associated with clinical improvement in this population, but it does not account for the large magnitude and reliable differences observed between the behavioral treatment and drug and alcohol counseling in these two trials. The relatively poor outcomes observed with drug and alcohol counseling in these trials are comparable with those reported previously in outpatient counseling for cocaine dependence (e.g., Kang et al. 1991).

Randomized Trial Comparing the Behavioral Treatment With Versus Without the Voucher System

It is not known at this time which components of this multicomponent behavioral intervention are contributing significantly to the outcomes observed. To begin to address that question, the authors currently are conducting a trial in which patients are randomly assigned to two groups. One treatment group receives the entire behavioral treatment as described above, while the other group receives everything except the voucher system. Described below are reported preliminary results collected from 30 patients (15 per group) during the first 12 weeks of treatment, which is when the voucher system is in effect (Higgins et al. 1993*a*). There were no significant differences in subject characteristics between the treatment groups, and all subjects were 18 years of age or older and met DSM III-R criteria for cocaine dependence as in the prior trials.

The voucher system improved treatment retention, with 93 percent of those who received vouchers completing 12 weeks of treatment versus

67 percent of those who did not receive them. Those who received the vouchers also achieved greater levels of documented cocaine abstinence (figure 3). For example, 67 percent of those who received vouchers achieved 6 or more weeks of documented continuous cocaine abstinence versus 40 percent of the group that did not receive vouchers.

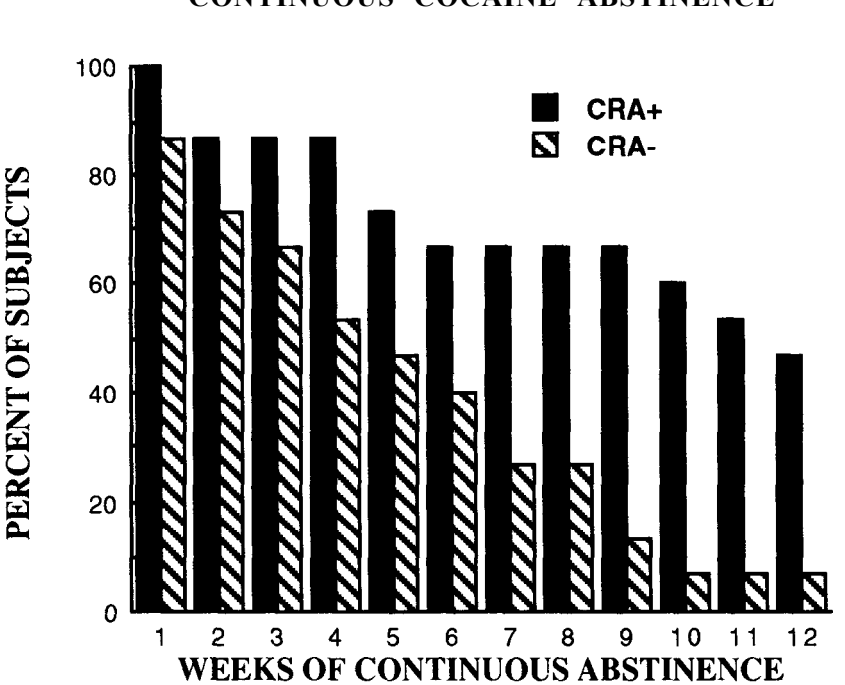

FIGURE 3. *Periods of continuous cocaine abstinence in patients receiving-behavioral treatment with and without the voucher system. The height of each bar represents the percentage of patients (y-axis) achieving a duration of documented cocaine abstinence greater than or equal to the number of weeks indicated (x-axis).*

KEY: CRA+ = Community Reinforcement Approach with vouchers; CRA- = Community Reinforcement Approach without vouchers

Importantly, if the performance of the standard drug abuse counseling group from the prior randomized trial is used as a historical control, graded functions emerge. That is, levels of treatment retention and cocaine abstinence are best with the complete treatment package, intermediate with the behavioral treatment without vouchers, and lowest with standard counseling (figure 4). When looked at in this manner, it seems that the voucher system contributes significantly to the efficacy of this behavioral treatment but other aspects of the treatment package are also important. The studies described below further support that position.

Retrospective Analysis of Predictors of Cocaine Abstinence

While the outcomes observed with the behavioral treatment package are impressive, not everyone responds equally well. Thus, an investigation of predictors of who succeeded in the treatment was initiated. Towards that goal, a study was conducted using a stepwise logistic regression to identify significant predictors of cocaine abstinence during the initial 12 weeks of treatment in 52 patients who received the behavioral treatment (Higgins et al., in press-*b*). Subjects were classified as "successes" and "failures" based upon their longest period of cocaine abstinence and the overall percentage of cocaine-negative urine specimens submitted. Success was defined as having achieved 9 or more weeks of continuous abstinence or greater than 92 percent overall cocaine abstinence during the initial 12 weeks of treatment. Subjects not meeting either of those criteria were classified as failures. The following variables were examined: age, gender, years of education, employment status, weekly income, years of regular cocaine use, average amount spent weekly on cocaine, average number of grams of cocaine used weekly, longest period of pretreatment cocaine abstinence since becoming a regular user, alcohol dependence, marijuana dependence, Addiction Severity Index (ASI) composite scores, and whether a subject had a significant other participate in treatment.

Using these abstinence criteria, 28 subjects were classified as successes and 24 as failures. The only significant predictor of success was

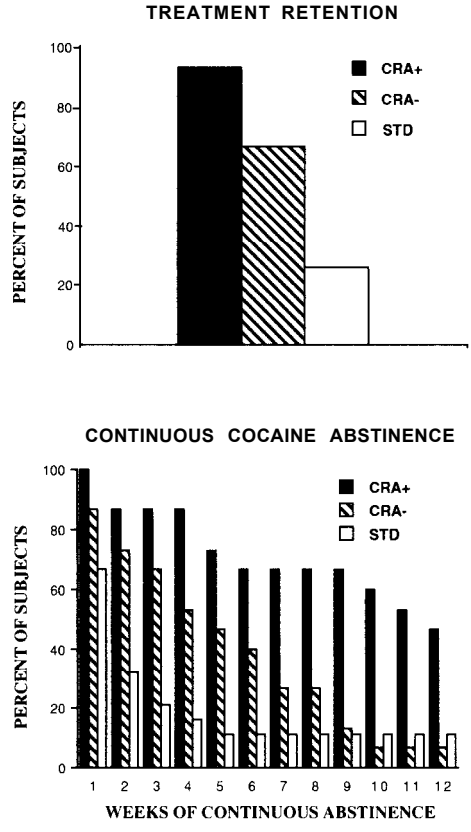

FIGURE 4. *Upper panel: The percentage of patients who completed 12 weeks of treatment in the behavioral treatment with and without the voucher system and a historical control group that received drug and alcohol counseling. Lower panel: Periods of continuous cocaine abstinence in patients receiving the same treatments shown in the upper panel. The height of each bar represents the percentage of patients (y-axis) achieving a duration of documented cocaine abstinence greater than or equal to the number of weeks indicated (x-axis).*

KEY: CRA+ = with Community Reinforcement Approach with vouchers; CRA- = Community Reinforcement Approach without vouchers; STD = Historical control group

having a significant other participate in treatment. Subjects who had a significant other participate in treatment were estimated to be almost 20 times as likely to achieve criterion levels of abstinence as those without a significant other participating in treatment.

Having a significant other participate in treatment was a robust predictor of abstinence in this study. To the authors' knowledge, this is the first study on predictors of treatment outcome in cocaine dependence to note a relationship between significant other involvement in treatment and cocaine abstinence. Although it must be documented in a prospective randomized trial, reciprocal relationship counseling may contribute significantly to the positive treatment outcomes observed with this multicomponent behavioral treatment.

Disulfiram Therapy in Patients Abusing Cocaine and Alcohol

As noted above, disulfiram therapy is a component of this behavioral treatment approach and is offered to all patients who, in addition to cocaine dependence, report evidence of concurrent alcohol dependence or abuse. In this study, the authors attempted to assess for significant clinical changes associated with that therapy (Higgins et al. 1993*b*). To do so, results were examined from 16 patients who met DSM III-R criteria for cocaine dependence and alcohol abuse/dependence. Subjects were chosen on the basis of having 2 or more weeks on and off disulfiram therapy, which provided an opportunity to assess for associated benefits. Because patients often determined when disulfiram therapy was terminated, causality for any changes observed could not be determined.

The average durations on and off disulfiram therapy were 69.5 days ± 11.9 S.E.M. and 93.4 days ± 10.7. The off-disulfiram period preceded the on period in 10 patients and followed it in 6 others. Patients reported to the clinic two or three times weekly and ingested disulfiram under staff supervision. Breath and urine specimens were collected under staff observation during those visits. Take-home doses of disulfiram were provided for the other days. Other than the attempts to supervise ingestion, disulfiram therapy was provided using standard procedures (Puller et al. 1986). Patients generally ingested a single 250 mg/daily dose. Disulfiram therapy was associated with

significant decreases in measures of drinking and cocaine use (figure 5).

Patients reported an average of 0.05 ± 0.02 drinking days weekly while taking disulfiram versus 1.5 ± 0.4 off the medication ($p = 0.001$). The average number of drinks per drinking occasion while taking disulfiram was 4.7 ± 2.2 versus 10.9 ± 2.6 off the medication. The frequency of cocaine use was already suppressed due to the efficacy of the behavioral treatment patients were receiving. Nevertheless, the percentage of cocaine positive specimens while taking disulfiram was 11 percent ± 3 versus 25 percent ± 6 off the medication ($p = 0.01$).

In summary, supervised disulfiram therapy was associated with significant decreases in alcohol and cocaine use. Controlled trials will be necessary to evaluate adequately the direct contribution of disulfiram therapy to these outcomes. Considering the large proportion of cocaine abusers who abuse alcohol, such trials merit serious consideration. It appears that in that subset of patients who are also alcohol abusers, including the disulfiram component may contribute significantly to the positive outcomes observed with this behavioral treatment package.

Contingency-Management Procedures in Patients Abusing Cocaine and Marijuana

This study examined the efficacy of the voucher system for controlling cocaine and marijuana use by multiple-drug abusers (Budney et al. 1991). Subjects were two males who received the behavioral treatment described above. Both were cocaine dependent; S-l also met criteria for marijuana dependence, while S-2 met criteria for marijuana abuse. Both subjects achieved almost complete cocaine abstinence but continued regular marijuana use during the 12 weeks in which vouchers were available contingent on cocaine abstinence (figure 6, cocaine-abstinence phase). In a subsequent phase, reinforcement magnitude was reduced to $1 lottery tickets delivered contingent on submission of cocaine-free urine specimens. Weekly l-hour behavior therapy sessions were continued during this period, and urine specimens were collected twice weekly (Monday and Thursday).

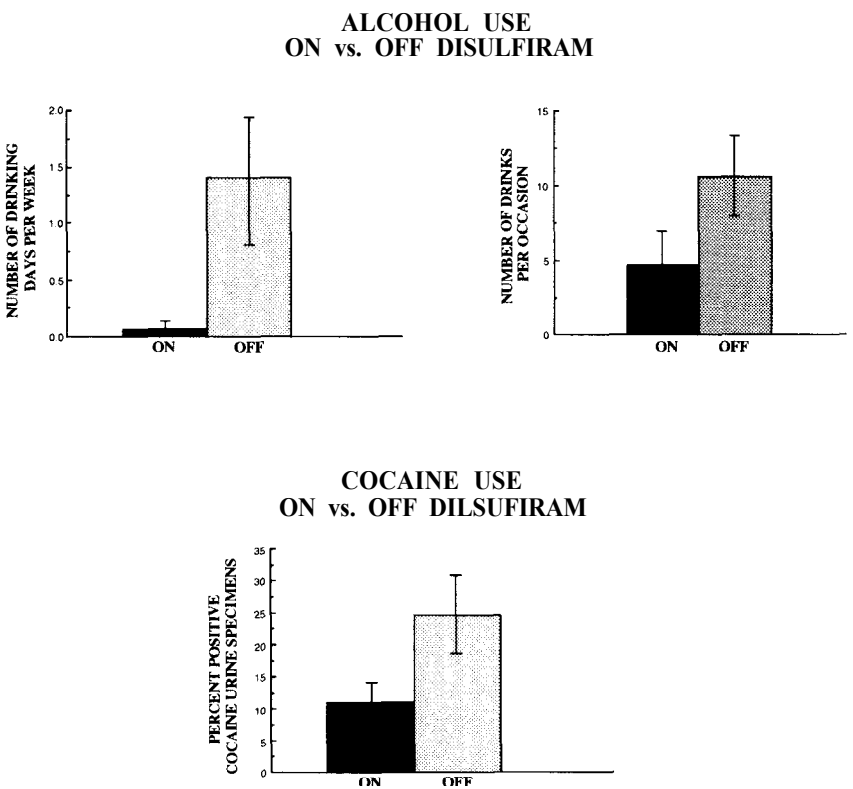

FIGURE 5. *Upper panels: Self-reported average number of alcoholic drinks per week and self-reported average number of drinks per drinking occasion. Lower panel: Average percent cocaine-positive urinalysis results while on and off disulfiram therapy. Brackets represent ± 1 S.E.M.*

During this period, both subjects maintained the patterns of cocaine abstinence and regular marijuana use exhibited in the initial phase (figure 6, cocaine-maintenance phase). Next, these individuals were given a 2-week notice that the reinforcement program conducted in the initial phase would be available for another 12 weeks but that points were now contingent on both cocaine and marijuana abstinence. Delivery of the notice to the individual subjects was staggered across time in the tradition of a multiple-baseline research design (Baer et al. 1968). Schedules of urine monitoring and therapy remained as in the second phase. The overall value of vouchers that could be earned during the 12 weeks of this third phase was the same as in the initial phase. During this third phase, S-l and S-2 provided 96 percent (23 of 24) and 100 percent (24 of 24) negative benzoylecgonine and cannabinoid urine specimens (figure 6, cocaine-marijuana-abstinence phase). The temporal order of the change in urinalysis results across the two subjects coincided with the staggered intervention times, strongly suggesting that the changed contingencies controlled the changes in marijuana use.

At followup visits scheduled at 1 and 5 months after treatment termination, both subjects remained cocaine abstinent but had resumed marijuana use. Interestingly, both subjects deemed cocaine use a serious problem and requested treatment for it but did not deem marijuana use a problem. The present results demonstrate that abstinence from both substances can be achieved by arranging the reinforcement contingencies appropriately, but treatment gains made with the substance not deemed by patients as problematic may be relatively transient.

DISCUSSION

This behavioral treatment is very acceptable to patients. The vast majority (98 percent) of individuals who have been offered the treatment have accepted. Treatment acceptability to dependent individuals is important, especially because many of the individuals treated thus far were intravenous users at risk for contracting and spreading AIDS and other diseases (Chaisson et al. 1989). Current pharmacotherapies often are rejected by 30 percent or more of those offered treatment (e.g., Gawin et al. 1989; Weddington et al. 1991),

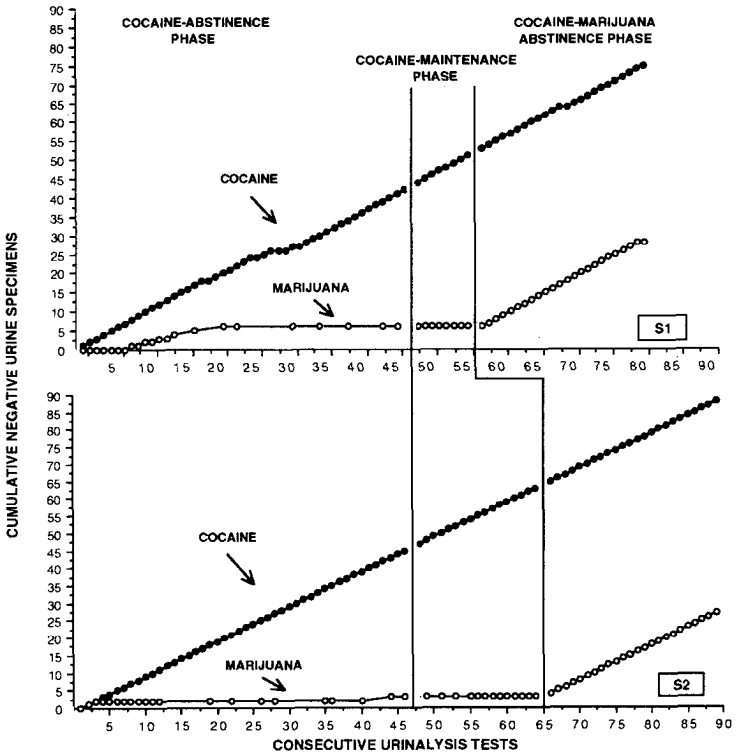

FIGURE 6. *The cumulative number of negative cocaine and marijuana urinalysis results obtained during three phases of treatment are shown as a function of consecutive urinalysis tests conducted throughout treatment. Cocaine and marijuana are represented by closed and open symbols, respectively.*

SOURCE: Budney et al. 1991

and behavioral therapies with aversive contingencies are rejected by as many as 50 percent of patients (Anker and Crowley 1982). Thus, this treatment may be more acceptable to patients than alternative pharmacological and psychological therapies.

The treatment is effective in retaining patients in treatment. Across the trials conducted to date, more than 85 percent of patients have completed 12 or more weeks of treatment. The same issues that underscore the importance of treatment acceptability apply to treatment retention. As long as the individual remains in treatment, opportunities exist to facilitate behavior change. Longer stays in drug abuse treatment are associated with improved outcomes (e.g., Anglin and McGlothlin 1984), and once patients exit treatment, all opportunities to influence any aspect of their characteristically high-risk behavioral repertoires are lost.

The behavioral treatment is effective in establishing initial cocaine abstinence, as this has now been replicated in several trials (Higgins et al. 1991, 1993*a*). The obvious challenge is to address questions of longer-term abstinence and the generality of these findings to other clinics and populations. The 6-month randomized trial described above was a first step towards addressing the challenge of longer term abstinence, and the findings were encouraging (Higgins et al. 1993*a*). Clinically significant periods of continuous cocaine abstinence were engendered in the majority of patients, and, at the end of 3 months of treatment, patients could be transitioned from the voucher system to the lower magnitude lottery tickets without a precipitous drop in cocaine abstinence levels. With regard to the issue of generality to other settings, several clinics located in large urban areas plan to examine the efficacy of either particular components of this treatment or the entire package. Thus, information regarding the generality of this treatment approach to other settings should be forthcoming.

This treatment can be adapted to address the high levels of alcohol and marijuana abuse common among cocaine-dependent individuals. Because the majority of cocaine-dependent persons also abuse these other drugs, any effective treatment for cocaine dependence must be able to address these other forms of drug abuse as well. The results observed with disulfiram therapy suggest that addressing alcohol abuse in this population is associated not only with significant decreases in

alcohol consumption but also with significant decreases in cocaine use (Higgins et al. 1993*b*). Considering that almost all cocaine-dependent individuals use alcohol and the majority do so in an abusive manner, this could be a very important observation (Grant and Harford 1990). Controlled trials examining the efficacy of disulfiram in the treatment of cocaine dependence are needed.

The information provided above on marijuana use suggests that some individuals can use regularly without it adversely affecting cocaine abstinence. Marijuana use in those subjects is readily modifiable by means of a direct contingency-management intervention, although such changes appear to dissipate when the contingency is removed. More information is needed on the influence of marijuana use on efforts to achieve cocaine abstinence so that clinicians can make informed decisions about how to address use of that substance during treatment for cocaine dependence.

An important feature of this treatment approach is its direct ties to basic research in behavioral pharmacology and behavior analysis. As was noted above, this treatment is conceptualized and structured in terms of the basic principles and concepts of those scientific disciplines. Operating according to a common set of concepts and principles in the basic research and clinical domains should support effective communication between those settings and facilitate a scientific approach to the treatment and prevention of drug dependence.

The preliminary results of the trial comparing the behavioral treatment with and without the voucher system indicate that including it improves treatment retention and cocaine abstinence. Although the costs of such a voucher system (maximum of $11-$12 per day across 3 months) may seem prohibitive at first blush, they pale, for example, in comparison to those incurred with the typical 28-day inpatient hospitalization for substance abuse or the costs incurred in caring for an individual who has contracted AIDS (Holder and Blose 1991; Drucker 1986). Additionally, it is important that the behavioral processes involved in the treatment described in this chapter receive attention, not just the nature of the incentives used. This intervention illustrates the potential utility of frequent, contingent use of positive reinforcement in the treatment of cocaine dependence. It is possible

that the nature of the reinforcers used could be quite varied (i.e., one should not assume that vouchers redeemable for retail items are a necessary feature). Also, if they are necessary, clinics may consider creative and cost-effective strategies for providing them. For example, nonprofit clinics may consider petitioning community retailers to donate items to be used as incentives. Use of access to community athletic facilities or other community resources is another possibility.

Results from the retrospective analysis of predictors of cocaine abstinence in this behavioral treatment strongly suggest that social reinforcers delivered systematically by significant others may play a significant role in establishing cocaine abstinence (Higgins et al., in press-*b*). Although those findings need to be documented in a prospective, randomized trial, they illustrate the varied ways in which differential reinforcement procedures can be applied in trying to engender and maintain cocaine abstinence.

Overall, the findings reviewed in this report illustrate that systematic application of basic behavioral concepts and principles can play an important role in effective treatment for cocaine and other forms of drug dependence.

NOTE

This chapter is based in part on the brief review published previously (Higgins et al., in press-*a*).

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Cognitive Therapy of Substance Abuse: Theoretical Rationale

Fred D. Wright, Aaron T. Beck, Cory F. Newman, and Bruce S. Liese

"The practical effect of a belief is the real test of its soundness."

James A. Froude

INTRODUCTION

Millions of Americans have substance abuse problems. In fact, at least 1 in 10 adult Americans has a serious alcohol problem (Institute of Medicine 1987). At least one in four adult Americans is addicted to nicotine (Centers for Disease Control 1991*a*). Approximately 1 in 35 Americans over the age of 12 is an illicit drug user (Institute of Medicine 1990a). Substance abuse results in profound social, medical, and psychological problems. For example, it has been estimated that approximately 434,000 people in this country die each year as a result of cigarette smoking (Centers for Disease Control 1991*b*). Many thousands also die as a result of alcoholism (Institute of Medicine 1987, 1990*b*) and illicit drug abuse (Institute of Medicine 1990*a*).

There are many different ways of conceptualizing substance abuse (Beck et al. 1993; Blane and Leonard 1987; Brickman et al. 1982; Cox 1990). Although the disease model and 12-step programs continue to dominate the treatment literature and practice, several authors have developed social learning, or cognitive-behavioral, approaches for understanding and treating substance abuse disorders (e.g., Abrams and Niaura 1987; Annis 1986; Marlatt 1978, 1982, 1985; Marlatt and Gordon 1980, 1985). In fact, efforts even have included rational emotive approaches to treating substance abuse (e.g., Ellis et al. 1988; Trimpey 1989). This chapter presents the theoretical rationale for the cognitive therapy of substance abuse based on work at the Center for Cognitive Therapy, University of Pennsylvania.

The Cognitive Therapy Model

Cognitive therapy is an active, collaborative, focused form of psychotherapy developed from the findings that psychological disturbances frequently involve habitual errors in thinking (Beck 1976; Beck et al. 1979). The underlying theoretical rationale stipulates that the way an individual feels and behaves is largely determined by the way he or she construes his or her experiences. Further, the model stipulates that psychological disorders are characterized by dysfunctional thinking derived from dysfunctional beliefs. Initial improvement results from modification of the dysfunctional thinking and durable improvement from modification of dysfunctional beliefs.

The cognitive model of substance abuse asserts that certain individuals have developed a cognitive vulnerability to drug abuse. Under particular circumstances, specific beliefs are activated that increase the likelihood of substance use (Beck et al. 1990a, 1992). Idiosyncratic beliefs such as, "I cannot socialize without getting high," are activated in certain provocative situations, leading to increased risk of succumbing to drug use.

Definition of Beliefs

Beliefs are relatively stable, enduring cognitive processes that, once formed, are not easily modified by experience. Depressed patients tend to have global negative views about themselves, the world, and the future, which contributes to their feelings of despair, guilt, and sadness (Beck et al. 1979). Similarly, anxious patients have specific negative beliefs about some future threat, which contributes to avoidance, anxiety, and, at times, panic attacks (Beck and Emery 1985). Without cognitive intervention, these pernicious beliefs tend to endure in spite of objective evidence that there is hope or that the perceived threat is minimal.

There are three major categories of dysfunctional beliefs associated with the patient's *acute* decision to engage in substance abuse:

1. Anticipatory,
2. Relief-oriented, and
3. Facilitative or permissive.

Anticipatory beliefs usually involve some expectation of drug use, such as, "I feel like a superman when I use." Relief-oriented beliefs are those that assume that using drugs will remove some uncomfortable state: "The urges and cravings will not go away unless I use." Facilitative or permissive beliefs are those that consider drug use acceptable even in spite of obvious potential consequences: "I deserve it. I am a hard worker. There is nothing wrong with taking risks."

The cognitive therapy model of substance abuse states that drug-using beliefs and desires typically are activated in specific, common, often predictable, high-risk circumstances. These circumstances can be external or internal. Examples of external circumstances are seeing drug paraphernalia or being at a party where cocaine or other drugs are being used. Internal circumstances include uncomfortable emotional states such as depression, anxiety, or boredom.

Numerous circumstances can trigger drug-related beliefs and, consequently, drug use. It should be noted that the circumstances previously mentioned do not directly cause drug use, though they may seem to give rise to spontaneous use. The authors have observed a sequence of events that occurs between the external/internal circumstances and the actual drug use. The sequence of conditions is as follows (see figure 1): the high-risk external/internal circumstance is followed by the activation of a basic drug-related belief, which in turn leads to associated automatic thoughts and further to craving/urges. This in turn leads to the activation of facilitating beliefs about drug use, which directs attention to instrumental strategies for obtaining the drugs, which in turn leads to use. At this point, drug use can serve as an additional external/intemal circumstance that triggers other drug-related beliefs (e.g., "Since I have broken my abstinence, I might as well go on a binge"), resulting in a vicious cycle (Beck et al. 1990*a*, 1992).

This series of conditions is illustrated in the following case. Mr. C. is a 34-year-old drug abuser who completed a 28-day residential treatment program. The following is an example of his first lapse. The situation occurred when Mr. C. went to a bar (external) in order to socialize because he felt extremely bored (internal). This, in turn, activated a common drug-related (relief-oriented) belief: "I cannot stand the boredom." In turn, this condition led to the associated

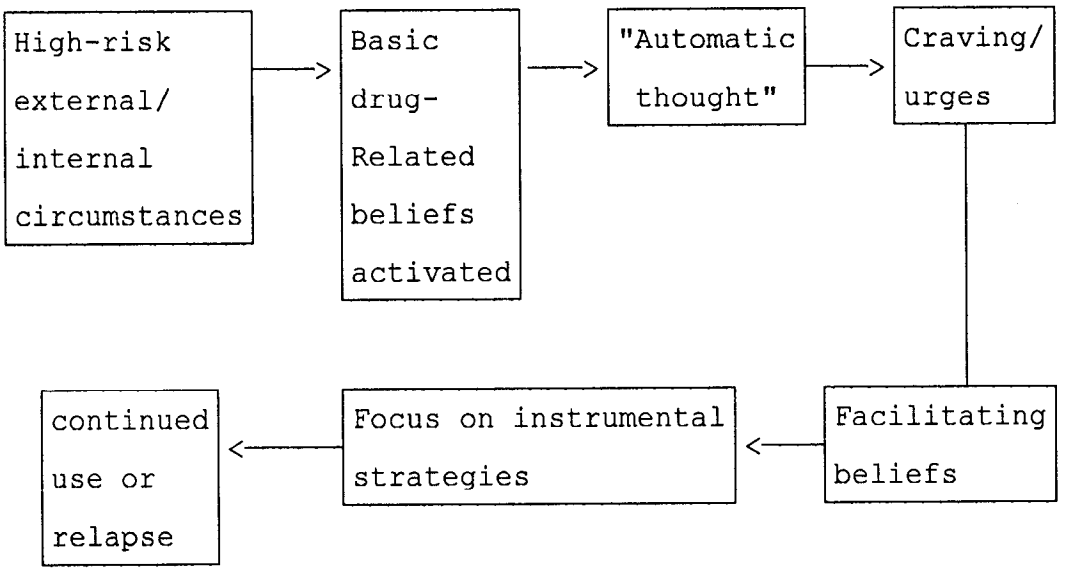


FIGURE 1. *Cognitive model of substance abuse*

automatic thought, "Go for it." Instantly, extremely strong cravings started, as he began to have images of the last time that he used. This, in turn, activated another belief, "Urges and cravings make me use," and the facilitating belief, "Everybody in this town uses, so why not me?" His instrumental strategy was to look around for someone in the bar who might have some cocaine. Like a heat-seeking missile, all of his attention was focused on hitting the target-getting cocaine. He found some cocaine, used, and later felt guilty and hopeless, which started the vicious cycle anew.

Case Conceptualization

There are four main components to the cognitive conceptualization of the substance abuser:

1. Relevant childhood data,
2. Dysfunctional core beliefs,
3. Conditional assumptions, and
4. Compensatory strategies.

With regard to relevant childhood data, therapists try to ascertain the early childhood experiences that contributed to the development and maintenance of general dysfunctional core beliefs. These core beliefs are the most central beliefs about how patients view themselves, generally falling into two categories: believing that one is *unlovable* or *incapable.* Conditional assumptions are implicit rules that patients attempt to follow in order to thrive or avoid harm. They can be in the form of a positive assumption, such as "If I gain control, then I will feel effective," or a negative counterpart: "If I do not do things perfectly, then I am inferior." Compensatory strategies are those behaviors that help patients to cope (albeit temporarily and ineffectively) with the core belief (e.g., avoiding tasks that they feel they cannot do perfectly or using drugs that make them feel effective and confident).

The case of Mr. C. illustrates these concepts. Mr. C. grew up in a very unpredictable family. His father was a heavy drinker who often acted impulsively and was emotionally abusive. He often would humiliate Mr. C. in public, making comments about how stupid he was and jokingly saying his son was adopted. The two core beliefs that the

authors hypothesize developed as a result of these early childhood experiences were, "I am inadequate and powerless" and, "I am unwanted and undesirable." Mr. C. developed a series of conditional assumptions that stemmed from these core beliefs, including:

- "If I am in control, then I will feel adequate."
- "If I do things perfectly, then people will like me."
- "If people show their emotions, then they are out of control, and they will be rejected by others."

In order to cope with his core beliefs, Mr. C. developed certain compensatory strategies, one being to avoid showing others how he really felt. That is, if he realized that he was going into a situation in which he might become extremely anxious, his tendency was to avoid the situation. He also developed an all-or-none style of handling tasks. If he could not do what he considered perfect work, he tended to procrastinate or avoid it altogether. Another compensatory strategy was to drink and use cocaine. When using cocaine and alcohol, Mr. C. tended to feel more powerful and more popular with others. He felt more in control when using and believed that everything was going perfectly and that people would like him.

Modifying Beliefs in Therapy

An important goal of cognitive therapy of substance abuse is to identify and modify drug-related dysfunctional beliefs, replacing them with more adaptive, functional beliefs. At the very least, the therapist attempts to teach the patient to build functional beliefs that become more *salient* than the drug-related beliefs. The ideal result is that the patient will abstain from drug use.

In order to modify drug-related beliefs, the cognitive therapist must have an accurate understanding of the role of such beliefs in the patient's life. Thus, a careful assessment of beliefs must be undertaken for each patient. In the assessment, the therapist collects data about the patient's beliefs using two vehicles: therapist-patient interactions during psychotherapy sessions and belief questionnaires.

During the therapy session, some basic tasks are important for the therapist to collect raw data and maintain a collaborative relationship with the patient. The most important of these tasks is the therapist's use of open-ended questions and probing. This strategy facilitates an examination of the structure and content of the patient's beliefs. Some examples of open-ended questions are the following: "What are your thoughts about that?" "How do you explain your reactions?" "How do you interpret what happened?" "What does that mean to you?"

As the patient responds to these questions, the therapist reflects what the patient has said, with particular emphasis on beliefs expressed by the patient. At various points in the interview, the therapist provides a summary of what has been discussed, again with strong emphasis placed on the patient's beliefs. This technique is illustrated in the following example. Mr. C. reported that during the week he was feeling extremely angry and anxious. The therapist then asked him to describe the specific situation. He reported that while at a party he saw other people using cocaine, and he started having urges to use again. The therapist then asked, "What thoughts were going through your mind then?" Mr. C. recalled, "They can use and I cannot. I will never be able to use again." The therapist said, "Let us assume for the moment that these thoughts are accurate. What about them is important? What is the meaning to you?" Mr. C. replied, "It means that I will always be this way" (angry and anxious). The therapist once again asked, "And what is the meaning of that to you? How does that impact on you?" Mr. C. replied, "I will always have these urges and feel anxious." The therapist asked, "And how does that impact on you?" Mr. C. replied, "It makes me feel helpless." Two important beliefs were uncovered in this brief interchange: "I will always have these urges and feel anxious," and, "I feel helpless about this."

In addition to the interview process, several questionnaires are available to collect data about an individual's beliefs. Some are designated to evaluate more general beliefs, such as the Dysfunctional Attitude Scale (Weissman and Beck 1978), while others are designed specifically to assess drug-related beliefs. This chapter will focus on those scales that are used specifically to assess the drug-related beliefs. The following are scales that can be used in making this assessment: the Beliefs About Substance Use (figure 2), the Craving Belief

Listed below are some common beliefs about drug use. Please read each statement and rate how much you agree or disagree with each one.

1	2	3	4	5	6	7
Totally Disagree	Disagree Very Much	Disagree Slightly	Neutral	Agree Slightly	Agree Very Much	Totally Agree

____ 1. Life without using is boring.

____ 2. Using is the only way to increase my creativity and productivity.

____ 3. I cannot function without it.

____ 4. This is the only way to cope with pain in my life.

____ 5. I am not ready to stop using.

FIGURE 2. *Beliefs about substance abuse: Sample of Items*

Questionnaire-CQ (figure 3), and the Relapse Prediction Scale (figure 4). These instruments are given to the patient at the beginning of therapy to provide baseline information. They also are completed at subsequent visits to assess changes that may occur as therapy progresses. During the therapy process, these questionnaires help therapists to understand the patient's beliefs as they relate to target areas for intervention. For example, during his initial visit, Mr. C. endorsed strongly the following statements on the Beliefs About Substance Use Questionnaire:

- "Life without using is boring."
- "My life will not get any better even if I stop using."
- "The urges and cravings will not go away unless I use drugs."

These responses give the therapist important information regarding target areas for intervention. They allow the therapist to quickly conceptualize some of the patient's problems and to target certain beliefs that will need to be modified.

On the Craving Belief Questionnaire, Mr. C. endorsed the following statements:

- "Since I will have cravings the rest of my life, I might as well go ahead and use cocaine."

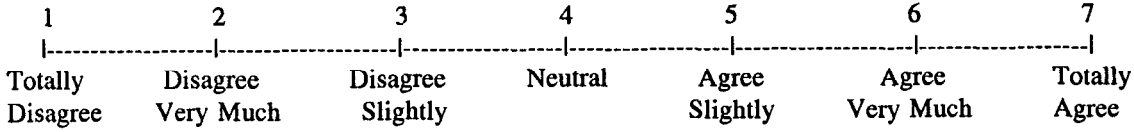
- "If the craving gets too intense, cocaine is the only way to cope with the feelings."

- "The craving makes me use cocaine."

Early in therapy, the therapist has been able to identify important drug-related beliefs that are maintaining the patient's drug use or making the patient vulnerable to a lapse or relapse.

On the Relapse Prediction Scale, Mr. C. endorsed items that clearly identify certain high-risk circumstances for him. For example, he stated that the likelihood of using again would be strong in the following circumstances:

- "I am having a drink."



____ 1. The craving is totally out of my control.

____ 2. The craving is a physical reaction, therefore, I cannot do anything about it.

____ 3. If I do not stop the cravings they will get worse.

____ 4. Craving can drive you crazy.

____ 5. The craving makes me use cocaine.

FIGURE 3. *Craving Belief Questionnaire (CQ): Sample of Ideas*

As you know, there are many situations that can trigger an urge to use cocaine or crack. This scale has *two parts:* (1) to determine *how strong you think* the urges will be in certain situations and (2) what is the *likelihood of your using* in these situations.

0	1	2	3	4
None	Weak	Moderate	Strong	Very Strong

	PREDICTION	
	Strength of Urges	Likelihood of Using
1. I am in a place where I used cocaine or crack before.	_____	_____
2. Around people with whom I have previously used cocaine or crack.	_____	_____
3. I just got paid.	_____	_____
4. I see co-workers using.	_____	_____
5. I am leaving work.	_____	_____

FIGURE 4. *Relapse Predication Scale: Sample of Items*

- "I am around people with whom I previously used cocaine and crack."

- "I feel bored."

As can be seen from this list of situations, the Relapse Prediction Scale allows the therapist to target certain vulnerable circumstances very quickly. This information allows the therapist to suggest prompt coping interventions early in treatment to reduce the likelihood of a lapse or relapse.

Orienting the Drug-Abusing Patient to the Cognitive Therapy Model

Most drug abusers have an external view of their problem. They may believe, for example, that, "Under my current circumstance, I have no control whatsoever," or, "I just need to submit myself to the doctors and they will cure me." Thus, it is important that patients be oriented to the cognitive therapy model in the initial stages of therapy. Orienting the patients involves modifying their beliefs about control from an externalized orientation (e.g., "Control is beyond me") to a more internalized control orientation such as, "I can expect some control over myself and my drug use." As part of the process of orienting the patient, key terms are defined, including drug-related beliefs, adaptive beliefs, automatic thoughts, external/internal circumstances, lapse, and relapse.

The interrelationship between these phenomena is explained with emphasis on the role of beliefs in drug use. The actual process of orienting the patient to the cognitive therapy model varies from person to person depending on each individual's aptitude for self-examination. For example, a psychologically minded individual might easily accept the idea that thoughts and feelings are important and worthy of examination. With such an individual, it might be relatively easy to explain the cognitive therapy model using diagrams, drawings, and analogies. On the other hand, some patients will be more concrete in their cognitive style, requiring repeated use of simple examples. Regardless of the process used, the primary goal of orienting the patient to the cognitive therapy model is to begin modifying

dysfunctional beliefs, with particular importance being placed on dysfunctional drug-related beliefs.

An essential part of this orientation involves helping the patient to understand how beliefs can develop and change over time. The development of various types of beliefs is illustrated in the following case. Mr. C. had the initial belief that he could not become addicted to cocaine. He felt that he had complete control and that he could be a recreational user. Initially, he used cocaine only in social situations. Later, he developed a belief that he could work better using cocaine and that the drug gave him more energy and made him more creative. This, in turn, led to the use of cocaine prior to going to work and especially when he was under pressure to meet deadlines. It is interesting to note that Mr. C. had the illusion that he was more productive at work when using cocaine, when, in fact, the objective data indicated that he became *less* productive because of missed days from work following weekend binges. Later, when he tried to stop using and he began to experience stronger urges and cravings, Mr. C.'s beliefs became focused on the cravings themselves. Some of these beliefs were: "I cannot stand the cravings." "The feelings will not go away." "The cravings make me use." Later, when his life appeared to be falling apart, he was in debt, and his wife was considering leaving him, he developed the belief that his problems would still be just as awful even if he stopped using cocaine.

As shown in the above illustration, Mr. C. had a series of beliefs that developed over time that lead to his feeling hopeless about his situation and facilitated his increased use of cocaine.

Examining and Testing Beliefs

Generally, beliefs develop over an extended period of time. As a result, they become overlearned and extremely resistant to change (Beck et al. 1990*b*; Young 1990). The drug abuser collects data supporting beliefs such as "Drugs are fun and very exciting," "Cocaine greatly enhances sex and many other activities," "Nothing is quite like using cocaine," and so forth. Many substance abusers have spent years rejecting more functional beliefs such as "Drugs are harmful." Though many patients have tried to quit using drugs, their

difficulty in doing so provides them with apparent validation for beliefs such as "I am not in control of my problem" or "I am helpless."

Given the resistant nature of drug-related beliefs, the process of modifying them requires much diligent therapeutic work. After the therapist has assessed the patient's beliefs and oriented the patient to the cognitive therapy model, an examination and testing of beliefs should begin. Examining drug-related beliefs involves asking patients probing questions that lead to closer scrutiny of these beliefs. This process is known as the Socratic method, or guided discovery. The following are some examples of questions appropriate for this process:

- "What is your evidence for that belief?"
- "How do you know the belief is true?"
- "Where did you learn that?"
- "How strongly do you believe that?"
- "How likely is it that your belief is true?"

The primary goal of Socratic questioning is to heighten the patient's awareness of his or her functioning. As the patient considers the therapist's questions, drug-related beliefs should begin to "loosen;" that is, he or she should begin to understand that these beliefs are biased and there is a possibility that they are incorrect and self-defeating.

Mr. C. had developed the belief that urges and cravings made him use. However, through questioning, the therapist was able to help him examine this belief. One of the key questions in helping Mr. C. to modify this belief was, "What is the *evidence* against the idea that cravings *make* you use?" Upon reflection, Mr. C. realized that he did not always use when he had urges and cravings. Nevertheless, he had the illusion that every time he had an urge he gave into it. The therapist instructed the patient to list recollections of times when he had had strong urges and cravings to use cocaine but in fact did not use. Reviewing this evidence helped to undermine Mr. C.'s very strong belief that the urges and cravings made him use.

Development of Adaptive Beliefs

The therapist's use of the Socratic method stimulates patients to examine their drug-related beliefs, to modify them, and ultimately to

replace them with more adaptive beliefs. For example, Mr. C. had the belief that "There is only one way for me to have fun–to use drugs." First, the therapist asked him to list those activities that he enjoyed before getting hooked on drugs. Mr. C. listed playing tennis, biking, and going out to dinner with his wife, among others. The therapist then asked Mr. C., "On a scale of 1 to 10, how much pleasure would you get out of playing tennis now?" He replied, "Probably a 2." The therapist then asked Mr. C., "For homework, would you go play a game of tennis and then rate on a 1-to-10 scale how much you enjoyed it?" He agreed to do it. At the next therapy session, Mr. C. reported that he did the homework and, to his surprise, he actually scored a 9, which would indicate that he had had a good time.

This experiment helped to chip away at Mr. C.'s belief that "There is only one way for me to have fun–to use drugs." Mr. C. experimented with other pleasurable activities, and eventually the aforementioned dysfunctional belief became very weak. A new belief began to emerge: "Besides doing drugs, there are many different things that I enjoy."

Another strategy for examining and testing drug-related beliefs and developing adaptive beliefs is the use of the daily thought record (DTR). The DTR is a structured form for listing and modifying distorted thoughts. Specifically, the DTR has four columns containing the following categories: situation, emotion(s), automatic thought(s), and rational response. An example of a completed DTR appears in figure 5.

For example, when patients experience urges or cravings, they write in the situation column the triggering event. In the next column, they list the feeling they are having. The automatic thoughts section is where they write spontaneous negative thoughts and images associated with how they are feeling. Alternative adaptive responses are written in the rational response section.

This is illustrated by Mr. C.'s DTR (see figure 5). Under the column entitled "situation," Mr. C. described how he was sitting at home, he recently had had an accident, his hand was broken, and he had plenty of money in his pocket. Under "emotions" he wrote, "Bored." Under the "automatic thoughts" column, he had listed the following: "There

DAILY THOUGHT RECORD (DTR)

SITUATION	EMOTION(S)	AUTOMATIC THOUGHT(S)	RATIONAL RESPONSE
Sitting at home; hand broken due to recent accident; plenty of money in my pocket.	Bored	There is nothing to do. I cannot stand the boredom. Therapy is not doing me any good. I need a hit to cool down.	I have tolerated boredom in the past, the same way I have tolerated other feelings. Them are plenty of things to do such as going to an AA meeting.

FIGURE 5. *Daily Thought Record (DTR)*

is nothing to do," "I cannot stand the boredom," "Therapy is not doing me any good." and "I need a hit to cool down." The therapist taught Mr. C. to examine these automatic thoughts by asking himself the following questions:

- "What is the evidence for and against my automatic thoughts?"
- "What are some other ways to look at this situation?"
- "What are the realistic consequences?"
- "What are the disadvantages of my continuing to say this to myself?"

  "What constructive action can I take?"

Mr. C. began by examining the thought "There is nothing to do" by asking himself, "What is the evidence that there is nothing to do?" He responded by saying, "There is *no* evidence that there is *nothing* to do. Actually, there are plenty of things I can do; for example, I can go to an Alcoholics Anonymous (AA) meeting or just get out of the house and take a walk."

Next he asked himself, "Is there another way of looking at this? Do I really mean that there is nothing to do?" His response to this was, "No, it is not true that there is nothing to do, but experiencing pain and boredom makes it difficult for me to see other things that I might be able to do."

He then asked himseIf, "What are the realistic consequences if it is true that there is nothing to do?" He responded, "Well, if it is true that there is nothing to do, then the consequences are that I feel bored and, although I do not like being bored, it is not the end of the world. The consequences are that I will feel bored, but eventually it will go away."

Mr. C.'s fourth question was, "What are the disadvantages of my continuing to say this to myself?" He responded, "The disadvantage is that I will feel helpless, which in turn will lead to the desire for cocaine." By examining these thoughts, he was able to produce adaptive rational responses, such as "I have tolerated boredom in the

past in the same way that I have tolerated other feelings. There are plenty of things to do, such as going to an AA meeting." These responses represented Mr. C.'s early development of new, more adaptive beliefs.

The final question ("What constructive action can I take?") led Mr. C. to consider what he could do to feel better without resorting to drugs. He decided that he would begin to make a schedule for himself in preparation for a return to work following the healing of his hand. This activity made Mr. C. focus on his abilities and goals, *not* his helplessness, and his concomitant drug urges diminished. Later, the therapist was able to help Mr. C. examine the remaining automatic thoughts and to come up with adaptive responses to those as well.

Another strategy for developing adaptive beliefs is the advantage/disadvantage analysis. People use drugs partly because they view the advantages of doing so as outweighing the disadvantages. Thus, the purpose of the advantage/disadvantage analysis is to direct the patient's attention to the disadvantages of using cocaine and the advantages of abstaining. The patient is taught to construct a 2x2 matrix where the advantages and disadvantages of using and not using are listed and explored (figure 6).

Mr. C. listed the following advantages for using cocaine:

- "I feel like a superman."
- "It takes away my shyness and insecurity."
- "I feel like king of the mountain."

Under the disadvantages for using cocaine, he listed the following:

- "I feel paranoid."
- "I have a terrible relationship with my wife."
- "I feel physically bad."

Similar work was done to generate lists of advantages and disadvantages for not using. The result was that Mr. C. learned that there were compelling reasons to remain abstinent and that his reasons

ADVANTAGE/DISADVANTAGE ANALYSIS

Advantages for Using:	**Disadvantages for Using:**
1. "I feel like a superman." 2. "I takes away my shyness and insecurity." 3. "I fell like king of the mountain."	1. "I feel paranoid." 2. "I have a terrible relationship with my wife." 3. "I feel physically bad."
Advantages for Not Using:	**Disadvantages for Not Using:**
1. "I save money." 2. "I do not have to lie to my family." 3. "I will feel physically great."	1. "I will be lonely." 2. "I will not do as well sexually." 3. "I will lose friends."

FIGURE 6. *Advantage/disadvantage analysis*

for using were based on falsehoods, rationalizations, and a preoccupation with an immediate sense of power.

Practice In Activating Adaptive Beliefs

Upon completion of some of the above exercises, such as the DTR and the advantage/disadvantage analysis, the patient is much more attentive to the disadvantages of using drugs. Furthermore, the patient is better able to successfully develop beliefs for resisting future drug use. However, the patient frequently has trouble accessing these beliefs when faced with the temptation. Hence, special attention must be paid to the deliberate activation of adaptive beliefs as part of therapy. There are several methods which serve this purpose. One method involves the use of flashcards.

After the patient has formulated an adaptive belief, flashcards can be used to reinforce and activate the newly developed belief. For example, upon completing the advantage/disadvantage analysis, the patient writes the advantages for not using on one or more 3"x5" index cards. In the case of Mr. C., he wrote, “I feel more secure and less paranoid when I do not use. I get along much better with my wife when I do not use. I feel physically great in the long run when I do not use.” He then read and repeated this card whenever he felt an urge to use, which focused his attention on the importance of abstinence.

Homework

Homework involves applying the skills learned in the therapy session to everyday life. Thus, homework is a vital extension of therapy (Persons et al. 1988; Primakoff et al. 1986). As a result of repeated use of homework in cognitive therapy, patients learn to use probing questions spontaneously in their lives, such as “What evidence do I have for this belief?” or “How else can I look at the situation?” or “What are the consequences of my beliefs?” Homework is an opportunity to practice applying adaptive beliefs in the real world (Newman and Haaga, in press). Patients practice activating adaptive beliefs in the face of tempting high-risk stimuli, since they inevitably will be confronted with such stimuli in life outside of therapy.

Homework also may involve testing drug-related beliefs to re-evaluate their validity, such as the belief that the only way to have fun is to use drugs. In the case of Mr. C., this belief was re-evaluated by getting him to try alternative, nondrug, pleasure-seeking activities.

Homework is assigned at the end of each session and is reviewed at the beginning of each following session. Initially, homework is quite structured. For example, many new patients are instructed to complete DTRs on a daily basis. Later, however, homework can be less formal and more creative as the patient demonstrates skill in applying adaptive patterns of thinking and action.

SUMMARY

In this chapter, the authors assert that drug-related *beliefs* are an important factor in drug abuse and its treatment. Three types of acute drug-related beliefs have been described that contribute to urges, cravings, and ultimate use of drugs: anticipatory beliefs, relief-oriented beliefs, and permissive beliefs, and various ways have been described to assess more general, long-term beliefs pertinent to drug use. The role of the cognitive therapist is to assess, examine, and test these beliefs with the patient in order to ultimately develop more adaptive beliefs. The active application of skills and homework that tap into the patient's adaptive beliefs helps the patient to become and remain drug-free.

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Harm Reduction: Application to Alcohol Abuse Problems

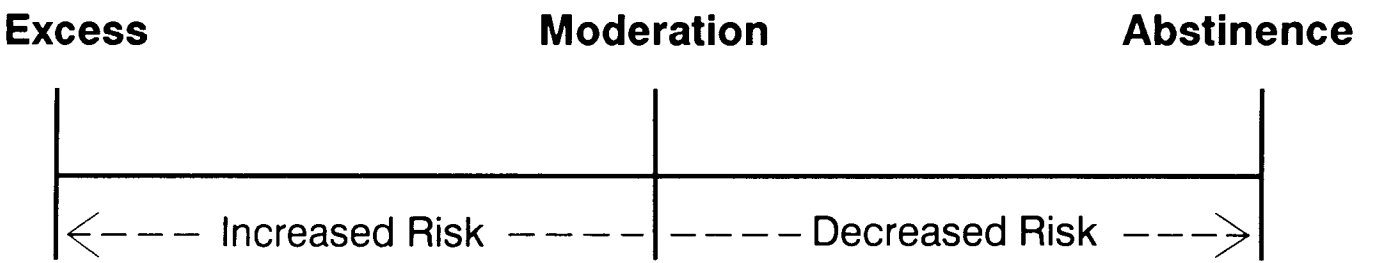
G. Alan Marlatt, Julian M. Somers, and Susan F. Tapert

> "Habit is habit and not to be flung out of the window by any man, but coaxed downstairs a step at a time."
>
> Mark Twain (Pudd'nhead Wilson's Calendar, chapter 6)

DEFINITIONS AND OVERVIEW

The terms "harm reduction," "harm minimization," and "risk reduction" often are used interchangeably in the addictive behaviors literature (Heather et al. 1993; O'Hare et al. 1992). Although they refer to the same general approach or model, Europeans (particularly the Dutch) call it "harm reduction," the British refer to "harm minimization," and Americans are more likely to prefer the term "risk reduction." In this chapter, harm reduction is defined as the application of methods designed to reduce the harm (and risk of harm) associated with ongoing or active addictive behaviors.

Harm reduction methods are based on the assumption that habits can be placed along a continuum ranging from temperate to intemperate use along with associated risks for harm (Marlatt and Tapert 1993). Figure 1 represents this continuum; the left side represents excess, the middle part is moderation, and at the farthest point to the right is abstinence. The risk of harm increases to the left and decreases to the right along this continuum. The goal of harm reduction programs is to move the individual with excessive behavior problems from left to right-to begin to take steps in the right direction to reduce the harmful consequences of the habit. It is important to note that this continuum model accepts abstinence as the ultimate risk-reduction goal. With the exception of eating habits, abstinence greatly reduces or entirely eliminates the risk of harm from most excessive behaviors.



"Any steps toward decreased risk are steps in the right direction."

FIGURE 1. *Continuum of excess, moderation, and abstinence*

But the harm reduction model promotes any movement in the right direction along this continuum as progress, even if total abstinence is not attained.

Below are, in the authors' view, some of the emerging themes that underlie current developments in the field of harm reduction.

1. Harm reduction is broad based and inclusive. As an approach to considering drug policy, harm reduction encourages the widest view possible of the varieties of harm associated with drug use and of ways to reduce this harm. As a function of this broad-based view, harm reduction provides a conceptual umbrella that integrates a variety of previously unrelated programs and techniques, including needle-exchange programs for injection drug users (IDUs), methadone maintenance treatment for opiate users, nicotine replacement therapy for smokers, and moderation-oriented drinking programs for problem drinkers.

2. Harm reduction tends to normalize rather than marginalize substance users. The harm related to substance use itself often can be wrenching for the users, their friends and family, and for the society to which they belong. However, the response to an individual's substance use can do much to either exacerbate or mitigate this harm. Harm reduction approaches acknowledge that, although it is difficult to eliminate the harm directly related to substance use, much can be done to eliminate the iatrogenic effects of interventions while enhancing opportunities for care. Within the normalization perspective,

   > . . . drug takers or even addicts should neither be seen as criminals, nor as dependent patients, but as "normal" citizens of whom we make "normal" demands and to whom we offer "normal" opportunities. Addicts should not be treated as a special category. (Engelsman 1989, p. 215)

   In this view, attention is focused on reducing the harmful or risky consequences of drug use rather than reducing drug use per se. Drug treatment programs that have "low-threshold" access to care illustrate this approach. Such programs attempt to address the health and social well-being of drug users without making these

services contingent on a commitment to change on the part of the user. Low-threshold programs make every possible attempt to include the needs of drug users within the broader context of health care and social services. For example, outreach workers in Amsterdam deliver a variety of health-related services and information to drug users in their communities. These and other projects "are not primarily intended to end addiction as such, but to improve addicts' physical and social well-being and to help them to function in society" (Engelsman 1989, p. 216).

3. Harm reduction places substance use on a continuum, relating levels of use to the severity of problems they engender for each individual. In this view, reductions in harm can be achieved incrementally. Although abstinence from drug use may be viewed as the ultimate objective, significant reductions in personal and societal harmfulness can be achieved en route to this goal. As explained by Allan Parry, a leader of harm reduction approaches to drug addiction and Acquired Immune Deficiency Syndrome (AIDS) prevention in Liverpool, England:

> Harm reduction takes small steps to reduce, even to a small degree, the harm caused by the use of drugs. If a person is injecting street heroin of unknown potency, harm reduction would consider it an advance if the addict were prescribed safe, legal heroin. A further advantage if he stopped sharing needles. A further advance if he enrolled in a needle-exchange scheme. A much further advance if he moved on to oral drugs or to smoked drugs. A further advance in harm reduction if he started using condoms and practicing safe sex practices. A further advance if he took advantage of the general health services available to addicts. A wonderful victory if he kicked drugs, although total victory is not a requirement as it is in the United States. (Parry 1989, p. 13)

4. Harm reduction deemphasizes the use of absolute restrictions on drug use as the primary means of reducing substance use problems. Many drug policy initiatives propose quantitative goals concerning substance use such as zero tolerance. Regarding alcohol, an often acrimonious debate has centered on whether the quantitative goal

for problem drinkers should be abstinence in all cases or whether moderate alcohol consumption is a viable option for this population. These policies and debates implicitly associate any use with abuse and fail to discriminate between the different degrees of harm associated with different levels of substance use. Adding further complexity to this equation are recent empirical studies that report good, if not superior, levels of adjustment among individuals who have experimented with drugs moderately compared with abstainers or drug abusers (e.g., Shedler and Block 1990). By avoiding quantitative prescriptions for change, harm reduction approaches can support any increment of change to reduce harmfulness. Also, because any degree of positive change is encouraged, harm reduction reduces the possibility of negative reactivity by individuals if a quantitative goal such as abstinence is not achieved or maintained.

HARM REDUCTION METHODS AND AREAS OF APPLICATION

Harm reduction methods can be employed in tenns of three main areas of application: (1) AIDS prevention (e.g., safe sex and condom use programs or needle exchange for IDUs); (2) treatment of ongoing, active addictive behaviors (e.g., methadone maintenance for opiate addiction or nicotine replacement therapy for tobacco smokers); and (3) secondary prevention of harmful addictive or excessive behaviors (e.g., controlled drinking or moderation of excessive food intake). Examples of each of these areas are provided below, followed by a summary of the harm reduction methods involved.

AIDS Prevention

AIDS prevention is one of the most critical examples of harm reduction (Sorenson et al. 1991). Public health officials around the world are acknowledging that the crisis of AIDS is more pressing than the threat of drug addiction or premarital sex, and several harm reduction measures can be taken to reduce the spread of Human Immunodeficiency Virus (HIV), including needle exchange, methadone maintenance treatment programs, and educational prevention programs. Harm reduction approaches offer at-risk populations simple behavior

changes that reduce the harm of high-risk activities, often with abstinence as the end point, but accepting that abstinence is not a realistic goal for all people. As relapse is common, people need skills to prevent harm if a relapse should occur. Harm reduction approaches work to empower rather than marginalize high-risk groups.

Open sex education is an often-controversial form of harm reduction. Sex education for students in primary and secondary schools has long been a topic of controversy. The nature of HIV transmission requires explicit sex education to inform young people, who may or may not be sexually active, how HIV is transmitted and how they can protect themselves and others. Sex education that deals with socioenvironmental influences on behavior (Walter et al. 1991), ideally accompanied by condom distribution, has been suggested as a major prevention effort for underage students. However, many school administrators advocate abstinence from sex despite the fact that more adolescents report having had sex and having had more partners than 10 years ago (Anderson et al. 1990). A 1989 national survey of 9th through 12th graders found that 58.5 percent reported having had sexual intercourse (Anderson et al. 1990). A recent national high school sample found that 2.7 percent reported having ever injected illicit drugs. Students who reported having learned about HIV in school were significantly less likely to report having ever injected drugs and having ever shared needles, reported fewer sexual partners, and were more likely to use condoms (Holtzman et al. 1991). Approximately 19.5 percent of U.S. AIDS cases to date were diagnosed in the 20- to 29-year age bracket, and many of these may have contracted HIV during their teenage years (Centers for Disease Control 1992). The spread of HIV could be stemmed by open sex education and HIV prevention programs that do not encourage sexual activity but acknowledge its presence among people of all ages while providing useful information and skills along with the tools necessary to have safe sex (condoms).

Treatment of Ongoing Addictive Behaviors

Harm reduction methods can be applied to the treatment of addiction problems in addition to AIDS prevention. Nonabstinent goals to reduce risk of harm include: (a) changing the route of drug administration, (b) providing alternative, "safer" substances, and (c)

reducing the frequency or intensity (quantity and dose level) or both of ongoing addictive behaviors. Although space does not permit a full discussion of each of these goals, a brief description of some examples may help clarify these methods.

In the first example, the goal is to reduce the harm of ongoing addictive behavior by changing the route of administration of the substance or drug. In AIDS prevention, needle exchange is the most obvious example: clean needles and syringes are used to administer injection drugs in place of dirty or shared needles (cf. Battjes and Pickens 1988; Brettle 1991; Stimson 1989). Another example is smoking or orally consuming drugs instead of using the injection method of administration. In the Merseyside region of Northwestern England, pharmacists provide drug clinics with noninjectable drugs in the form of "reefers" (herbal or tobacco cigarettes injected with heroin, methadone, cocaine, or amphetamine). Reefers are prescribed through drug dependency units located in Liverpool and other Merseyside hospitals or in self-contained units near town centers. For those who cannot immediately give up injecting drugs, a combined injection and reefer prescription can be given. For users who are able to move toward stabilizing on oral drugs, a combined oral and reefer prescription can be used (Canadian Center on Substance Abuse 1991). The Liverpool model of harm reduction has pioneered the policy of making illicit drugs available to addicts on a controlled basis (Marks 1991).

A related treatment method for nicotine dependence is nicotine replacement therapy (Benowitz 1988). Nicotine replacement therapy changes the route of administration of nicotine from smoking to either nicotine gum or a transdermal nicotine patch. The risk of cancer associated with smoking is thereby reduced by changing the method of drug ingestion. Although this form of treatment is recommended as a method of reducing withdrawal symptoms associated with smoking cessation with the eventual goal of abstinence, some smokers may maintain ongoing use with these replacement strategies or use them as a way of reducing intake or tapering down (Gross and Stitzer 1989; Russell 1991).

A second goal of nonabstinence harm reduction methods is the provision of a safer alternative substance or drug to replace the more harmful substance. The Dutch approach to decriminalizing cannabis use is an illustration of this approach. Here the rationale is that providing "soft drugs" as a means of experimenting with intoxicating substances will prevent users from turning to substances of higher risk such as cocaine or heroin (Engelsman 1989). The same argument applies to alcohol: programs that recommend moderate consumption of beverages low in alcohol content (e.g., wine and beer) promote alternatives to the excessive use of stronger beverages (e.g., distilled spirits).

Perhaps the most widely known example of this method is methadone maintenance as an alternative to opiate injection or heroin use. Methadone reduces risks associated with illicit substance use and injection and provides a realistic option for some drug users. Many clients report preferring this form of treatment to drug-free treatments (Chaney and Roszell 1985; Mavis et al. 1991). Methadone dispensing programs utilizing contingency contracting interventions that use urinalysis to test for illicit drug use have been indicated as most successful in keeping clients from using illicit drugs (Dolan et al. 1985; Higgins et al. 1986). Positive reinforcement by increasing methadone dosages for negative urinalyses has been shown to reduce dropout rates (Stitzer et al. 1986).

Secondary Prevention and Harm Reduction

The third goal of harm reduction applies both to the secondary prevention and treatment of addictive behaviors: to reduce the frequency or intensity or both of the target behavior. Risk-reduction programs based on moderation or responsible-use principles have been applied in prevention programs geared toward alcohol use (see below). Similar principles have been applied in promoting moderate food consumption for overweight individuals or those who have binge eating problems (cf. Brownell and Foreyt 1986). In addition, sex education for AIDS prevention may focus on reducing the frequency of high-risk sexual activity (e.g., promoting monogamous sex, reducing the number of unsafe sexual episodes, or moving toward less risky forms of sex).

One of the most controversial harm-reduction strategies is controlled or moderate drinking as an alternative to abstinence for people with alcohol problems (Heather and Robertson 1983; Marlatt 1983; Marlatt et al. 1993; Sobell and Sobell 1978). In the treatment of alcohol dependence in the United States, controlled drinking programs are rarely available compared to other countries (e.g., Canada, Australia, and many European countries). The bulk of the resistance to this approach stems from abstinence advocates of the medical model, who view alcoholism as a progressive disease that cannot be cured (i.e., moderation can never be attained by "recovering" alcoholics). According to these critics, abstinence is the only acceptable goal for both treatment and prevention-no amount of moderation training can stem the tide of this insidious disease.

One of the apparent paradoxes of controlled drinking programs for problem drinkers is that many clients exposed to this approach eventually end up abstaining from alcohol (Miller et al. 1992). From the perspective of harm reduction theory, such a "paradoxical" outcome is not surprising. Problem drinkers who otherwise might resist the high-threshold commitment to abstinence as a precondition for treatment or participation in an abstinence-based self-help group may well be attracted by a moderation program instead. Once they have entered such a low-threshold program and are taking steps in the right direction, it is little wonder that many of these clients end up abstinent. Many of the skills and coping strategies employed in these cognitive-behavioral programs can be used to foster both moderation and abstinence goals (cf. Nathan and McCrady 1987). The greater the number of options available to the large mass of otherwise unreachable problem drinkers, the more people will be motivated to seek help for their drinking. Instead of requiring that clients uniformly quit in a "cold turkey" approach, harm reduction provides the client with options to taper their use gradually, to opt for a "warm turkey" alternative route to quitting (Miller and Page 1991).

ALCOHOL AND YOUTH

Within the United States, the consumption of alcohol by young people is associated with numerous health problems, including alcohol-related accidents, academic failure, vandalism, relationship difficulties, and

acquaintance rape (Institute of Medicine 1990). Alcohol-related accidents are the leading cause of death among youth (National Institute on Alcohol Abuse and Alcoholism 1984). Alcohol is also the drug of choice among American youth. While the use of most illicit drugs has declined over the past decade, self-reported alcohol consumption has remained relatively constant (Johnston et al. 1989).

Of particular concern to health officials has been the pattern of drinking among youth, which often involves large quantities of alcohol consumed relatively infrequently. A pattern of so-called binge drinking has been identified among this group. If binge drinking is defined as having five or more drinks in a row during the previous 2 weeks, it has been reported that 41 percent of America's college students and 34 percent of their noncollege counterparts engage in binge drinking (Johnston et al. 1991). Although the frequency of binge drinking appears to have decreased in individuals of college age who are not enrolled in college between 1980 and the present, the frequency of this behavior among college students has remained relatively constant (Johnston et al. 1989). Moreover, between 1977 and 1989 the proportion of college students reporting that they drink to get drunk has increased two to three times, reflected in the finding that students drank greater quantities of alcohol with greater regularity in 1989 than in 1977 (Wechsler and Isaac 1992). These trends have prompted Federal Government agencies to recommend stricter legal controls on the availability of alcohol to youth and greater enforcement of punishment for the consumption of alcohol by those under the age of 21 (Kusserow 1991). Additional programs sponsored by the Federal Government are targeted at reducing binge drinking among college students (Eigen and Quinlan 1991).

Although there is agreement among college administrators, health officials, and others that the consumption of alcohol by college students constitutes a serious problem, there is little agreement regarding what to do about substance use among young people in general. In a recent comprehensive review of the treatment and prevention literature, the Institute of Medicine reported:

> There is perhaps no special population about which so much has been written; yet, despite the more than 2,000 published papers, the common feeling among investigators in this area is

> that very little is known about how best to treat youth with alcohol and other drug problems. (Institute of Medicine 1990, p. 359)

Many existing alcohol treatment facilities for youth are modeled on adult residential programs. However, the appropriateness of these programs for young people has been challenged on a number of points (e.g., Durst 1988; Woltzen et al. 1986). Several unique characteristics of college-age drinkers have been identified (see Marlatt 1988) that may support certain styles of intervention and contraindicate others. The pattern of drinking among college students, as well as the problems that they are likely to experience, is different from those of older problem drinkers. In contrast to the classic symptoms of alcohol dependence (e.g., daily drinking and withdrawal), college students are more likely to experience more acute alcohol-related problems relating to drinking in certain times and settings (e.g., weekend parties). Most collegians will fail to identify themselves as problem drinkers, and the labeling of young persons as "alcoholic" may restrict their opportunities to mature out of heavy drinking in the modal fashion (e.g., Fillmore et al. 1979). Also, because many college drinkers are under 21 years of age, they are engaging in illegal behavior. This legal conflict has led several important national organizations to denounce "responsible drinking" as a viable objective for underage collegians. In the absence of alternative sources of information, students tend to develop their drinking habits based on the behavior of peers as well as media depictions of drinking norms.

Among the challenges faced by those working with college drinkers are: (1) how to motivate students to participate in alcohol-related programs when students do not perceive themselves to have a problem, (2) how to moderate and, in some cases, challenge the influence of peer norms and media depictions, and (3) how to accelerate rather than impede the process of maturing out of risky drinking behavior. Another difficulty faced by workers in this area arises from the illegality of underage drinking. Options for intervention are limited because of the official position that the behavior under consideration should not occur in the first place. In this view, programs that attempt to develop responsible drinking habits are seen as promoting rather than solving the problem. Similar arguments are familiar to proponents of condom distribution and needle exchange programs.

THE HIGH RISK DRINKERS PROJECT

The High Risk Drinkers Project is a campus-based program for the reduction of alcohol-related problems among members of the University of Washington community (Marlatt et al., in press). This project has applied many of the principles of harm reduction to provide an alternative to traditional services for this population. Because alcohol use is associated with normal development among students, a program was developed in which a variety of risk factors and problems are assessed but labels such as "problem drinking" or "alcoholic" are avoided. As in other harm reduction approaches, this program attempts to place both alcohol-related problems and varieties of interventions on a continuum. Attempts are made to match individuals to levels of care based on the extent of their alcohol-related problems and, significantly, their willingness to receive any form of help or treatment.

In order to test the efficacy of this approach, a longitudinal study was conducted involving more than 400 students who entered the University of Washington as freshmen in 1990 (cf. Baer 1993). Students were selected from among the entire incoming class based on their reports of risky high school drinking or their experience of negative alcohol-related consequences prior to entering the university. Because the members of the sample are at increased risk for experiencing alcohol-related problems, this study is one of secondary prevention.

One of the features of many harm reduction programs is the utilization of low-threshold services. It is essential that the criteria for receiving services do not exceed the interest or commitment level of potential recipients. In this sample, few students would identify themselves as candidates for any form of treatment. In order to encourage students to participate in the program, the authors have developed a user-friendly stepped-care approach that is modeled after existing therapeutic practices for hypertension (see Sobell and Sobell 1993). The first step of the program consists of a single hour in which each subject meets with a member of the staff to receive feedback concerning his or her drinking risks and to review practices for reducing harm. Previous research has shown that brief interventions can have a significant and enduring impact on drinking habits (Baer et

al. 1992). Subsequent levels of care are available to subjects if the initial intervention is not sufficiently effective.

The therapeutic style is based largely on the principles of motivational interviewing (Miller and Rollnick 1991). This technique is designed to cultivate and strengthen an individual's level of commitment to change. Consistent with Prochaska and DiClemente's (1982) model of the stages of behavior change, the motivational interviewer's task is to help an individual advance from considering change to attempting change. Prochaska and DiClemente (1982) describe several levels of preparedness for change that individuals may pass through: precontemplation, in which change is not being considered; contemplation, in which the idea of changing emerges; action, in which some attempt to change is made; maintenance, in which successful actions are maintained; and relapse, in which the previous undesired behavior reemerges. Consistent with harm reduction, any movement toward taking and maintaining action is viewed positively.

Preliminary results of this ongoing project indicate that students assigned to the stepped-care program reported significantly lower levels of drinking after 2 years than students in a randomly assigned comparison group (Marlatt et al., in press). A measure of alcohol-related problems (the Rutgers Alcohol Problem Index; White and Labouvie 1989) recorded a similar decline among students receiving this intervention versus a comparison group.

Consistent with the above mentioned motivational orientation, a considerable part of clinical attention goes toward maintaining good rapport with the subjects. If an individual continues to report risky drinking practices or negative consequences of alcohol use subsequent to the initial interview, the student is advised and an attempt is made to engage the individual in a discussion of what might be the best course of action to take. A range of options is presented, but the decision to undertake any action is left to the student. This clinical style is informed by a body of research in the addictions field that underscores the importance of commitment to change as a contributor to the ultimate success of any program (Hall et al. 1990, 1991).

Certain parallels may be evident between this secondary prevention program, programs such as needle exchange to prevent the spread of

HIV, and tertiary prevention programs such as the mobile methadone clinics in Amsterdam. In each case, the program makes an attempt to enter the lives of the persons who might benefit from its services. The practitioners of these programs, like therapists of many schools, are advocates for the individuals they serve. Services and information are made available but are not forced on people.

For example, the workers who staff Amsterdam's mobile methadone clinics become personally familiar with many of the addicts that they serve and offer encouragement for change in addition to multiple services such as exchanging needles, administering oral doses of methadone, and providing condoms and first aid supplies. A great benefit of this approach is that a large proportion of the target population is in contact with some form of health promotion agency (Marlatt and Tapert 1993). In Amsterdam, it is estimated that 60 to 80 percent of IDUs are in contact with health agencies (Engelsman 1989, p. 217). This proximity greatly enhances the opportunities for care that may be administered. It also illustrates a type of societal response to drug-related problems that avoids alienating individuals by identifying them as either sick or criminal, but seeing them instead as people who are part of society and who need help.

HARM REDUCTION AND AMERICAN DRUG POLICIES

In 1992, the United States budgeted $11,680 million for Federal drug programs, 70 percent of which was allotted to interdiction and law enforcement and 30 percent of which went toward education and treatment programs. This division of resources will do little to reduce the numerous impediments to treatment for addicts and IDUs in the United States. More than 107,000 individuals were on waiting lists for treatment in 1991 (National Commission on AIDS 1991), but there are vastly more individuals who might benefit from some care. New York City has an estimated 200,000 IDUs but only 38,000 publicly funded treatment positions. Inadequate funding is only one of the factors that limits access to proper health care for drug users: needle exchange programs remain illegal in many cities and States; most treatment programs require abstinence as a condition of admission or continuation of services; the most widely available forms of treatment in the United States tend to incorporate disease model concepts or

involve submission to a "higher power," which many individuals find personally objectionable; and the threat of arrest and possible imprisonment for use deters many (e.g., pregnant females who may fear prosecution for child abuse). In contrast to low-threshold policies advocated under harm reduction. U.S. drug policy sets a very high threshold on drug-related services.

Beyond the harm that is done by underfunding treatment and educational programs, it is apparent that considerable harm is being added, rather than alleviated, by spending vast sums on interdiction and law enforcement. The persecution of addicts and recreational drug users alike is exacting an inconceivably high toll and is fiscally irresponsible because prison is a tremendously expensive form of treatment that is also demonstrably ineffective.

NOTE

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Behavioral Treatments for Drug Problems: Lessons From the Alcohol Treatment Outcome Literature

William R. Miller

INTRODUCTION

There are striking parallels in the nature, etiology, and course of addictive behaviors. Alcohol, tobacco, and other drug problems overlap substantially in epidemiology, are all influenced by a combination of biomedical and psychosocial factors, involve impaired personal control, and are characterized by high rates of relapse (Brownell et al. 1986; Miller 1980). These similarities extend to a broader range of compulsive behaviors (Heather et al. 1991; Orford 1985; Peele 1985).

Yet, both treatment programs and research for alcohol versus other drug problems have developed with an astonishing degree of isolation. Although clients of the Center on Alcoholism, Substance Abuse, and Addictions are increasingly difficult to classify as alcohol versus other drug abusers and there is increasing public recognition that alcohol is a drug, there remain separate treatment systems and staffs, research institutes, and self-help organizations. Markedly different emphases have evolved for both treatment and prevention strategies. The reasons for this partition arise from historical and political events rather than from compelling differences inherent in the problems and clients.

In considering how to advance behavioral treatment for drug abuse and dependence, it may be informative to consider the state of research knowledge in treatment related to one particular drug: alcohol. Treatment research is well developed in the alcohol field; currently, more than 250 controlled trials have been published. Behavioral treatments in particular are well studied, comprising more than half of the trials to date. For several behavioral strategies, dismantling

research has been conducted to examine theoretical and practical foundations of efficacy. Alcohol treatment assessment technology has advanced substantially during the past two decades, permitting better quantification of outcomes. Further, important gains have been made in knowledge on the interaction of client and treatment characteristics ("treatment matching"), and a multisite collaborative trial on this subject is underway at the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

This chapter will summarize this broad literature on alcohol treatment outcome, emphasizing behavioral treatments. It also will highlight issues that have emerged along the way, which may be informative for research and practice in the behavioral treatment of drug problems more generally.

TREATMENT OUTCOME REVIEWS

Reviews of the alcohol treatment outcome literature have progressed through several stages. The first-generation reviews were narrative summaries of findings with some commentary on methodology (e.g., Baekeland 1977; Bowman and Jellinek 1941; Voegtlin and Lemere 1941). As studies accumulated, a second wave of reviewers attempted to derive average outcome statistics for treatment in general or for particular modalities, but these reviews remained largely narrative (Costello et al. 1977; Emrick 1974, 1975; Miller and Hester 1980).

In an attempt to discern more reliable patterns, Miller and Hester (1986*a*) provided a narrative review restricted to controlled trials-comparisons of two or more groups that were equated before treatment by randomization or matching. This review concluded that only six treatment methods were "currently supported by controlled outcome research": aversion therapies, behavioral self-control training, the community reinforcement approach, behavioral marital therapy, social skills training, and stress management. It is noteworthy that all six of these are behavior therapies. This list was contrasted with "treatment methods currently employed as standard practice in alcoholism programs": the 12-step method, alcoholism education, confrontation, disulfiram, group therapy, and individual

counseling-none of which, it was concluded, were then adequately supported as effective treatment modalities by controlled research (Miller and Hester 1986*a*, p. 162).

A subsequent review by Holder and colleagues (1991) added two dimensions. First, controlled studies pertaining to each treatment modality were classified as positive or negative trials, and a weighted evidence index (WEIn) was compiled for each modality as a kind of box score of efficacy. Second, through the polling of clinical experts, the optimal number and type of units of service required to deliver each modality were determined, and these units were costed to estimate the average cost (not price) of delivery for each modality. This permitted the construction of a grid in which treatment modalities were located in two-dimensional space according to cost category and evidence for efficacy (WEIn). The 10 modalities judged to have good or fair evidence of effectiveness included all six previously identified by Miller and Hester (1986*a*), as well as behavior contracting, brief motivational counseling, antidepressant medication, and disulfiram. A striking finding was a significant negative correlation ($r = -.385$, $p < .05$) between the cost and effectiveness of modalities. Like the National Academy of Sciences (1990), Holder and colleagues (1991) concluded that it is wrong to ask: "Is alcoholism treatment (cost-) effective?" Treatment modalities appear to differ dramatically in both cost and effectiveness, and no blanket endorsement can be given for "treatment." They recommended instead focusing on the question, "Which alcoholism treatment modalities are most effective for the least cost?" (Holder et al. 1991, p. 533)

None of these reviews took into account the methodologic quality of studies in other than a narrative way. Thus, in the Holder and colleagues (1991) analysis, a poorly designed and conducted study was given the same weight in a modality's WEIn score as a study with exemplary design and performance. Two reviews are currently underway to take this next step: one at The University of New Mexico (UNM) and one at the National Drug and Alcohol Research Centre (NDARC) in Sydney, Australia. Using different approaches, each group is classifying studies on a variety of methodologic dimensions, with plans to use these ratings to improve the interpretation of study outcomes.

The plan at UNM is to calculate cross-products of methodologic strength scores and a treatment outcome classification. A sum of these cross-products, interpreted in relation to the total volume of research conducted, will provide a more refined index of research evidence for the efficacy of each modality.

The NDARC group, under the direction of Dr. Richard Mattick, is adding another important dimension to its review: the calculation of effect sizes. This will be the first comprehensive review of outcome literature in this area to include effect sizes. Furthermore, the reviews encompass treatments for alcohol, tobacco, and other drugs.

PROMISING BEHAVIORAL STRATEGIES

From these reviews, what behavioral approaches appear to be most promising? Supported modalities can be grouped subjectively into two general strategies:

1. Treatments designed to suppress use:

    - Antidipsotropic medication with compliance contracting,
    - Aversion therapies (covert sensitization),
    - Behavior contracting,
    - Behavioral self-control training, and
    - Brief motivational counseling.

2. Methods to teach skills for successful sober living:

    - Behavioral marital therapy,
    - Community reinforcement approach,
    - Social skills training, and
    - Stress management training.

All five modalities designed to suppress use are readily applicable to other drug problems. Pharmacologic parallels to disulfiram are drug antagonists or agonist/antagonist combinations. The principal problem in the use of medications such as disulfiram and naltrexone is compliance. Various procedures have been used to increase disulfiram compliance, including behavior contracting, spouse monitoring and

encouragement, more frequent clinic visits with monitoring, and implantation (Fuller 1989). Behavior contracting more generally has been found helpful in maintaining sobriety, and it is a familiar approach in treating drug abuse.

Aversion therapies have a long and controversial history. Holder and colleagues (1991) found adequate experimental support for covert sensitization, the only form of aversion therapy that involves no physical unconditioned stimulus but is conducted in imagination. It clearly is possible to induce a conditioned aversion reaction through covert sensitization, and the establishment of conditioning has been found to be predictive of favorable outcome (Elkins 1980; Miller and Dougher 1989). More broadly, conditioning-based procedures (e.g., cue exposure) have been explored as relevant processes in treatment for alcohol and other drug problems (Greeley and Westbrook 1991).

Behavioral self-control training (BSCT) involves teaching learning-based procedures to clients to assist them in altering their own behavior. In the Holder and colleagues (1991) review, BSCT had the largest number of trials (17) and the second highest WEIn score (after social skills training) of any modality. BSCT has most often been applied with a goal of moderation of alcohol use (Hester and Miller 1989) or other drug use (Wilkinson and LeBreton 1986), but it also has been applied with a goal of abstinence (e.g., Sanchez-Craig et al. 1984). Typically, BSCT includes a combination of strategies designed to modulate use (e.g., specific goal-setting, self-monitoring, alteration of the topography of use, stimulus control, self-reinforcement, and refusal training) and methods for altering the probability of future use (e.g., functional analysis and coping skill training). Applications to other drug use are straightforward.

The success of brief counseling in altering problem drinking has been documented consistently. In a recently completed review, Bien and colleagues (in press) identified 32 controlled trials with strikingly consistent results. The methodology of these studies compares favorably with that for the alcohol field in general (mean of 13 on a composite methodologic quality scale of 0-17). Brief counseling (typically one to three sessions) has been found consistently superior to untreated controls and in 11 of 13 randomized trials has had

comparable impact to that of more extensive treatments. These brief interventions have included virtually no behavioral skill training, medication, or contracting. Their content is more cognitive-motivational (Miller and Rollnick 1991). Six elements, summarized in the acronym FRAMES, have been described as common components of effective brief interventions (Miller and Sanchez, in press):

- FEEDBACK of personal assessment results,
- Emphasis on personal RESPONSIBILITY for change,
- ADVICE to change use,
- Description of a MENU of options for change,
- Therapeutic EMPATHY as a predominant counseling style, and
- Support for client SELF-EFFICACY and optimism.

In the Holder and colleagues (1991) grid, brief motivational counseling was the only entry in the box with highest evidence of efficacy and lowest cost. Researchers at UNM have developed and tested a "Drinker's Check-up" to manifest the FRAMES elements (Miller and Sovereign 1989; Miller et al., in press) and are exploring the extension of this model to a brief intervention for other drug use.

All four effective behavioral methods that support a sober lifestyle are also readily applicable in the treatment of drug problems in general. Behavioral marital therapy teaches skills for more effective communication and positive reinforcement within intimate relationships (O'Farrell and Cowles 1989). Social skills training focuses more generally on communication skills such as assertiveness for effective social relations (Monti et al. 1986). Studies of stress management procedures in alcohol treatment have focused primarily on relaxation training and systematic desensitization, although a broader array of technologies can be applied (Stockwell and Town 1989). Azrin's community reinforcement approach, which has yielded some of the largest treatment effects in the literature, combines many of the well-supported components described above, including monitored disulfiram, behavior contracting, motivational counseling, behavioral marital therapy, social skills training, and mood management (Sisson and Azrin 1989). As with other behavioral strategies, the community reinforcement approach can be applied directly in the treatment of other drug problems (e.g., Higgins et al. 1991). Investigators at UNM currently are conducting three clinical trials of this approach with

alcoholics (R0l-AA07564), heroin addicts (R18-DA06953), and dually diagnosed homeless individuals (R0l-AA08331).

CONTRAST WITH STANDARD PRACTICE

The presence of a large body of treatment outcome research in general, and of behavioral treatment studies in particular, has had little apparent impact on standard practice. Alcoholism treatment programs continue to rely on a reasonably standard (if unspecified) melange of counseling strategies loosely derived from psychodynamic and disease model conceptions that have changed surprisingly little in 50 years (Miller, in press-*a*). Group therapy is a common program component, often emphasizing confrontation of denial, group processes, and general exploration and expression of emotions (e.g., "inner child" work)– themes frequently pursued in individual counseling as well. Educational lectures and films are likewise normative, typically teaching an attributional model that emphasizes a unitary disease that is biologically based and involves irreversible loss of control (Miller, in press-*b*). Attendance at Alcoholics Anonymous meetings is usually advocated and sometimes mandated. Various forms of relapse prevention counseling commonly are practiced (e.g., Gorski and Miller 1982). None of these components has been shown in controlled trials to contribute significantly to the improvement of treatment outcomes. Aggressive confrontational counseling tactics, in fact, appear to be associated with poorer outcomes (e.g., Miller and Rollnick 1991; Miller et al., in press) and may be particularly detrimental for individuals with low self-esteem (Annis and Chan 1983).

Counselor Behaviors

There appear to be large differences in effectiveness among counselors delivering allegedly similar treatments (e.g., McLellan et al. 1988; Miller et al. 1980). In all studies to date evaluating counselor style, a reflective, empathic, listening approach has been predictive of more favorable alcohol treatment outcomes (e.g., Miller et al. 1980, in press; Valle 1981). It is conceivable that characteristics of counselor style account for more variance in treatment retention, compliance, and outcome than declared therapeutic approach. In studying the effectiveness of behavioral treatments for drug abuse, therefore, the

influence of therapist characteristics and behavior should not be overlooked.

Client Characteristics

Client characteristics represent another determinant of treatment outcome (Moos et al. 1990). Reviewers have had little success in identifying universal prognostic characteristics of individuals in treatment for alcohol problems (e.g., Gibbs and Flanagan 1977). It is conceivable, however, that profiles of optimal responder characteristics could be identified for specific treatment modalities (Miller and Hester 1986*b*). If such responder profiles are consistent across studies, criteria can be derived for a priori matching of clients to treatment approaches. Kadden and colleagues (1989) found that behavioral skills training was more effective than interactional therapy with alcoholics higher in psychopathology in general and sociopathy in particular. Project MATCH, an NIAAA multisite collaborative trial, is comparing 12-step, cognitive-behavioral, and motivational strategies in seeking differential predictors of response. It is likely that behavioral treatments are not optimally effective for all drug abusers, but they may be for definable subgroups. Different approaches may be more effective for clients with other characteristics.

RECOMMENDATIONS FOR RESEARCH

The accumulated research on treatment for alcohol problems suggests several general recommendations for future research on treatment (including behavioral treatment) for drug abuse more generally. Treatment researchers may be able to avoid some of the same pitfalls and blind alleys by considering this large existing literature.

1. It would be sensible to adapt and replicate for treatment of other drug problems those therapeutic modalities (primarily behavioral) that have been shown to be most effective in treating alcohol problems. A half century of outcome research points to specific treatment methods that are more (and less) promising, and this knowledge can be used to guide future research and practice.

2. Paralleling the recommendations of the National Academy of Sciences (1990) with regard to alcohol problems, drug use and problems can be understood as lying along a continuum of severity. Different intervention strategies are likely to be effective at various points along that continuum. Brief cognitive-motivational interventions may be particularly cost-effective in addressing the large population of individuals with less severe drug problems and dependence.

3. The impact of treatment settings should be separated from therapeutic modalities. The alcoholism literature suggests that there is little or no overall difference in effectiveness (but substantial difference in cost) between residential/inpatient programs and outpatient/community approaches (Miller and Hester 1986*c*; U.S. Congress 1983). It remains to be determined whether particular treatment modalities are differentially effective in alternative treatment settings.

4. Clinical trials and other treatment studies should include measures of therapist behavior and treatment processes. Attrition from and effectiveness of treatment in general, and of behavioral modalities in particular, appear to be impacted substantially by the characteristics of those who deliver the therapies.

5. Relevant client characteristics also should be assessed so pretreatment markers of therapeutic response can be identified. In trials comparing different treatments, tests for interaction effects with client characteristics should be routinely explored.

6. Studies of behavioral and other treatments will advance knowledge more effectively when designed to detect the *mechanisms* of therapeutic effect. Theory-grounded treatments are hypothesized to work for particular reasons, and it is worthwhile to test whether observed relationships between independent and dependent variables are consistent with these accounts.

7. Treatment research should include procedures to measure the cost of delivering the services under study. Treatment policy can be guided by knowledge not only of the relative effectiveness of alternative strategies, but also of relative cost.

8. Given the substantial overlap between alcohol and other drug abuse in clinical populations, it would be advantageous for clinical trials in both NIDA and NIAAA to include state-of-the-art outcome measures for drug use (including alcohol use) in general Alcohol treatment research to date has been plagued by a lack of consistency in outcome measures. It would be particularly beneficial to develop consensual prototypic assessment procedures to permit comparison of outcomes across studies.

SUMMARY

Behavioral approaches have a strong track record in the treatment of alcohol problems. They are generally cost-effective (Holder et al. 1991), can be readily combined with and enhance the effectiveness of pharmacologic interventions (e.g., Azrin et al. 1982), and have been found to be applicable all along the continuum of problem severity. Cognitive-behavioral strategies appear to be particularly helpful in addressing common problems of treatment motivation, retention, and compliance. There is no reason to expect substantially different findings when behavioral strategies are applied in the treatment of other drug problems.

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Multisystemic Treatment of Serious Juvenile Offenders: Implications for the Treatment of Substance-Abusing Youths

Scott W. Henggeler

INTRODUCTION

This chapter provides an overview of the multisystemic approach to treating serious antisocial behavior in adolescents and builds a case for using multisystemic therapy (MST) (Henggeler and Borduin 1990) in the treatment of substance-abusing adolescents. As such, sections in the chapter focus on similarities between delinquency and substance use in their identified correlates, recalcitrance to treatment, and service delivery issues; results from controlled outcome studies supporting the effectiveness of MST and future directions in the validation and diffusion of MST; and an overview of clinical interventions used in MST.

DELINQUENCY AND SUBSTANCE ABUSE

Research findings within the areas of delinquency and substance abuse have at least three important commonalities. First, the identified correlates and risk factors of delinquency and substance abuse are largely the same. Second, delinquency and substance abuse have proven to be recalcitrant to treatment, with few controlled studies demonstrating that any particular treatment is superior to any alternative treatment or to no treatment. Third, the delivery of mental health services to juvenile offenders and to substance-abusing adolescents share several obstacles.

Indentified Correlate

Reviewers consistently have concluded that criminal activity in adolescents is associated with important characteristics of the individual youth, family, peer system, school system, and community (e.g., Henggeler 1989; Melton and Hargrove, in press; Quay 1987). In light of the numerous correlates of delinquency, several investigators have developed multidimensional causal models (for a review, see Henggeler 1991). In each of these models, factors from several ecological systems contributed directly or indirectly to delinquency. For example, Elliott and coworkers (1985) found that delinquency was predicted directly by previous antisocial behavior and by association with deviant peers; association with deviant peers was predicted by difficulties pertaining to the family system and the school system.

Adolescent substance abuse also has been associated with youth characteristics, family factors, peer factors, and school factors (Schinke et al. 1991), and investigators have developed multidimensional causal models examining the relations among these correlates. For example, Elliott and colleagues (1985) found results similar to those noted above when predicting substance use. Similarly, Dishion and coworkers (1988) reported that parental drug use and deviant peer influences directly predicted youths' drug use and that parental monitoring predicted association with deviant peers. Again, factors across several ecological systems contributed directly or indirectly to substance use (or abuse).

Recalcitrance to Treatment

The development of effective treatments for delinquency has been extremely problematic. In the late 1970's, for example, several reviewers of treatment outcome studies with delinquents concluded that "nothing works" (e.g., Romig 1978). More recently, reviewers (e.g., Kazdin 1987) suggested that promising new treatment strategies (e.g., cognitive behavior therapy, behavioral parent training, and functional family therapy) have emerged. Although these treatments have been moderately successful with mild forms of antisocial behavior, controlled studies have not supported their effectiveness with serious antisocial behavior (Bank et al. 1991; Guerra and Slaby 1990; Weisz et al. 1990).

Likewise, little evidence suggests that any particular treatment of adolescent substance abuse is more effective than no treatment (Beschner and Friedman 1985; Martin and Wilkinson 1989; Newcomb and Bentler 1989; Schinke et al. 1991). Although several large-scale, uncontrolled studies have documented positive changes on adolescent substance use variables (e.g., Friedman et al. 1986; Sells and Simpson 1979), the conclusion that treatment produced such changes is mitigated by design limitations inherent in such studies. Moreover, in those few studies in which random assignment to treatment conditions has been used (Lewis et al. 1990; Szapocznik et al. 1986), differential treatment effects were not observed.

Service System Issues

Difficulties in the development of effective treatments for delinquency and substance abuse are compounded by several problems in the delivery of children's mental health services. First, as numerous reviewers have noted, children's mental health services are seriously fragmented (e.g., Burns and Friedman 1990; Dougherty 1988) and lack coordination with other key service systems such as juvenile justice (Tuma 1989). Second, large gaps are evident between service needs and service system capacities (Burns and Friedman 1990; Tamowski 1991). Third, in spite of the need for services, especially among disadvantaged youths, a grossly disproportionate amount of revenue is devoted to the small percentage of youths who receive out-of-home care (Burns 1991). Fourth, expensive out-of-home treatments might be justified if they were effective. Inpatient hospitalization and residential treatment programs, however, have received virtually no support in controlled clinical trials (U.S. Congress 1991).

In light of extant problems in mental health service delivery, policy analysts have argued that the various child service systems must undergo substantive changes, at least three of which are pertinent to this chapter. First, treatment systems must recognize that children's mental health difficulties reflect interactions between individual characteristics and environmental conditions (see Saxe et al. 1988). Thus, interventions must strive for ecological validity through treating youths in the natural environment, rather than placing youths in artificial settings that are segregated from the community. Second, the emphasis on passive, office-based services that pervades most

community mental health centers rarely meets the needs of disadvantaged families with adolescents who are criminal offenders or substance abusers (Henggeler and Borduin, in press). Intensive and persistent outreach efforts are needed to engage such families in treatment. Third, the development of effective community-based programs, especially for disadvantaged minority youths, requires the reallocation of funds that currently are devoted to institutional treatment (see Burns 1991).

Implications

Findings in the delinquency and substance abuse literatures are consistent with the contention that different deviant behaviors share common influences (e.g., Donovan et al. 1988; Osgood et al. 1988). Moreover, across the delinquency and substance abuse literatures, reviewers have concluded that effective treatments should be relatively complex and should recognize the multiple determinants of deviant behaviors (e.g., Dishion et al. 1988; Henggeler 1989; Morgan et al. 1989; Mulvey et al. 1990; Rhodes and Jason 1990; Tolan 1990). Regarding the delivery of such treatments, reviewers (e.g., Burns and Friedman 1990; U.S. Congress 1991) have concluded consistently that treatments should be family focused, community based, and cost-effective. As described subsequently, MST addresses each of the aforementioned concerns. More importantly, findings from controlled clinical trials support the short-term and long-term effectiveness of MST in treating serious antisocial behavior in adolescents as well as the significant problems often experienced by their families.

OUTCOME STUDIES EVALUATING MST

Rigorous evaluation has been a cornerstone of the development of MST. Two substantive evaluations of MST with long-term followups have been completed recently, and the results from these projects are presented next. Although most earlier studies did not include such followup, findings clearly supported the promise of MST, and earlier studies also are presented briefly. In addition, projects funded by NIDA and by the National Institute of Mental Health (NIMH)

currently are evaluating issues of conceptual and practical importance to the validation of MST, and these projects are described at the conclusion of this section.

Family Preservation Using MST

In the first evaluation of MST to train therapists from an existing community mental health center in the MST model, multisystemic family preservation was examined in the treatment of serious juvenile offenders (Henggeler et al. 1992). The family preservation model of service delivery was used because of its theoretical and clinical compatibility with MST. As discussed more extensively later in the chapter, family preservation emphasizes services that are home based, family focused, pragmatic, goal oriented, and time limited (Wells and Biegel 1991). In addition, therapists are primary service providers (not brokers of services), with low caseloads and around-the-clock availability. An important goal of family preservation is to empower families and to prevent costly out-of-home placements.

Multisystemic family preservation was compared with usual services provided by the Department of Youth Services in a pretest-posttest control group design with random assignment to conditions. Participants were 84 serious juvenile offenders averaging 3.5 prior arrests and 9.5 weeks of prior incarceration. Fifty-four percent had at least one arrest for a violent crime. They were judged to be at imminent risk for out-of-home placement by probation staff. Assessment batteries were conducted pretreatment and posttreatment, and followup on recidivism and incarceration was conducted at 59 weeks postreferral.

Results supported the effectiveness of multisystemic family preservation in reducing the institutionalization of serious juvenile offenders and in attenuating their criminal activity (figure 1). At posttest, offenders in the multisystemic condition reported significantly fewer criminal acts than did their counterparts in the usual services condition. At followup, offenders in the multisystemic condition had significantly fewer rearrests and spent significantly fewer days incarcerated (an average of 73 fewer days). Moreover, MST was effective at changing key correlates of delinquency. Parent figures and youths in the multisystemic condition reported increased family

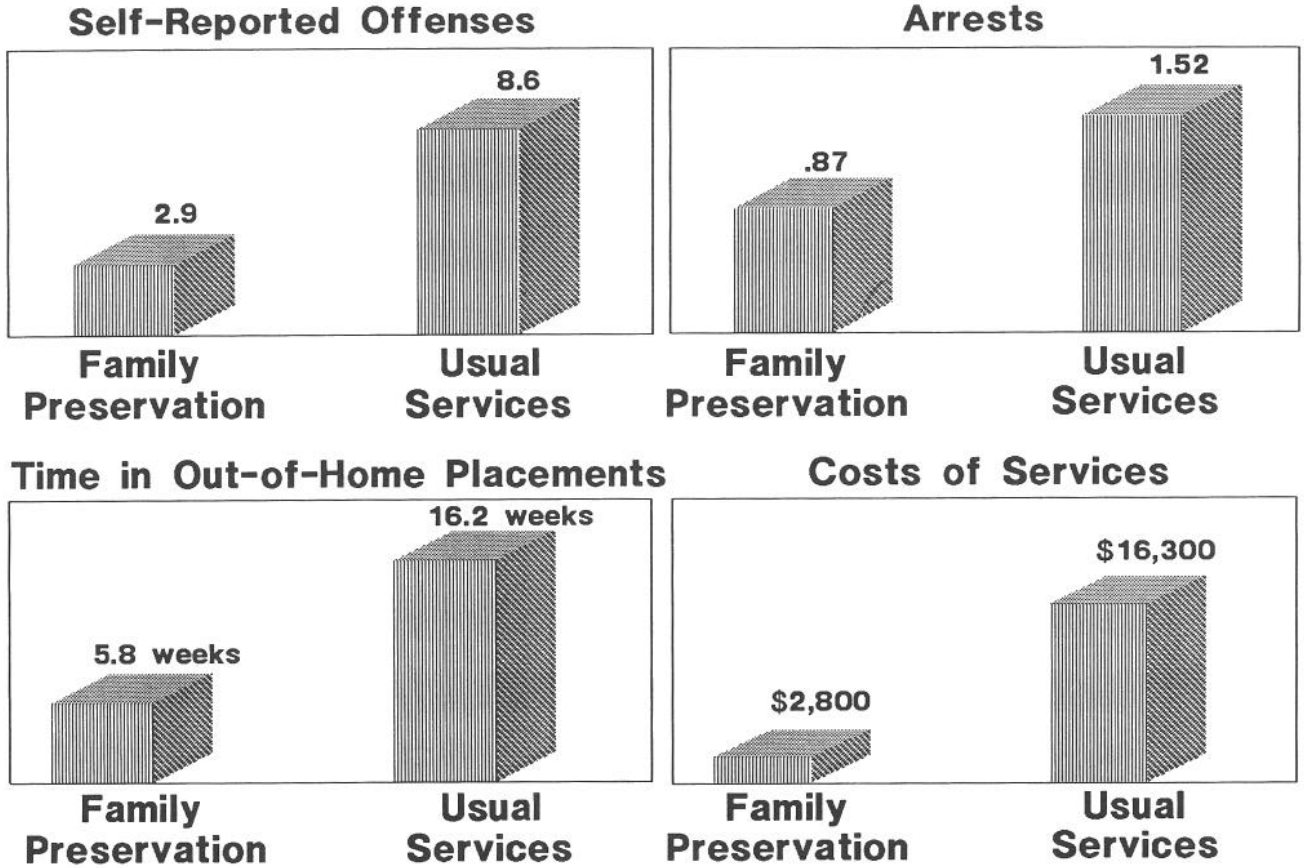

FIGURE 1. *Key outcomes in serious offender project*

cohesion and decreased youth aggression with peers as compared with counterparts in the usual services condition. Analyses also showed that MST was equally effective with youths and families of divergent sociocultural backgrounds and with varying strengths and weaknesses. Finally, multisystemic family preservation was not only more effective than usual services, it was much less expensive. The average cost per client for MST was $2,800, which compares favorably with the average cost of $16,300 per client in the usual services condition (Melton et al., in press).

The Missouri Delinquency Project

A manuscript is currently in preparation that describes the outcome of the most extensive evaluation of MST to date (Borduin et al., unpublished). Approximately 200 juvenile offenders averaging 4.2 arrests were randomly referred to receive either MST or individual counseling that focused on personal, family, and academic issues. Assessment batteries, which included self-report and observational measures, were completed at pretest and posttest, and recidivism data were collected at 4 years posttreatment.

Analyses of the 4-year followup data strongly support the long-term effectiveness of MST. Recidivism rates were 22 percent versus 71 percent for therapy completers (42 percent versus 72 percent for premature terminators) in the MST and individual counseling conditions, respectively. Overall, youths who completed MST were arrested for 29 crimes, compared with 161 crimes for youths who completed individual counseling. Moreover, crime seriousness ratings (Hanson et al. 1984) showed that recidivists in the MST condition perpetrated significantly less serious crimes than did their counterparts. Analyses of the psychosocial measures also supported the relative effectiveness of MST. For example, observational measures revealed significantly improved communication in the families that received MST compared with families of youths who received individual counseling.

Adolescent Sexual Offenders

Borduin and colleagues (1990) published the first controlled evaluation of any treatment with adolescent sexual offenders. Sixteen juvenile sexual offenders were assigned randomly to either MST or outpatient individual counseling. The small sample size precluded analyses of psychosocial measures, but findings from 3-year recidivism data are noteworthy. Six of eight juveniles in the individual counseling condition had been rearrested for at least one sexual offense, in contrast with only one of the youths in the MST condition. Moreover, youths in the individual counseling condition also had more arrests for nonsexual criminal offenses than did youths who received MST. Although results from this study are certainly not conclusive-due in part to the small sample size-findings are suggestive and support the external validity of MST.

Substance Use and Abuse in Serious Juvenile Offenders

Using data from two aforementioned studies (Borduin et al., unpublished; Henggeler et al. 1992), Henggeler and colleagues (1991) evaluated the effects of MST on substance use and abuse in samples of serious juvenile offenders. Analyses of 4-year recidivism data from the Missouri Delinquency Project showed that offenders who participated in MST had significantly fewer arrests for substance-related crimes than did youths who participated in individual counseling. Similarly, posttest results in the multisystemic family preservation study showed that offenders who received MST reported significantly less substance use than did counterparts who received usual services. Such findings suggest that MST may be an effective treatment of adolescent substance abuse, and, as discussed subsequently, a controlled clinical trial is currently being conducted.

Child Abuse and Neglect

Brunk and colleagues (1987) compared the effectiveness of MST versus behavioral parent training in the treatment of abusive and neglectful families, with random assignment of families to treatment conditions. A strength of this study was that MST was contrasted with an approach that is considered among the most promising in the child maltreatment literature. Findings at posttest showed that both

treatments ameliorated key correlates of child maltreatment, including parental symptomatology and family stress. In addition, MST was more effective than behavioral parent training in modifying important parent-child interactional correlates of maltreatment. In the MST condition, maltreating parents showed improved effectiveness, neglectful parents were more responsive, and maltreated children were more compliant.

Inner-City Juvenile Offenders

The first outcome study done by Henggeler and coworkers (1986) compared the effectiveness of MST versus standard community treatment with adolescent criminal offenders. Results showed that MST produced favorable changes in key correlates of delinquency, including behavior problems, association with deviant peers, and parent-adolescent relations. These promising findings set the stage for the subsequent studies noted above and below.

Current Refinements In the Development and Validation of MST

MST is being validated further in two separate projects. The first, a multisite study funded by NIMH, evaluates several important aspects of the effectiveness and diffusion of multisystemic family preservation with serious juvenile offenders. Comprehensive followup assessments of psychosocial functioning are being conducted for the first time to assess the stability of changes in family relations, peer relations, and other areas. Issues pertaining to the training of therapists and to the integrity of treatment delivery are being evaluated. Treatment process is being studied in an attempt to assess the active ingredients in MST. Issues pertaining to the diffusion of multisystemic family preservation to rural sites are being examined.

The second project is evaluating the effectiveness of MST with substance-abusing juvenile offenders. As noted previously, effective treatments of adolescent substance abuse have not been validated, and related results from earlier studies (Henggeler et al. 1991) suggest that MST may be effective. Particularly interesting aspects of this study include an examination of treatment process issues, comprehensive

6-month and 12-month followups, and an evaluation of the effects of continued therapeutic monitoring after termination from MST.

CLINICAL FEATURES OF MST AND SERVICE DELIVERY ISSUES

MST is based primarily on a social-ecological model of behavior (e.g., Bronfenbrenner 1979). The social-ecological model posits that youths are embedded in multiple transactional systems (e.g., family, peer, and school) and that behavior is the product of the reciprocal interplay between the child and these systems. Such a perspective is consistent with findings from the aforementioned causal modeling studies of delinquency and of adolescent substance use.

If a social-ecological model accurately reflects the determinants of behavior problems, a logical inference is that treatment interventions should focus on multiple aspects of the youth's ecology to be effective. Thus, MST stresses the importance of considering a broad array of ecological variables when assessing identified problems and intervening within and between systems as needed on a case-by-case basis.

MST is unique in its comprehensive conceptualization of clinical problems, multifaceted nature of interventions, and ecologically valid location of treatment delivery (i.e., treatment usually is delivered directly in real-world settings). MST, however, includes few novel treatment techniques. Therapists delivering MST are trained in the use of a variety of strategies developed from other theoretical perspectives. For example, the emphases on family systems and goal-oriented treatment are similar to those of pragmatic family therapists (e.g., Haley 1976; Minuchin 1974), and behavioral (e.g., Blechman 1985) and cognitive behavioral interventions also are used.

The complexity of MST treatment, however, presents problems in dissemination and diffusion. Highly circumscribed treatments can be disseminated with relative ease, but the inherent flexibility of MST increases the probability of inappropriate treatment. To address this problem, the South Carolina Department of Mental Health commissioned the development of an MST Strategic Procedures

Manual (Henggeler 1990). Here, the nine central principles of MST are delineated, and several related issues are discussed. Although still in the process of field-testing the manual, the authors hope that such a manual will accurately represent the fundamental nature of MST while allowing therapists to take advantage of their personal strengths.

Principles of Multisystemic Treatment

1. The primary purpose of assessment is to understand the "fit" between identified problems and their broader systemic context. One of the therapist's initial tasks is to evaluate factors in the youth's and family's social ecology that may be contributing to identified problems. Such an evaluation is performed through discussions with various family members and other key informants (e.g., teachers, peers, and minister). The discussions assess others' perspectives and provide a mechanism for the therapist's direct observations of family transactions. Hypotheses regarding the determinants of the identified problems are based on the assessment, and targets for intervention are derived directly from the hypotheses. As new information is gathered throughout the course of treatment, hypotheses either will be supported or disconfirmed. In the case of the latter, new hypotheses (and interventions) will be formulated. Thus, assessment is ongoing, and treatment is responsive to feedback and changing hypotheses.

2. Interventions should be present-focused and action oriented, targeting specific and well-defined problems. Treatment goals are specified concretely to reduce ambiguity regarding the direction of treatment and progress toward identified goals. All participants in treatment are informed of therapeutic goals and of the rationale for pursuing such goals. Although historical issues interfering with therapeutic progress may be addressed (e.g., a mother's sexual victimization during childhood), the primary thrust of treatment is on changing the here and now.

3. Interventions should target sequences of behavior within or between systems. Treatment focuses on changing problematic relations within systems (e.g., mother-adolescent interactions) or between systems (e.g., mother-teacher interactions). Although individual cognitive changes may be needed to facilitate

interactional change, the ultimate goal is changing transactions. As such, the vast majority of interventions address interactions directly (e.g., family therapy) or indirectly (e.g., teaching the youth how to resist peer pressure). In the latter case, homework assignments and followup always attend to the outcome of in vivo practice.

4. Interventions should be developmentally appropriate and should tit the developmental needs of the youth. Primary developmental tasks from early adolescence to late adolescence include emancipation from parents, attaining educational and vocational direction, and forming positive peer relations. Although implementation of restrictive parental discipline often is needed with juvenile offenders, therapists never lose sight of important developmental tasks, and intervention emphases shift toward these tasks as behavior problems are reduced. Moreover, the degree of emphasis on a particular task will vary with the age of the youth.

5. Interventions should be designed to require daily or weekly effort by family members. Because presenting problems are usually serious and treatment is time limited, extensive efforts are needed by all participants to facilitate positive change. Daily homework assignments serve the dual function of actualizing treatment goals and of indexing the participants' efforts. Thus, the rate of positive change is optimized, and client resistance is identified quickly.

6. Intervention efficacy is evaluated continuously from multiple perspectives. Positive change is expected each day, and barriers to obtaining such change are identified as soon as possible. Continuous evaluation of efficacy provides feedback to the therapist regarding the accuracy of his or her hypotheses and interventions. Such feedback enables the therapist to modify hypotheses and interventions accordingly and to obtain additional feedback regarding the modifications. When multiple perspectives of intervention efficacy are obtained, the therapist is less likely to be fooled by the false reports of respondents.

7. Interventions should be designed to promote treatment generalization and long-term maintenance of therapeutic change. Therapists should not enter the system and affect positive outcome through the force of their personalities and skills because such

change will dissipate after the case is terminated. Rather, interventions should maximize the capacity of family members to effect changes in their lives. That is, treatment aims to empower parents and adolescents.

8. Therapeutic contacts should emphasize the positive. and interventions should use systemic strengths as levers for change. Although the inherent nature of the situation (i.e., serious offender referred from juvenile court) tends to focus attention on the deficits of the youth and family, considerable attention should be devoted to identifying the strengths of the youth, the family, and their social-ecological context. Identifying strengths can bolster the family members' confidence in themselves, and such strengths usually serve as useful vehicles for positive change.

9. Interventions should be designed to promote responsible behavior and to decrease irresponsible behavior among family members. Essentially, parents should behave as parents (e.g., nurturing and guiding their children), and children should behave as growing members of the family and community (e.g., helping the family and building positive extrafamilial relations). Traditional diagnostic labels are rejected as counterproductive (e.g., psychopathic personality), and it is assumed that all therapy participants have the capacity for loving and constructive behavior.

The Family Preservation Model of Service Delivery

The family preservation model of service delivery has developed primarily from a social work perspective and has been applied most often to cases of child abuse and neglect (Nelson et al. 1990). Nevertheless, the family preservation approach is entirely compatible with MST. In general, the family preservation model includes direct provision of services in the home; the provision of 'total care,' attending to the broad range of needs presented by multiproblem. disadvantaged families (versus brokering of services); a team approach to treatment planning; a low client/therapist ratio; staff availability 24 hours per day, 7 days per week; frequent (often daily) contact with families; time-limited treatment (usually 2-4 months); provision of treatment to the system rather than to the individual; treatment success defined as the responsibility of the treatment team rather than of the

client; and expectations for immediate, maximum effort by family members and staff.

MST is delivered using a family preservation model for several reasons (Henggeler and Borduin, in press). First, delivery of home-based treatment helps to overcome resistance, which is a major obstacle to working with families of serious juvenile offenders. Second, home-based treatment overcomes logistical problems (e.g., lack of transportation and adjusting parent's work schedule). Third, the therapist's travel to the family's home conveys a sense of respect that promotes a positive therapeutic alliance. Fourth, assessment data are more likely to be accurate because they are obtained in settings with relatively high ecological validity. Fifth, interventions are more likely to be successful when they are implemented in the natural environment. Sixth, positive change is more likely to be maintained when the natural environment has been altered to promote such change.

SUMMARY

MST has proven to significantly decrease rates of antisocial behavior in serious juvenile offenders. In light of the similarities between the problems of delinquency and adolescent substance abuse, MST holds promise as an effective treatment of the latter. Hence, conceptual, clinical, and service delivery features of MST are presented.

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Dialectical Behavior Therapy for Treatment of Borderline Personality Disorder: Implications for the Treatment of Substance Abuse

Marsha M. Linehan

The purpose of this chapter is to describe a behavioral treatment approach designed specifically for chronically parasuicidal individuals meeting criteria for borderline personality disorder (BPD). Both the overlap between substance abuse and BPD as well as common correlates between the two disorders suggest that Dialectical Behavior Therapy (DBT), in whole or in part, might be effective as a treatment for substance abuse in general and for substance abusers who also meet criteria for BPD in particular. The chapter will first give a brief overview of the overlap between substance abuse and BPD. Second, it will describe the central elements of a broad-band, behaviorally based treatment (DBT) for BPD. Finally, it will briefly describe the empirical evaluations of the effectiveness of this treatment regime.

BORDERLINE PERSONALITY DISORDER AND SUBSTANCE ABUSE

Overlap

Impulsiveness in areas that are potentially self-damaging is part of the criteria for BPD. Substance abuse counts as half of this criterion in both DSM-III-R (American Psychiatric Association 1987) and DSM-IV (American Psychiatric Association Task Force on DSM-IV 1991). Thus, it is not surprising that, compared with individuals with all other personality disorders (except antisocial disorder) and with psychiatric patients with no personality disorders, individuals meeting criteria for BPD score higher on substance abuse scales (Pitts et al. 1985; McCann

et al. 1992), more commonly report a history of substance abuse (Akiskal et al. 1985), and also meet criteria for current substance abuse (Loranger and Tulis 1985; Zanarini et al. 1989; Dulit et al. 1990; Koenigsberg et al. 1985). In the study conducted by Zanarini and colleagues (1989), 84 percent of 50 borderline outpatients had met criteria for substance abuse/dependence at some point in their lives. In the study conducted by Dulit and coworkers, 67 percent of BPD patients met criteria for substance abuse disorder. When substance abuse was not used as a criteria for BPD, the incidence dropped to 57 percent, still a significant portion of the population. Koenigsberg and colleagues (1985), reporting on a sample of 2,462 inpatients and outpatients, found that 21 percent of borderline patients had a primary Axis I diagnosis of substance abuse. Furthermore, two studies suggest that BPD individuals are more likely to be polydrug abusers, usually combining drug and alcohol abuse, than are non-BPD individuals (Kosten et al. 1989; Nace et al. 1983).

The high incidence of substance abuse among borderline individuals suggests that, at least some of the time, patterns diagnosed as indicative of BPD may be better viewed as sequelae of substance abuse patterns. Indeed, Zweben and Clark (1990-1991) argue that the overlap between substance abuse and BPD may be a result of correlates and consequences of substance abuse that masquerade as BPD symptoms. For example, they note that instability of mood, inappropriate expression of anger, chaotic interpersonal relationships, impulsiveness, and persistent feelings of emptiness or boredom (all criteria for BPD) are characteristic patterns found among serious substance abusers and may clear up with sufficient abstinence. However, although the BPD-substance abuse overlap is substantial, not all substance abusers meet criteria for BPD. In a study of 64 female psychiatric outpatients meeting criteria for substance abuse, Vaglum and Vaglum (1985) found that 66 percent also met criteria for BPD. In a more restricted sample, Nace and colleagues (1983) found that 13 percent of 94 consecutive admissions to an alcohol treatment program also met criteria for BPD. Tousignant and Kovess (1989) found that one-third of substance abusers showed a high number of BPD traits. BPD substance abusers, however, are uniformly more disturbed than those abusers who do not meet criteria for BPD. Studies have shown that they are more commonly comorbid for depressive disorders, have more frequent suicide attempts and accidents, and score higher on

impulse dyscontrol and antisocial tendencies and lower on reality testing (Kosten et al. 1989; Inman et al. 1985).

Of particular interest for treatment is the overlap between suicidal behaviors and both substance abuse and BPD. Suicidal behaviors, including threats, "gestures," and suicide attempts, represent one of the eight (or nine in DSM-IV) criteria for BPD. Parasuicidal behavior (all acute, intentional, nonfatal, self-injurious behavior, including suicide attempts) has been called the behavioral specialty of BPD (Gunderson 1984). Although much of this behavior is without lethal intent, the percentage of those followed after an index treatment who eventually die by suicide is at least 5 to 10 percent (Stone et al. 1987; Paris et al. 1987; Frances et al. 1986). Similarly, substance abuse is associated with an increased risk of suicidal behaviors, including both completed suicides and parasuicide (see Lester 1992). Roy and Linnoila (1986) estimated that 18 percent of alcoholics subsequently complete suicide. What is not clear at this point is whether the high rate of suicidal behaviors among substance abusers is mediated by the concomitant BPD associated with the substance use disorders.

Achieving treatment success with both BPD and substance abuse has been notoriously difficult. Although there have been few randomized controlled trials investigating treatment for BPD, followup studies of individuals who have received substantial inpatient and outpatient psychiatric care suggest that current treatments are marginally effective at best when measured 2 or 3 years following treatment (Perry and Cooper 1985; Tucker et al. 1987). In contrast, there have been many controlled trials of treatments for both alcohol and drug abuse. Although efficacy of treatments has been demonstrated, lasting positive outcomes have been difficult to achieve (Marlatt and Gordon 1985; Miller and Rollnick 1991). Substance abuse combined with BPD may be particularly difficult to treat. Nace and colleagues (1985) reported that at several years following treatment for substance abuse, these individuals have more severe problems remaining than do non-BPD substance abusers.

OVERVIEW OF DBT

DBT was developed from a combined motivational and capability deficit model of BPD. The idea was twofold: (1) borderline individuals lack important interpersonal, self-regulation (including emotional regulation), and distress tolerance skills, and (2) personal and environmental factors inhibit the use of behavioral skills that the individual does have and often reinforce inappropriate borderline behaviors. The emphasis on capability enhancement is similar to that in substance abuse treatment models that stress relapse prevention (Marlatt and Gordon 1985). The emphasis on changing motivational factors is similar to the motivational interviewing proposed by Miller and Rollick (1991) and to aversive conditioning models (although DBT provides a greater emphasis on reinforcement than on punishment).

DBT presumes that attention to both skill acquisition and behavioral motivation is essential. In developing the treatment, however, it quickly became apparent that (1) skill training to the extent believed necessary is extraordinarily difficult, if not impossible, within the context of a therapy oriented to reducing the motivation to die or act in a borderline fashion, and (2) sufficient attention to motivational issues cannot be given in a treatment with the rigorous control of therapy agenda needed for skill training. From this, the idea developed to split the therapy into three components, one that focuses primarily on ski acquisition, one that focuses primarily on motivational issues and skill strengthening, and one designed explicitly to foster generalization of skills to the everyday life outside the treatment context. The three modes in standard outpatient DBT are psychosocial groups (for skill training), individual psychotherapy (addressing motivational issues and skill strengthening), and telephone contact with the individual therapist (addressing generalization). Within each treatment mode, DBT is characterized by a philosophy of dialectics, a biosocial theoretical perspective, a hierarchy of treatment targets specific to the mode, and a set of treatment strategy groups. Space here is too brief to give a detailed description of each component of the treatment. The interested reader is referred to the treatment manual and associated updates (Linehan, 1993*a*, 1993*b*).

Theoretical Base

As one might suppose from the title of the treatment, DBT flows from a dialectical philosophical position. "Dialectic" is used here in two contexts, that of persuasive dialogue and relationship and that of the fundamental nature of reality. From the point of view of dialogue and relationship, it refers to change by persuasion and by making use of the opposition inherent in the therapeutic relationship, rather than by formal impersonal logic. Thus, unlike analytical thinking, dialectics is personal, taking into account and affecting the total person, and it does not seek absolute truth but instead attempts to facilitate the construction or evolution of truth over time. As a world view, dialectics convey these coexisting multiple tensions that must be addressed within the therapeutic relationship, as well as the emphasis in DBT on (1) a systems perspective (asking always, "What is being left out of our understanding here?"), (2) searching for synthesis and balance (to replace the rigid, often extreme, and dichotomous response characteristics of suicidal and borderline patients), and (3) enhancing comfort with ambiguity and change, which are viewed as inevitable aspects of life. The overriding dialectic for the therapist is the necessity of acceptance of the patient as he or she is within the context of simultaneously trying to produce change. Treatment strategies are polarized into those most related to *acceptance* and those most related to *change,* although it is this very polarization that is the mot of many therapeutic failures. DBT requires that the therapist balance use of these two types of strategies within each treatment interaction.

The author has proposed elsewhere (Linehan 1993*a*) that BPD is primarily a systemic disorder of emotion regulation. Characteristics of this dysregulation include a high sensitivity to emotional stimuli, intense response to even low-level stimuli, and a slow return to baseline combined with an inability to modulate emotional states. Borderline behavioral patterns either function to remediate negative emotional arousal directly (a view similar to one that sees substance abuse as self-medication) or indirectly (e.g., by eliciting help from the environment) or are inevitable outcomes of unregulated and unstable emotionality. In short, borderline patterns either are attempts to solve problem emotions or are problematic sequelae, either of the initial emotions or of the dysfunctional attempts to reduce emotionality. The author has further hypothesized that this pattern of dysregulated

emotion and behavior is a result of an initial temperamental disposition to emotionality, and perhaps inadequate modulation, combined with an invalidating rearing environment. Such an environment is characterized by a tendency to disregard emotional experiences, especially negative ones, and oversimplify the ease of solving difficult problems, and it puts a high value on positive thinking. Although such attitudes are certainly beneficial for some, if not most, this type of environment invalidates the experiences of vulnerable individuals and does not take seriously their communications, especially when such communications have to do with nonpublic events and with difficulties in meeting social expectations. Invalidating environments, especially physically and sexually abusive families, contribute to the development of emotion dysregulation and fail to teach the child how to label and regulate arousal, how to tolerate emotional distress, and when to trust one's own emotional responses as reflections of valid interpretations of events. At the adult level, borderline individuals adopt the characteristics of the invalidating environment. Thus, they tend to invalidate their own affective experiences, look to others for accurate reflections of external reality, and oversimplify the ease of solving life's problems. This oversimplification leads inevitably to unrealistic goals, an inability to use reward instead of punishment for small steps towards final goals, and self-hate following failure to achieve these goals. The shame reaction, a characteristic response to uncontrollable and negative emotions among borderline individuals, is a natural result of a social environment that "shames" those who express emotional vulnerability. These two polar extremes, vulnerability versus invalidation, represent the central dialectical dilemma of the borderline patient and therapist.

Treatment Targets

Treatment targets for individual DBT therapy and for DBT as a whole are the same and are hierarchically arranged as follows:

1. Reducing high-risk suicidal behaviors (parasuicide and high-risk suicide ideation and plans);

2. Reducing therapy-interfering behaviors-all responses or behaviors of *both the patient and the therapist* that make therapy progress or continuation difficult (e.g., missing or coming late to sessions,

phoning at unreasonable hours, refusing to collaborate or work in sessions, remaining interpersonally aloof or too clinging, invalidating the other, and not returning phone calls);

3. Reducing behavioral patterns serious enough to substantially interfere with any chance of a reasonable quality of life (serious substance abuse would qualify here);

4. Behavioral skill acquisition (skills in emotion regulation, interpersonal effectiveness, distress tolerance, and self-management, as well as a number of "core" [mindfulness] abilities to observe, describe, participate spontaneously, be nonjudgmental, focus awareness, and focus on effectiveness);

5. Reducing posttraumatic stress responses related to previous traumatic events;

6. Increasing self-respect; and

7. Meeting other goals of the patient.

With respect to each target, the task of the therapist is first (and many times thereafter) to elicit the patient's collaboration in working on the target behavior, then to apply the relevant treatment strategies described below. Attention to each target within individual therapy, ordinarily involving direct and focused work on the behaviors relevant to the target, is jointly determined by the hierarchy list above and by the behaviors and problems that have surfaced since the last session or during the current session. Thus, treatment is oriented to current behaviors. Therapy is somewhat circular in that target focal points revolve over time.

The hierarchy of targets (i.e., what is attended to) is somewhat different in group skills training and in phone calls. In skills training, as one might imagine, skills acquisition is the top priority. The only behaviors that would take precedence are behaviors that threaten to destroy skills training (e.g., aggression toward other group members or not coming to sessions). Behavioral skills are taught in modules concentrating on mindfulness skills (observation, description and spontaneous participation, nonjudgmentalness, focused attention, and

"doing what works"), interpersonal effectiveness for conflict situations, emotion regulation, and distress tolerance. During telephone calls, generalization of skills is the top priority, preceded only by threats to the patient's life. Thus, during phone calls the focus is always on, "What skills could you use here?"

Treatment Strategies

DBT addresses all problematic patient behaviors and therapy situations in a systematic, problem-solving manner that includes conducting a collaborative behavioral analysis, formulating hypotheses about possible variables influencing the problem, generating possible changes (behavioral solutions), and trying out and evaluating the solutions. The context for this analysis- and solution-oriented approach is that of validation of each patient's experiences, especially as they relate to the individual's vulnerabilities and sense of desperation. In standard outpatient DBT, individual therapy sessions meet weekly for 60-90 minutes. During the first year of therapy, all patients attend the weekly 2- to 2½-hour weekly skills training class. Phone calls for extra coaching between sessions are encouraged and are accepted within the therapist's personal limits.

There are five strategy groups that are combined to deal with specific problematic situations. Not all strategies are necessary or appropriate for a given session; the pertinent combination may change over time, and the emphasis on particular strategies varies depending on mode of treatment. These are more fully described in the treatment manual (Linehan 1993*a*, 1993*b*).

Dialectical strategies are woven throughout all treatment interactions and involve both a focus upon the dialectical issues in the therapist-patient relationship as well as promotion of dialectical thought on the part of the patient. The primary dialectical strategy is the balanced therapeutic stance described above. Thus, the constant attention to combining acceptance with change is the essence of the dialectical strategy. The goal is to bring out the opposites both in therapy and the patient's life and to provide conditions for syntheses. The key idea guiding the therapist's behavior is that, for any point, an opposite position can be held. Thus, synthesis and growth require a continuous search for what is being left out in both the therapist's and patient's

current ordering of reality and then assisting the patient to create new orderings that embrace and include what was previously excluded. The therapist helps the patient move from "either-or" to "both-and." Strategies include extensive use of stories, metaphors, myths, and paradoxes; the therapeutic use of ambiguity (i.e., removing ambiguity is not necessarily a goal); drawing of the patient's attention to the fact of reality as constant change as well as the nonavoidance of change in the therapeutic conditions; cognitive challenging and restructuring techniques; and reinforcement for use of intuitive, nonrational knowledge bases. Dialectical strategies, especially a dialectical framework on the part of the therapist, are essential in every interaction with the patient and also inform the treatment supervision and staff meetings.

Core strategies consist of the balanced application of validation and problem-solving. Validation requires the therapist to search for, recognize, and reflect the *current* validity, or sensibility, of the individual's response. Pointing out how a response was functional in the past but is not now is invalidating, not validating. Nor is validating simply building up self-esteem, although cheerleading–focusing on the strengths of the individual and believing in the individual no matter what-is an important part of validation. If a person says that he or she is stupid, saying that the person is smart invalidates the experience of being stupid. The therapist invalidates the patient's comment if he or she interprets it as indicative of the patient's experiences in similar relationships in which hostility may have been the norm, rather than searching openly for his or her own behavior that might actually communicate anger. The essence of validation is the communication that a response is understandable in the current context. At times, it is like searching for a speck of gold in a cup of sand. Not every part of a response is valid, nor is that which is invalid ignored. However, enough valid responses (or parts of responses) can be found that validating is done in every interaction.

Problem-solving strategies are a two-stage process involving, first, an acceptance of the problem at hand and, second, an attempt to generate, evaluate, and implement alterative solutions that might have been made or could be made in the future in similar problematic situations. The acceptance stage employs both insight and behavioral analysis strategies; the second stage, targeting change, employs solution

analysis, commitment, and orientation to change and treatment plans. Behavioral analysis requires a very detailed chain analysis of the events and situational factors leading up to and following the particular problematic response at hand. Insight strategies, no more different here than in other treatment approaches, include observing and labeling patterns of behavior and situational influence over time. The behavior analysis strategy is repeated for every instance of targeted problem behaviors until the patient achieves an understanding of the stimulus-response patterns involved. The second stage requires the generation of alternate response chains (i.e., adaptive solutions to the problem) as well as an analysis of the individual's response capabilities. This process usually leads into skills training and work on motivation through attention to reinforcement contingencies, therapeutic exposure to reduce emotions inhibiting functional behavior, and changing of cognitions that lead to dysfunctional behaviors.

There are three *case management strategies* designed to guide each therapist during interactions with individuals outside the therapy dyad. The consultation/supervision strategy requires that each DBT therapist meet regularly with a supervisor or consultation team. DBT is designed as a treatment of a community by a community. Thus, in most settings this strategy will dictate a weekly meeting of all therapists applying DBT. The treatment specifies a number of guidelines for conducting these meetings. The consultant-to-the-patient strategy is simple in concept but very hard to carry out. The strategy is the application of the principle that the DBT therapist teaches patients how to interact effectively with their environment rather than teaching the environment how to interact with the patients. As a general norm, DBT therapists do not intervene to adjust environments for the sake of the patient, nor does the DBT therapist meet or consult with other professionals about how to treat the patient unless the patient has an active part in it. This strategy represents a point of view that looks at adversity and "bad" treatment of the patient by the environment (including other professional helpers) as an opportunity for practice and learning. From another perspective, it views the role of the therapist as teaching the patient to adjust to the world *as it is,* with all its problems and inequities. Patients are dealt with as responsible parties in their interactions with others. A key aspect of the strategy, of course, includes a definition of who the therapist is. For example, on an inpatient unit, the entire staff might be deemed the

"therapist." However, even within the staff, application of the strategy is possible. It simply requires that each therapeutic agent be responsible for his or her own behavior and not each other's Thus, it is not the job of one therapist to defend another therapist, nor is treatment consistency particularly valued in DBT. As in the real world, rules may change depending on who is enforcing them. Although patients not present are discussed in staff meetings, the goal is to obtain information, not necessarily to influence or change the other therapist. The information then is used in working with the patient. (One can immediately see why that is easy in concept and difficult in practice! Humility is a requisite for this strategy not to go astray.)

The exception to the consultant strategy is in the following circumstance: the patient does not have the requisite capability (or sometimes willingness) to influence the environment, the immediate outcome is very important, and the therapist can influence it. In this instance, the therapist uses the environmental intervention strategies to effect immediate changes that are both essential and that the patient cannot yet produce. For example, the therapist will consult with emergency room staff about medications taken by an uncommunicative patient who overdosed, send required treatment plans to insurance companies, and possibly go and pick up a teenager trying to come to a session whose car breaks down.

In DBT, the therapist balances two *communication strategies* that represent rather different interactional styles. The modal style is the reciprocal strategy that includes responsiveness to the patient's agenda and wishes, warmth, and self-disclosure of personal information that might be useful to the patient as well as immediate reactions to the patient's behavior. Reciprocity is balanced by an irreverent communication style that is characterized by a matter-of-fact attitude. The therapist takes the patient's underlying assumptions or unnoticed implications of the patient's behavior and maximizes or minimizes them in either an unemotional or overemotional manner to make a point the patient might not have considered before. The essence of the strategy is that it "jumps track," so to speak, from the patient's current pattern of response, thought, or emotion.

A set of *structural strategies* specifies for the therapist how to start and end therapy, how to set an agenda and organize time during sessions, and how to terminate DBT. For example, DBT uses a number of strategies drawn from social psychology to create and enhance commitment to therapy and to change. There are, as well, a number of *integrative strategies* covering crisis management, suicidal behavior, compliance and relationship issues, medication, and use of ancillary treatments.

TREATMENT EFFICACY FOR DBT

DBT has been evaluated in a controlled treatment trial comparing DBT to treatment-as-usual (TAU) in the community (Linehan et al. 1991). Forty-seven women meeting criteria for BPD with a history of multiple parasuicides (including one within 8 weeks of referral) were randomly assigned to the two treatment conditions. Treatment lasted 1 year, and evaluations were conducted at 4-month intervals during a 1-year followup. Results indicated that DBT was significantly better than TAU at reducing parasuicidal behavior (including suicide attempts), days of inpatient hospitalization, and treatment dropouts. In a reanalysis of the data, Linehan and Heard (1993) found that the superiority of DBT could not be accounted for by the simple fact that subjects assigned to DBT had greater access to psychotherapy or to telephone contact with their therapist. The original study was conducted in two somewhat independent waves with approximately equal numbers of subjects in each. Analyses of the second wave (Linehan et al. 1992), in which a number of additional outcome measures were added to the assessment battery, indicated that subjects assigned to DBT, as compared with those assigned to TAU, also reported significantly less anger, greater social adjustment (including better employment performance), better work (in employment, school, and household roles) performance, and less anxious rumination, and they were rated by the interviewer as more socially adjusted and as less severely disturbed on the Global Adjustment Scale. At followup (Linehan et al., in press), gains were maintained in almost all areas of therapy improvement. The finding that DBT reduces parasuicide episodes has been replicated by Barley and colleagues (in press) in an inpatient sample.

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Substance Abuse Research: Outcome Measurement Conundrums

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INTRODUCTION

This chapter has two purposes: to identify outcome assessment problems that arise in treatment studies of substance abuse and to propose strategies that can address some of the problems. The outcome assessment problems become particularly evident when the technology model of psychotherapy research (Carroll and Rounsaville 1990; Docherty 1984) is adopted for treatment studies of substance abuse. This model, as developed and first implemented in the National Institute of Mental Health (NIMH) Treatment of Depression Collaborative Research Program (TDCRP) (Elkin et al. 1985, 1988*a*. 1988*b*, 1989), has become the standard in psychotherapy research.

The technology model arose from the application to psychotherapy of clinical trial methods that are used in psychopharmacology research. The essence of the technology model is attention to procedures that ensure a study's internal validity (Campbell and Stanley 1963) and that thereby maximize the interpretability of outcome findings in terms of the efficacy or the comparative efficacy of different psychotherapeutic interventions for certain types of problems. So, for example, the treatments studied are specified and standardized in detailed manuals, and therapists are trained and then monitored throughout the study to ensure that they conduct the designated treatments in a standard way (Elkin 1984). In addition, careful attention is given to patient selection because a primary goal is to generalize the outcome findings to patients with specific types of problems. Thus, structured diagnostic interviews often are used, and procedures are implemented to ensure that the diagnosticians make reliable diagnoses when compared to each other and to an external (nonstudy) standard.

The advantages of the technology model for psychotherapy research have been reviewed by others (e.g., Carroll and Rounsaville 1990). Suffice it to say that the field of psychotherapy research developed for about 30 years before the technology model was applied. For at least the last 10 of those years, leaders in psychotherapy research were noting the need for a new paradigm. The call was spurred in part by the recognition that the results of psychotherapy studies repeatedly led to the same conclusion: all treatments were equally effective (improvement was found in about 66 percent of treated patients), and no treatments were found to have specific effects (Frank 1979). Furthermore, it was difficult to replicate psychotherapy studies because the actual conduct of the treatments remained unspecified. Thus, although the technology model of psychotherapy research as realized in the NIMH TDCRP has been frequently criticized, particularly initially, the model has in fact become the standard in the field. In support of the model, it can be noted that the model is consistent with the logic of "strong inference" (Platt 1964).

Several characteristics of substance-abusing patients and of substance abuse treatment practices can lead to uninterpretable outcome findings when procedures associated with the technology model of psychotherapy research are either ignored or adopted without modification for treatment studies of substance abuse.' In the next section, features of substance abuse patients and treatment practices that can create problems for standard psychotherapy outcome assessment procedures are identified and discussed. The points are summarized in table 1. Then, strategies are considered to address some of the problems (summarized in table 2). In the final section, possible strategies for improving outcome assessment in substances abuse studies are summarized (table 3).

FEATURES OF SUBSTANCE ABUSE TREATMENT STUDIES THAT CAN COMPROMISE OUTCOME ASSESSMENT

Co-Presence of Multiple Problems

Substance-abusing patient populations such as cocaine and opiate abusers tend to have multiple problems (McLellan et al. 1980), including polysubstance abuse (e.g., alcohol, marijuana, and nicotine)

TABLE 1. *Features of substance abuse treatment that compromise outcome assessment.*

Feature	Effect	Impact on Outcome Assessment
Patient Variables		
Co-Present Multiple Problems	Tendency to provide multiple interventions	Can't attribute outcome to treatment of interest
Polysubstance abuse; Comorbid mood, anxiety, and personality disorders; Environmental (e.g., housing, low income); Social (legal and criminal); Interpersonal (e.g., conflictual close relationships, low social support)	High dropout rate	Can't generalize outcome findings to patient population of interest
	Low followup assessment rate	Can't evaluate enduring effects of treatment
Low Motivation for "Cure"	High early dropout rate	Can't generalize outcome findings to patient population of interest
Seeking a drug holiday, rather than enduring change	Substance abuse has an episodic course	Can't attribute outcome to treatment of interest
Episodic Course of Substance Abuse		Can't necessarily attribute outcome to treatment of interest
Poor Education	Difficulty reading, comprehending, and completing assessment instruments	Reduced reliability and validity of commonly used outcome measures
Frequent Substance Use	Affects phenomenological experience (including memory encoding)	Reduced reliability and validity of self-report measures and measures that rely on self-report such as DSM-III-R diagnoses
	Has side effects that mimic common psychiatric symptoms	Reduced differential diagnostic reliability of self-report

TABLE 1. *Features of substance abuse treatment that compromise outcome assessment (cont).*

Feature	Effect	Impact on Outcome Assessment
Patient Variables (cont.)		
Self-Reported Drug Use Can Be Unreliable		Poor reliability of self-report drug use outcome measures
	Reduced reliability of intake diagnoses	Substance use diagnoses of study samples are unreliable; generalizability of outcome findings are uncertain
	Urinalysis results are used as major outcome measure	(See below)
Treatment Variables		
Urinalysis Results Used as Treatment Intervention	Can motivate patients to adulterate urine or fail to provide urine samples when using drugs	Reduced reliability and validity of major outcome measure
Participation in 12-Step Programs is Recommended	Some patients attend 12-step programs while in treatment study	Can't attribute outcome to treatment of interest

(Chitwood 1985), comorbid psychiatric disorders (Regier et al. 1990; Rounsaville et al. 1982, 1991; Weiss et al. 1986), medical problems, environmental problems (e.g., housing or poverty), social problems (e.g., legal and criminal cases), and interpersonal problems (lack of stable family or other sustaining relationships or conflict-laden close relationships).

Issues for Outcome. The fact that substance-abusing patients often have multiple problems typically is associated with three events that compromise outcome measurement: multiple interventions are provided in studies, a large proportion of patients drop out of treatment programs, and followup assessment rates tend to be very low. The impacts of each of the three events on outcome assessment will be discussed in turn.

Multiple Interventions. The natural clinical impulse to provide multiple interventions to patients who have multiple problems is manifested in substance abuse research treatment programs. Thus, for example, treatment programs like those at the Treatment Research Unit at the University of Pennsylvania Department of Psychiatry often provide adjunctive services such as medical interventions, assistance with obtaining benefits from social service agencies, and psychopharmacological interventions that are not the treatments being examined. Furthermore, adjunctive services often are provided on an as-needed basis.

When standard procedures are not followed for dispensing adjunctive services and when they are provided based on the needs of individual patients, the adjunctive interventions are not controlled in a study design. Some patients receive much more frequent interventions and more types of interventions that could have therapeutic effects than other patients do. Thus, when adjunctive interventions are dispensed in a naturalistic way in substance abuse treatment studies, the outcome findings cannot be attributed to a specific independent variable (i.e., a form of treatment that is being studied).

High Dropout Rate. Although little evidence exists of why substance abuse patients drop out of treatment, high dropout rates are well documented. For example, in an outpatient treatment study of cocaine abusers, Kleinman and colleagues (1990) reported that 42 percent of

148 patients dropped out before the first therapy session and, of those who remained, only 25 percent stayed for 6 or more sessions. The high dropout rates probably are related in part to the fact that many substance abuse patients have multiple problems. In fact, the high dropout rate is another variable that prompts investigators to provide multiple interventions to substance abuse patients in treatment outcome studies: the interventions often are offered to retain patients.

High rates of attrition pose serious problems for outcome assessment because patients who drop out are generally harder to schedule for termination assessments than are patients who do not drop out. In other words, outcome data are more difficult to obtain from dropouts than from remainers. The difficulty of obtaining outcome data, in addition to the high dropout rates, leads to another problem: study findings cannot be generalized to the patient population of interest because the findings are based on only a small subset of those who were randomly assigned to treatment (Howard et al. 1990).

Low Followup Rate. Some of the types of problems that co-occur in substance abuse patients (e.g., social, environmental, and interpersonal problems) contribute to an unstable lifestyle with many moves, incarceration, lack of a postal address, and unreliable telephone numbers. Such variables make it difficult to locate patients for posttreatment followup assessments that are needed to evaluate long-term treatment outcome.

Low Motivation for Cure

It has been observed that many people who seek treatment for substance abuse want a period of respite from drug use, a "drug holiday," rather than long-term abstinence or cure (e.g., Rounsaville and Kleber 1985).

Issues for Outcome. The fact that many patients who seek treatment want a period of remission, not long-term discontinuation of drug abuse, contributes to the observation that substance abuse tends to have an episodic course (e.g., Khalsa et al. 1990). Patients seeking only a drug holiday also probably add to the relatively high *early* dropout rate in substance abuse treatment. The effects on outcome assessment of

both of the preceding behavior patterns of substance-abusing patients are discussed next.

Episodic Course. The fact that substance abuse can have an episodic course complicates outcome assessment because remission of symptoms cannot necessarily be interpreted as a treatment effect; remission can be a manifestation of the natural course of substance abuse behavior patterns. Of course, substance abuse is not the only problem that has an episodic course. Panic disorder is another DSM-III-R (American Psychiatric Association 1987) Axis I diagnosis that tends to be episodic: the frequency of panic attacks often changes spontaneously. Episodic disorders require special outcome assessment strategies to obtain findings that can be reasonably attributed to treatment interventions.

High Early Dropout Rate. To the extent that many patients drop out of treatment early because their primary goal is to have a brief respite from drug abuse and the financial, physical, and interpersonal stresses it creates, outcome assessment is compromised for reasons that were previously discussed. In addition, if outcome data on early dropouts are obtained, self-report might indicate that the patient is improved (e.g., Mercer and Moras 1992), particularly if the measure is frequency of drug use. However, interpreting such data as evidence that the treatment was effective is questionable. A change in frequency of drug use in a person who was seeking to reduce his or her drug use for a brief period does not indicate that the treatment was effective from a public health perspective because neither the person's willingness to abuse drugs nor his or her pattern of drug abuse was changed.

Poorly Educated Patients

Many substance-abusing patients are educationally disadvantaged. Poorly educated individuals can have difficulty reading, comprehending, and completing common outcome measures. Poor reading comprehension particularly affects self-report measures. Also, poor education can lead to impaired verbal comprehension and limited vocabulary, which affect commonly used interviewer-administered instruments such as the Structured Clinical Interview for DSM-III-R (Spitzer et al. 1992).

Issues for Outcome. Many of the outcome measures that often are used in psychotherapy research were not developed for individuals with low levels of reading comprehension. Thus, some measures are unlikely to have adequate reliability and validity when used without modification in substance abuse treatment studies.

Frequent Substance Use

Drugs affect people's perceptual, memory, and biochemical processes; they affect phenomenological, cognitive, and somatic experience. The fact that drugs can have pervasive and marked effects on the experiential and biochemical systems of the human organism means that the responses of substance-abusing patients to commonly used outcome measures (e.g., the Hamilton Rating Scale for Depression, Hamilton 1960) are likely to be influenced in complicated and, as yet, unmeasured ways compared to the responses of non-substance-abusing patients.

Issues for Outcome. The fact that substance-abusing patients use substances creates the most fundamental problems for outcome assessment. The problems are of several types.

Confounded Pretreatment Scores on Outcome Measures. Outcome measurement typically involves pretreatment and posttreatment administration of the same instruments. Pretreatment to posttreatment differences are interpreted as treatment effects. However, the pretreatment responses of substance abuse patients are necessarily affected by the impact that substances have had on their most recent perceptual processes and phenomenological and somatic experience. Moreover, those processes and experiences are patients' main source of the information required to respond to many outcome measures, both self-report (e.g., Symptom Checklist-90, Derogatis et al. 1974) and interviewer-administered (e.g., Hamilton Rating Scale for Depression).

Pretreatment responses to outcome measures are complicated further by an individual's recent drug ingestion history, such as how long it has been since drugs were used before completing the pretreatment assessment and which drugs were used recently (Weiss et al. 1992). Furthermore, the effect of an individual's recent drug history on

pretreatment assessment measures will differ depending upon the time period enquired about. For example, no standard exists for the inquiry for the Hamilton Rating Scale for Depression (Hamilton 1960): 1 month is used in some studies; 1 week is used in others. Thus, depending upon the relationship between how long it has been since a person used drugs and the period of time inquired about, a pretreatment measure could obtain scores that reflect the effects of drug use, withdrawal from drug use, or symptoms that exist when the patient is drug free. In general, substance abuse studies do not control for the effect of the preceding variables on pretreatment scores on outcome measures.

A third problem is that when outcome is assessed, pretreatment scores are compared to posttreatment scores. If a person has discontinued or markedly reduced drug use during treatment, then posttreatment responses will reflect his or her symptom experience when he or she is drug free. If the pretreatment assessment did not control for recent drug ingestion status,the comparison of pretreatment to posttreatment symptom scores cannot be assumed to be a valid index of treatment-related changes because the patient's pretreatment to posttreatment self-report will have changed simply because drug effects were affecting his or her experience and response tendencies at pretreatment but not at posttreatment.

Symptoms of Drug Use Mimic Some Psychiatric Symptoms. Drug abuse creates very complicated problems for certain outcome measures such as DSM-III-R (American Psychiatric Association 1987) diagnoses (Nathan 1991). For example, many DSM-III-R anxiety and mood disorders have symptoms that also occur with drug use. Overlapping symptoms can create insurmountable differential diagnostic problems because the assignment of some diagnoses (e.g., major depression) requires the diagnostician to determine if symptoms that were present for a diagnostically required length of time were likely to be due to drug use or not. Such determinations often are compromised because many substance-abusing patients are unable to provide the precise timeframes needed to determine if psychiatric symptoms were occurring during a drug-free period.

Self-Reported Drug Use Is Unreliable

It is generally observed that substance-abusing patients can be wittingly unreliable informants about their drug use during treatment as well as about their pretreatment drug use. Some data suggest that the degree of unreliability of self-report is related to the specific type of questions asked (Hser et al. 1992).

Issues for Outcome. Unreliable self-report data about substance use create obvious problems for outcome assessment because the patient is typically the principal source of information about his or her drug use. Furthermore, drug use is a major outcome variable in substance abuse treatment studies, given that drug abuse is usually viewed as the most serious problem to be treated from a public health perspective.

Unreliable information at pretreatment compromises the validity of comparisons between pretreatment and posttreatment indices of drug use that are the basis of outcome assessment. In addition, of course, unreliable reports of drug use can lead to unreliable initial diagnoses, thus compromising the internal validity of an outcome study because the patients studied might not have had the disorders that they were determined to have and might have had other disorders that were not detected.

Urinalysis Results Used as Treatment Interventlon and as Outcome Measure

The clinical observation that substance-abusing patients can be unreliable informants about their substance use has led to the collection of urine samples to monitor drug use The results of urinalyses also are often used by drug counselors to discuss unacknowledged drug use. Moreover, experienced substance abuse counselors strongly believe that the use of urinalysis results is a necessary component of effective substance abuse treatment, although no systematically collected evidence exists to support this belief.

The fact that urinalysis results often are used in substance abuse treatment can prompt investigators to conclude that urinalysis results must be used in treatments that are being studied in order to preserve the generalizability or external validity (Campbell and Stanley 1963) of

studies. Urinalysis results also generally are regarded by substance abuse researchers as the most reliable and valid outcome measure of substance abuse treatment, given that patient self-report is viewed as unreliable. Furthermore, the results of urinalyses often are used as an ongoing, repeated measure of treatment effects during the course of drug abuse treatment.

Issues for Outcome. A problem is posed for outcome assessment when urinalysis results are used both as a treatment intervention *and* as an outcome measure. A patient's knowledge that the results of urinalyses will be provided to his or her therapist can create demand characteristics for the collection of urine samples that will compromise the reliability and validity of the data. In other words, the fact that results of the urine tests will have consequences for patients (consequences that presumably lead them to give unreliable self-report information about drug use) can motivate them to adulterate urine samples or fail to provide samples when required, thereby making the results either unreliable or unobtainable.

Some support is available for the preceding hypothesis that collecting urine samples under conditions in which the results have an impact on patients affects the data obtained. For example, in one opioid maintenance study in which urinalysis results were not communicated to therapists and not used in treatment and the patients knew this was the case, at least 60 to 80 percent of the urinalysis results showed evidence of drug use, even in high-dose methadone subjects. The positive urine rates were much higher than generally found in the same clinic when urine results affected treatment decisions (e.g., take-home methadone or discharge from treatment) (J. Blaine, personal communication, March 1992).

Participation in 12-Step Programs Recommended

It is generally believed among experienced substance abuse treatment personnel and researchers that participation in lay treatment programs based on the 12-step model, such as Alcoholics Anonymous, is a necessary adjunct to clinic-based treatment programs. This belief is firmly held, although no controlled evidence exists to support it (London 1990). The belief has an impact on outcome assessment in substance abuse research because patients in research treatment

programs often are exhorted to participate in 12-step programs while they are involved in research treatments.

Issues for Outcome. The issues for outcome are essentially the same as those previously discussed under the subheading "Multiple Interventions," namely: the outcome findings cannot be attributed to the treatment(s) being studied when other interventions that could affect outcome are being dispensed in a naturalistic, uncontrolled way. In substance abuse studies, typically no attempts are made to measure or control 12-step meeting attendance. Thus, only some patients will attend 12-step programs, some will attend more meetings than others will, and patients will attend different 12-step meetings. The last is a problem because the qualities of meetings held in different places vary widely, according to people who regularly attend them.

STRATEGIES TO ADDRESS OUTCOME ASSESSMENT PROBLEMS

Seven features of substance abuse treatment studies that compromise outcome assessment were identified in the previous section. Some features are more directly under the control of investigators than others are and, therefore, have relatively straightforward solutions. For example, encouraging patients to attend 12-step program meetings while they are participating in research treatments can be addressed simply. Investigators can either chose to discontinue the practice *and* ask study patients to refrain from attending 12-step meetings while receiving treatment in the study or include 12-step meetings in a standard, replicable way in their research treatment programs. Similarly, for the use of urinalysis results as both a treatment intervention and an outcome measure, investigators can decide not to use the results in the study treatments if urinalysis results are to be used as an outcome measure. The impact of a third feature on outcome, poorly educated patients, is at least partially under the control of investigators. Standard self-report outcome measures can be assessed to determine the reading level required. Instruments can be modified to match the expected reading level of study samples. In some cases, investigators might need to exclude commonly used instruments if modifying them will compromise their purpose.

Four other features of substance abuse treatment studies were identified in the previous section that are not directly under the control of investigators. All are features of some substance-abusing patients who present for treatment: multiple problems, low motivation for cure and the related episodic course of substance abuse, frequent substance abuse, and unreliable self-report information about drug use. A fifth major problem, high dropout rate, came up in the discussion of two of the preceding five features. Strategies for addressing each of the foregoing features are discussed next. (For summary, see table 2.)

Co-Presence of Multiple Problems

Adopt Assumption That Homogeneous Subsets of Patients Exist With Etiologically Different Substance Abuse; Test Theoretically Derived Treatments on the Subsets. The fact that some but not all drug-abusing patients have multiple problems suggests that substance-abusing patients might be an etiologically heterogeneous group (cf., Robins 1990; World Health Organization 1981). For example, substance abuse in some patients might be a secondary problem, a correlate of social-environmental problems (such as poverty, poor educational and career opportunities, or unstable family structure) that lead to low hope and few aspirations. For such patients, treating only the substance abuse would be predicted to be ineffective in alleviating it, particularly in an enduring way. In other patients, substance abuse might be secondary to some other psychiatric problem such as an anxiety disorder, chronic depression, or personality disorder. A third subset of substance-abusing patients might exist whose primary problem is substance abuse. Such patients might enjoy using substances or have particular vulnerabilities to addiction and have life problems that develop secondary to the addictive properties of substances.

The preceding heterogeneous group hypothesis implies that: (1) not all substance abuse patients require multiple interventions because not all have multiple problems, and (2) various subtypes of multiproblem substance abuse patients exist and the subtypes might respond optimally to multicomponent treatments that have components designed *specifically* for the set of problems that a patient has. Furthermore, the heterogeneous group hypothesis is consistent with the

TABLE 2. *Research strategies to improve outcome assessment in substance abuse treatment studies.*

Feature	Research Strategy	Procedure
Co-Present Multiple Problems	1. Develop classification of subtypes of substance abuse that is linked to etiological models of substance abuse	1. Develop procedures (e.g., questionnaires) to identify subtypes
	2. Develop theoretically derived treatments, based on etiological models for subtypes of substance abuse	2. Design outcome studies that test effectiveness of treatments developed for specific subtypes
		3. When multiple interventions are theoretically required, provide them in standardized and controlled ways
Low Motivation for Cure	1. Exclude patients who are seeking a drug holiday	1a. Develop procedures (e.g., interview questions) to distinguish patients seeking long-term remission of drug abuse from those seeking a drug holiday
		1b. To facilitate reliable self-report on treatment goals (cure vs. drug holiday) offer short-term abstinence-support program to those seeking temporary abstinence
		2. Develop abstinence-support intervention to include in study design

TABLE 2. *Research strategies to improve outcome assessment in substance abuse treatment studies* (cont.).

Feature	Research Strategy	Procedure
Episodic Nature of Drug Abuse	1. Conduct prospective and retrospective descriptive studies of patterns associated with different drugs of abuse	1a. Retrospective pattern assessment might use timeline follow-back methods (Sobell et al. 1980) 1b. Prospective pattern assessment would require recruitment of nontreatment seeking patients and payment for multiple assessments. Could be done by phone to increase participation Limitation: potential impact of self-monitoring on natural patterns
	2. Obtain retrospective baseline assessment of drug use patterns for $\geq$ 2 years before entry into outcome study	2. Timeline follow-back (Sobell et al. 1980)
	3. Conduct $\geq$ 2 year followup assessment to obtain drug use pattern data to compare to pretreatment baseline pattern	3. Offer generous incentives that are valued by patients (e.g., day care coupons, restaurant coupons) for followup assessment and rely on patient's social network to locate them Limitation: Close self-monitoring required for followup can affect drug use patterns that are being measured

TABLE 2. *Research strategies to improve outcome assessment in substance abuse treatment studies* (cont.).

Feature	Research Strategy	Procedure
Frequent Substance Abuse	1. If symptom outcome measures are used, collect pretreatment data only on those that are not affected by use of drug being studied	1. Carefully review symptom measures of interest. Either exclude those that will be affected by type of drug abuse being studied, or do not do pre- to post-treatment outcome comparisons on measures that will be affected by drug use status at intake
	2. Control for effects of recent drug ingestion status on pretreatment responses to outcome measures	2a. Use procedures to ensure that patient is/was drug free during interval that would affect pretreatment response to measures
		2b. Adjust inquiry for measures to ensure drug-free period is time frame inquired about
		2c. Record recent drug ingestion history at time measures are obtained, if drug ingestion status cannot be controlled
	3. Reduce reliance on self-report measures when responses are likely to be affected by drug ingestion status	3. Carefully review measures of interest; search for or develop measures not affected by recent drug use status

TABLE 2. *Research strategies to improve outcome assessment in substance abuse treatment studies* (cont.).

Feature	Research Strategy	Procedure
Self-Reported Drug Use Can Be Unreliable	1. Reduce negative consequences of admitting to drug use	1a. Study patients' perspectives on feared or wished for consequences that prompt them to either under- or over-report drug use
		1b. Use information on patients' common reasons for distorting drug use to explicitly address common feared and wished for consequences that motivate distortion of self-reported drug use
	2. Develop measures of drug use that do not rely on self-report	2. Develop objective (e.g., physiological) or observational methods to collect drug use data
	3. Use daily self-monitoring to obtain more reliable baseline drug use data	3a. Use daily self-monitoring forms during a baseline pretreatment assessment phase
		3b. Check in with patient frequently during baseline period (e.g., every 3 days) to review self-monitoring and to obtain data missed for days since last check-in
	4. Accept unreliability of self-reported drug use	4. Do not use self-report measures as primary outcome indices

TABLE 2. *Research strategies to improve outcome assessment in substance abuse treatment studies* (cont.).

Feature	Research Strategy	Procedure
High Dropout Rate	1. Exclude patients who are seeking a drug holiday	(See "Low Motivation for Cure" section)
	2. Select patients who meet criteria for a subtype of drug abuse for which the treatment studied was specifically developed	(See "Co-Present Multiple Problems" section)
	3. Obtain outcome data from all patients who drop out as close as possible to the time of their last treatment session (or intake assessment if they dropout before treatment)	3a. Offer generous incentives to dropouts for participating in all scheduled assessments after drop out 3b. Include measures that do not require patients to travel to the research setting to complete (e.g., use telephone and mail data collection) 3c. Use patients' social networks to help locate them

development of theoretically driven treatments based on etiological models of different subtypes of substance abuse.

Developing and testing multicomponent treatments that are based on etiological models of substance abuse subtypes would address the problems posed to outcome assessment when multiple interventions are included in substance abuse treatment studies in naturalistic ways. The research strategy would increase the probability that all interventions used would be provided in a standard, controlled way because the interventions would be theoretically driven. Also, the strategy would lead to examination of the assumption that effective substance abuse treatment requires multiple interventions.

Low Motivation for Cure

Exclude Patients Who Are Seeking Drug Holidays. If a goal of research is to identify and develop treatments that have lasting effects on substance abuse, then the treatments should be tested with patients who also are seeking that result. In other words, a way to deal with the problems posed by low motivation for cure to obtaining meaningful outcome data is to select patients who are more similar to those who commonly enter psychotherapy studies (i.e., patients who seek treatment because they want permanent remission of their presenting problems).

The preceding strategy requires the development of selection procedures that can distinguish patients seeking cure from those seeking respite. The distinction might be relatively easy to make based on self-report if no unwanted consequence occurs to patients who admit to seeking only temporary abstinence or reduction of drug use. One way to enhance the probability that patients will reliably state their treatment goal is to provide something for both types of patients (cure and respite) in a study design. For example, patients who mainly want help reducing their drug use would be offered a short-term drug-use reduction and detoxification program.[2] Those seeking cure would be assigned to the treatments being studied.

Episodic Nature of Drug Abuse

Obtain Baseline Measures of the Pretreatment Substance Use Patterns for >2 Years Preceding Treatment. Use the Data to Compare With >2- Year Followup Assessments. Although episodic drug use patterns might be most parsimoniously explained in some cases as reflecting a desire for drug holidays rather than cure, episodic patterns also might have other causes. Thus, a useful first step toward improving the validity of outcome findings with substance abuse disorders would be to do retrospective and prospective descriptive studies designed to identify common patterns associated with the abuse of different substances. The conduct of such studies would both contribute to the development of methods to obtain drug use pattern information and identify common patterns that treatments need to affect.[3]

If data indicate that substance abuse (or certain types of substance abuse) is typically an episodic disorder, valid outcome assessment would require baseline drug use pattern data pretreatment and followup pattern data posttreatment. Because many patients who seek treatment have a long history of drug use (Anthony and Helzer 1990; Rounsaville et al. 1982), baseline data should be obtained for at least 2 years pretreatment, and followup data should be obtained for a comparable period. Procedures need to be developed to compare pretreatment and posttreatment substance use pattern data. For example, retrospective data could be obtained by month using time-line follow-back methods (Sobell et al. 1980) for the 2 years that preceded treatment. Several drug use indices could be obtained this way, such as number of months using per year, average frequency of drug use for highest and lowest month/year, average number of different drugs used for highest and lowest month/year, and average amount of money spent on drugs for the highest and lowest month/year. These indices then could be compared to similar data for a 2-year posttreatment followup period.

If the type of substance abuse to be studied generally has an episodic rather than stable course, pattern-of-use data pretreatment and posttreatment must be obtained to assess treatment efficacy. Unfortunately, a limitation is that the collection of the type and amount of data needed in a reliable way can affect the patterns that are being

measured. In other words, if close self-monitoring is fostered by needed data collection, behavior can be affected. A second potential problem is the difftculty of obtaining the needed followup data for 2 entire years. The latter problem can be addressed by providing a variety of highly valued incentives for participating in needed assessments (such as child care coupons, food coupons, transportation coupons, or payment) and enlisting patients' social networks to help locate them.

Frequent Substance Abuse

Limit Symptom-Related Outcome Assessment to Measures That Are Not Affected by the Type of Drug Use Being Studied. This recommendation requires careful consideration of the probable impact of pretreatment substance abuse on the data obtained with each outcome measure of interest. Measures that will be affected by the type of drugs used or the length of time that substances were abused before the pretreatment assessment should be excluded or modified. For example, if the substance abuse to be treated is cocaine, it might not be possible to reliably diagnose major depression at pretreatment unless patients are required to meet an abstinence criterion before the diagnostic interview (Nathan 1991; Weiss et al. 1992). The diagnosis then should be excluded from a pretreatment structured diagnostic interview.

Control for Effect of Recent Drug ingestion on Pretreatment Measures. The effect of drug use on pretreatment outcome measures that it will affect should be controlled. One way to do this is to obtain ratings on symptom measures like the Hamilton scales (Hamilton 1960) for periods when the patient was drug free and unlikely to be experiencing withdrawal effects. Thus, for example, the Hamilton inquiry would cover the week preceding the Hamilton interview, and procedures would be used to ensure that the patient was drug free and not in withdrawal during that week.

Possible procedures to control for drug use in the week preceding pretreatment assessments would be to obtain pretreatment ratings on outcome measures only after a patient had successfully completed a 7-day abstinence program in which urine samples were obtained that documented drug-free status during that period. Limitations of the

procedure are that the abstinence intervention itself might influence a patient's symptom experience during that week, and 1 week is unlikely to provide a reliable index of a person's symptom status. An alternative strategy would be to eliminate pretreatment measures that will be affected by acute drug ingestion history, acknowledging that valid scores on them cannot be obtained without introducing a drug use control procedure which, itself, is likely to affect the validity of the data (i.e., if the pretreatment data are to be interpreted as indicating patients' "natural" and drug-free status on the variables measured).

Reduce Reliance on Measures That Are Based Primarily on Self-Report When Self-Report Is Likely To Be Affected by Drug Ingestion Status. A third strategy is simply to eliminate pretreatment assessment on measures such as the Hamilton scales and the SCL-90 (Derogatis et al. 1974) that are designed to assess symptoms likely to be affected by recent drug ingestion. Resources then could be redirected toward finding meaningful measures that would not be invalidated by recent drug use status.

Self-Reported Drug Use Can Be Unreliable

Two reasons are probably the primary contributors to unreliable self-reported drug use: the wish to avoid negative anticipated consequences of honesty (e.g., the fear that desired benefits will be withheld if one reveals the truth) and poor or inaccurate memory for required information. The two reasons require different research strategies.

Reduce Negative Consequences of Admitting to Drug Abuse. The assumption behind this recommendation is that in some patients, at least to some extent, the unreliability of self-reported drug use is motivated and therefore under the control of the respondent. Generally, motivated unreliable self-report is believed to result in underreporting either the amount or number of types of drugs abused. To the extent that the wish to avoid an anticipated negative event prompts unreliable self-reported drug use, procedures that reassure patients that the consequences they fear will not occur can reduce the problem. The development of procedures requires knowledge of the feared consequences.

A useful contribution to research in substance abuse would be to systematically obtain patients' perspectives on feared and wished-for consequences that can prompt them to either underreport or overreport drug use. This information is needed to determine what, if any, reassurances might be provided to offset common reasons for motivated unreliable self-reported drug abuse. However, such studies could lead to the conclusion that the preceding strategy is not feasible because needed reassurances cannot reasonably be provided.

Develop Measures of Drug Use That Do Not Rely on Self-Report. To the extent that self-reported drug abuse is unreliable because individuals often do not have mnemonic access to accurate information, other methods to obtain the information are needed if the data are regarded as critical to assessment of a treatment's efficacy. For example, some individuals who frequently abuse more than one drug seem unable to report accurately on the frequency, amount, periods of time, and so on. If self-report generally cannot provide needed information reliably, alternative sources and methods need to be used such as objective (public records) or observational data.

Use Baseline Daily Self-Monitoring To Obtain Drug Use Data. If the desired information cannot reasonably be obtained by methods other than self-report, one strategy is to provide patients with daily self-monitoring forms during a baseline pretreatment assessment phase. During this time, patients would be asked to keep forms with them to be completed daily, perhaps several times a day. For example, cards that fit into shirt pockets or wallets have been used in alcohol abuse studies to facilitate accurate recording of the number of drinks and drinking episodes. To help ensure that patients remember to record, frequent telephone check-ins or clinic visits (e.g., every 3 days) can be used to review records and to prompt short-term memory when data are missing.

Accept Unreliability of Self-Reported Drug Abuse: Do Not Use Such Measures as Primary Outcome Indices. This recommendation is self-explanatory and does not require elaboration.

High Dropout Rate

Procedures discussed in prior sections (e.g., selecting patients who are motivated for cure and selecting subtypes of substance abuse patients who are offered treatments that are specifically designed for the set of problems with which they present for treatment) might help lower dropout rates in substance abuse treatment studies. However, because attrition is a major handicap to obtaining interpretable treatment outcome findings, the use of procedures that directly address the problem also is indicated.

A recommended strategy is to aggressively attempt to locate and obtain outcome data from patients who drop out rather than to include retention incentives such as additional services in the treatment program. The rationale for focusing resources on getting outcome data from dropouts rather than trying to induce retention is twofold. First, techniques to induce retention undermine the internal validity of a study that is designed to evaluate treatment efficacy. Secondly, attrition rates are an excellent outcome measure as long as outcome data are obtained from dropouts at the time they leave a study. Regarding the latter point, for example, if dropout is due to patients' perceived lack of benefit or the unacceptability of a treatment approach, attrition rates indicate the proportion of patients for whom a treatment is unlikely to be effective. Alternatively, if dropout is mainly due to early recovery ("early" in terms of the anticipated length of treatment required for optimal effects), attrition rates actually would enhance efficacy evidence for the treatment being studied.

Incentives for Participating in Assessments After Dropout. Research experience generally indicates that financial incentives are effective in increasing the proportion of dropout patients from whom outcome data can be obtained. Payments are usually based on consideration of the inconvenience associated with an assessment (e.g., difficulty of transportation to the site, including parking difficulty and costs; child care costs and arrangements; and the amount of time required to complete the assessment). Fees should be large enough to defray costs to the patient that are associated with the assessment, provide compensation for time spent, and provide additional incentive so that the patient is likely to perceive a personal advantage from cooperating.

Concerns are sometimes raised about using money as an incentive for substance abuse patients because it can be used to buy drugs and cash might help create an overwhelming impulse to get high. Alternative incentives can be used such as coupons for daycare, food, restaurants, and transportation. Dropout outcome data are so important to obtaining interpretable results from a treatment study that generous incentives, whatever their nature, are indicated.

Use Assessments That Do Not Require the Patient To Travel To Complete Them. A second approach to increasing the proportion of dropout patients from whom outcome data are obtained is to use telephone interviews. Many observer-rated outcome measures can be obtained by telephone. However, some measures or some parts of measures (e.g., Hamilton scales) use observations made in face-to-face interviews. Items that require direct observation can be excluded from both pretreatment and outcome data analyses if an instrument includes only a few such measures.

Dropouts also can complete self-report questionnaires by mall. Payment or other incentives can be provided upon receipt of completed questionnaires. Incomplete responses to returned questionnaires can be inquired about in telephone interviews. Finally, self-report instruments can be administered by telephone, although such a procedural modification should be reported in publications.

SUMMARY: PROCEDURAL RECOMMENDATIONS TO ENHANCEOUTCOMEASSESSMENTINSUBSTANCEABUSE TREATMENT STUDIES

Table 3 summarizes the main recommendations that were made in this chapter to eliminate or reduce outcome assessment problems associated with substance abuse treatment research when the primary goal is to obtain interpretable efficacy or comparative efficacy data. Substance abuse treatment research was reviewed in this chapter from the perspective of the technology model of psychotherapy research. The main overall conclusion is that substance-abusing patients pose unique problems for treatment outcome research, most notably: symptoms of substance use that mimic psychiatric symptoms, low motivation for cure, and a tendency to drop out of treatment at high rates. These and

TABLE 3. *Summary: Procedural recommendations for substance abuse treatment outcome studies.*

Inclusion Criteria	Treatments	Pretreatment Data Collection	Followup Data Collection	Outcome Measures
1. Select patients motivated for cure	1. Provide temporary abstinence support intervention to patients who don't meet "motivated for cure" criteria	1. Collect retrospective or prospective baseline data that indicate pattern of drug use over an extended period, to control for episodic nature of drug abuse	1. Collect prospective pattern of drug use data for a period long enough to assess change in pattern of use, pre- to post-treatment	1. Use outcome measures that are appropriate for lowest educational level to be accepted into the study
2. Select patients who meet criteria for theoretically derived, treatment-relevant substance abuse subtypes	2. Test treatments that are theoretically linked to etiological models of subtypes of substance abuse	2. NB. #5. under "Outcome Measures"		2. If urine samples are to be used as a major outcome measure, do not also use as a treatment intervention
	3. If theory suggests that a multicomponent treatment is needed, provide all components in a standardized, controlled way			3. Do not use self-report measures when self-report is generally an unreliable index of the outcome variable of interest
	4. Do not provide adjunctive services in a naturalistic way: If such services are believed to be needed, include them in the treatment program in a standard, controlled way			4. Carefully review measures and exclude those whose validity at pretreatment is likely to be affected by frequent and/or long-term substance abuse

TABLE 3. *Summary: Procedural recommendations for substance abuse treatment outcome studies* (cont.).

Inclusion Criteria	Treatments	Pretreatment Data Collection	Followup Data Collection	Outcome Measures
	5. If participation in 12-step programs is posited to be necessary to the efficacy of the treatment being examined, include 12-step meetings that are conducted in a standard way in the treatment program			5. Use procedures to control for impact of recent drug ingestion on measures that it will affect 6. If a variable is a central outcome indice and self-report measures of it are unreliable, develop a new method to obtain the needed information 7. Obtain outcome data from all dropouts. Use highly valued incentives, telephone and mail response data collection, and systematic and exhaustive procedures to locate patients

NOTE: The recommendations are based on the assumption that the technology model of psychotherapy research (Carroll & Rounsaville, 1990; Docherty, 1984) is the research strategy of choice, and that treatment efficacy or comparative treatment efficacy is the main question to be addressed. For additional detail on each entry, refer to Tables 1 and 2.

related features require thoughtful modification of well-established procedures that are used in randomized clinical trial outcome research on psychiatric disorders in adults,

NOTES

1. The discussion is focused on features of substance abuse research that are generally true but not always true because, for example, characteristics of substance-abusing patient samples can differ depending upon socioeconomic status.

2. The cost-effectiveness and efficiency of different detoxification programs also could be examined by such a design.

3. Furthermore, descriptive data of this type can be usefully incorporated into treatments as an informational component. An example of this is information on the physiology of symptoms of panic that is used in cognitive behavioral treatments for panic disorder (Moras et al. 1990). Such information can provide nonspecific benefit to patients and increase therapists' potential influence because their perceived knowledgeableness will be increased.

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Between-Group Therapy Outcome Research: Design and Methodology

T.D. Borkovec

INTRODUCTION

In the simplest case, the fundamental goal of any between-group experimental design and its associated methodology is to hold all factors constant other than the one variable about which cause-and-effect conclusions are to be drawn. Any differences observed between comparison conditions representing the manipulation of that variable cannot be due to the ways in which the experimental conditions are the same, but only to the ways in which they are different. Each of the known and unknown ways in which conditions do, in fact, differ represents a rival hypothesis that could just as likely explain any observed difference. The fewer rivals that exist (i.e., the fewer ways in which the conditions differ), the more confident researchers can be in concluding that the specific difference among the conditions that were remanipulated experimentally actually caused the difference between conditions in measured outcome. Random assignment is the method for increasing the likelihood that the characteristics of the subject sample are evenly distributed and, thus, held constant over conditions. Standardization of procedures across all subjects and the matching of treatment and control conditions on all procedures except for the crucial manipulation are ways of holding constant aspects of the environment and the experience of the subjects in that environment. The purpose of this chapter is to review how these general methodological guidelines specifically apply to the case of between-group therapy outcome research and to suggest a general context in which such research might be considered most usefully.

The goal of therapy outcome research often is thought to be the demonstration of the efficacy of a therapy technique. Although the ultimate goal of therapy research is the development and evaluation of increasingly effective methods of therapy, the position taken here is

that primary focus on the issue of efficacy in any study is the wrong approach, short-sighted in its intention and unanswerable in its customary form. Research that merely aims to show that a method is effective is, at best, only the starting point of a program of research and, by itself, is extremely limited in usefulness at both the applied and the theoretical levels, no matter what types of designs are employed. Rather, the more heuristic approach is to focus in any outcome study on the experimental elucidation of the processes by which a therapy has causative effects on a problem or elucidation of the nature of the psychopathology being treated. The direct product of such research is increased understanding of something basic about human beings, and the evolution of increasingly effective techniques for helping them to change is best when based on such knowledge. The indirect product of such research is an ability to draw some relative, albeit very limited and short-term, conclusions about technique efficacy.

Because several resources exist on the design and methodology of therapy outcome research (see especially the excellent and comprehensive monograph by Lettieri 1992), the present chapter will summarize in brief form some of these considerations and will elaborate on those that require special emphasis. To facilitate both goals, table 1 provides an outline of (1) the basic types of outcome design and (2) some of the more important features of an outcome study that need to be considered and the general types of questions to be asked in making decisions about the potential relevance of each feature in interpreting a study's results and about choosing methodological devices that maximize their unambiguous interpretation. These questions are the same, irrespective of whether the investigator's purpose has to do with drawing conclusions from existing research or with designing an outcome investigation.

INDEPENDENT VARIABLE CONSIDERATIONS: DESIGNS

Although an investigator may choose any one of the major between-group design options listed at the top of table 1 to begin a program of research, the history of evaluative investigation for a particular therapy typically begins with a no-treatment comparison and

TABLE 1. *Considerations in therapy outcome research.*

Independent Variable Considerations:

Designs

No-treatment comparison design	Additive (constructive) design
Nonspecific comparison design	Parametric design
Component control (dismantling) design	Comparative design

Independent Variable Considerations: Methodology

Random assignment within waves	Clients randomly assigned to conditions within temporal waves?
Session parameters	Number of sessions and length of sessions specified? Matched across conditions? Time and amount of treatment by a condition or condition component not confounded in dismantling or additive designs?
Therapy manuals	Used operationally to define treatments? Detailed? Available to readers to allow evaluation and replication?
Integrity checks	Adherence checked by independent raters? What percentage of sessions? Found to have minimal breaks in protocol? Equivalent adherence across conditions?

Table 1. (continued) *Considerations in therapy outcome research.*

Expectancy/credibility checks	Ratings obtained from clients early in therapy? Equivalent across conditions?
Attrition (dropout, missing data, and deterioration)	Total number? Equivalent across conditions? Comparisons to completers provided?
Client Considerations	
Source(s)	Numbers specified from each source? Balanced across conditions? Analyzed for effect?
Selection criteria	Operationally defined? Reliable? Levels balanced across conditions?
Representativeness	Numbers of clients screened for what reasons?
Client characteristics	Described? Means, standard deviations, and/or frequencies provided? Balanced over conditions?
Severity and duration of the problem	Specified? Means and standard deviations provided? Balanced over conditions?
Concurrent and past treatment and psychosocial treatment	Types and number of clients specified? Balanced over treatment conditions? Method of holding medication constant? Analyzed for effect?

Table 1. (continued) *Considerations in therapy outcome research.*

Diagnosis	Structured interview? Diagnosis base such as Diagnostic and Statistical Manual (DSM)? Independent reliability checks on diagnosis?
Therapist Considerations	Multiple therapists? Characteristics described? Training and supervision in general and in protocol described? Not confounded with condition? Possibility of therapist-bias effects?
Dependent Variable Considerations	
Multiple domain assessment	Valid and reliable measures from multiple perspectives and methods?
Assessors	Characteristics? Blind to condition? Reliability checks? Multiple assessors balanced across conditions?
Followup assessment	Duration? Completeness? Includes determination of further treatment?
Clinically significant change	Defined in a meaningful way?
Statistical Analysis Considerations	Pretherapy equivalence across conditions through nonconservative tests? Base-free measures of change? MANOVA on related measures? Significance of change within condition? Outcome analyses with and without endpoint scores? With and without clients receiving further treatment by followup? Sufficient power?

Table 1. (continued) *Considerations in therapy outcome research.*

Increasing Basic Knowledge in the Context of Therapy Outcome Design	Basic research questions asked through: Design conditions? Additional outcome and process measures focused on client characteristics and sites of effect? Comparisons to nonclient samples? Analysis of possible predictors of outcome?

subsequent attempts to rule out nonspecific factors before proceeding with more elaborate designs. This is done in recognition of the risks involved in prematurely choosing a certain type of more powerful, but more costly, research design as the start point.

No-Treatment Comparison Design

For a technique not yet researched, ensuring that it has effects greater than those associated with history, maturation, repeated testing, instrumentation, statistical regression, selection, attrition, and interactions of these variables with client characteristics through the use of a no-treatment comparison condition (Campbell and Stanley 1963) is a wise beginning. The design is less expensive in time and cost, usually yields sufficiently large effect sizes that thus require a smaller number of clients for adequate power, and provides an opportunity to rule out the above rival explanations of any observed differential outcomes sufficient to conclude that something about the provision of therapy with any or all of its associated characteristics is superior to nothing at all.

The ordinary no-treatment condition is a waiting-list condition. Ethics requires that clients in this condition be provided with therapy at the end of the waiting period. Two further ethical considerations are associated with this control condition. First, it is essential for the investigator to have some method of monitoring client status during the waiting period so that if deterioration in clinical status occurs, removal from the protocol and provision of appropriate treatment can take place. This often takes the form of periodic phone contacts with

the clients and assessment of their psychological state by a clinical assessor or instructions to the client to contact the project staff if any worsening of the condition occurs. While such procedures make it possible that client data will be lost (see the later discussion on the methods for dealing with missing data and the potential compromise of the researcher's confidence in the success of random assignment when people who deteriorate are removed), ethical treatment of participating clients takes precedence.

Second, the decision on whether to use a no-treatment condition in the first place must be carefully made on the basis of knowledge of the nature, course, and severity of the disorder being investigated in combination with the duration of the waiting period. The extremes of this decisionmaking dimension are easy to specify: lengthy waiting periods before treatment for a severe problem known often to deteriorate are not defensible from an ethical perspective, whereas brief waiting periods for analog problems with a benign course are defensible. Making decisions in the gray area between these extremes requires careful thought. All of these considerations obviously indicate that, under the usual circumstances of therapy outcome research, there is no way to secure long-term followup information on clients who are left without treatment after postassessment. Outside of the therapy outcome literature, there are sometimes longitudinal studies and clinical experience that provide information on the developmental course of some disorders. These sources of information may give some indication of the degree of change or lack of change that ordinarily can be expected from a particular type of clinical sample over various waiting periods. Moreover, documenting the duration of and the intensity of fluctuations in the disorder for each client who is entering the therapy study at the time of the initial interview (although fallibly based on retrospective report) can provide (1) some empirical sense of how likely it is that deterioration will occur during the trial and (2) how long the problem has been present as a baseline against which to evaluate change during the trial with some (albeit limited) confidence that any observed change over the typically 3-4 month therapy period was not due merely to the passage of time and its associated historical events.

Nonspecific Comparison Design

From a strong inference point of view (Platt 1964), after conducting a crucial experiment that rules out some rival hypotheses that might otherwise explain observed change (e.g., a no-treatment design), researchers take whatever remains unrejected as a possible explanation of the cause-and-effect relationship and create a new design with contrasting conditions that allow the ruling out of further, more specific rival explanations. What was left over from the no-treatment study was something about the provision of therapy. Taking this unrejected portion, researchers can further specify its content and create comparison conditions that represent differing aspects of that content. Traditionally in therapy research, this next step often has involved a division of a therapy into two general parts: those aspects that are common across most therapy techniques and those that are specific to the therapy under consideration. All therapies share common ingredients such as contact with a therapist, attention to the problem, suggestions that therapy generally will be useful in helping to change the problem, specific suggestions of the ways in which this therapy will promote change, and, in terms of the client's hypothetical internal process, the generation of faith, hope, and expectancy for improvement. Researchers are interested ultimately in whether or not a specific therapy contains active ingredients for change in addition to these common ingredients. The use of placebo conditions, based historically on pharmacological research contrasting chemically active medication with inert substances, became for a while the sine qua non of psychotherapy research as the vehicle for ruling out the nonspecific rival hypothesis (Paul 1969). Because of the conceptual, methodological, and ethical problems that became increasingly apparent in the use of placebo conditions in psychosocial treatment research (O'Leary and Borkovec 1978), their deployment in outcome research with actual clinical disorders has all but disappeared while the field continues to attempt to develop and use alternative methods to control for crucial nonspecific effects. Placebo conditions remain useful, however, in analog samples with mild "problems," as long as certain other methodological considerations are taken into account (see Expectancy/Credibility Checks on page 265).

A commonly used alternative to the placebo condition that circumvents some of these problems is a "commonly used" or "best available"

therapy control condition. In this approach, the investigator chooses a therapy that has no existing empirical data validating its efficacy for the disorder under investigation but is considered by the practicing community to be a frequently used or, if some consensus informally exists, the best clinical intervention that exists. Methodological (see Expectancy/Credibility Checks on page 265) and ethical (such as monitoring for deterioration) considerations will remain with this choice, but they are often not as problematic as they are in the case of pure placebo conditions.

Component Control or Dismantling Design

In order to control for nonspecific factors in a way that decreases ethical concerns, conceptual difficulties, and methodological problems and at the same time potentially generates the greatest amount of important basic knowledge, the use of the next design, the component control or dismantling design, is nearly ideal. The investigator specifies the various methods of a therapy technique and creates treatment conditions that provide some elements but not others, often with a final condition representing the entire package of methods. Ethical considerations are less severe at this point in time because, even though the package may have been previously determined to be superior to some other control condition, it is unknown which procedural element or combination of elements actually is causing the change-any one of them could be responsible. Methodologically, the various conditions derived for component analysis are or can be very closely matched in many procedural details; thus, more factors are held constant than is the case with alternate comparison conditions. Empirically, it has been shown that the likelihood of conditions being equivalent in degree of nonspecific factors is greater to the degree that the contrast conditions are procedurally similar, but such an equation needs to be checked through expectancy/credibility scales (see page 266). Demonstrations of differential outcome among components or between certain components and the total package provide extremely useful information regarding both the nature of the pathology itself and the nature of the therapeutic processes and mechanisms that lead to change.

Differential outcome among components draws the investigator's attention to more precise questions about (1) the factors responsible for

therapeutic change (e.g., what the mechanisms of change must be like, so that these particular components impact on the disorder) and (2) the factors responsible for maintenance of the disorder (e.g., what the mechanisms of maintenance must be so that these components impact on them). The empirical outcome limits the possibilities of what those hypothetical factors might be and guides the investigator's thinking in the direction of the most likely possibilities. This especially will be the case when component designs are used in conjunction with other methods described later in this chapter that focus on acquiring basic knowledge about the disorder and change process within the general context of a therapy outcome research design.

Ethics again requires monitoring for client deterioration, removal of the client from the study if such occurs, and the provision of alternate treatment for all conditions. The same is true for the following three designs as well.

Additive or Constructive Design

A design in which two or more therapy techniques are combined into one package and are compared to each of the single methods is identical to the component control design in nearly all respects; such an additive design has the same methodological and ethical advantages previously described. Its goal is to create a new therapy by adding two techniques together, each of which is considered by theory or empirical results to influence some aspect of the problem such that their combination would hypothetically provide even greater efficacy. The distinction between component control and additive designs really has more to do with historical perspective than with anything essential to their nature.

An example will clarify this point. Assume the year is 1950. Someone might already have evidence that relaxation methods are effective for some types of anxiety. The investigator also might know from extensive animal learning data that graduated, repeated exposure to feared situations reduces anxiety. So, this investigator proposes an additive design to evaluate the separate and combined effects of each of these therapies in the treatment of a simple phobia. Although Wolpe (1958) had somewhat different and more elaborate theoretical and empirical foundations for creating this very package, the actual

result of this type of thinking and its early research was the development of systematic desensitization. By 1968, experimental evaluation of this therapy had entered the component control design phase (e.g., Davison 1968). Contrasting component conditions were being used in an attempt to isolate the role of relaxation by itself, the role of imaginal exposure by itself, and their combination, thus representing a component control. The eventual results of the use of these designs led to some rather fundamental knowledge about the nature of the change process and the nature of fear.

Both component control and additive designs provide rather powerful tools from the strong inference point of view. Independent variables are held constant to a greater degree than is the case with other designs, and there may be no limits on the extent to which investigators can continue to further break apart efficacious therapy elements or to combine separate technique elements to test crucial rival hypotheses regarding therapeutic change on the basis of their comparison. The labels associated with these two designs, however, reveal an unnecessarily narrow perspective on their usefulness. It is the case that two elements may each separately contribute to overall efficacy in an additive manner. However, the even more exciting possibility is that one element may catalyze the effectiveness of the other in addition to whatever additive effects each may have. Indeed, such a synergistic process was at the heart of Wolpe's original theory about change mechanisms in desensitization.

Parametric Design

The creation of comparison conditions based on sampling along a fundamental dimension of a therapy approach or of a particular therapy element represents the most theoretically sophisticated design and provides the greatest methodological opportunity for holding all factors constant but one. In this design, the investigator chooses what he or she thinks is one of the most crucial theoretical or procedural dimensions of the change process induced by a therapy or one of its elements and constructs conditions that represent differing degrees of representation along that dimension. Examples of therapy dimensions from which one could construct contrasting conditions include: duration of exposure to phobic stimuli; depth of emotional processing; depth of interpretation; degree of warmth, congruence, and

unconditional positive regard; variations in schedules of reinforcement or punishment; degree of therapeutic focus on intrapersonal or interpersonal process; depth of focus on underlying beliefs; or the degree to which the developmental origins of an underlying belief are targeted. Because only a single dimension is being manipulated and because all clients will be receiving some level of that singular dimension, the investigator's ability to match conditions on all other procedural features is maximal. Because the design can sample more than two points along the critical dimension, functions can be determined that provide a much stronger basis for determining actual laws of behavior (i.e., two points can yield only a linear function that may not reveal completely the true underlying function). Similar to the component and additive designs and for analogous reasons, ethical problems are also less severe.

Comparative Design

Comparing two different therapies representing different theoretical and historical traditions certainly has a very high profile in the outcome research literature. There is good reason for the seeming importance of such investigations. The mental health profession and society in general, for many reasons, want to know the answer to the question of which therapies are most effective for which disorders.

The author claims, however, that comparative research of this type does not provide valid answers. Most comparative studies are of such limited value for both applied and theoretical purposes that they should not be conducted. The applied implications of their results are, at best, of excessively short-term significance even if the comparative methodology employed were internally valid (which it is not). Further, the usual ways in which such investigations are conducted preclude the acquisition of any meaningful basic knowledge. Different therapies vary from each other in so many ways that the experimental ideal of holding constant what the client experiences is not even nearly accomplished; differential outcome could be due to many, many differences in procedure. Thus, the investigator's ability to rule out rival hypotheses is extremely limited, and, consequently, little basic knowledge will be provided by this design. The design does allow ruling out nonspecific factors (assuming equation of the therapies on

this factor; see Expectancy/Credibility Checks, page 265), but only if differential outcome actually is observed.

The greatest threat to internal validity, however, resides in an issue surrounding the quality with which each therapy is provided. If differences between conditions exist in how well the therapies are conducted, comparison of the conditions is meaningless. In an extreme hypothetical example, it is obviously not fair to compare one treatment that is conducted very poorly to another that is provided with high quality and expertise. So, it is essential for internal validity that the therapies be matched on the degree of the quality of their provision. For the sake of ruling out the rival hypothesis of differential quality, it actually does not matter whether the therapies are matched at 50-percent, 75-percent, or 100-percent quality levels as long as they are matched. How can such matching be ensured? The therapy research field has made little progress in addressing this question, and despite some beginning attempts for some types of therapy (e.g., the Cognitive Therapy Scale, Vallis et al. 1986), researchers can say that there currently is no valid way to measure quality for any therapy technique. Thus, researchers cannot be sure that two different therapies are equivalent on this crucial, potentially confounding factor in comparative studies.

To minimize this problem, some investigations have employed expert therapists from each therapy tradition who conduct only their own therapy in the comparative trials. However, three problems remain. (1) This approach does not provide measured information on quality. (2) It is difficult to know for certain that expert therapists in one tradition provided quality equivalent to that provided by experts in another very different therapy. (3) The use of separate experts for each condition inherently confounds therapy condition effects with therapist characteristics, a significant problem for internal validity (see Therapist Considerations, page 276). The quality issue is ordinarily much less severe in the case of component, additive, and parametric designs because the therapists are typically trained in and clinically experienced with each element to an equal degree. If a therapist has been trained in desensitization and if he or she serves as a therapist in a component study contrasting relaxation therapy alone to relaxation plus imagery exposure, it is highly unlikely that this therapist would provide differential degrees of quality of relaxation training for clients

in the two conditions. Absence of valid measures of that quality still precludes empirical certainty of this, however.

Even if researchers could solve these methodological problems, a demonstrated differential outcome in a comparative trial would have only limited applied significance. Researchers could conclude that this one therapy is more effective than another, but for how long would this be a meaningful conclusion? Each therapy technique is undergoing constant modification based on further clinical experience, theoretical developments, and empirical information about its mechanisms of change and the nature of the pathology that it treats. Thus, researchers can reasonably expect on the basis of the past therapy developments that the efficacy of a particular technique and knowledge about the specific client or therapist characteristics best predictive of favorable outcome with a particular therapy will improve over time. Any comparative demonstration is, at best, a comment on relative efficacy at a particular point in time, with unknown future relevance as each method experiences growth and change at unknown, but probably differential, rates over time.

In summary, by their nature comparative outcome studies provide little basic knowledge by virtue of their inability to hold things constant and their limited internal validity by virtue of the currently unresolved issue of the potential confounding factor of differential quality. Thus, they yield little in either basic knowledge or applied significance, and their outcome would have only short-term significance even if these serious problems were to be overcome. The alternative approach is to go deeply into one therapy technique, using increasingly sophisticated designs, methods, and measures that explicitly provide basic knowledge about the pathology and the therapeutic change mechanisms of that therapy from which to devise hypotheses about increasingly effective modifications of that therapy.

Besides the basic design choices for therapy outcome research, researchers must take into account a variety of additional methodological considerations. Table 1 summarizes the major domains and the types of issues relevant to each domain.

INDEPENDENT VARIABLE CONSIDERATIONS: METHODOLOGY

Random Assignment Within Waves

Rarely in large-scale outcome research am all clients available at the same time. More often, referrals come continuously over the duration of the project period, which can last in some studies for 3 or 4 years. Because of possible seasonal variation, changes in the experience level and expertise of the therapists in conducting protocol therapy, changes in the experience of assessors, changes in personnel, and other considerations, ensuring that clients in each condition are balanced for such factors requires that random assignments be conducted within each consecutive wave of clients who become available for the treatment trial.

Session Parameters

To avoid confounding conditions with the amount of treatment provided, conditions need to be matched on the number of sessions and the length of each session. A particular problem arises when using those component control or additive designs in which treatment elements are contrasted with a combined package. In this instance, a confounding factor of either the total amount of treatment time or the amount of therapy devoted to any particular element exists. For example, if one were to compare therapy A to therapy B and to the combination of A and B, the combined group necessarily will receive either twice the amount of therapy time that A and B receive, yet still be given the full amount of exposure to each therapy, or it will receive only half of the amount of exposure to each therapy, yet be matched for total treatment time. The former methodological choice results in a rival hypothesis that total treatment time accounts for between-group differences, whereas the latter results in confounding the amount of exposure to each element. One solution to this problem would be provided if the study was conducted twice, once with one confounding factor present and once with the other confounding factor present. If similar between-group differences emerge, both rival hypotheses could be ruled out. Because this is an expensive solution, the more frequent method is to match conditions on total treatment time within an individual study by adding “best available” or other nonspecific

elements in the therapy sessions of the single-element conditions to increase the total amount of therapy time to match that of the combined condition. In this way, all conditions receive equal amounts of any active treatment components without an imbalance in the total time in contact with the therapist.

Therapy Manuals

Perhaps the single most important development in therapy research has been the creation of clear, detailed, well-operationalized definitions of the independent variable through the use of therapy manuals. The protocol manual provides several advantages: it allows for replication of therapy studies by other investigators, provides a basis for evaluation of the faithfulness and adequacy of the specific methods to the original theory and therapy technique from which it was derived, and maximizes the likelihood that the therapists in a study will adhere only to those procedures allowed by each particular therapy being investigated. A well-constructed manual specifies the conceptual underpinnings of the technique, the rationale given to the client for understanding his or her problem based on this conceptualization, and the particular procedures that arc to be used to facilitate therapeutic change.

The greater the degree of detail provided, the more the manual accomplishes its purposes. The best manuals give (1) session-by-session outlines and elaborations on the content within each outline step sufficient for the therapist to be able to follow the proscribed procedures as stated with every client and (2) specific guidance through clear statements of the theory underlying the technique so the therapist can deduce what specific interventions should be used in any given circumstance. The former provides the basic methods to be used with every client, whereas the latter allows for the needed flexibility to respond to the unique nature of each client while still remaining within the spirit of the therapy's protocol. Of course, the same degree of detailed instruction needs to be provided within protocol manuals for each therapy condition being investigated in the study.

Integrity Checks

Although the use of well-defined manuals is extremely important for the above reasons, there is no guarantee that the therapists actually do adhere to the protocol with every client or in every portion of every session. An essential check on protocol integrity involves independent ratings by staff knowledgeable in all of the various protocol techniques. These checks are conducted by randomly selecting an equal number of sessions for each therapist in each condition (typically 20-25 percent of all sessions) and by categorizing every therapist utterance from the audiotape of the entire session onto a checklist of protocol-allowed and not-allowed interventions. The latter checklist ideally includes all of the procedures involved in any of the contrasted therapy conditions as well as methods of therapy from other therapy traditions that are not explicitly a legitimate part of the investigated condition. Some operational definition of major and minor breaks in protocol needs to be established along with decisionmaking rules for when a client's data will be excluded due to significant departure from proscribed procedure. This approach is the most thorough, and it best precludes any confounding between conditions either from the contamination of one condition's unique methods with the methods of another condition or from the inappropriate use of techniques outside of the theory or therapy methods being evaluated. Less complete approaches to adherence rating have been employed (e.g., mere judgment about which condition was being conducted after listening to the entire session or sampling only a small portion–5-10 minutes–of a session), but these are largely inadequate to provide the empirical assurance of integrity that is required. It is essential that nonprotocol statements are found to be minimal in frequency and that study conditions do not differ in the frequency of such statements; otherwise, a confounding factor exists.

Expectancy/Credibility Checks

A central goal in attempts to control for nonspecific factors is to ensure that all therapy conditions in the trial are equivalent in their generation of expectancy for improvement and in the degree to which demand characteristics may contribute to client reports and behaviors at postassessments. Just because the treatment conditions are procedurally matched on the amount of therapist contact and attention

to the problem, the presentation of a meaningful rationale for the treatment, the provision of suggestions, and other factors, this does not necessarily mean that the conditions are equated on how much expectation and demand actually are generated in the client. The frequently used method to assess the degree of equivalence among conditions on these crucial elements of nonspecific influence has been the administration of expectancy/credibility scales early in the therapy trial. The expectancy scale asks the client to estimate the percentage of improvement that he or she expects to occur by the end of therapy, whereas credibility scales ask for ratings of how logical or believable the rationale and methods of treatment being offered appear to be and how willing the client would be to recommend such treatment to a friend who has the same type of problem. Ordinarily, such scales are given once the client has heard the rationale for the type of treatment that he or she will be receiving and a description of, if not actual exposure to, all of the intervention methods to be employed based on that rationale. It is important to obtain these ratings at an early point in therapy (often at the end of the first session) because client attitude about such factors may change over the course of therapy in response to actual improvement or lack of improvement and thereby confound the assessment.

Attrition

At each stage of the selection process, there likely will be clients who decide not to participate. As long as random assignment does not occur until a client is about to begin the first session, early termination is not a problem for internal validity, although it does affect generalizability. More importantly, virtually all clinical outcome studies will have attrition due to clients choosing to discontinue their participation after the start of their therapy ("dropouts"). Reasons for noncompletion may be varied, but they commonly include dissatisfaction with the type of therapy or the therapist, failure to experience any signs of improvement soon enough, excessive discomfort with the emotional experiences generated by the treatment (e.g., relaxation-induced anxiety in response to relaxation training), perceived lack of time to commit to sessions or to required homework assignments, and leaving the geographic area. Much has been made of the presumed devastating effects of dropout on the internal validity of a therapy investigation (e.g., Howard et al. 1990). The valid point is

this: if internal validity depends partly on the success of random assignment to distribute known and unknown client characteristics equally across conditions such that researchers can assume with statistically specifiable likelihood that the conditions am held constant on these variables and thus do not confound interpretations of condition differences, then any loss of clients after random assignment destroys confidence in this equation. Although researchers should compare dropout clients with completing clients by using all measured pretherapy demographic and outcome assessment variables, and, furthermore, again compare conditions using only the completing clients (with a demonstration of equivalence in both cases increasing the likelihood that these known variables do not confound the interpretation of results), there is no way that they can be sure that the conditions did not differ on unknown, unmeasured variables. Thus, there is no way to be confident that between-group differences in outcome are caused by the crucial condition manipulation.

The important point to be emphasized, however, is that everything researchers do in experimental research rests not on certitudes but on probabilities. In the present case, this means that the likelihood of undermined equivalence due to dropout falls on a continuous dimension of probability, and the best guess about where along that dimension a particular study falls depends on the size of the dropout rate. Again, extreme examples help to clarify this point. If only one client terminates prematurely out of 75 clients, there will be little, if any, impact on the assumption of initial equivalence of conditions. If 40 clients fail to complete the trial, the likelihood of equivalence among conditions with remaining clients is much reduced. Even in the latter example, however, the conditions have some probability of still being equivalent on all known and unknown client characteristics, although that probability is less than in the previous case. Because researchers have no way of knowing about the unknown, they cannot know where to draw the line between too much dropout and not enough dropout. Nor would they want to, because all rests on probability dimensions, not all-or-none decisionmaking. So, with no or small dropout, researchers are more confident in the absence of client characteristic confounding factors; with large dropout rates, they are less confident and need to point this fact out in their paper as a potential limitation on their conclusions.

Another crucial issue involves differential dropout among conditions. In itself, this is important empirical information regarding the range of applicability and consumer acceptability of the therapy techniques, but it also has implications for internal validity. The greater the differential dropout rate, the less probable it is that completing clients were equivalent between conditions before therapy began. There is less concern over (i.e., less probability of) confounding effects when dropout rates are equivalent. Dropout in general and differential dropout among conditions both have two possible elements: those independent of the type of therapy condition and those attributable to the type of condition. Notice that many of the reasons for early termination mentioned earlier could be either common for all conditions or specific to a particular condition. In the case of common reasons, initial random assignment allows a reasonable (probability-based) assumption of equivalence between conditions in likely frequency of termination, reasons for termination, characteristics of terminators, and initial characteristics among completing clients (i.e., no confounding with condition). Differential dropout for either type of reason is more problematic, but again only in terms of reduced probability of initial equivalence and, thus, in the increased probability that one or more client characteristics confound the therapy conditions. Like total dropout rate, differential dropout due to common reasons reduces confidence in condition equivalence in increasing degrees as the amount of dropout discrepancy between conditions becomes greater. In the case of differential dropout specific to the type of therapy, researchers have in addition even less confidence that terminators do not differ from nonterminators differentially between conditions on other characteristics because in this instance there is not a common stimulus to which they are responding.

In summary, dropout and differential dropout are problematic for interpreting results because they lessen the likelihood that the clients compared at postassessment were comparable at the start of therapy on all known and unknown variables, but it is essential to remember that these problems are always a matter of degree. As the size of attrition or the degree of discrepancy in differential attrition due to dropout increases, the probability of nonequivalence grows. However, this does not necessarily mean that the conditions are confounded by client characteristics at all. Additionally, in a certain sense, this entire issue is an empirical question. The reference is not to what a single study

might tell researchers or to being able to know the unknown (which is really the fundamental problem associated with the possible effects of attrition), but it is linked to the patterns of results from several replication studies over time, each involving varying degrees of attrition. A very meaningful, bottom-line question is this: historically, what is the evidence that this fallible procedure-for which logic dictates the possibility that random assignment does not do its crucial job because of the attrition enigma-has still produced significant and unconfounded conclusions about the relative effectiveness of a therapy or its components and has led to increasingly effective developments and modifications of that therapy based on those results? To this observer, there are several clear and compelling examples in which the answer is unequivocally affirmative; the cognitive model of panic and its associated treatment methods is a very good case in point.

Identifying common reasons for early termination and the development of methods within a therapy technique and in general to reduce its likelihood is an important area of clinical concern and research in its own right. Attrition during the screening process and after therapy has begun potentially affects external validity, and it may relate importantly to the issues of consumer acceptability and usefulness. Interestingly, however, the dropout problem is, in some significant ways, no different than the one faced by practicing clinicians. The modal number of sessions in general clinical practice is very small and indicates that many clients are therapy "dropouts." With this realization comes the ironic conclusion that an outcome study without dropout lacks a certain kind of external validity to the real clinical world.

One further consideration should be mentioned. The ideal procedure under the unfortunate circumstance of dropout is to conduct postassessments with terminating clients, both to identify the reasons for terminating and to obtain outcome measures. Although some clients may be unwilling to do so, many will. How to incorporate this information into data analyses will be discussed later.

Finally, two additional subcategories of client attrition are important to mention: (1) people who deteriorate and are removed for ethical reasons from the protocol because of clinically significant worsening of the problem and are provided with clinically sensitive, nonprotocol

therapy and (2) missing-data clients who are unwilling, unable, or unavailable to complete followup assessments. In terms of how these bear on the interpretation of results, the same comments outlined above for dropout clients can be made about both subcategories in all respects. Thus, it is similarly important to report the number of clients in each condition falling into each subcategory and to take these results into account when drawing conclusions. In the case of missing data, there are some additional considerations regarding statistical analysis, but these will be considered later.

CLIENT CONSIDERATIONS

Sources

Clients participating in therapy research potentially can come from various sources. The most common examples include: referral from other agencies or private practitioners, referral within the inpatient or outpatient services of the hospital in which the project is housed, self-referral to the project, and response to advertisements in the media announcing the availability of treatment. Indicating the number of contacts from each source is important for providing a basis for characterization of the client sample and for judging the generalizability and clinical relevance of the findings. Furthermore, ensuring that client sources are distributed evenly over the different treatment conditions of the project is essential in order to hold this variable constant. Initial analyses contrasting clients from different sources on demographic characteristics, pretherapy levels of dependent measurement, and outcome change can identify whether or not source variation makes a difference with this particular disorder.

Selection Criteria

Operational definitions of selection criteria for client participants need to be specified for required characteristics and those characteristics that would preclude a client from being entered into the therapy trial. Some common examples are gender, intelligence quotient, age, severity and duration of the problem, types of problems or primary and additional diagnoses, and status on certain co-occurring medical or psychological problems. Different studies may treat such features differently (e.g., some studies of an anxiety disorder may exclude

clients with moderate or severe depression, whereas others may include depression as an additional factor). The important requirements are that all such criteria are specified, that they are reliably determined, and that they are based on a valid rationale related to the nature of the disorder and the nature of the questions being asked in the therapy investigation. Furthermore, when such features are variable within the selected sample instead of being held constant at a chosen level, it is essential that those features are balanced over conditions to reduce the chance of differential representation and consequential confounding of the experimental manipulation. Carefully chosen criteria maximize the homogeneity of the sample on those characteristics thought to be critical to an understanding and treatment of a disorder (thus reducing error variance) and allow a determination of the extent of the generalizability of the study's findings. In general, the more restrictive the selection criteria are, the less the likelihood that subject-related confounding factors exist between conditions, but the lower the generalizability of the findings to samples with differing characteristics.

Representativeness

Tracking the number of client contacts with the project and recording reasons for exclusions allows a determination of the characteristics of the entire group from which the study sample was selected. Such information bears on generalization issues for a particular study, but it also provides heuristic data on the number of clients who have the target problem. Other therapy trials might be developed in the future for those clients. The ultimate result might be new therapeutic developments and research areas and eventual empirical extension or restriction of generality. A good example might be a controlled trial for helping depressed women in dysfunctional marriages and contrasting cognitive therapy with and without marital therapy. Both depression level and quality of the marital relationship would be among the critical selection criteria. A colleague recently discovered that, whereas large numbers of appropriate clients wished to participate, the partners of many refused to enter couples therapy (Mark Whisman, personal communication, August 1992). The results from such a study would be limited to clients whose spouses agreed to participate, but this investigators experience also suggested the importance of developing and evaluating therapy methods specifically designed for the other women and focused on the difficult and largely

unresearched area of helping individuals to cope with, and perhaps to change, a dysfunctional relationship without the cooperation of the partner.

Client Characteristics

Whether or not various client characteristics are used as selection criteria, it is important to describe clients in the trial sample to allow evaluation of generalizability and to analyze for condition equivalence to ensure absence of possible confounding features. Critical characteristics may vary depending on the nature of the problem being treated; common examples include age, gender, ethnicity, medication status, marital status, and education level. Providing means and standard deviations (or frequencies for categorical data) by condition will facilitate evaluation of the study itself as well as the possible use of its data in future reviews or meta-analyses. Testing for condition equivalence should be nonconservative (e.g., using *t*-tests or one-way ANOVAS on each variable rather than using either MANOVA on all variables or Bonferroni corrections of alpha when conducting multiple tests). Actual test results need to be reported; two groups that do not differ significantly in mean age with $p < 0.10$ have a greater chance of an actual confounding age factor than if $p < 0.05$. Whereas with $p < 0.50$, researchers would have less concern that age differences account for outcome differences between the conditions.

Severlty and Duration of the Problem

From the point of view of selection criteria, sample description, and the need for condition equivalence, the characteristics of severity and duration of the problem are no different than the others described above except that they warrant special mention because of the degree to which they are important in characterizing the sample and potentially confounding of interpretation if they differ at all among conditions. Pretherapy scores on the various measures of both the central problem and any associated problems are inherent aspects of outcome measurement. So, information on operational definitions of severity are available routinely in study reports. They must, however, be valid and reliable assessment devices, not only for reflecting therapeutic change but also for characterizing the degree of clinically meaningful problems in the selected sample. Thus, the use of some

measures for which there is preexisting empirical information on how well they distinguish the disorder being treated in the research trial and the means and cutoff scores for disordered and nondisordered groups would facilitate evaluation of this issue. In many outcome study reports, information on the duration of the problem is lacking or incomplete. Some device (interview or otherwise) should be used to specify as accurately as possible how long the problem has been present. Some studies report a minimum duration as a selection criterion, but this does not replace the requirement that average duration and its variance for each condition be specified. As was the case earlier, nonconservative preliminary analyses of condition similarity or difference on the pretherapy levels of the principal outcome measures and duration of problem are essential, and full report of means and standard deviations by condition should be made.

Concurrent and Past Treatment

Outcome studies have varied in how they handle the presence of concurrent pharmacological or psychosocial treatment and any history of exposure to therapy. Often, no information is provided, so one cannot evaluate the possible influence of such factors. Two approaches have been used with regard to the presence of concurrent medication when it is reported. One approach excludes clients on psychotropic drugs. In this case, treatment condition differences are not confounded by medication status, but external validity is lessened. This generality issue may be important, particularly with disorders in which drug treatment is very common. Furthermore, it is important to determine with each client whether he or she independently has obtained psychotropic medication during the course of the therapy trial to ensure that a potential confounding factor has not emerged since the beginning of trial participation.

The second approach is to include clients on medication, thus increasing external validity. There are likely to be further stipulations associated with this. Some investigators admit clients on medication only if they have been using the medication for several months. This suggests that drug effects have stabilized, but a significant problem level (indicated by severity selection criteria, for example) still remains. Moreover, not all drugs necessarily will be allowed. In the generalized anxiety disorder program at Penn State University, for

example, use of antidepressive medication is an exclusionary criterion because the drug effectively may be controlling or masking a severe depression, and severe depression is an exclusionary criterion for this program in its own right.

If medication in any way is allowed, it is important to add certain methodological features that lessen threats to internal validity and maximize the amount of useful information about the effects of medication in the context of the particular investigation. First, clients should agree, with knowledge and consent of their prescribing physician, to maintain customary pretherapy dosage and frequency until postassessment is completed. Otherwise, increases or decreases in medication during the trial could result in outcome changes (improvement or worsening) that are not a function of the treatment condition to which the client had been assigned. Second, it is essential that medicated clients be distributed equally over conditions to eliminate the confounding factor inherent in differential drug status among the conditions. Third, analyses of pretherapy information and pre-post-followup change should examine the main effect of the medication factor and its interaction with the psychosocial treatment conditions.

Concurrent psychological treatment can be viewed similarly, although it is often an explicit exclusion criterion because of the long-standing view of many in the profession that participating in two different therapies at the same time can adversely affect the usefulness of both of them and create antitherapeutic conflicts within each. A few exceptions have allowed outside treatments as long as the problem being treated is unrelated to the disorder targeted in the controlled therapy trial. This can be a risky judgment, however, given that insufficient knowledge of the variety of psychopathologies and problem areas does not always allow researchers to draw confident conclusions about this in individual cases. If concurrent treatment is allowed, however, information on the number of clients receiving what kinds of treatments for what kinds of problems should be reported, and balanced representation of the presence of outside treatment across conditions is required. Again, statistical analyses of the impact of this factor should be reported.

Past psychosocial treatment experience is rarely reported, although some studies have excluded clients who have received therapy in the past that is similar to the methods available in the treatment trial. The assumption is that continuation of the problem, despite adequate prior provision of a particular technique, indicates the likely ineffectiveness of that technique for this particular client and that inclusion in the trial would consequently bias the results for that method when compared to other conditions. Past medication treatment is reported more frequently, although its relevance to the current trial is minimal if the clients have not been taking the medication for a suitably long period (depending on the type of drug, its dosage, and the duration of its use) before the start of the psychosocial treatment.

Diagnosis

In many therapy outcome investigations, a specific diagnostic group is the focus, and the selection criteria include the diagnostic criteria for that disorder. When this is the case, there are further methodological requirements to be met. First, the particular system of diagnosis needs to be indicated. The most frequent is DSM. Second, the operational definition of the interviewing approach for making the diagnosis should be explicit and based on an accepted method. This often means the use of a previously developed semistructured interview. Finally, it is often essential to include reliability checks on diagnosis along with a report of the results from reliability analysis (e.g., interclass correlation coefficients). The ideal method involves the use of two independent interviews conducted in their entirety by two different well-trained clinical assessors. Some diagnostic categories have an ordinarily high degree of inter-rater reliability; in this case, only periodic checks with dual interviews would be necessary. For other disorders, diagnostic agreement has been shown to be very poor. Generalized anxiety disorder is a good example; kappas typically are below 0.60 (Barlow 1988). In this case, it is very important to have dual interviews on every case, and admission to the trial contingent should be based on both assessors agreeing that the diagnostic criteria for inclusion are met or based on staff consensus in the case of disagreements. Although some false negatives will be excluded, there is significantly less likelihood that false positives will be entered. This increases the homogeneity of the sample on the most crucial and relevant subject characteristic and reduces a significant source of error variance.

An alternative to the independent interviews involves two assessors listening to the same live or taped interview and making independent diagnoses. Although this is better than no reliability check at all, clients often can change their responses to critical diagnostic questions between interviews; they have had time to think about the questions further between interviews and may realize that a different answer is more accurate or mom likely to gain them entrance to the project.

THERAPIST CONSIDERATIONS

Similar to the specification of client characteristics, the therapists conducting the treatments should be described in terms of background, training, and experience, both in general and with regard to the specific protocols employed in the study. Most typical in clinical research has been the deployment of Ph.D. clinical staff, advanced clinical graduate students, or a combination of the two. Weekly supervision by the principal investigator is a commonly employed method to increase adherence and quality of therapy provision. For the sake of both internal and external validity, it is essential that more than one therapist conduct the treatments, With only a single therapist, therapist characteristics alone represent a major rival hypothesis for any observed differential outcomes. To avoid a therapist-by-condition confounding effect with multiple therapists, each therapist should be assigned an equal number of clients in each condition. As mentioned above when discussing comparative research design, there are situations in which the investigator deliberately chooses to confound condition and therapist factors. In this case, it is essential to realize that differential outcome would be attributable only to the particular therapy-therapist combinations, not at all to the treatment conditions per se. Such a limitation may or may not be very important, depending on the nature of the questions being asked and the particular moment in the history of research findings on the therapies being investigated.

There is one particular therapist characteristic that may confound an investigation and has not yet been addressed fully in outcome methodology. A therapist's bias or preference for one condition over another could potentially lead to subtle, undetectable differences in his or her general behavior during client contacts. These differences potentially could impact on nonspecific factors and on the expertness

with which a particular condition is offered and, thus, on the outcome. There exists only one certain methodological solution to this problem, and it has been used rarely because it is exceptionally conservative and therefore risky. If all of the therapists in a study are well trained and thoroughly experienced in a particular therapy tradition, if these therapists are trained in a new method for the specific purposes of a study, and if the comparison of the familiar technique to the new technique yields significantly greater change for the latter intervention, then one could rule out therapist bias. One of the rare examples of precisely this set of conditions was reported by Paul (1966) in his comparison of insight-oriented therapy and systematic desensitization in the treatment of speech anxiety. Such an outcome in the context of this methodological feature provides a conservative estimate of the relative efficacy of the nonpreferred therapy because even therapist bias could not overcome the superiority of that nonpreferred intervention. As is the case with most rival hypotheses, the potential for the confounding effect of therapist bias in any particular design is a matter of degree. There is less likelihood of its contribution in dismantling, additive, and parametric designs than in nonspecific designs or in comparative designs in which therapists are crossed with conditions but have differential experience in the contrast conditions. The reasons for this reduced likelihood are the same as those mentioned previously for lessening the concern about the quality of the therapy conditions in the former designs. Also, the possibility of bias affecting results probably is lessened in comparative studies in which expert therapists treat clients only in the condition for which they are expert; presumably, bias is held constant because therapists in each condition prefer the therapy that they are providing and they are not administering the other condition(s).

DEPENDENT VARIABLE CONSIDERATIONS

Thorough discussion of measurement issues occurs elsewhere in this monograph (Moras, this volume), but there are certain methodological features that require emphasis.

Multiple Domain Assessment

Multiple measures from different domains of assessment (e.g., cognitive, affective, physiological, and behavioral) and from different methods of assessment (e.g., pre- and post-assessment questionnaires, daily diaries, assessor ratings from interviews, observational measures, significant-other reports, and physiological laboratory assessments) provide more compelling outcome assessment than single domain measurement by a single instrument for the sake of providing converging and valid improvement indices. Moreover, depending on the type of problem being treated, outcome might usefully be defined and measured both in narrow ways (measures of the specific problem) and in broad ways (general functioning in various life areas).

Assessors

Any assessment staff involved in the collection of data must be unaware of the client's therapy condition; the same requirement would be a useful recommendation for data managers. If more than one assessment staff member is involved in data collection, it is crucial that they are balanced over treatment conditions. Ideally, especially if assessment includes staff ratings or interview measures, having the same staff member conduct all of the assessments (including followup) for a particular client would reduce error variance within a client's data due to assessor characteristics.

Followup Assessment

Evaluating the long-term maintenance of therapy is a crucial aspect of outcome research. Given the typically tremendous cost of large-scale therapy investigation in time, money, and emotion as well as the critical nature of the maintenance question, a thorough followup with its relatively small cost is more than just recommendable; it should be required. Little standardization exists in the outcome literature regarding followup assessment. First, length of the followup period varies from none at all to as long as 2 or even 3 years. In general, a minimum of 1 year would be a wise choice. Second, studies differ in the completeness of the followup assessment. Some repeat all of the same measures used at the posttherapy assessment and follow the same

procedures. Others merely select one or a small subset of the most easily obtained measures, often through materials mailed to clients. This creates highly nonstandardized assessment circumstances that likely increase error variance. Complete assessment is the wisest choice. Third, very few studies assess at followup whether clients have received further treatment after their participation in the therapy trial. This is a critical piece of information because conclusions about maintenance effects for any condition cannot be drawn if confounding, additional treatment were to be received. The degree to which this is true is a function of how many clients in that condition received such additional therapy and how much therapy was provided. Moreover, conclusions about differential rates of maintenance are compromised if comparison conditions differ in the frequency or extent of further treatment. In the case in which medicated clients were originally admitted to the trial, data on patterns of drug use during followup also would provide important outcome information in and of themselves and in relationship to potential between-condition confounding factors.

Clinically Significant Change

Even though statistically significant change may occur by the end of therapy, there is no assurance that the change is clinically meaningful. Although there are a variety of methods for translating continuous scores on psychometrically sound outcome assessment devices into categories representing high, moderate, and low degrees of clinically meaningful change, two generic approaches are becoming common. One involves the operational definition of "responder status" (i.e., the percentage of clients in each condition who show any improvement on a given measure). This often is defined in a somewhat arbitrary way to be a 20-percent change from the pretherapy level or, alternately, a postassessment score with an effect size (e.g., postassessment score minus preassessment score divided by the preassessment standard deviation) that falls one standard deviation below the pretherapy mean. Sometimes investigators define a "responder" as one who shows such improvement on a majority of specified, crucial outcome measures; at other times, the percentage of clients meeting this criterion on a small, moderate, or large number of all of the outcome measures (e.g., with eight measures, the percentage of clients with 20-percent or more improvement on zero to two, three to five, and six to eight measures) is reported. Responder status is a relatively weak criterion for

clinically significant change, but it does convey how many clients showed at least some response to treatment. It is also a common method for determining nonresponders at postassessment and relapsers at followup, all of whom then are provided with additional treatment after the assessment. Although this has implications for the interpretation of the followup data of such clients, outcome researchers increasingly are viewing this situation from an ethical perspective and choosing to place client welfare at increasingly high priority. The second approach used, often in conjunction with the first, is the more stringent definition of "endstate functioning rate" (i.e., the percentage of clients in each condition who achieve "normal functioning" levels on a given measure). "Normal" is defined by posttherapy scores that fall within a standard deviation of normative means or, in the absence of such information, below a face-valid cutoff score representing an adaptive level. Again, the investigator may define high, moderate, and low levels of endstate categorization through the achievement of such "normal" scores on a specified majority of main outcome measures or through report of the percentage of clients meeting this criterion on a small to large number of all outcome measures. Although standardized agreement on the precise definitions to use has not been achieved yet, progress obviously has been made, and the importance of such definitions for drawing conclusions both about cause-and-effect relationships for theoretical purposes and about relative efficacy along a clinically meaningful dimension is becoming widely accepted.

STATISTICAL ANALYSIS CONSIDERATIONS

A full discussion here of appropriate methods for analyzing outcome data is precluded by both the scope of this chapter and the limited knowledge of the author. However, some salient points should be emphasized.

First, as mentioned throughout the text, nonconservative tests for condition equivalence on pretherapy demographic and dependent variables should be reported before presenting the outcome results.

Second, it is advisable to conduct primary outcome analyses on base-free measures of change. The most common choices are analysis of covariance and residualized gain score analysis. The reason for this

is the desire to reduce as much error variance as possible in outcome tests, and statistically removing the contribution of variations among clients in their pretherapy scores from their subsequent assessment scores contributes to that goal. This is advisable, whether or not condition differences existed in pretherapy scores, and is necessary for a particular measure when there are pretherapy differences on that measure. The emergence of a pretherapy difference, despite random assignment attempting to prevent this low probability event, is an unfortunate circumstance, nonetheless. Although the use of covariance-adjusted or residualized gain postscores statistically removes the influence of pretherapy scores, there is no guarantee that the clients in the different conditions are *psychologically* equivalent. For example, if one group is more severely disordered than another, as partly reflected in a specific pretherapy measure, this difference has potential implications for differences in the psychological process and, therefore, for possible differential responsiveness to treatment. Consequently, when conditions do differ at pretherapy, conclusions must be drawn cautiously from the outcome results, even if base-free measures of change were used. As always, this caution is a matter of degree (probability) that depends on the number of pretherapy measures that differed between conditions and the size of those differences.

Third, because it is advisable to use multiple measures from multiple domains to provide converging assessments of outcome improvement, a significant (statistically specifiable) likelihood exists that some measures will show significant condition effects due to chance, and this likelihood increases as the number of measures increases. Consequently, it is essential to take this into account by using statistical adjustments that reduce their likelihood of occurrence. The most common methods include (1) Bonferroni adjustments of the alpha level required before a condition effect on a measures will be considered significant (e.g., with eight outcome measures requited p-value $< 0.05/8$, or .0063) and (2) multivariate analysis of variance on sets of multiple outcome measures the preferred method. In the latter case, a single MANOVA can be conducted for all of the outcome measures together. More likely, because of the partial independence of some measures (different outcome measures arc measuring somewhat different problems or aspects of the problem), separate MANOVAs can be run on distinct sets of variables. Each set is composed of (1) scores

obtained from the same measurement domain (e.g., all behavioral measures and all self-report measures), (2) scores reflecting the same construct (e.g., all anxiety measures together or all depression measures together) or, most appropriately, (3) factor scores derived from a factor analysis of the entire group of outcome measures in order to establish empirically the separate sets of measures for MANOVA analysis. If a significant condition effect is found, followup univariate ANOVAs with posthoc comparisons to identify which condition or combination of conditions specifically differed from other conditions on which specific measures will complete the analysis.

Fourth, even though conditions are found to differ significantly in the degree of change from the previous analyses, this does not indicate whether or not a specific condition actually showed a significant change in a dependent measure. In fact, it is possible for one condition to show a small (but nonsignificant) increase in a measure and another to show a small (but nonsignificant) decrease while the between-group comparison indicates significant difference in the degree of change. Commonly, within-condition *t*-tests are reported to demonstrate whether a particular condition actually showed a significant degree of increase or decrease on a particular measure between any two assessment periods. This test is particularly important for testing whether or not a condition is showing (from postassessment to each of the followup assessments) maintenance, further improvement, or a return to pretherapy values.

Fifth, if some clients have received additional treatment since the time of postassessment, this potential influence on followup scores needs to be taken into account. The typical method is to analyze the results separately-with and without inclusion of the data from these clients. A similar approach can be employed when missing data exists at followup, except that here the measures are analyzed with and without the use of endpoint scores (i.e., the score obtained at the last completed assessment substituting for the subsequent missing score). Neither of these methods is without interpretive problems. Further treatment potentially confounds both (1) the effects of trial therapy depending on how many clients were involved and (2) condition comparisons to the extent that differential amounts of additional therapy were received among the conditions. The same can be said for missing data. However, if outcome analyses differ little in results irrespective of

these variations, researchers would have greater confidence (though no certitude) that these factors do not explain all of the effects.

Finally, it is important to realize that the absence of a difference in outcome between any two conditions may be due to insufficient power (i.e., the number of clients in the trial was too small to detect the difference). Thus, researchers need to be very cautious when concluding that two conditions are equivalent in effectiveness unless power analysis (cf. Cohen 1977) has indicated a low probability of Type II error.

INCREASING BASIC KNOWLEDGE IN THE CONTEXT OF THERAPY OUTCOME DESIGN

Outcome research is best viewed as the experimental elucidation of the mechanisms of the disorder being treated and of the processes of change invoked by the treatment procedures. As such, it is in no way different from any other scientific approach to the understanding of a phenomenon. Therapy is an independent variable whose manipulation will tell us something about the nature of things. The strong inference approach–in which researchers adopt a disconfirmatory stance by devising rival hypotheses, conducting crucial experiments in a carefully controlled manner to rule out one or more rival explanations, and recycling this sequence on whatever remains unrejected–is the most effective general strategy for rapidly acquiring knowledge through the scientific method (Platt 1964). The design options outlined earlier represent an application of procedural strong inference to therapy investigation. Dismantling, additive, and parametric designs provide great power to acquire systematic and increasingly specific knowledge about those procedures and elements of procedure causatively related to change. Programmatic research following this strategy, thus, inherently provides the opportunity to increase the amount of basic knowledge about the nature of the problem and about the nature of its change. It also yields the strongest and longest-lasting foundation upon which to develop therapy methods that are increasingly effective.

Strong inference in outcome research is not limited only to the systematic application of these independent variable designs, however. Several ways exist in the context of a general outcome investigation to

increase further the amount of basic knowledge acquired. An example will help to clarify how this can be done. In the early 1970's, beginning trials on the effects of relaxation training on insomnia were initiated based on two sets of earlier research that suggested that (1) people with insomnia experienced autonomic hyperactivity and (2) relaxation was effective in reducing autonomic activity. The first controlled trial compared progressive relaxation, hypnotic relaxation, self-relaxation, and waiting-list no-treatment conditions on daily self-reports of latency to sleep onset. The results of this study allowed the conclusion that relaxation was effective in reducing reported sleep disturbance (i.e., the three relaxation groups showed superior outcome relative to the no-treatment group). This is not a very specific conclusion because in the absence of differences among the three treatment conditions, the only rival explanations that could be ruled out were history, maturation, repeated testing, and the other internal validity threats ordinarily controlled by a no-treatment condition.

Six years later, from systematic, strong inference-based studies by various laboratories, the following conclusion could be drawn: Progressive relaxation is significantly effective in reducing the subjective distress of the subjective insomniac and the subjectively and objectively (EEG) defined distress of the psychophysiological insomniac; of the two elements of progressive relaxation procedure (tension-release of muscle groups and focused attention on the resulting sensations), it is muscle tension-release that maximally yields this effect, and reduction in cognitive intrusions at bedtime rather than reduction in autonomic activity is the site of effect.

Both of the above conclusions say that relaxation helps insomnia, but the latter is far more specific. It emerged from applications of strong inference strategy to (1) the independent variable of progressive relaxation through component control designs, (2) the dependent variable of sleep disturbance through breaking it into subjective and psychophysiological elements for measurement, (3) client characteristics through empirical identification of contrasting subtypes of people with insomnia complaints, and (4) mechanisms of change through theoretically based hypotheses about the cognitive and autonomic maintaining conditions of the disorder and their role as potential sites of effect for the treatment elements. Even these statements are only relatively true because they represent only what

has not yet been rejected, and subsequent research will lead to even greater specificity as further rival hypotheses generated from the unrejected remainder arc ruled out. Notice that both basic and applied knowledge have been increased by this history of research: researchers know much mom about the nature of the disorder and its change and what areas are heuristic to pursue in order to increase further the efficacy of the treatment method, and they know that certain elements of the original progressive relaxation technique are unimportant for the client to learn.

Careful choice of experimental and control conditions is one way to increase the amount of basic knowledge derived from a therapy study. Selecting measures that assess more than just the target problem is another way. Prior theory and empirical results about the nature of the disorder and the nature of the therapy technique serve to guide the selection of measures of possible client characteristics and sites of treatment effect for evaluation from a strong inference point of view. Each of these potentially important variables can be seen as representing rival hypotheses. Each can be contrasted to the others, or contrasting levels along the dimension(s) underlying any one of them can be created. When important client characteristics are empirically identified, subtypes representing potentially different functional relationships can be defined, investigated in their own right, and factored into experimental therapy designs involving the matching and mismatching of client type with theoretically related treatment elements along with process measures theoretically linked to each type, each treatment element, and each hypothesized interaction of type and element. Given the enormous cost in time and resources associated with a therapy outcome trial, the use of such carefully selected measures is a relatively low-cost investment with a potentially large payoff in knowledge.

One other recommendation can be made that can serve the above mission and contribute to the important operational definition of clinically significant change. Comparing clients on carefully selected measures to a sample of individuals who do not have the presenting problem can provide correlational data that hint at potentially crucial mechanisms of disorder and, thus, potential sites of effect for change process. Furthermore, by acquiring data from a healthy group on all outcome measures used in the therapy trial, the basis for establishing

local norms for definition of high endstate functioning is laid. Strong inference can proceed further by continuing to develop contrasting dispositional groups to rule out crucial additional rival hypotheses. Consider, for example, the possible controls established within a group comparison study by the following types of contrast groups for generalized anxiety disorder (GAD): affective disorder (to control for the frequent depression experienced in GAD), pure obsessions (to control for excessive, uncontrollable cognitive activity), social phobia (to control for this most frequent additional diagnosis among GAD clients), and any of the preceding groups (to control for the presence of a psychological problem). The outcomes of the dispositional group comparison, whether involving "normal" or other clinical samples, must be viewed very cautiously, however. Many rival hypotheses exist to explain a difference between two groups whose members were not determined randomly. Matching the groups on variables known to relate to the employed measures helps somewhat because matched variables can be ruled out from explaining any differences found on the other measures of interest. Even then, however, there are many unknown ways in which the groups might have differed that may be the actual cause of observed differences, and without random assignment researchers have no basis for assuming equivalence on all other variables.

CONCLUSION

Scientific method in any discipline, and in areas within a discipline, is constantly evolving. New designs and methodological requirements emerge from time to time as researchers learn more about a phenomenon and more about the necessary conditions for being able to draw valid conclusions from the experimental method. Because research always is involved in the movement from what is known into what is unknown, investigators will discover routinely that how they went about investigating something in the past had some flaws in it, and these discoveries will in turn lead to improved methods. The history of therapy outcome research provides good examples of this. For example, in retrospect, outcome research using placebo conditions prior to the mid-1970's was flawed by nonspecific procedures that were later found to be inadequate for controlling for the very features of therapy (e.g., expectancy) for which they had been created

originally, This recognition led to the development of expectancy/ credibility assessments, greater care in the creation of therapy and control conditions, and the ultimate demise of placebo conditions in clinical psychosocial therapy research. Conversely, valid measurements of therapy quality have not yet been developed, and without such measures the possibility of confounding differences in quality among contrasting conditions will remain a serious methodological problem. Although this chapter suggests design options that likely will reduce the potential confounding influence of differential quality among conditions, final resolution will depend on advances yet to be made in the valid and reliable measurement of therapy quality. The present chapter has summarized and highlighted some of the more crucial features of what currently are held to be essential characteristics of therapy outcome investigation. Researchers can count on changes in these requirements in the future. At the same time, they can celebrate the significant advances in knowledge about some forms of psychopathology and the treatments that have emerged recently as a consequence of the application of the best scientific methods that were available at the time.

The present paper also argues that the appropriate goal for therapy investigation is the acquisition of basic knowledge. Thinking of therapy as an independent variable no different from any other independent variable and designing outcome studies whose primary orientation is the application of strong inference methods to independent variables, mediating variables, and dependent variables in order to elucidate the nature of the change process and the nature of pathology represents the very best approach for acquiring such knowledge and, ultimately, for developing increasingly effective techniques for treating psychological disturbance.

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When Clinical Trials Fail: A Guide to Disaggregation

Kenneth I. Howard, Merton S. Krause, and John S. Lyons

INTRODUCTION

Unless all patients in an experimental treatment and none in the control condition are cured, a clinical trial, to some degree, has failed. Such failure, however, can be mitigated through the use of disaggregation techniques. The present chapter discusses how the design, execution, analysis, and interpretation of clinical trials can be enhanced through the measurement and consideration of uncontrolled variables likely to influence treatment outcome. Unless treatments exist that will cure all of the people all of the time, such disaggregation provides important mechanisms for uncovering who is likely to be helped by any given treatment.

A spirit of orthodoxy–research correctness–has swept the land. Investigators and critical reviewers have adopted Sir Ronald Fisher as their prophet and his revelations in the early part of this century (Fisher 1925, 1935) as their gospel. The clinical trial is the way to truth; there is no other. Random assignment and power analysis are its banner.

These thoughts are offered not in the spirit of ecumenism, for internal and external validity can never be reconciled, but in the name of investigatory eclecticism. A great deal of empirical knowledge has been established without the benefit of Fisherian orthodoxy–without the benefit of "true" experiments. It is also the case that a large number of clinically important variables (e.g., gender, age, education, diagnosis, chronicity, and severity of disturbance) do not lend themselves to experimental control through random assignment. There needs to be tolerance for different approaches to the establishment of knowledge–tolerance for the distribution of emphasis on internal versus external validity.

One major issue is to find a balance between methodological rigor and the research questions that investigators seek to answer, for it is folly to allow methodological rigor to lead empirical inquiry to trivial results. The fundamental and immediate goal of treatment research is to determine to which of a specified set of treatments future patients are to be assigned. A longer term goal is to refine the best treatments available in order to make each treatment more nearly optimal for patients. Ultimately, the hope is to devise a set of treatments that will cure the target illness in all patients. This clinical goal must be kept clearly in mind when research data are analyzed.

In a clinical trial, if one treatment is statistically significantly better (i.e., has a higher enough mean outcome) than another, therapists are now inclined by statistical tradition to assign all subsequent patients to the better treatment (once they are satisfied that this is indeed a statistically reliable finding over replications). If no treatment is reliably significantly better than the others, they are inclined by statistical tradition, other things (e.g., dollar costs and side effects) being equal, to assign subsequent patients indifferently to one treatment or the other. All of this seems quite unexceptional and is quite logical if and only if a certain familiar and simple statistical model holds. If all the variance in outcomes within the experimental and control groups is error variance (i.e., due to random error in the form of patient compliance error, treatment dosage error, and measurement error) while the groups' sample means are unbiased estimators of their respective population means, then making patient assignment decisions on the basis of mean differences is quite justifiable. This has the great advantage of making clinical trial data very easily and directly interpretable in terms of subsequent patient assignment decisions and, so, very obviously satisfying the immediate clinical purpose for conducting clinical trials. The main effects plus random error model is, of course, the principal contributor to all of this convenience and decisiveness. Yet, how many investigators and therapists believe that a single treatment will be the best for all patients? Nature seems to abhor such main effects.

THE IDEAL CLINICAL TRIAL

In order to understand the functions of disaggregation, investigators have to understand what an ideal clinical trial would be, because disaggregation ought to move them closer to that ideal. The ideal clinical trial would be a demonstration of a fully specified causal model of a treatment and all of its clinically relevant consequences manifested by all the different kinds of treatment settings, therapists, and patients to be encountered in actual practice. This could be thought of as the time course (over treatment) of points representing single cases in an abstract space WXY, where the W are uncontrolled variables (e.g., severity of disturbance, pattern of abuse, and vocational stability), the X are controlled independent variables (treatment conditions), and the Y are dependent (outcome) variables. Each point in WX would map one-to-one on to one and only one point in Y. Thus, in this ideal model, investigators would know the necessary and sufficient condition for each outcome.

In the simplest case, Y could have only two locations (e.g., abstinent and not abstinent). Y becomes more complex as the number of outcome variables and values is increased to include such constructs as being free of crime, living independently, and being psychologically healthy. For clarity of example, however, assume the simplest case for Y–one outcome variable, two values.

The simplest case of X would be two treatment conditions. X becomes more complex as characteristics of the treatment conditions are included (e.g., treatment integrity, therapeutic relationship, and dosage). Again, assume the simplest case–two treatment conditions. W contains all of the variables that were meant to be controlled through random assignment. These are all of the possible causal influences that interact with treatment conditions to produce a particular outcome.

In a one-to-one mapping, all of the patients at a particular location in W who have the same treatment have the same outcome. A many-to-one mapping occurs when patients at different locations in W who have the same treatment have the same outcome-this would allow for aggregation over these locations in W. A one-to-many mapping means that patients at the same location in W who have the same treatment

have different locations in Y (different outcomes). In this case, supplementation of the W space is called for.

Clinical trials succeed fully when and only when the experimental treatment cures everyone and the control treatment cures no one and this is due solely to these treatments. Theoretical expectations for each and every patient are corroborated unambiguously by such a result and by no other, and, except for cautionary replications, the line of investigation as to the treatment of some pathology in some sort of patient is finished for the time being.

Whenever a clinical trial does not succeed fully, it fails to some degree. Anything short of total cure by the experimental treatment, of absence of any overlap of results between the experimental treatments, and the control treatment constitutes some degree of failure.

Disaggregation is one kind of salvage operation for such failure. Just what kinds of patients under what kinds of conditions are cured by the experimental treatment? By the control treatment? By both? What kinds of patients under what kinds of conditions have what sorts of better outcomes short of cure for the experimental treatment? For the control treatment? For both? What confounds may be involved? These are disaggregation issues requiring further distinctions, a supplemented WXY space, to be addressed (Krause 1985).

Disaggregation is called for whenever this mapping is one-to-many in one or more of the localities of the abstract WXY space (i.e., patients in the same location in WX have different outcomes, or different locations in Y). Disaggregation is undertaken in the hope that some supplementation of WX, some additional independent variables, will allow one-to-one mappings. The essence of disaggregation is adding distinctions among cases so cases that are identical in a particular WX (but different in Y) become distinct in a supplemented WX.

Statistical tradition has been just the opposite of such disaggregation. It has been typified by reliance upon mean values as the best estimate for all cases in a treatment group, forcing a one-to-one mapping from WX to Y for each treatment group. Any underlying one-to-many mapping is dismissed as random error, which is, of course, quite proper when the residual variance is indeed nothing but random error.

SIGNS OF FAILURE

In the actual implementation of a clinical trial, there are several signs that indicate the need for disaggregation.

The Possibility of Treatment Confounds

Randomization Does Not Produce Equivalent Pretreatment Groups. This is a very probable event. As an example, suppose that there is a confounding variable that has only two values (present or absent) and the probability of its presence in the population is 0.50. Further, suppose a sample of 48 people is drawn from this population and randomly assigned to two groups of 24 people. What is the probability that the confounding variable has been orthogonalized? In other words, what is the probability that each group will contain the same number of people who have that variable (e.g., the same number of males)? The answer is 0.115! The presence of more than one confounding variable decreases the probability of orthogonalization even more. One approach to this problem, if circumstances permit, is to rerandomize until equivalence on plausible confounds is attained before treatment is administered.

There Is Data Attrition (i.e., Some Data are Missing for Some Subjects) During the Execution of the Study. Attrition always compromises randomization (Howard et al. 1986, 1991), and there is no way for correcting this without the assumption that the attrition was random. At the very least, pretreatment equivalence should be established for the groups actually used in the analysis of treatment completers. Rogers and colleagues (1993) have proposed a method for testing the equivalence of two groups that also allows for the assessment of how different the two groups could be based on the observed means and variances. In addition, this chapter also shows how equivalency testing is more appropriate and informative than power analysis.

There is a Large Amount of Within-Group Variance With Regard to the Outcome Measure. Lyons and Howard (1991) have proposed a statistical test to evaluate whether within-cell variance is real or random. If within-cell variance exceeds measurement error, the F-test is significant, and the amount of variance left unaccounted for is

relatively large, then there are real differences in outcome among patients who have received the same treatment.

The Distribution of the Outcome Scores Overlaps for the Comparison Groups. Outcome overlap, as well as the presence of treatment failures in the superior treatment, indicates the importance of interaction effects with other independent variables (i.e., the need to supplement the WX space). Howard and colleagues (submitted) have shown that, in the presence of outcome overlap, comparison of means can be quite misleading. In this previous work, they also gave a method for converting effect sizes into probabilities similar to the approach advocated by McGraw and Wong (1992). An effect size in group comparisons is quantified as the difference between group means in units of standard deviation. Since 95 percent of observations fall between ± 1.96 standard deviations from the mean, it takes a large mean difference to ensure that the two group distributions do not overlap. For example, for a small effect size (0.2), the probability of a patient in the superior group having a better outcome than a patient in the inferior group is 0.556. Similarly, for a moderate effect size (0.5) the probability is 0.638, while for a strong effect size (0.8) the probability is 0.714. It takes an effect size of about 3.0 (e.g., the mean of the treatment group is 3 standard deviations from the mean of the control group) to be reasonably sure that the superior treatment is better for all patients of the kind included in the trial.

The Presence of Treatment Failures in the Superior Treatment. In addition to indicating the importance of interaction effects with other independent variables, the presence of treatment failures in the superior treatment indicates that, unless this is merely error variance, some alternative treatment is desirable for these cases.

DISAGGREGATION

In the course of a clinical trial, there are various phases in which disaggregation can be utilized: design, execution, analysis, and interpretation. In each phase, there are rules for investigators to follow.

Design Rules

Space out the treatment points widely in the WX space and stage the data collection for flexible sampling at each of these treatment points. Investigators always are designing for salvage (disaggregation), not for balanced full factorials. It is in this regard that a randomized clinical trial tends to be a poorly designed quasi-experiment.

Do Not Undertake the Impossible. Investigators need to be clear about what variables may have causal impact other than the ones under investigation (whether these are substantively causal or sources of measurement bias) so that there is sufficient preparation for later disaggregation. For example, in a study of a residential program for homeless persons with substance abuse disorders, it is important to measure prior housing stability, vocational capacity, and family involvement. It is likely to be less important to include variables such as insurance coverage or body image. The thrust of this suggestion is to supplement W (the unmanipulated, measured, possibly causal variables) as much as sensibly possible as to the number of variables, their ranges, the density of variables' scales, and number of subjects.

Use Multistage Sampling. When one-to-many mappings are encountered, investigators should augment the sampling of that treatment or locale in the X (the manipulated independent variable space) so that there will be sufficient sample size to investigate the efficacy of other potential causal variables (W) and to allow them to have accumulated the coverage of their full range in order to manifest themselves significantly. In other words, try to avoid attenuation of correlation due to restriction of range and try to avoid insignificance of correlation due to small sample size.

Execution Rules

Sequentially and Widely Sample, Adjusting Sampling Fractions. As results from the study become available, adjust sampling to ensure sufficient density at promising points in WXY.

Maintain Full Information on Each Case. A case is a unique point in the supplemented WXY space, so the lack of information on even one variable makes it impossible to define a unique location. Thus,

any loss of supplemental information is equivalent to losing the case itself.

Sample W and X (Manipulated Variables such as Treatments) Widely. This is to allow main effects to manifest themselves strongly and to detect interactions (i.e., local one-to-many mappings in the original WXY space). More subjects always are better than fewer for purposes of disaggregation. It is desirable to have to have at least 10 subjects for each disaggregation variable, but even one subject is instructive.

Replicate at Each Point in the Supplemented WXY Space. Without such replication, there will be no way to estimate residual variance. In other words, there will be no way to allow one-to-many mappings to manifest themselves and thus no way to know whether or not the model is still underspecified. Residual error estimates have to be made at each WXY point (locale); it remains to be determined later whether or not it is appropriate to pool them.

Analysis Rules

Analyze, Analyze, Analyze, Test Next Time. Diverse and thorough analysis of results provide information for further studies. Do not depend exclusively on statistical significance.

Assess High-Priority Alternative Hypotheses. As a first check on treatment confounds, investigators should measure what the treatment confounds could be contributing.

Do All the WX to Y Mappings Possible in the Data. This will enable investigators to capture more plausible explanatory hypotheses. Investigators also can define clinical responders versus nonresponders, establish the reliability of this distinction, and then look for factors in which these two groups differ. In this way, it is possible to begin to form exclusion and inclusion criteria with regard to the circumstances under which the treatment is most appropriate and efficacious. Research is expensive (in monetary and human terms), so investigators cannot afford to disregard any information that might lead to the optimization of treatment assignment. These analyses should be done

in stages while data collection is proceeding so the preliminary results can be used to guide further data collection.

Estimate the Best Aggregations. Wherever the mappings are one-to-one in the original WXY space, the distinctions implied by supplementary variables are unnecessary–this elimination (ignoring) of unnecessary variables in a locale is the essence of aggregation.

Interpretation Rules

Speak softly in drawing conclusions and carry in mind that the fully specified model may be much larger and different than the one assumed in the design of a particular experiment.

Do Not Assume That There are No WX Errors (e.g., That the Actual Location in WX Is Not Where It Was Planned To Be) and Do Not Assume Random Error of Y. Instances of one-to-many mappings must be presumed to contain information about either an apparent WX location really being a different location or the presence of confounds (i.e., the need to supplement WX).

Do Not Interpret a Regional Sample as a Comprehensive Sample. Investigators should carefully qualify any findings with regard to where they appear in the supplemented WX space.

CONCLUSION

Post hoc analyses take several forms and should be planned from the beginning of the study. There are three types of variables that have proven useful in disaggregation:

1. Input variables (W)–patient, therapist, treatment, and site characteristics;

2. Process variables (X)–technical procedures, therapeutic relationship, and treatment (integrity and dosage); and

3. Outcome variables (Y)–effectiveness and efficiency.

These variables can be processed through the SAS Rsquare program (SAS Institute 1985). This program finds the best predictor, the best two predictors, the best three predictors, and so forth. Of course, any result would have to be replicated, but this program generates all of the alternative hypotheses available in the data. It will be through the specification of the combination of these kinds of variables with specific treatments that therapists will be able finally to determine to which of a specified set of treatments future patients are to be assigned.

A clinical trial must be flexible rather than predesigned completely, and it must be designed for optimum salvage. The process of doing a clinical trial is one of dynamic responsive redesign, not adherence to a rigid a priori design. Orthogonality is secondary to full specification for cures (i.e., to a particular regional completeness of WXY). Establishing the average superiority of the experimental group is secondary to getting some cures for further study in order to get full specification for them.

It seems that reliance on the clinical trial has always been somewhat tongue-in-cheek. After all, if investigators were to do clinical trials by the standards of the prevailing statistical tradition (not those proposed in this chapter), there would be nothing to discuss. They merely would report the significance of the difference between means and the effect size of the main contrasts. In fact, as Lyons and Howard (1991) have indicated elsewhere, investigators always move on to a variety of secondary analyses regardless of the outcome of the major comparisons. Often this is motivated by execution difficulties such as attrition, but these secondary analyses also seem to be motivated by a genuine desire to discover other causal influences on the outcome of the treatment. After all, confounds are not a nuisance; they are plausibly efficacious independent variables whose influence should be assessed in any attempt to find fully specified causal models that will lead to optimal treatment assignment.

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Behavioral Treatments for Drug Problems: Where Do We Go From Here?

William R. Miller

INTRODUCTION

When I was invited to serve as the discussant for this technical review, I was asked to attune my ear, which is accustomed to alcoholism treatment research, and comment on what I heard from an outsider's perspective. After listening to these 2 days of papers, I feel not at all like an outsider, for there are many familiar issues and problems for me here.

COMMONALITIES IN ADDICTIVE BEHAVIORS

Obviously, there are many overlaps between alcohol and other drug abuse. Our clients, in fact, do not seem to realize that there are two separate Institutes. We treat and study substantially overlapping populations. It is rare these days to find a client who has problems only with alcohol, and we have heard here that perhaps half of methadone-maintained people have active drinking problems. Relapse is a familiar phenomenon to us all (as Dr. Marlatt's writings have emphasized), as is the issue of impaired control of behavior. The etiology of alcohol and other drug problems is clearly complex, involving biological, psychological, and social factors and (some of us would add) spiritual dimensions. The papers presented here suggest, not surprisingly, that the general treatment strategies that work well with drug problems resemble those with demonstrated efficacy for alcohol problems. We even seem to make the same mistakes in treatment and research.

I had rather hoped to find that the treatment of drug abuse is less mired in a dispositional disease model, but I see the same wide gap between science and practice that has plagued the alcohol field. The

popular disease model posits that addicts (or alcoholics) are qualitatively different from normal human beings, not only in their behavior but in genetics, physiology, and character, and that this is why they have the problems they do. In this way, the dispositional disease model is oddly like the moral model that creates "them" and "us." In a recent dissertation in our lab, Moyers (1991) studied the factor structure of treatment providers' beliefs about alcoholism; she found a robust first factor reflecting all of the traditional beliefs of the disease model. The moralistic items included on the questionnaire (e.g., "Alcoholics are liars and cannot be trusted') also loaded on this primary factor, as did characterologic attributions. The essence of the factor seemed to be that alcoholics are all like each other but different–biologically, genetically, morally, and characterologically–from normal human beings.

The papers presented here, in contrast, suggest that drug abusers are fundamentally like other people except that they use drugs and suffer the consequences. This is the same picture that emerges with alcohol. "Alcoholics" are as unique and different from one another as snowflakes. No replicable prealcoholic personality has been found after half a century of searching for it (e.g., Vaillant 1983), and behavioral precursors are limited to the same childhood conduct and school problems that are related to drug abuse more generally (Miller and Brown 1991). People with alcohol and other drug problems do not respond any more favorably to being confronted than do the rest of us (Miller et al., in press).

DRUG USE AS BEHAVIOR

Another familiar picture from this conference is that drug use-even with supposedly "out of control" drugs and people–responds to operant contingencies. This was demonstrated in the early 1970s with alcoholics (for a review, see Heather and Robertson 1981). Drug use is, first and foremost, behavior, shaped by and responsive to principles of learning such as reinforcement, punishment, classical conditioning, and modeling. This is one of the messages that I seek to convey to psychologists and other mental health professionals: "Alcohol and drug abusers are not Martians, governed by different laws of behavior and requiring referral only to an initiated inner circle of experts with

unique knowledge and techniques. Everything that you have learned in your training is directly applicable because use is behavior, and users are people like everyone else." In 10 years, I hope, this statement will be seen as an uninformative and obvious observation. Today, in the United States, it remains embarrassingly controversial.

A common behavioral strategy for which I have heard many applications here is successive approximation. Dr. Grabowski advocated reinforcing successive reductions in drug use, and Dr. Marlatt pointed out, in arguing for a harm reduction perspective, that steps in the right direction are just that. Dr. Schuster also reinforced this point: if an addict gives up shooting heroin, prostitution, crime, and smoking crack cocaine but continues to use marijuana, both the individual and society benefit nonetheless. Again, one hopes that readers in 10 years will ask how anyone could not see this. In a recent article (Miller and Page 1991), we described a variety of "warm-turkey" alternatives for clients unwilling to accept immediate, permanent, cold-turkey abstention. These include a trial period of abstinence (sobriety sampling), gradual fading of dosage toward abstinence, or a trial span of moderation to reduce or eliminate problems and dependence. In a long-term followup study (Miller et al. 1992), we found that drinkers treated with a goal of moderation more often opted, in the long run, for abstinence-about twice as often, in fact, as those maintaining problem-free drinking. Even though the practitioner's ultimate goal for the client may be abstinence, insisting on immediate, total, and permanent abstention from all psychoactive drugs is not necessarily the most effective way to achieve that goal. In a way, this has been acknowledged more readily in drug abuse treatment (e.g., methadone and nicotine substitution) than in alcoholism treatment. One speaker here did advocate excluding from treatment those clients who say they want only a drug holiday–a view at odds with a harm reduction approach that provides people with whatever treatment and degree of improvement they are ready to accept. Such flexibility in treatment goals may lead to better retention and improved outcomes (Sanchez-Craig and Lei 1986).

Several examples were provided here that behaviors commonly believed to be nearly intractable or to lie beyond the person's conscious control behave as operants and respond to reinforcement contingencies: cocaine use, illicit drug use to supplement methadone,

and the parasuicidal and therapy-disrupting behavior of borderline patients. In Dr. Higgins' data, I saw a suggestion that the community reinforcement approach was less successful with those who might be judged to have the most impaired control: daily, heavy cocaine users. Perhaps we will find parameters of drug use that predict differential modifiability by operant and volitional efforts (cf., Miller and Brown 1991).

It is likewise clear that the social environment more generally exerts strong influence on drug use. Dr. Higgins reported that employment and spouse involvement–two longstanding predictors of alcohol outcomes–were prognostic of cocaine outcomes as well. Dr. Henggeler provided a causal model in which neighborhood and peers exert separate and direct effects on the likelihood of adolescent drug use. Clearly, we should not underestimate the "social" in "psychosocial."

Skill training strategies, as I indicated in my review, have accounted for at least half of the treatment methods with demonstrated efficacy for alcohol problems. Here I note the findings of Dr. Childress that active, not passive, coping strategies reduced craving. Dr. Higgins' encouraging success with the community reinforcement approach, which relies heavily on skill training, mirrors its reported strong effects with alcohol abuse and dependence.

BEHAVIORAL INTERVENTION RESEARCH

Although the National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA) have sponsored both biomedical and psychosocial intervention research, I am struck by the seemingly different patterns that have arisen–surely from historical and political factors rather than from inherent differences in our populations. In prevention research, the alcohol field has emphasized "the quest for the test"–the search for pathognomonic biological factors that differentiate alcoholics from normal people. The preventive implications of this approach are limited at best, implying a program of identification and exhortation of alcoholics possessing the tainted gene or physiology. NIDA, in contrast, seems to have emphasized, to the dismay of some researchers, a supply-and-demand

reduction approach that relies on interdiction and psychosocial strategies. The idea of limiting the supply of (or access to) alcohol in our society, however, is difficult to sell to legislators, and the Norwegian Government's official slogan, "Drink less alcohol," seems as alien here as goat cheese.

When it comes to treatment, oddly enough, the roles have been reversed. NIDA has invested heavily in biomedical interventions for addicts, as shown by the proposed inauguration of a new $65 million initiative for medication development. The occasion of this conference witnesses a new interest at NIDA in strengthening behavioral treatment research. At NIAAA, behavioral treatment research has a long and strong history, and psychosocial and biomedical studies share roughly equal proportions of the research budget. It was in a 1990 program announcement that NIAAA solicited new pharmacologic trials for alcoholism treatment.

Again, we are dealing with heavily overlapping populations. In treatment studies in our center, we now routinely include other drug use in our outcome measures. Alcohol use is obviously a significant factor in drug abuse treatment and trials. It is time, I believe, to explore how NIDA and NIAAA can cooperate in facilitating, coordinating, and funding treatment trials that increasingly bridge the missions of these Institutes. It is time to develop consensus state-of-the-art followup measures for alcohol and other drug use, the central dependent variables of our research. There are also many common issues in assessment methodology. Urine testing represents a gold standard in drug use assessment, a technology for which there is as yet no good parallel to verify recent drinking. Consequently, alcohol treatment researchers have refined other methods for corroborating client self-reports–particularly collateral interviews, which have received curiously little attention in drug abuse treatment studies. It remains to be seen how well the reports of significant others might serve to verify use or nonuse of cocaine, heroin, or marijuana, for example. The validity of collateral reports may vary from drug to drug. Heroin use, for example, is not as likely to be observed by nonusing spouses, and its effects may be harder to detect. Cocaine runs, as Dr. Higgins commented, have more obvious effects observable by significant others. Marijuana use may be more readily observed directly by others. Collateral reports could serve as a further check on

self-report, particularly in light of the known false positive rate (for recent drug use) inherent in urine testing due to residual traces of prior use. NIDA and NIAAA researchers face similar assessment problems and could work profitably together to forge common treatment outcome measurement strategies. The growing awareness of multidiagnosis cases suggests that similar interface with the National Institute of Mental Health (NIMH) is overdue, and it is likely that quality alcohol and drug assessment will be of equal importance to research in other parts of the National Institutes of Health (NIH).

The reasons for joint measurement of alcohol and other drug dimensions are not limited to assessment concerns. Dr. Higgins reported that disulfiram, in essence, constitutes an effective treatment for cocaine use, specifically among those who also drink heavily. A cocaine relapse may begin with drinking alcohol, suggesting a new meaning for the concept of "gateway" drugs. Similar attention should be paid to tobacco use, which is being explored in current NIAAA research as a correlate of alcohol use and relapse. Suppression of only one drug, without paying attention to the impact on and effects of other drug use, makes little sense in a population in which polydrug abuse is normative.

Further, research should seek to disaggregate the effects of treatment modalities from settings. Residential and inpatient treatment have consumed the lion's share of treatment dollars, despite the fact that nearly every literature review of the past two decades has concluded that such settings offer no overall benefit above that afforded by outpatient treatment (Annis 1985; Kiesler 1982; Miller and Hester 1986; U.S. Congress 1983). If a specifiable subgroup does benefit differentially from more intensive and expensive care (a sensible possibility), this remains to be demonstrated, and the characteristics of this group should be documented and replicated.

Treatment process also deserves much greater attention.
Dr. Borkovec's call for research to delve deeply into treatment processes is well taken. Careful process research can help us understand how and why change occurs and elucidate the nature of the very problems we are treating. Yet, such depth is not logically precluded in comparative clinical trials. It is possible to study two or more treatments deeply and simultaneously, gaining both process and

relative outcome knowledge. The comparison of different strategies is, I believe, entirely appropriate at this stage of knowledge development. The "horse race" pejorative unfairly oversimplifies the modem well-designed clinical trial. New insights into the nature of a disorder can arise from main effects and interaction (matching) effects as well as from the same within-treatment analyses that are possible in a single-treatment study. The randomized trial also provides a level of causal inference not achieved readily through other designs. "Comparative" and "depth" are not alternative designs but different possible aspects within designs. Like process and outcome, both types of knowledge can be obtained from a well-designed trial.

Dr. Howard also was eager to hobble and humble randomized trials, or at least, by polemic attack, to inspire a defensive improvement in them. I surely favor the latter goal, and the methodologic criticisms he raised are worthy considerations, but they are worries for which remedies already exist. His concern that randomization can result in nonequivalent groups on critical pretreatment variables is mitigated in larger samples, and it can be addressed by a variety of methods for ensuring balance while retaining essential randomization such as L.J. Wei's (1978) urn randomization procedure. The problem of data attrition is not unique to randomized trials, but, as several presenters here have shown, there are various effective ways to improve the retention of subjects in treatment and research. Dr. Howard's worry that the distributions of experimental and control groups may overlap is real enough, but it is not properly solved by eliminating the control group from one's design! Noncomparative designs simply ignore the problem of relative outcomes. Having reviewed the alcoholism outcome literature over the past two decades, it is my experience that the relative contrasts of comparative trials yield a much more consistent picture across replications than do uncontrolled trials (cf., Holder et al. 1991; Miller and Hester 1980).

At the same time, I hasten to agree that randomized trials are not always the most appropriate method for generating new knowledge about treatment. Consider, for example, the need for new research with Alcoholics Anonymous (AA) and other 12-step groups, a priority highlighted by the National Academy of Sciences (1989). Twelve-step group participation is too often regarded by researchers as a nuisance variable to be minimized. Yet, the vast majority of alcohol and drug

treatment programs in the United States espouse a 12-step philosophy and commend or require group attendance, and the 12-step fellowships serve far more individuals every year than do all treatment efforts combined. What happens to people over a course of involvement in such groups? Why do some stay and others fail to return? What attracts people to 12-step fellowships? How, when, and for whom does change occur? These and many other questions can be answered by research (McCrady and Miller, in press), but the 12-step groups do not readily lend themselves to randomized trials because of their ubiquity. Incidentally, contrary to statements made here, there is no official institutionalized resistance to research in AA. To the contrary, Bill Wilson wrote a memorandum encouraging AA members to participate in scientific research that continues to be circulated by the AA central offices. My point though, for which this is but an illustration, is that there are behavioral outcome questions for which designs other than randomized trials are optimal. Both types of research are needed.

On the issue of studying heterogeneous versus homogeneous samples, again it depends upon one's purpose. In seeking to discover client-by-treatment matching interactions, it is essential to start with a sample that is heterogeneous with regard to the predictor variables. Recent Federal requirements to represent females and minority groups in study samples whenever feasible also favor heterogeneity. The limiting of a treatment study to a homogeneous sample may be warranted once there is already persuasive evidence that the intervention(s) under study will be differentially appropriate for that subsample. We have little such knowledge regarding drug abusers. Had the NIMH collaborative trial been limited to "exogenous" depression, for example, the field would have been deprived of the important information that "endogenous" depression responds comparably to pharmacotherapy and cognitive therapy–a finding that in itself raises questions about the exogenous/endogenous distinction and related etiologic assumptions.

IMPROVING TREATMENT

With regard to improving treatment, it is clear from the presentations made here that retention and compliance are crucial issues in treating drug problems in general as they are with alcohol problems in

particular. People who stay in treatment longer, follow advice, do homework assignments, and practice active coping strategies are generally found to fare better at followups. The tendency in this field is to regard these as the "good" patients and to blame attrition and noncompliance on poor client motivation or character. There are persuasive reasons, however, to reevaluate this view. We have argued elsewhere that motivation, denial, and compliance are not client problems but therapist and program problems (Miller and Rollnrick 1991). Dr. Higgins showed us data in which treatment retention varied from 11 percent to 93 percent across groups in randomized trials. Therapist behaviors have been shown to be strong predictors of client dropout, resistance, progress, and outcome (McLellan et al. 1988; Miller and Rollnick 1991). Dr. Linehan described for us a treatment program that has retained 80 percent of its borderline patients for one year, an impressive achievement with a population usually assumed to be characterologically incapable of sustaining treatment. If the characteristics of therapists and programs determine the rates of client retention and compliance, which in turn drive treatment outcomes, high priority ought to be given to identifying those characteristics and to learning how to train and influence them. As Dr. Grabowski observed, all treatment programs stand somewhere on these characteristics (contingencies) and, thus, are already influencing client behavior in crucial ways, for better or worse.

This, in turn, raises for me some reservations about selecting research subjects on the basis of their "wanting" or "willingness" for particular treatment(s). The willingness to accept disulfiram, for example, has been used as an inclusion criterion for clinical trials (e.g., Azrin et al. 1982; Fuller et al. 1986). Yet, if client willingness (motivation) is so susceptible to influence, we need, at the very least, to specify the procedures used to "sell" interventions to potential subjects–an aspect of research procedure often unmentioned in proposals and reports. These procedures will, in turn, impact recruitment rates, sample characteristics, external validity and replicability, and human research review considerations. Here is another area for study!

I believe that there is a real opportunity now to improve treatment by inculcating evaluation values in local programs. One way to do this is by tightening up accountability for program (or therapist) outcomes, and the Joint Commission on Accreditation of Healthcare

Organizations is already taking steps in this direction. The astounding lack of accountability in this field for using research-supported treatments needs to be remedied.

At least as important, however, is encouraging and empowering treatment programs and professionals to evaluate their own work as a method for obtaining feedback and improving practice. Learning does not occur without feedback; yet, most practitioners work in a nearly total feedback vacuum, receiving little or no useful information to help them become more effective. Apparently, this problem is recognized by clinicians. Dr. Schuster reported here that, in a survey of drug abuse practitioners, the need for help in program evaluation was placed at the top of a wish list. It is possible to promote excitement and expertise for program staff by having them engage in evaluation studies, which need not be large-scale time-intensive trials. Relatively simple studies of immediate practical importance can be conducted in ongoing care delivery settings (e.g., Chafetz 1968).

How might this be accomplished? Develop intriguing do-it-yourself research workshops for program staff, and market and deliver them on a national scale. Find ways to reward staff and programs for evaluation that go beyond the documentation of effort and demographics. Encourage replications of promising treatment methods at the local level. Dr. Higgins pointed out the importance of evaluating new methods in one's own clinic to fine tune them and determine how and for whom they work. Contracts for such onsite replications in clinical settings could be offered through special programs in NIDA or the Center for Substance Abuse Treatment (CSAT). Regional continuing education events could provide training on how to conduct program evaluation at the local level with ample opportunities for input and ideas from participants.

Significant progress also might be accomplished through training and research centers. A predoctoral National Research Service Award at our center has had this effect as an originally unforeseen side effect of training. Six trainees per year have been placed in community treatment and prevention programs with the sole focus of helping staff conduct program evaluation research. Rather than bringing preconceived projects with them, these trainees typically have interviewed program staff to ask what questions would be of particular

importance and interest to them. Studies then are designed to meet these needs, with the trainee serving as a free consultant. Over the first 5 years of this training program, we have developed not only trainees but also a number of community program research sites that now compete with each other for trainees. Publishable research has emerged from several sites, which also has had immediate practical importance for the sites. Treatment training and research centers could be asked to propose plans for community training and dissemination efforts in new and renewal proposals.

At the same time, as Dr. Moras discussed, we need to strengthen treatment research methodology. There is a wealth of know-how scattered among investigators with regard to the usually undiscussed but critical aspects of how to conduct research: selecting and training personnel; recruiting and retaining samples; collecting, entering, and cleaning data; conducting interviews; instrumentation; and other aspects. Examples of this know-how have been shared at this meeting. It is time to gather some of this accumulated wisdom together and make it accessible to new and current researchers before those who possess it are lost to retirement, burnout, or other fields. Special attention and development should be devoted to evaluation procedures that can be implemented in local program settings.

KNOWLEDGE DISSEMINATION

I have elsewhere bemoaned the immense gap that exists between practice and research in the alcohol field and suggested some possible causes and remedies (Miller 1987). This gap is, I believe, one of the most significant problems in the field of alcohol and drug abuse. The move of our Institutes to NIH could worsen this gap, separating the research institutes further from the primary Federal program mechanisms of CSAT, the Center for Substance Abuse Prevention (CSAP), and the block grants. The fault does not lie clearly on either side, and there is much we can do as researchers to help bridge the gap. In order for research findings to be implemented in practice, for example, it is essential to do far more than publish them in scientific journals. A broad range of practitioners must be informed, motivated, trained, and empowered to implement the new technology. There are models already available (e.g., drug companies), and we could draw

upon the expertise of those who specialize in knowledge dissemination and technology transfer. Let me suggest just a few ideas.

1. Make knowledge and technology accessible to practitioners. Few clinicians (and, for that matter, few researchers) are likely even to read a particular article in a scientific journal. Research needs to be made available, interesting, and comprehensible to service providers. This means publishing in the periodicals that practitioners read, attending and presenting at popular clinical conferences, and working with professional organizations. The more practical the material, the better. Therapist manuals, as they are developed in research, can be reviewed and published for general use, and they are likely to be consumed eagerly. Self-help materials might be generated from some technologies and tested in separate studies. National and regional training (preferably free) could be offered in the newest clinical methods to emerge from research as an alternative to the tired recapitulations of unproven lore that currently characterize most substance abuse professional meetings.

2. Market new knowledge and technologies in ways that speak to the perceived needs and problems of clinicians. People are motivated to change when they: (a) perceive a significant problem or opportunity and (b) perceive an effective solution that is possible for them to implement (Rogers and Mewborn 1976). The striking popularity of "relapse prevention" training is a case in point: substance abuse clinicians recognize the problem of relapse and are searching for effective ways to address it.

3. Provide a carefully edited information resource for practitioners. *The Prevention Pipeline* and Brown University's *Digest of Addiction Theory and Application* are examples of such efforts, though both are broader and contain little practical knowledge. *The Journal of Substance Abuse Treatment* has this potential, but most of the material it presents is lacking in a research base.

4. Require potential grantees to include, as part of an application for research or training funds, a plan for dissemination of research findings to be reviewed with the proposal. This would heighten attention to this issue and draw on the creativity of researchers to

address it. Alternatively, researchers with meritorious and applicable findings could be encouraged to apply for separate Phase II dissemination funding by proposing such a plan. Dissemination phase funding of this kind is already represented in the prevention programs of the U.S. Department of Education's Fund for the Improvement of Post-Secondary Education and in Phase II review for Small Business Innovation Research grants. Still another possibility is for independent contractors to propose plans for disseminating an Institute's significant clinical findings to the practice field.

5. Create two-way research and practice partnerships. To the extent that service delivery programs can be recruited as partners with researchers through the training efforts described earlier, channels are created through which knowledge dissemination in both directions is possible. Mechanisms for the formation of such partnerships could be developed. Again, investigators and centers applying for funding, particularly programmatic funding, could be asked to propose ways in which they will interact with their communities to establish such relationships with service providers. It is our experience that these are long-range efforts in which significant fruit is borne over the span of a decade or more.

A CONTINUUM OF INTERVENTIONS

Finally, I would offer the challenge of fully recognizing and implementing in the drug abuse field the National Academy of Sciences' (1990) perspective that the problems we address lie along a continuum. In fact, it appears that there are a number of loosely interrelated continua of severity, including: (1) use, (2) life problems, (3) dependence, (4) biomedical sequelae, (5) neuropsychological impairment, and (6) other quality-of-life factors. In the drug abuse treatment field, as in the treatment of alcohol problems, the bulk of intervention efforts and funding have been concentrated on the tip of the triangle. As one proceeds away from this tip, the base broadens, and one encounters ever larger numbers of people with less severe but nevertheless significant problems. The use of binary diagnosis has supported the notion that those above a certain severity cutoff point require intervention and those below it do not.

A continuum of interventions can be conceived, ranging from primary prevention to intensive treatment (National Academy of Sciences 1990). It has been the "middle classes" of the severity triangle who have received the least attention. Primary prevention and intensive treatment both are offered widely. The former is insufficient and the latter too heroic for those with midrange severity. In the alcohol field these are the problem drinkers and risky drinkers, whose behavior is already worrisome and who account for the majority of alcohol problems in society (Moore and Gerstein 1981), but who do not evidence the deterioration and dependence that treatment programs usually are designed to address. Many such individuals are currently identified through employee assistance programs (EAPs) and arrests for impaired driving. They are left, typically, to choose between disease-model treatment or no treatment at all. It is here that brief interventions and behavioral self-control training have shown the greatest promise, producing consistent improvement with individuals in the mild-to-moderate severity range.

NIDA faces a similar challenge. Drs. Higgins and Grabowski both presented data indicating that those who are less impaired at intake fare better in treatment-an argument for still earlier outreach. Dr. Marlatt appealed for brief services on a harm reduction model through which contact can be established with a broader range of drug abusers. The rapid growth of drug testing is already turning up a substantial number of drug users with low severity of use, problems, and dependence, many of whom are employed and functioning well. As drug-testing practices spread, this number will continue to grow.

What is to be done with and for these less severe users? They are unlikely to respond well to being told that they have the primary disease of chemical dependency, confronted in group psychotherapy, sent to hospitals or 12-step groups, and instructed to abstain from all licit and illicit psychoactive drugs for life. A harm-reduction perspective holds that less use is better than more use and that fewer problems and risks represent an improvement. Politics run high here, particularly in a zero-tolerance atmosphere, because illegal substances are part of the picture. Behavioral interventions with demonstrated efficacy for problem drinkers that are logically generalizable to other drug problems do exist. Behavioral self-control training, for example, has a strong track record in reducing alcohol use (Holder et al. 1991)

and already has been applied with polydrug users (Wilkinson and LeBreton 1986). Initial trials indicate that motivational interviewing and a "drinker's check-up" suppress alcohol use in midseverity drinkers (Miller et al. 1988, in press) and increase responsiveness to treatment (Bien 1991; Brown and Miller, in press). Other researchers have applied this approach in addressing heroin use (Saunders et al. 1991; Van Bilsen 1991). The alcohol field has long struggled with how to serve the midrange severity population who seem to require less intensive treatment and greater goal flexibility, How will the drug abuse field respond?

Perhaps it will be economics that, in the long run, forces a response. While EAPs, courts, and drug testing provide an ever-growing base of clients for treatment, public funding for services continues to wane. The result, like it or not, will be briefer, less-intensive interventions for many. This is not necessarily a negative outcome. Dr. Grabowski reported here that less frequent visits increased patient retention in treatment, while the requirement of more visits after positive drug tests tended to elevate the relapse rate. Dr. Stitzer listed less frequent counseling as a reinforcer for clients! In the alcohol field, few differences have been found in the efficacy of inpatient versus outpatient or brief versus extended treatment (Bien et al., in press). Deaton and Olbrisch (1987) have proposed, tongue-in-cheek, that brevity of contact with therapists is the active ingredient in treatment effectiveness. For certain therapists, at least, it appears that less contact is indeed better (McLellan et al. 1988; Miller et al. 1980).

The brighter side of this picture is that brief, well-conceived treatment appears to be at least as effective as traditional intervention for many people, particularly those with less severe problems. This makes it possible to provide services to a broader range of clients. It is an unanswered question whether and which people, failing to remit with brief intervention, will benefit differentially from additional treatment. In any event, the development of midrange interventions for less severe drug abusers remains important uncharted territory. The realities of increasing demand and decreasing funding for treatment leave us with two options: continue trying to provide ever-diluted treatment in the traditional model or develop a well-planned system in which different levels and types of intervention are provided to people based on their needs and characteristics.

I am grateful for the privilege of reflecting on the proceedings of this interesting conference, and I look forward to the fruit this meeting may bear in the years ahead.

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