

EFFECTS OF SUPPORTIVE SERVICES IN A  
METHADONE TREATMENT PROGRAM

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A preliminary investigation of the extent to which supportive services contribute to the effectiveness of a methadone treatment program was conducted. Supportive services were operationally defined in terms of frequency of "significant" patient-staff contacts. The treatment effects of (1) high frequency, (2) medium frequency, and (3) low frequency patient-staff contacts were compared with respect to five behavioral adjustment measures: (1) days employed, (2) "dirty" urines, (3) arrests, (4) payment of fees, and (5) days in treatment. The latter two measures were considered as measures of the acceptability of the treatment program to the target population. The first three measures were directly indicative of the S's level of behavioral adjustment to the demands of society.

Chapter I introduces the problem of authors' emphasizing metabolic and pharmacological aspects of addiction and methadone treatment, while devoting little attention to the social and psychological aspects. Reports of experimental manipulation of non-medication treatment variables are rare. Due to the growing controversy regarding the need for supportive services, this variable was chosen as the focus of this study. It was hypothesized that (1) retention in treatment and (2) level of behavioral adjustment would significantly improve with the

application of frequent supportive services as compared with the results obtained when little or no supportive services are provided.

A review of related literature is presented in Chapter II beginning with a documentation of the seriousness of the addiction epidemic. Treatment approaches prior to the advent of methadone maintenance experienced limited success. The pharmacological properties of methadone, such as its long duration of action and oral administration, have greatly contributed to the success of this treatment.

Disparities in results of methadone treatment appear primarily attributable to population and treatment variables such as the extent of supportive services provided. Frequency of patient-staff contact provides a gross measure of the supportive services provided.

Chapter III presents the method used in conducting the study. Seventy-five consecutively admitted narcotic addicts were randomly assigned to one of the three treatment groups. Differences between the groups, with respect to various demographic and pre-treatment variables, were minimal. The only control exercised over the frequency of patient-staff contact was in terms of staff-initiated contacts.

The results of this study, presented in Chapter IV, indicate that retention of patients in treatment was improved significantly by the application of frequent supportive services. The high- and medium-frequency groups stayed in treatment

significantly longer and had fewer dropouts than the low contact group. The high contact group also accumulated significantly less debt than the other two groups. This finding in conjunction with the results on retention in treatment suggests an increased attractiveness of the program associated with increased frequency of patient-staff contact.

Analysis also revealed a tendency toward improvement on all other measures of behavioral adjustment employed that had been associated with increased frequency of patient-staff contact. Still, only the improvement in number of arrests reached significance.

It was concluded that the patients' level of behavioral adjustment was improved by the application of frequent supportive services as compared with that obtained when few or no supportive services were provided. All treatment groups showed a tendency toward improved behavioral adjustment, but a significantly greater improvement in adjustment was found to be associated with increased frequency of patient-staff contact.

From the results obtained, it was concluded that supportive services can significantly contribute to the effectiveness of a methadone treatment program by contributing to greater retention in treatment and improvement in measures of behavioral adjustment.

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## CHAPTER I

### INTRODUCTION

Since the concept of utilizing methadone in a maintenance approach to the treatment of narcotic addiction was first introduced by Dole and Nyswander (Dole and Nyswander, 1965, 1966, 1967; Dole, Nyswander, & Kreek, 1966; Nyswander, 1967), there has been a rapid proliferation of methadone maintenance programs throughout the United States. There are in excess of four hundred such programs now in existence.

Leading the way for this rapid spread of prolonged methadone treatment have been news media reports (Bert, 1965; Cushman, 1971; Jaffe, 1970; Meritz, 1969; Samuels, 1967) and "scientific" publications which have created the illusion that methadone maintenance is a simple treatment procedure that approaches a panacea for narcotic addiction. Such homogeneous and simplistic answers as espoused by these reports have, however, traditionally been offered for heterogeneous and complex problems. All too often the uncritical acceptance of these answers has led to unexpected negative consequences.

The efficacy of methadone maintenance treatment for "hard core" narcotic addicts appears to have been fairly well documented (Dole, 1970; Dole and Nyswander, 1965, 1966, 1967; Dole, Nyswander, & Kreek, 1966; Dole, Nyswander, & Warner,



1968; Dole, Robinson, Orraca, Towns, Searcy, & Caina, 1969; Methadone Maintenance Evaluation Committee, 1968; Nyswander, 1967, 1971). Numerous investigators have been able to report findings similar to those of Dole and Nyswander (Blachly, 1970; Bloom & Sudderth, 1970; Davis, 1970; Jaffe, Zaks, & Washington, 1969; Perkins & Bloch, 1970; Primm, 1970; Wieland, 1960). These replications of earlier results tend to support the assumption that methadone maintenance is an effective therapeutic tool for aiding in the rehabilitation of many narcotic addicts. They do not, however, demonstrate, as some reports suggest and as many individuals assume, that the simple daily administration of high doses of the synthetic narcotic methadone will result in the spontaneous rehabilitation of all or even most narcotic addicts. Several later studies have, in fact, reported results considerably less favorable than those of Dole and Nyswander (Borden, 1972; Bowling, Moffett, & Taylor, 1971; Dobbs, 1971; Jaffe, 1970a, 1970b; Johnston & Williams, 1970; Maddox, 1972; Wieland & Moffett, 1970). One rather disgruntled investigator suggested that perhaps the methadone he was using in San Antonio was not as strong as that used by Dole and Nyswander in New York.

Thus, aside from the ethical controversy surrounding the maintenance approach to the treatment of narcotic addiction, there is still considerable controversy regarding the effectiveness of methadone treatment. This controversy appears to be a back lash against the excessively optimistic and simplistic

claims of early investigators who emphasized medical or metabolic aspects of addiction and its treatment while minimizing the importance of the social and psychological aspects. These aspects were, however, certainly not ignored in the development of their programs. Still, the impression received from many early reports was that methadone maintenance was a relatively simple procedure which would result in the rehabilitation of most addicts. Numerous investigators have obviously found the procedure neither simple nor effective.

In actuality, the disparities in results reported by the various investigators appear to be primarily attributable to differences in patient populations and differences in treatment procedures. With regard to treatment variables, the primary focus of this paper, little is reported beyond procedures for dispensing methadone, adjusting methadone dosage, and collecting behavioral adjustment data. It is frequently noted that rehabilitative services such as medical care, vocational counseling, family counseling, group therapy, etc., are available. Rarely is there any indication as to whether or not any of these rehabilitative measures are ever compulsory. The orientation or goals of these services are not mentioned. Never is there any indication as to which patients utilize the rehabilitation services, how much these services are utilized, or how effective these services have been. Also, there is rarely any mention of the staffing pattern, the general staff orientation, and weekly staff contacts of the

average patient. Nor is there any mention of rules, how they are enforced, or by whom they are enforced. It is frequently reported that certain patients who appear to be doing well in the program and who appear to be responsible enough are allowed to take some doses of methadone home so they will not have to come to the clinic every day. However, who grants these privileges, under what circumstances they are granted, or for what reasons they may be withdrawn are not stated. Frequently, the employment of ex-addict counselors, rehabilitated or abstinent addicts, is reported along with a brief outline of their duties. Selection and training procedures are usually omitted.

Obviously few, if any, of these treatment variables could be exactly specified for all patients. In any cases, for any treatment procedure to be exactly specified, it must be quite rigid, and as Jaffe points out, "the less flexibility available in a program, the greater the likelihood of not meeting the needs of the slower changing patients." (Einstein, p. 343). Still, the laxness in reporting at least some of these treatment variables suggests a rather lukewarm attitude toward rehabilitative services on the part of many investigators. A few have gone so far as to openly express doubt as to the value of such services and have attributed the success of methadone programs, almost exclusively, to the pharmacological action of methadone (Goldstein, 1970; Pearson, 1969; Perkins, 1970; Sells & Watson, 1970).

Skepticism regarding the value of rehabilitation services is understandable in the light of results obtained in more traditional programs such as at the United States Public Services Hospitals in Fort Worth and Lexington, where extensive rehabilitation services were available (Duval, Locke, & Brill, 1963; Maddox, 1962; Scrignar, 1967). On the other hand, recent research has created considerable doubt regarding the validity of some of the pharmacological properties claimed for methadone. In particular, the so-called blockading property, where high doses of methadone are said to block the effects of intravenous injection of rather high doses of heroin, has come into question (Bowling, Moffett, & Taylor, 1971; Singh, Castet, & Nix, 1971).

In summary, it appears that early claims regarding methadone treatment and the pharmacological properties of methadone can be an effective therapeutic tool in the treatment of narcotic addiction, if only because it tends to hold addicts in treatment. On the other hand, there is little evidence to indicate that the daily administration of methadone without adjunctive rehabilitation services is sufficient to bring about improved behavioral adjustment in a significant proportion of addicts applying for treatment (American Medical Association Committee on Alcoholism and Drug Dependence, 1967; National Research Council Committee on Problems of Drug Dependence, 1970; Dobbs, 1971; Gearing, 1970; Trigg, 1970). Furthermore, there is no evidence to indicate that the daily

administration of methadone without adjunctive rehabilitation services would be as effective as would the daily administration of methadone in conjunction with adjunctive rehabilitation services in promoting improved behavioral adjustment in a randomly selected group of narcotic addicts applying for treatment.

Since there are now more than 60,000 narcotic addicts in the United States (Bloom, 1967; Gould, 1972), a number which is growing at near epidemic rates and crossing all socio-economic and cultural barriers (Lipinski, 1972; St. Pierre, 1971; Smith, Gay, & Ramer, 1970), it seems imperative that pertinent treatment and population variables associated with the effectiveness of methadone maintenance and prolonged detoxification programs (Sells & Watson, 1970) be delineated. Also, considering the large cost involved in providing a comprehensive treatment program (Borden, 1972; Trussell, 1970), as well as the fact that most methadone programs have an extensive waiting list, it would seem advisable to investigate the value of the various supportive services or supportive services in general. If the pharmacological effects of methadone are found to be sufficient in themselves to bring about the rehabilitation of most narcotic addicts, or if staff efforts at aiding in the social rehabilitation of the addicts are found to have no significant effect, then much of the money now being expended to provide adjunctive services could be used to expand admissions and methadone dispensing facilities so that more addicts can be treated.

As alluded to previously, defining or specifying supportive or adjunctive rehabilitation services can easily become a rather thorny task; thus, making the evaluation of their effectiveness is rather difficult. However, since supportive and adjunctive rehabilitative services are generally provided by staff members of the methadone program and by staff members at agencies to which patients are referred, a gross quantitative measure of the amount of supportive or adjunctive rehabilitation services provided might be obtained through a simple tabulation of the average number of "significant" contacts which patients have with staff members and cooperating agencies during a specific time period. A program which offered no supportive or adjunctive rehabilitation services would be expected to have a rather low frequency of "significant" patient-staff contacts.

The frequency of patient-staff contacts has previously been found to be a significant variable in the rehabilitation of hospitalized psychiatric patients (Jenkins & Gurel, 1959; Jones & Sidebotham, 1962; Linn, 1970; Ullmann, 1967). It would seem logical to expect this variable to be associated with changes in the behavioral adjustment of narcotic addicts in an out-patient methadone treatment program. Investigating differences in behavioral adjustment associated with various frequencies of "significant" patient-staff contacts would appear to be a preliminary step in ascertaining the extent to which supportive and/or adjunctive services are needed in a methadone treatment program.

### Problems

The problem of the present study was to compare the treatment effects of three levels or frequencies of patient-staff contact on patients admitted to a methadone treatment program for narcotic addicts. Assessment of treatment effects was in terms of five measures of behavioral adjustment during treatment.

The problem arose because many investigators, feeling that narcotic addiction is primarily a medical and/or metabolic problem, have de-emphasized the value of supportive and rehabilitative services, as well as the importance of other treatment variables. Inconsistent results continue to be reported, although medication questions, such as dosage and schedule of methadone intake, are within broad limits consistently reported to be of little consequence (Garbutt & Goldstein, 1972; Goldstein, 1970, 1972; Jaffe, 1970a, 1970b; Wieland & Chambers, 1970; Wieland & Moffett, 1970; Williams, 1970). Disparities in treatment results appear to be due primarily to non-medication variables and population variables. Reports of experimental manipulations of non-medication treatment variables are quite rare. The extent to which supportive and/or adjunctive rehabilitation services are needed is a matter of controversy, due not only to their cost, but also due to differences in theoretical orientation. There have apparently been no studies reported regarding the relative effectiveness of methadone treatment alone, as opposed to methadone treatment

in conjunction with rehabilitative efforts. This study is seen as a preliminary step in ascertaining the extent to which supportive and/or adjunctive rehabilitation services are needed in a methadone treatment program.

### Hypotheses

The following hypotheses were investigated:

(1) That the record on the retention of patients in a methadone treatment program would be significantly improved by the provision or application of frequent supportive services as compared with that obtained when few or no supportive services are provided.

(2) That the level of behavioral adjustment of patients in a methadone treatment program would be significantly improved by the provision or application of frequent supportive services as compared with that obtained when little or no supportive services are provided.

For the purposes of this study, supportive services were defined as any patient-staff contact which met all of the following criteria: (1) duration of one minute or longer, (2) dialogue relating specifically to the individuals involved or directly concerning the treatment program, and (3) dialogue which could not be classified as primarily in the category of "old dope stories."

For the purposes of this study, the frequency of patient-staff contacts was assumed to be roughly indicative of the



extent to which supportive or rehabilitative services, in addition to methadone treatment, were applied, offered, or encouraged.

For the purposes of this study, significance was defined as  $p < .05$ .

#### Limitations of the Study

The principle limitations of this study are as follows: (1) because of the relatively short study period, no conclusions could be drawn with respect to long term adjustment or rehabilitation since such data were not within the scope of this study; (2) because of the difficulty in defining treatment variables within the methadone program, the response of a population to treatment in this program can only suggest how they might respond to manipulation of the same treatment variables in another methadone program; (3) because of the grossness of the measure of supportive services, the quality or exact nature of these services was not considered; and (4) because of the complexity of behavioral adjustment, the measures of behavioral adjustment employed in this study do not necessarily reflect the subjects' actual overall adjustment and can be considered only suggestive of the level of overall adjustment.

## CHAPTER II

### REVIEW OF THE LITERATURE

Narcotic addiction has long been considered a significant social problem in this country. Raskin refers to the rapidly increasing use of heroin as "just like any communicable disease pattern" (Lipinski, 1972, p. 171). Moreover, the increase in the use of heroin in the last few years, particularly since 1969, has come to be considered a problem of epidemic proportions in some areas of the country (Gould, 1972; Lipinski, 1972; St. Pierre, 1971; Smith, Gay, & Ramer, 1970). The cost of narcotic addiction to the community and society, in general, is so enormous, both in terms of material goods and in terms of human resources, that the problem has received considerable notoriety and public exposure.

Cushman (1970) investigated the cost to society of 81 long-term heroin addicts in New York. In the year prior to their entry into a methadone treatment program, these 81 addicts "used approximately \$900,000 worth of heroin, or nearly \$11,000 each. Over half of the heroin was obtained by selling the drug to others." Still they "obtained \$258,000 worth of heroin through the sale of stolen property. The fair market value of this property amounted to about \$720,000, considerably more than its value on the black market. The cost to society, however, does not stop here, but must include money spent to

control the distribution and sale of heroin, the cost of police investigation of thefts and protection from theft, the cost of courtroom proceedings against addict offenders, welfare payments and hospital treatment of narcotic addicts, and finally the cost of narcotic addiction rehabilitation programs."

(Cushman, 1970) All told, the cost to society of the 81 addicts was estimated to be in excess of one million dollars per year.

Given these circumstances, it is not difficult to understand why federal, state, and local governments, as well as numerous private organizations, have become involved in attempts to rehabilitate narcotic addicts and prevent the spread of narcotic addiction. Various approaches have been tried, ranging from incarceration in prison-like situations (Scrignar, Alderette, Marr, Bloom, & Mehl, 1970; Smith, Gay, & Ramer, 1970; Trussell, 1970) to narcotic clinics where registered addicts were provided with narcotics to maintain their habits at a relatively low cost (Mahon, 1971; Phillipson, 1970). None of these approaches, however, proved to be very effective (Bloom, 1967; Duval, Locke, & Brill, 1963; Maddox, Berliner, & Bates, 1971; Phillipson, 1970; Scrignar, 1967; Scrignar, et. al., 1970; Smith, et. al., 1970; Trussell, 1970; Vaillant, 1966) because of a number of difficulties inherent in each treatment approach. Consequently, narcotic addiction soon came to be considered as a problem highly resistant to treatment. This attitude tended to reinforce and perpetuate the philosophy that addiction is a criminal problem which should

be dealt with by confinement and punitive measures. Although such measures have consistently proven quite ineffective (Nahrendorf, 1968; Scrignar, 1967), it was not until recent years that this philosophy has become less widely accepted.

More recently, therapeutic community approaches, such as Synanon and Phoenix House, began to receive wider recognition and acceptance. This therapeutic modality has shown some promise (Bloom, 1967), but the effectiveness of the therapeutic community approach has been difficult to evaluate because of lack of uniformity in reporting data and lack of objectivity. It appears that most proponents of the therapeutic community approach are so protective of its image that data on the effectiveness of therapeutic communities tend to be somewhat biased in their favor. Available data do, however, suggest that the effectiveness of therapeutic communities is limited to a rather select population of addicts. Thus, although it does appear that the therapeutic community approach may be more effective than the more traditional approaches, the prognosis for the social rehabilitation of any given narcotic addict must remain poor (Jaffe, 1970).

This state of affairs prevailed until Dole and Nyswander (1965) introduced the concept of methadone maintenance. As previously noted, the concept of maintaining a narcotic dependent person's habit is not entirely new. It has been tried previously both in the United States and in England.

supplying the addict with the narcotics his body needs, two important things happen: (1) the necessity for committing anti-social acts is eliminated or greatly diminished, and (2) the physical craving and the anxiety created by the fear of withdrawal symptoms are eliminated or greatly reduced so that rehabilitative efforts might be more successfully undertaken (Phillipson, 1970). These two effects should, theoretically, create a situation where the addict's anti-social life style and preoccupation with drugs are less likely to be reinforced, and the addict will have time to incorporate other forms of adaptive behavior while functioning in society.

The early narcotic maintenance programs in the United States and England did not prove acceptable for several reasons. First and foremost, it became immediately necessary to provide addict patients with narcotics to be used outside the treatment facility where intake could not be monitored. Thus, since the patient's narcotic intake could not be accurately monitored, patients were soon able to obtain large quantities of narcotics which they could use themselves, sell, or give away. The availability of surplus narcotic medication soon resulted in the spread of addiction and deaths due to overdoses (American Medical Association Committee on Alcoholism and Drug Dependence, 1967; Bloom, 1967; Phillipson, 1970; Scrigner, 1967).

The problem of having to give patients narcotics for use outside of a treatment facility was a direct by-product of the

relatively short duration of action of the drugs used, i.e., morphine. A second problem created by the short duration of action of the drugs used at that time was the roller-coaster-like effect that patients experienced most of the time when they were either "high" or "beginning to get sick." There was relatively little time in between when they could function as normal members of society (Nyswander, 1971).

A third problem associated with the short duration of action drugs was that it was almost impossible to satisfactorily stabilize an addict at any particular dosage level for any length of time. Dosage had to be periodically increased in order to avoid the onset of withdrawal symptoms. The use of short acting narcotics resulted in variations in the concentration of the drug in the blood which were too abrupt to be well tolerated (Goldstein, 1972). The problem was compounded by the use of injections as opposed to oral administration of the drug. The use of injectable narcotics interfered with rehabilitation because of the strong reinforcing effect of the needle itself and the "rush" this form of administration produces (Brill & Jaffe, 1967; Jaffe, 1970; Mathes & Lynch, 1971).

These problems, which were prime contributors to the ineffectiveness of early maintenance programs in transforming addicts into productive members of society, as stated above, are directly related to the drugs used to maintain the addict's habit. The maintenance program of Dole and Nyswander, on the

other hand, proved more effective due at least partially, to some important pharmacological properties of methadone. Probably the most important property of methadone as a drug used in the maintenance treatment of narcotic addiction is its relatively long duration of action (Bloom, 1967; Jaffe, 1970; Jaffe, Schuster, Smith, & Blachley, 1970). Martin, Jasenski, and Manski (1970) found both subcutaneously and orally administered methadone to have a much longer duration of action than subcutaneously administered morphine as measured by pupil constriction and a subjective drug questionnaire. Objective pupil constriction lasted 24 hours while, subjectively, methadone was reported to last well for 12 hours with declining effects between the 12th and 24th hours. A second study by Jaffe, Schuster, Smith, and Blachley (1970) reported no change from base line scores on the Addiction Research Center Inventory's opiate withdrawal subscale or on a symptom checklist 24 hours after oral administration to tolerant subjects. At 36 hours the subjects expressed considerable subjective distress on the Inventory's withdrawal subscale, and by 48 hours two-thirds of the subjects were experiencing considerable distress with observable symptoms of withdrawal.

This twenty-four hour duration of action demonstrated by methadone allows methadone intake to be rather precisely monitored, as well as allowing the program officials to minimize the potential for diversion of their methadone into illicit channels. Also, because of its long duration of action and oral

administration, methadone has a relatively slow onset so that there is little, if any, euphoria experienced by tolerant patients, while their craving for narcotics may be greatly diminished, if not eliminated. Thus, the roller coaster effect experienced with other narcotics is virtually absent in tolerant patients because of the relatively flat blood level concentration curve which is characteristic of methadone (Goldstein, 1972). Finally, because methadone is administered orally, the reinforcing effect of the needle is eliminated (Brill & Jaffe, 1967; Jaffe, 1970).

The relatively flat curve representing the concentration of methadone in the blood which was mentioned above also means that a person can be stabilized at a certain dosage level with no necessity for periodic increases in doses in order to prevent the onset of withdrawal symptoms. Increasing tolerance to the maintenance effect does not take place because the concentration of methadone in the blood remains relatively stable. The body develops a tolerance to this concentration, and as long as this concentration is not exceeded, tolerance will not increase (Goldstein, 1972). It must be pointed out that for any narcotic to produce analgesic, tranquilizing, or sedating effects, the concentration of the narcotics in the blood must exceed the body's tolerance level. Thus, if methadone is to be used to produce analgesic, tranquilizing, or sedating effects, the dosage level will have to be periodically increased just as it would with any other narcotic.



Perhaps the most publicized pharmacological effect claimed for methadone is the narcotic blockading effect, which is more accurately described as narcotic cross-tolerance. Dole and Nyswander reported that patients maintained on high doses of methadone, between 80 and 120 mg. per day, developed such a tolerance to narcotics that most subjects subjectively felt and objectively exhibited little or no effects from the injection of rather large quantities of other narcotics. It was theorized that since little or no pleasurable effects were obtained from the injection of a previously quite satisfying quantity of narcotics, this narcotic using behavior would gradually be extinguished (Dole & Nyswander, 1966).

This methadone induced cross-tolerance to heroin was later verified in a study by Zaks, Fink & Freedman (1970). They found that "subjects receiving a daily schedule of 100 mg. of methadone exhibited a cross-tolerance to heroin which persisted 48 hours following the last dose of methadone."

More recently, the cross-tolerance effect has been questioned by several authors (Bowling, Moffett, & Taylor, 1971; Singh, Castet, & Nix, 1971). These authors feel that the cross-tolerance phenomena is not completely effective at all times. They point out that continued use of heroin by some patients makes it apparent that patients are able to experience some euphoric effects from the injection of heroin, even when they are receiving relatively large doses of methadone. They consider the proportion of patients who continue to use heroin too great to designate them all as simply "needle freaks."

Although the cross-tolerance phenomena may not be entirely effective, there is little doubt that the pharmacological properties of methadone have significantly contributed to the success of the methadone maintenance program. Some investigators have, however, proposed that the pharmacological properties and actions of methadone are the only significant factors accounting for the successes achieved in methadone maintenance programs (Blachly, 1970; Perkins, 1970; Perkins & Bloch, 1970). Furthermore, they feel that auxiliary psychological and sociological services have not significantly contributed to the results obtained by methadone maintenance programs and that controls involved in the dispensing of methadone have not significantly contributed to the social rehabilitation of the addicts in methadone programs (Dobbs, 1971; Johnson & Williams, 1970; Garbutt & Goldstein, 1972; Pearson, 1969; Perkins, 1970).

The wide disparity in results reported by various programs suggests, however, that factors besides the pharmacological properties of methadone are having significant effects. This belief is even more strongly supported by recent findings which indicate that after a certain point, approximately 30 mg., methadone dosage level has little effect with regard to social rehabilitation criteria (Garbutt & Goldstein, 1972; Goldstein, 1970, 1972; Jaffe, 1970b, 1970c; Wieland & Moffett, 1970; Williams, 1970).

While disparities in results exist which cannot be accounted for on the basis of drug effects and while controversy exists regarding the need for psychological and sociological rehabilitation services, there is as yet little or no research in the literature which compares the effects of various treatment variables. In fact, there is very little mention of treatment variables outside of dosage levels of methadone. "Rapid expansion of methadone treatment is occurring before many questions relevant to optimal program design can be answered by empirical test," (Sells & Watson, 1970, p. 21).

One way to measure the extent of the need for inter-personal services, in addition to the dispensing of methadone, is to measure the effects of various levels of inter-personal services which are provided. Inter-personal services might be represented in a rather gross way by the number or frequency of patient-staff contacts (Sells & Watson, 1970). Linn (1970) used this technique in a study of the effectiveness of a psychiatric in-patient program. He found the frequency of patient-staff interactions to be positively correlated with the number of patients who were working and with a high patient involvement in treatment programs (Linn, 1970). In general, Linn found the frequency of patient-staff interaction to be positively related to patient improvement. These results reinforced previous similar results obtained by Jones and Sidebotham (1969), Jenkins & Gurel (1959), and Ullmann (1967).

These studies support the feasibility of using frequency of patient-staff interaction as a gross measure of rehabilitative services provided in addition to methadone treatment. If these services have a significant effect, there should be a significant difference in results obtained at various levels of rehabilitative services provided. It should be pointed out, however, that rehabilitative services used in the context of this study refer more to the creation of a therapeutic milieu than to a number of discrete services such as individual counseling, vocational counseling, general health care, family counseling, etc. While each counselor involved in this study may have his own special areas of interest, he is and was expected to be involved in the patient's total rehabilitation, offering whatever services he can, making appropriate referrals when necessary, and following the outcome of the referral.

## CHAPTER III

### METHOD

#### Subjects

The subjects for this study were seventy-five patients consecutively admitted to the methadone treatment program at the Drug Treatment Center in Fort Worth, Texas. All subjects were active narcotic addicts who voluntarily presented themselves at this facility and requested methadone treatment. The criteria for admission to this program are (1) that the individual be actively addicted to narcotics as evidenced by observable symptoms of withdrawal and tolerance to a moderate dose (30 to 40 mg.) of methadone, (2) that the individual be eighteen years of age or older, (3) that the individual be free of seriously debilitating physical disorders, (4) that the individual be free of active psychosis, and (5) that the individual be able to come to the Drug Treatment Center at least once daily to receive doses of methadone.

At the time this study was undertaken, there was no waiting list for admission to the methadone program. All subjects, for the purposes of this study, were admitted according to a standard admission procedure outlined in Appendix A. Upon completion of this procedure, each subject was randomly assigned to one of three treatment groups, consisting of 25 subjects per group.

A summary of the population statistics of the three treatment groups is presented in Table I. No statistical analysis was conducted on this data as none of these variables was considered as likely to have significant effect on the outcome of this study. Inspection of the data presented in Table I reveals minimal differences across treatment groups on all variables except length of addiction. The high patient-staff contact group had an average length of addiction which was approximately twenty months longer than either of the other two treatment groups, although all treatment groups were approximately the same average age. One might hypothesize that this fact might make the high patient-staff contact groups somewhat more resistant to change, particularly if the metabolic disorder theory of addiction (Dole & Nyswander, 1967) is accepted, and in light of the fact that all groups had approximately 0.018 treatment attempts per month of addiction (Berle & Lewinson, 1970; Gearing, 1970; Johnston & Williams, 1970).

TABLE I  
POPULATION STATISTICS

Group	Caucasian Male	Age	Education Level	No. of Prior Treatment Attempts	Months of Addiction	
High	72%	60%	29.8	11.1	1.9	103.7
Medium	64%	56%	29.4	10.4	1.6	83.0
Low	60%	56%	28.9	11.5	1.5	84.3

Inspection of Table I also reveals that the subjects utilized in this study probably do not represent a random sample of narcotic addicts. In comparison with data from the New York City Narcotic Register (Gearing, 1970a, 1970b), minority races are somewhat under represented. The Mexican-American addict population is particularly under represented with this group representing only 2/3% of the entire sample. Female addicts also appear to be somewhat over represented. The average age of this sample appears to correspond rather closely to what might be expected in the general addict population with the exception of the under-eighteen-years-of-age group being unrepresented in this sample. Food and Drug Administration guidelines, however, prohibit the treatment of addicts under eighteen years of age via methadone maintenance or prolonged detoxification without a special IND permit. Finally, this sample has probably sought treatment more frequently than members of the general addict population.

The differences represented between this sample and the general addict population suggest that this sample would have a more favorable prognosis for social rehabilitation than would a randomly selected sample from the general addict population. Differences between treatment groups within this sample do not, however, seem to favor significantly any groups with respect to prognosis for social rehabilitation.

A summary of the self-reported, pre-treatment measures for the three treatment groups is presented in Table II. Again

no statistical analysis was conducted. Inspection of this table, once again, reveals little difference between the three treatment groups. This data might appear to favor the high and medium patient-staff contact groups. These groups show a higher average number of days employed when housewives and retired or disabled patients are considered as fully employed. The differences here would, however, almost completely disappear if housewives and retired or disabled patients were not considered.

TABLE II  
SUMMARY OF PRE-TREATMENT MEASURES

Group	Mean No. of Arrests During Previous 3 Months	Employed on Admission	Housewives or Disabled	Average Days Employed*
High	1.84	28%	16%	24.76
Medium	1.88	24%	12%	26.80
Low	1.84	28%	8%	17.64

\*Housewives, students, and fully disabled patients were considered fully employed.

Housewives and retired or disabled patients are more likely to remain in treatment, partially due to their somewhat restricted mobility (Berle & Lowinson, 1970; Brill & Jaffe, 1967; Gearing, 1970; Johnston & Williams, 1970). The differences between treatment groups represented by the data presented in Table II do not appear to favor significantly any group with respect to the level of behavioral adjustment prior to entering treatment.



### Procedure

The three treatment conditions were (1) low level of patient-staff contact--average of less than one contact per week, (2) medium level of patient-staff contact--average of 1.0 to 2.0 contacts per week, and (3) high level of patient-staff contact--average of greater than 2.0 contacts per week. Subjects were unaware of their assignment to treatment groups. All subjects were assigned one counselor upon being accepted for admission to the methadone treatment program and were told that they should consult that counselor regarding any problems they might have or encounter during treatment. Subjects in the high patient-staff contact treatment group were assigned a second counselor, but were left unaware of this second counselor assignment. It was this second counselor's responsibility to assist the patient's primary counselor in maintaining the high level of contact desired for the patients in the high patient-staff contact group. All counselors were informed as to what level of contact was desired for each subject and, in most cases, the counselors were aware of the nature of the study being undertaken.

Patient-staff contacts were defined as any patient-staff contact meeting all of the following criteria: (1) duration of one minute or more, (2) dialogue relating specifically to the individuals involved or concerning the treatment program, and (3) dialogue which could not be classified as primarily in the category of "old dope stories." Thus, contacts involving

only casual greetings and contacts involving casual conversation about past or current events were, for the purpose of this study, not generally considered as patient-staff contacts. Counselors were instructed to attempt to orient their contacts with patients toward dealing with current life situations and current functioning. Emphasis on indepth personality restructuring was discouraged. Direct confrontations with patients, regarding how they and their behavior affected others, were not discouraged and occurred with considerable frequency.

Patient-staff contacts were monitored via brief progress notes made by all staff members after each contact which met the above stated criteria. Included in these progress notes were (1) the patient's name, (2) staff member's name, (3) date, (4) approximate length of the contact, and (5) a brief summary of the content of the contact or the dialogue that took place.

By means of these progress notes, the investigator was able to provide the various counselors with feedback regarding any discrepancies between the desired number of contacts and the number of contacts actually taking place. The only control exercised over the level of contacts was in terms of staff-initiated contacts. Staff members were instructed that no patient-initiated contacts were to be ignored. A second function served by the progress notes was to allow the investigator to verify that the contacts met the criteria for patient-staff contact set forth above and that counselors were generally orienting their contacts with patients along the lines set forth above.

There were three primary counselors utilized in this study along with one secondary counselor. Each of the primary counselors was assigned twenty-five subjects, eight in two of the treatment groups and nine in the third treatment group. Thus, each of the three counselors should have had an approximately equal effect on each of the treatment groups. None of these counselors had had any formal training as a counselor. The one secondary counselor initiated contacts with the high patient-staff contact group only. It should be pointed out, however, that since all staff members were instructed not to ignore any patient-initiated contact, the influence exerted by the staff on any patient was not necessarily limited to the efforts of any one or two staff members.

All subjects were initially required to come to the clinic once each day to receive their daily dosage of methadone. After being in treatment for two full weeks, subjects were allowed to take their Sunday dose home on Saturday so that they were required to come to the clinic only six days per week. No further take-home privileges were allowed until the patient had been in treatment for three full months. Methadone was administered orally, dissolved in Tang, and consumed under the direct observation of a nurse and a counselor. This counselor was not necessarily the counselor assigned to the patient.

After admission to the treatment program, each subject's methadone dosage was increased 10 mg. twice each week until a stabilizing dosage was reached. Stabilizing doses ranged from

40 mg. per day to 110 mg. per day. The three treatment groups were, however, matched with regard to methadone dosage throughout the duration of this study. Further, once a stabilizing dosage had been arrived at, no dosage manipulations were undertaken until the three-month study period had expired. Counselors were instructed never to initiate dialogue regarding dosages. In cases of patient-initiated dialogue regarding dosage, counselors were instructed to attempt to turn the discussion toward discussion of symptoms and adjustment to stresses. If the patient persisted in dialogue about methadone dosage, the counselor instructed him to make out a written request for dosage alteration which would be submitted to the medical director. Further, counselors were instructed never to give the patient their opinion as to the validity of the requested manipulation in dosage.

#### Measures of Behavioral Adjustment

Success of rehabilitative efforts was measured in terms of five behavioral adjustment measures. These measures were (1) number of days employed in a gainful occupation or going to school, (2) frequency of arrests, (3) abstinence from the use of illicit drugs as approximated by periodic urine sampling, (4) the number of days remaining in treatment, and (5) payment of fees for treatment.

Measures one, two, and three are considered to be indications of social rehabilitation, while measures four and five might be

considered as indicators of the acceptability of the program to the target population. The first four measures are the measures most commonly used as criteria in evaluating the effectiveness of methadone treatment programs.

#### Number of Days Employed or Going to School

Self-reported employment and educational histories were obtained from each subject on admission to the treatment program. Subjects were required to provide verification of their employment and educational activities during treatment. Incentive for providing verification of employment or educational activities was provided through a semi-formal token economy system (see Appendix B). No attempt was made to verify pre-treatment employment or educational activities.

#### Frequency of Arrests

Arrest records were obtained from each subject at the time he was admitted to the methadone program. These were self-reported arrests. Convictions were, however, verified when possible. Arrests taking place during treatment were generally known to the staff through self-report or reports from other patients. Also, if a subject failed to pick up his medication for three consecutive days, the subject's counselor called the city and county jails to see if the subject was incarcerated. Arrests for offenses occurring prior to admission to the treatment program were considered as arrests occurring prior to entering treatment.

### Abstinence from Use of Illicit Drugs

Degree of abstinence from use of illicit drugs was approximated through analysis of randomly collected urine specimens. At least one urinalysis per week was run on each subject throughout the duration of this study. The analyses were done by a professional laboratory specializing in this kind of work. A triple extraction, thin layer chromatography technique was used. Urines were analyzed for morphine, codeine, Demarol, methadone, cocaine, barbiturates, amphetamines, phenothizines and destromethorphan. All positives, other than methadone positives, were verified by gas chromatography. This process yields a very low number of false positives. False negatives, however, are fairly common.

Urine specimens were obtained on a random basis at least once weekly and under observed conditions. Subjects were not aware of when they would be asked to give a urine specimen. In order to avoid difficulty in obtaining specimens, subjects were not dispensed methadone until the urine specimens were obtained. Thus, if any subject was unable to give a urine specimen, he was given no methadone that day and his urine was assumed to be dirty; i.e., containing drugs of abuse other than methadone. Subjects were not, however, punished for producing dirty urines.

### Number of Days Remaining in Treatment

Retention in the treatment program is simply the number of days a subject remains in active treatment beginning with

the first day he actually receives a dose of methadone and ending with the last day he receives methadone.

#### Payment of Fees for Treatment

After one month of treatment, all subjects were required to pay seven dollars per week to help cover the cost of treatment. The official policy of the Center was that any patient falling more than two weeks behind in fee payments would begin being slowly detoxified, and this process would continue until the patient either paid all of his back fees or was completely detoxified. In actuality, this detoxification process is never begun until the patient falls at least one month behind in his payments. This fact was fairly common knowledge among the patients at the Drug Treatment Center. The detoxification process was not undertaken with any of the subjects utilized in this study, regardless of how far behind they might have been in their fee payments. Also, the topic of payment of fees was never initiated by staff members in any of the contacts with subjects in this study. Counselors were instructed not to initiate discussions regarding payment of fees, but were not instructed to avoid such discussions.

#### Analysis of Data

A single factor analysis of variance was performed on the number of days remaining in treatment using Fisher's t test to isolate significant differences between the various groups. The significant covariate obtained in this analysis was used

in performing a series of single factor analyses of covariance on the four remaining measures of behavioral adjustment. An analysis of covariance was obviously required since the number of days an individual remains in treatment directly limits the possible values of each of the other four measures of behavioral adjustment. Adjusted group means were obtained on each of these four measures of behavioral adjustment (Winer, 1962).

No statistical analysis was performed on population data or pre-treatment behavioral adjustment measures. After inspection of this data, it was felt that none of these variables were likely to have any significant effect on the during-treatment measures of behavioral adjustments.



## CHAPTER IV

### RESULTS

The data obtained according to the method presented in the previous chapter are presented in this chapter along with the statistical analyses of these data. A single factor analysis of variance was used to test hypothesis number one, which states that the level of retention of patients in a methadone treatment program would be significantly improved by the provision or application of frequent supportive services as compared with the level achieved when few or no supportive services are provided. Thus, an analysis was conducted to test for a significant difference across treatment groups with respect to the number of days Ss remained in active treatment.

Results of the single factor analysis of variance on the number of days remaining in treatment are presented in Table III. The analysis of variance on this measure of behavioral adjustment proved to be highly significant ( $F = 8.4809$ ,  $p < .005$ ), indicating a significant treatment effect across groups with respect to this variable.

TABLE III  
ANALYSIS OF VARIANCE ON NUMBER  
OF DAYS IN TREATMENT

Source	Sum of Squares	df	Variance Estimate	F Ratio	p
Between Groups	15344.9600	2	7672.4800	8.4809	0.0005
Within Groups	65137.0400	72	904.6811	. .	. .
Total	80482.0000	74	. .	. .	. .

A series of Fisher's t tests were conducted to isolate significant differences between the three treatment groups. The results of these tests are reported in Table IV. From these statistics it can be seen that the difference between the low patient-staff contact group and the high patient-staff

TABLE IV  
FISHER'S T RATIOS FOR DIFFERENCES BETWEEN GROUPS  
ON NUMBER OF PATIENT-DAYS IN TREATMENT

Group	High Contact	Medium Contact	Low Contact
High Contact	0.0	1.3447	4.0436**
Medium Contact	-1.3447	0.0	2.6989*
Low Contact	-4.0436**	-2.6989*	0.0

\*p < .01.

\*\*p < .001.

contact group is highly significant ( $t = 4.0436$ ,  $p < .001$ ), and the difference between the low patient-staff contact group and the medium patient-staff contact group is slightly less significant ( $t = 2.6989$ ,  $p < .01$ ). The difference between the medium patient-staff contact group and the high patient-staff contact group, however, did not reach significance. Thus, the medium and high patient-staff contact groups showed a significantly greater tendency to retain subject in treatment than did the low patient-staff contact groups.

The mean length of stay in treatment and the rate of retention in treatment for the three treatment groups are reported in Table V. Inspection of the data presented in Table V reveals a strong relationship between the frequency of patient-staff contacts and retention in treatment. The

TABLE V  
MEAN STAY IN TREATMENT AND RATE OF RETENTION IN TREATMENT

Group	Mean No. of Days in Treatment	Standard Deviation of Days in Treatment	No. of Ss Remaining in Treatment for 3 Mos.
High N = 25	93.68	19.89	21 (84%)
Medium N = 25	72.24	28.31	16 (64%)
Low N = 25	49.28	38.95	10 (40%)

greater the frequency of patient-staff contacts, the more likely the patients are to remain in treatment. The high patient-staff contact group retained 84% of its patients in treatment for at least three months. The medium patient-staff contact group retained 64%, and the low patient-staff contact group retained only 40%. The average length of stay in treatment for Ss in the high patient-staff group was over a month longer than was the average stay of patients in the low-contact group, and the average length of stay in treatment for patients in the medium patient-staff contact group was just over three weeks longer than the average stay of patients in the low-contact group. Thus, with respect to both length of stay in treatment and rate of retention in treatment, improvement was found to be associated with increased frequency of patient-staff contact.

As stated previously, the retention in treatment variable directly affects the remaining measures of behavioral adjustment by limiting the number of days a S could possibly be employed, the number of dirty urines he could produce, the amount of treatment fee debt he could accumulate, and the number of times he could be arrested, since these data were collected only while a S was in active treatment. The number of days in active treatment variable was, therefore, selected as the covariate for further analyses conducted on the other measures of behavioral adjustment employed in this study.

Thus, a series of single factor analyses of covariance were conducted to test hypothesis number two. This hypothesis states that the level of behavioral adjustment of patients in a methadone treatment program would be significantly improved by the provision or application of frequent supportive services as compared with that obtained when few or no supportive services are provided. The analyses tested for significant differences across treatment groups with respect to (1) the number of dirty urines produced during treatment, (2) the number of arrests during treatment, (3) the amount of treatment fee debt accumulated, and (4) the number of days employed during treatment, with a correction for differences between groups in the number of days Ss remained in treatment.

The results of the series of single factor analyses of covariance are presented in Table VI. The differences between treatment groups in the amount of treatment fee debt

✓TABLE VI  
ANALYSES OF COVARIANCE ONE-WAY DESIGN ON MEASURES  
OF BEHAVIORAL ADJUSTMENT

Behavioral Adjustment Variables	Treatment Sum of Squares	Treatment Mean Square	df	F	p
Number of Dirty Urines	345.5078	172.7539	2	2.7788	0.0689
Number of Arrests	8.6649	4.3324	2	3.2537	0.0445
Debt	2926.9883	1463.4941	2	7.0896	0.0016
Days Employed	1752.4063	876.2031	2	1.0054	0.3710

they accumulated were found to be very highly significant ( $F = 7.0896$ ,  $p = .0016$ ). The differences between treatment groups with respect to the average number of arrests while in treatment were also found to be significant ( $F = 3.2537$ ,  $p = .0445$ ). In addition, the differences across groups with respect to the average number of urine specimens produced which contained evidence of the use of drugs other than methadone approached significance ( $F = 2.7788$ ,  $p = .0689$ ). The differences between the three treatment groups with respect to the number of days employed, however, did not approach significance. Although the high patient-staff contact group had both a greater percentage of Ss employed at the end of the study period (61.9%) and a higher adjusted group mean number of days employed than did either the medium contact group (56.25%) or the low patient-staff contact group (50.00%), the differences across groups with respect to this variable are quite small and should be attributed to chance.

The adjusted group means for each of these last four dependent variables are reported in Table VII. Inspection of

TABLE VII  
ADJUSTED GROUP MEANS

Groups	Dirty Urines	Arrests	Debt	Days Employed
High	0.0356	0.1822	5.3809	50.3271
Medium	1.3478	0.7254	20.1202	38.5299
Low	5.6167	1.0925	18.1389	41.7029

the data presented in this table reveals that the high patient-staff contact group showed the best behavioral adjustment with respect to all measures employed, although the differences were not in all cases significant. It should be noted that these adjusted means do not show a very consistent trend toward greater improvement in behavioral adjustment associated with greater frequency of patient-staff contacts; i.e., the adjusted group means do not show a progression toward improved behavioral adjustment from the low patient-staff contact group to the medium patient-staff contact group to the high patient-staff contact group with respect to all measures employed.

## CHAPTER V

### DISCUSSION AND CONCLUSION

This study focused on the effects of experimental variation of the level or frequency of patient-staff contact on behavioral adjustment measures taken on patients in a methadone treatment program for narcotic addiction. The level of patient-staff contact was assumed to be roughly indicative of the extent to which rehabilitative services, in addition to methadone treatment, were applied, offered, or encouraged (Linn, 1970; Sells & Watson, 1970).

In general, the results tended to support the contention that at least during the early months of treatment, methadone treatment in conjunction with other rehabilitative efforts is more effective in improving behavioral adjustment than is methadone treatment alone. No conclusions could be drawn, however, with respect to long-term improvement in behavioral adjustment since these data were not within the scope of this study. Thus, extensive rehabilitative efforts, represented by the high level of patient-staff contact group, may have proven more effective in terms of short-term or immediate improvement in behavioral adjustment associated with the extensiveness of rehabilitative efforts. This possibility, however, seems rather remote.



Perhaps the most significant finding of this study was that a high frequency of patient-staff contact or methadone treatment in conjunction with extensive rehabilitative efforts was much more effective in holding addicts in treatment. The low patient-staff contact group had many more dropouts and significantly fewer patient-days in treatment than did either the medium or high patient-staff contact groups. Also, there appeared to be a strong tendency toward fewer dropouts and more patient-days in treatment as the frequency of patient-staff contacts increased. This finding is particularly significant in light of the fact that of 95 patients who have dropped out of treatment at the Drug Treatment Center over the first year of operation, 88.4 percent did so within the first three months of treatment.

The obvious implication is that a significant proportion of addicts applying for treatment in a program of the type utilized for this study need more than methadone or the elimination of the fear of withdrawal in order to remain in treatment. While these results may be highly specific to this particular treatment program, federal guidelines (see Appendix C) dictate considerable uniformity in the operation of methadone treatment programs so that the specificity of these results is somewhat limited. It would appear most likely that a significant proportion of addicts who apply for treatment at a methadone program are not motivated strongly enough to tolerate daily visits to the clinic, observed urine sampling, payment

of treatment fees, conforming to clinic rules, etc., in addition to pressure toward modifying an entire life style, without external support and assistance such as might be provided through contacts with staff members (Brill, 1968; Brill & Jaffe, 1967; Jaffe, Zaks, & Washington, 1969; Martin, 1970; St. Pierre, 1970; Scrignar, 1967; Scrignar, Alderette, Marr, Bloom, & Mehl, 1970). In addition, although most addicts applying for treatment in a methadone program state that they want help in getting away from the use of heroin, such statements are most frequently not altogether true. "When the prospective patient says, 'I need treatment,' he speaks truthfully, when he says, 'I want treatment,' his communication needs interpreting. . . . The professional will learn to know or at least review several possible meanings: 'I have no money to get drugs on the street, I want methadone for a day or two until I can finance my next fix,' or 'I am being sought by the police, I want any protection membership in this program may confer, or 'I have a bag (push drugs), membership in the program will allow me to sell the drugs I would otherwise have taken myself,' or 'My spouse also has a habit, for me to receive methadone will reduce the cost of our combined habits,' or 'I have enemies looking for me, I need to get out of circulation,' or 'My spouse is threatening to leave me, unless I make the appearance of seeking help,' or 'It's cold outside.' The list could, no doubt, be extended; motivation is often overdetermined," (Knowles, Lahiri, & Anderson, 1970, p. 409).

In many cases where the motivation is primarily situational such as those listed above, the addict is very likely to leave treatment when the crisis situation which brought him to treatment has passed, unless something has happened in the interim to make the patient want to stay in treatment (Brill & Jaffe, 1967). The results of this study indicate that contact with staff members can help provide the needed motivation to remain in treatment after the crisis has passed. This observation seems to be particularly true in a relatively young program where a core group of relatively successful patients is not yet available to provide new patients with support and assistance which they need to maintain motivation. Such a group could probably function more effectively in these roles than could any number of staff members (Jaffe, Zaks, & Washington, 1969). Nevertheless, providing an addict with sufficient methadone to prevent the onset of withdrawal symptoms apparently does not necessarily eliminate his desire for narcotics, and this freedom from fear of withdrawal symptoms does not necessarily lead to a strong desire to modify his addict life style. In fact, it appears very probable that, unless more than methadone is provided or offered, most addicts will return to their old life style when the opportunity presents itself.

This finding, although it does not necessarily contradict Dole's metabolic disorder theory (Dole & Nyswander, 1967) of addiction, does indicate that the treatment of this disorder

is much more complicated than simply correcting a metabolic imbalance.

Perhaps the problem of retaining addicts in treatment is more difficult in Fort Worth, where this study was conducted, than it would be in larger cities, such as New York, Chicago, and San Francisco. Certainly the dropout rate in this study, even in the high patient-staff contact group, is greater than what has been reported in several other programs. The absence of adequate descriptions of the various program variables in reports of other studies makes it impossible even to speculate about what effect differences in various program variables might have on dropout rates (Martin, 1970; Perkins, 1970; Sells & Watson, 1970). Patients, however, have stated repeatedly that maintaining a habit in a large city, such as those mentioned above, is much more difficult than it is in a smaller city, such as the one where this study was conducted. It appears likely that this statement is true and may partially account for the higher dropout rates reported in this study. Possibly, the addiction population taped in this study are less motivated toward treatment because they have experienced less difficulty in surviving as an addict. This lower level of motivation may well have resulted in more dramatic differences in survival rates associated with the various levels of patient-staff contact than would have been found with a more highly motivated population such as might be found in larger cities.

The significantly greater survival rate associated with greater frequency of patient-staff contacts does, however, suggest that these contacts somehow made the treatment program more attractive to patients. This hypothesis would seem to be supported by the finding of a highly significant difference between groups in the amount of treatment-fee debt accumulated. Patients in the high patient-staff contact group tended to pay treatment fees much more regularly and, therefore, accumulated far less debt than did patients in either the medium patient-staff contact group or the low patient-staff contact group. Since patients were not directly coerced into paying treatment fees, this data would tend to reflect the acceptability of the program to the patients, and the results obtained with regard to this variable tend to support the assumption that a high frequency of patient-staff contact makes the program significantly more attractive to many patients. It should be pointed out that the increased attractiveness of the program associated with the higher frequency of patient-staff contact is not the result of more privileges being given to this group. None of the patients in this study were given any special privileges of any kind. It appears that the high frequency of patient-staff contact made the program attractive to patients in that group so that they not only remained in treatment, but also tended to pay their treatment fees. Most of the patients in the medium frequency patient-staff contact group apparently found the program to be attractive enough to

remain in treatment, but not attractive enough to pay their treatment fees. Patients in the low patient-staff contact group apparently did not find the program attractive enough either to remain in treatment or pay their treatment fees. Obviously, the results of this study, regarding retention in treatment and payment of treatment fees, indicate that the high frequency of patient-staff contact in conjunction with methadone treatment made the program significantly more attractive than methadone treatment alone.

The results of this study also indicated that patients who were exposed to a high frequency of patient-staff contacts in addition to methadone treatment tended to do better with respect to some measures of behavioral adjustment, namely avoiding arrests and producing urine samples containing no evidence of the use of drugs other than methadone. The differences between the three treatment groups with respect to the number of urine samples produced which contain evidence of the use of drugs other than methadone did not quite reach the .05 level of significance ( $p = 0.069$ ). This level of probability was, however, considered as indicating a tendency toward improvement on this variable associated with higher frequency of patient-staff contact. Moreover, the adjusted group means for this variable show a definite progression toward fewer dirty urines as the frequency of patient-staff contact increases.

This same progression is seen in the adjusted group means for the frequency-of-arrests variable. The differences between

groups with regard to this variable were found to be significant beyond the .05 level of significance.

The tendency toward fewer dirty urines and the significantly fewer arrests associated with more frequent patient-staff contacts suggests that such contacts can, indeed, be considered as having some therapeutic benefit. It can not, however, be assumed that these contacts were necessarily the most appropriate rehabilitative efforts or even that these improvements in behavioral adjustments were indicative of an overall improvement in adjustment (Einstein, 1970; Johnston & Williams, 1970; Martin, 1970; Perkins, 1970; Sells & Watson, 1970). Obviously, a patient can do very well with respect to all of the behavioral adjustment measures employed in this study and still not be making any real progress toward social rehabilitation. Several such patients have been and are in treatment at the Drug Treatment Center. These people make it very obvious how difficult it is adequately to define and measure adjustment. Still, these results do suggest a tendency toward improved social rehabilitation associated with higher levels of patient-staff contact.

The one measure of behavioral adjustment which during the course of this study showed no indication of improving with increased frequency of patient-staff contacts was the number of days employed. The high patient-staff contact group showed a greater percentage of patients employed at the end of the study period than did the medium patient-staff contact group,

and this group showed a greater percentage of patients employed at the end of the study period than did the low patient-staff contact group. The differences in these percentages would not, however, appear to be significant. These differences do suggest that the differences between the treatment groups with respect to the days-employed variable might have approached or achieved significance if a longer study period had been used. In light of current economic and social conditions and the fact that few addicts possess marketable skills or educational achievements (Scrignar, 1967), it appears probable that educational or occupational achievements will frequently take longer to reach significance than other measures of behavioral adjustment such as cessation of heroin use and avoiding arrests, acts which are more exclusively dependent on the motivation and efforts of the patient (Brill & Jaffe, 1967; Maddox, 1972; Primm, 1970). This proposition tends to be supported by the fact that four of the thirteen patients in the high patient-staff contact group who were employed at the end of the study period had gained employment only within the last month of treatment. Again it appears that methadone treatment, in conjunction with a high level of patient-staff contact, was somewhat more effective in promoting improved behavioral adjustment than was methadone treatment alone.

From the foregoing results and discussion, it was concluded that the retention of patients in a methadone treatment



program may be significantly improved over what might be obtained when few or no supportive services are offered, by the provision or application of frequent supportive services. The degree of improvement obtained would be highly dependent on a number of other treatment variables, such as how liberal the program is in granting "take home" privileges. The results of this study, however, indicate that the provision or application of frequent supportive services may significantly enhance the attractiveness of the program to the point that the target population would be more willing to tolerate adverse aspects of the program, such as limited "take home" privileges and payment of fees for treatment. Hypothesis number one, regarding retention in treatment, is strongly supported.

It may, also, be concluded that the level of behavioral adjustment of patients in a methadone treatment program may be improved by the provision or application of frequent supportive services over what might be obtained with little or no supportive services provided. The improvement in behavioral adjustment is most likely to be in terms of those variables which are more exclusively dependent upon the motivation and efforts of the patient, such as discontinuing the use of drugs and avoiding arrests. Behavioral adjustment measures such as employment and/or educational status frequently are resistant to change because of social and economic conditions. In addition, vocational rehabilitation agencies, such as the Texas Rehabilitation Commission, rarely are able to provide immediate services because

of procedural requirements regarding eligibility, so that qualified applicants frequently spend as much as three months fulfilling admission requirements before they are placed in a vocational training program. Several authors have reported little or no improvement in employment or educational status despite significant improvements with regard to other measures of behavioral adjustment (Borden, 1972; Jaffe, 1970c; Wieland & Moffett, 1970). Thus, despite the lack of significant differences between treatment groups with regard to the employment variable, the results obtained do support hypothesis number two by showing an improvement in behavioral adjustment associated with an increased quantity of supportive services applied.

In a more general sense, from the results of this study, it might be concluded that supportive or adjunctive services can significantly contribute to the effectiveness of a methadone treatment program by contributing to greater retention in treatment and to improvement in behavioral adjustment. Numerous studies have been reported which tend to support this conclusion (Borden, 1972; Brill, 1968; Dobbs, 1971; Jaffe, 1970b; Jaffe, 1970c; Jaffe, Zaks, & Washington, 1969; Johnston & Williams, 1970; Maddox, 1972; Sells & Watson, 1970; Wieland & Moffett, 1970), but none of these studies have attempted an experimental test of this hypothesis.

It must be pointed out that the results and conclusions of this study are limited by the relatively short, three-month

period of study. No conclusions can be drawn with regard to long range retention in treatment or improvements in behavioral adjustment. A longer study period with more Ss might provide more conclusive evidence regarding the value of high frequencies of patient-staff contact or adjunctive rehabilitation services.

## CHAPTER VI

### SUMMARY

The present investigation compared the treatment effects of three levels or frequencies of "significant" patient-staff contacts on narcotic addicts in a methadone treatment program using five measures of behavioral adjustment as the criteria of improvement during the three-month study period. "Significant" patient-staff contacts were operationally defined as any patient-staff contact which met all of the following criteria: (1) a duration of one minute or longer, (2) dialogue relating specifically to the individuals involved or concerning the treatment program directly, and (3) dialogue which could not be classified as primarily in the category of "old dope stories." The three levels of patient-staff contact employed were (1) low--average of less than one contact per week, (2) medium --average 1.0 to 2.0 contacts per week, and (3) high--average of more than 2.0 contacts per week. The behavioral adjustment measures of treatment effects included (1) number of days remaining in treatment, (2) payment of treatment fees, (3) number of urine samples produced which contained evidence of the use of drugs other than methadone, and (5) number of days employed or going to school. The first two measures were considered primarily as measures of the acceptability of the

treatment program to the target population, while the latter three measures were more directly indicative of the subjects' level of behavioral adjustments.

The methadone maintenance approach to the treatment of narcotic addiction has received considerable notoriety and public acclaim, based primarily on early studies with rather select population and extensive adjunctive rehabilitation services provided. Reports of this research, however, emphasized the role of the pharmacological properties of methadone in the successes obtained while the role of the adjunctive rehabilitation services was de-emphasized. Research has demonstrated that methadone can be used as a valuable and effective therapeutic tool. It has not, however, been demonstrated, as some researchers have implied, that the simple daily administration of high doses of methadone will result in the spontaneous rehabilitation of most narcotic addicts. Several more recent studies have produced results considerably less favorable than those reported earlier. Since the pharmacological properties of methadone obviously have not changed, the disparity in results can only be attributed to the effects of various population and treatment variables, particularly since within broad limits, medication variables such as dosage and schedule of administration have consistently been found to have no significant effect on treatment results. Still, there has been very little research concerning the effects of the many treatment variables. In light of the understandable

skepticism regarding the value of adjunctive rehabilitation services, expressed or implied by some authors, this variable was chosen as the focus of the present study. The level or frequency of patient-staff contacts was assumed to be grossly indicative of the extent to which adjunctive rehabilitation services in addition to methadone treatment were applied, offered, or encouraged.

It was hypothesized that (1) the retention of patients in a methadone treatment program would significantly improve with the provision or application of frequent supportive services in comparison with the retention rate obtained when few or no supportive services are provided and (2) that the level of behavioral adjustment of patients in a methadone treatment program would significantly improve with the provision or application of frequent supportive services as compared with the level of behavioral adjustment obtained when few or no supportive services are provided.

Seventy-five consecutively admitted narcotic addicts from the Drug Treatment Center in Fort Worth, Texas, served as Ss. The criteria for admission to the methadone treatment program were (1) active addiction to narcotic drugs, (2) eighteen years of age or older, (3) freedom from seriously debilitating physical disorders, (4) freedom from active psychosis, and (5) ability to come to the Center at least once daily to receive doses of methadone.

Ss were randomly assigned to one of the three treatment groups, and each S was assigned to one of the three counselors.

Ss were not aware of the nature of the study or that they were being assigned to treatment groups. The frequency of patient-staff contacts for each S was monitored via brief progress notes made by all staff members following each contact with an S which met the stated criteria of a significant patient-staff contact. The only control exercised over the frequency of patient-staff contacts was in terms of staff-initiated contacts.

Methadone was administered orally once daily, dissolved in Tang, and consumed in the presence of the dispensing team. The three treatment groups were matched with regard to dosage, and no special privileges were granted any S during the study period.

Results of this study indicate that the pattern of behavioral adjustment was significantly different across treatment groups. Hypothesis number one was strongly supported by a highly significant difference between groups with regard to the number of days Ss remained in treatment. The high- and medium-level patient-staff contact groups stayed in treatment significantly longer and had fewer dropouts than did the low-level group. In addition, there appeared to be a tendency toward remaining in treatment longer and fewer dropouts as the frequency of contacts increased.

A significant difference across groups was also found with regard to the payment of treatment fees, with the high-contact group accumulating significantly less debt than either the

medium or low patient-staff contact groups. These results in conjunction with the results obtained with regard to retention in treatment were seen as indicating an increase in the attractiveness of the program to the addict population associated with increased frequency of patient-staff contacts.

Analysis also revealed a tendency toward better adjustment with regard to the other measures of behavioral adjustment employed associated with increased frequency of patient-staff contacts. The difference across treatment groups in number of arrests was the only remaining measure which reached significance. The differences with regard to the number of dirty urines produced just missed significance, and data regarding the number of days employed suggested that this measure might have reached significance if a longer study period had been used. It was concluded, therefore, that the data also tended to support hypothesis number two.

In general, all treatment groups showed a tendency toward improved behavioral adjustment, but a significantly greater improvement in adjustment was found to be associated with increased frequency of patient-staff contacts.

It must be pointed out that the results of this study are limited and that a longer study period might provide more conclusive evidence regarding the value of high frequencies of patient-staff contact or adjunctive rehabilitation services.



## APPENDIX A

The following two pages contain the standard admission procedure that was used in admitting all of the subjects utilized in this study.

## Drug Treatment Center Methadone Treatment Program

## Admission Procedure

1. Prospective applicant presents himself at this center claiming to be a narcotic addict and requesting admission to the methadone treatment program.
2. Prospective applicant is interviewed briefly by a counselor. During this interview the counselor is to (1) explain the dangers of this treatment modality (2) explain how the methadone treatment program operates and what will be expected of the patient if he is accepted (3) make a preliminary assessment of the prospective applicant's eligibility for methadone treatment and (4) record on the second page of the medical history form symptoms and signs of withdrawal.
3. If, at the conclusion of this interview, the applicant still desires admission to methadone treatment and the counselor has found no reason to exclude him from this form of treatment, the applicant will be asked to fill out the necessary forms. These forms include (a) informed consent for treatment (b) arrest record (c) addiction record (d) drug use record (e) medical history (f) application for treatment and (g) release of information.
4. A urine specimen is to be obtained under observed conditions.
5. Processing fee collected (\$7.00).
6. Appointment for interview with medical director made.
7. Appointment for psychological testing made.
8. The applicant is interviewed more extensively by the counselor. The objectives of this interview are (a) to correct or clear up mistakes or ambiguities on the forms just completed by the applicant (b) to obtain a brief social history and drug use history (c) to explain all aspects

of the methadone treatment program in detail (d) to clear up any questions the applicant might have and (e) to observe and record signs and symptoms of addiction and withdrawal from narcotics.

Note: At any time after the preliminary interview if the counselor observes signs of withdrawal from opiates, he may at his discretion ask the nurse to contact the medical director who may order a moderate dose of methadone (30 - 40 mg.) for the applicant if he thinks the situation warrants this. If methadone is ordered a urine should be obtained prior to its dispensing. The applicant is then to be observed for a minimum of 90 minutes and evidence of non-tolerance or continued withdrawal signs recorded. Evidence of non-tolerance suggests the applicant is not actively addicted and this should be carefully investigated.

9. The applicant is assigned a case number.
10. The applicant is interviewed and given a preliminary physical examination by the medical director who will at this time either accept or reject the applicant for further methadone treatment. If accepted for treatment the medical director will set the patient's initial dosage and schedule and order lab work, if required.
11. The patient will be assigned a regular counselor and an appointment made for him to see his counselor as soon as possible.

## APPENDIX B

The following four pages contain a semi-formal token economy system which was used at the Drug Treatment Center throughout the duration of this study.

It should be noted that with regard to Section III, page 1, Ss involved in this study were not given any points for participation in a therapeutic activity if this activity was initiated by a staff member.

In order for this, or any rehabilitation program to be most effective there should be some reasonably objective means of evaluation and encouraging the patient's progress. The system outlined below is one means of meeting these needs. Basically the system offers a means of earning freedom or privileges by behaving in a responsible manner and by seeking self-improvement. Most of the freedoms and privileges a person has in society are gained in this manner. While this system will not be perfect for every individual it is sufficiently flexible to benefit everyone.

Points may be earned according to the following schedule:

#### I. Employment

1. Working full time: 5 points/week (employment must be verified at least monthly in order that points may be awarded. Providing verification is the responsibility of the patient.)
2. Working part time: 0 to 5 points/week depending on the number of hours worked. (Employment as well as the number of hours worked must be verified at least monthly. Providing verification is the responsibility of the patient)
3. Student full time: 5 points/week. (The patient must provide verification of his enrollment and passing work in order to obtain full point credit.)
4. Student part time: 0 to 5 points/week depending upon the number of credits for which the patient is enrolled. (The patient must provide verification of his enrollment and passing work in order to obtain the appropriate point credit.)
5. Self-employment: 0 to 5 points/week depending upon the amount of time spent working. (Reasonable verification must be provided at least monthly in order to receive the appropriate point credit.)
6. Housewife: 0 to 5 points/week depending upon the number of people in the household and extent of outside activities. (The patient is responsible for providing verification.)
7. Disabled: 0 to 5 points depending upon the extent of verifiable disability and the extent to which the person makes use of what physical abilities he has.

#### II. Attending and participating in "Therapeutic Activities"

1. Wednesday afternoon rap sessions (5:00 to 7:00 p.m.): 2 points
2. Sessions with counselor: 0 to 3 points depending on the counselor's estimation of the patient's sincerity and participation during the session.
3. Group counseling sessions: 0 to 3 points depending on the group counselor's estimation of the patient's sincerity and participation during the session.

III. General appearance and behavior: 0 to 5/week depending on the patient's counselor and other staff members rating of the patient's general appearance and behavior during the week. These ratings will be based on neatness, sobriety, motivation, and cooperation. (Due to the very general nature of this category and the fact that the final rating will be based on the rating of more than one person the number of points awarded can not be debated.)

#### IV. Bonus points for consistent motivation and responsible behavior

1. Earning 12 points or more each week for four consecutive weeks:  
2 points. The number of bonus points awarded for this level of consistent performance will be increased by one every other week after the fourth week so that the patient will be awarded 3 bonus points on the sixth consecutive week of earning 12 or more points and 4 bonus points on the eighth consecutive week of earning 12 or more points, etc. Bonus points will not be counted as part of the patient's weekly point earnings although they may be used in the same way as points earned by any other means.
2. Earning 14 points or more each week for four consecutive weeks:  
3 points. The number of bonus points awarded for this level of consistent performance will be increased by two every other week after the fourth week as long as this level of performance is maintained. Thus on the sixth consecutive week that the patient has earned 14 points or more he will be awarded 5 bonus points and on the eighth consecutive week of earning 14 points or more he will be awarded 7 bonus points, etc. Again, bonus points will not be counted as part of the patient's weekly point earning.
3. Earning 16 points or more each week for four consecutive weeks:  
4 points. The number of bonus points awarded for this level of consistent performance will be increased by three every other week after the fourth week as long as this level of performance is maintained in the same manner outlined above.

\*NOTE: No points may be earned by any patient until all admission requirements have been completed. The patient is solely responsible for seeing that these requirements are fulfilled. Admission requirements include:

- (1) Completing all necessary forms
- (2) Paying initial fee
- (3) Completing psychological tests
- (4) Seeing Dr. Foster for initial evaluation
- (5) Completing lab work (if required)
- (6) Having I.D. card made.

Each patient's point record will be kept by his or her counselor. Therefore patients should consult their individual counselor with any questions they may have regarding this system or how many points they have accumulated. Suggestions as to how to improve the system will be welcomed.

Points earned according to the above outlined schedule may be spent in any or all of the following ways: <sup>64</sup>

- I. Acquiring take home medicine for special occasions if approved by your counselor and Dr. Foster. (Two days advance notice is required. Please note that this is not extra medicine only medicine to be taken home when you won't be able to come in. Also no more than 3 days supply can be taken home.)
  1. 1 days medicine to be taken home: 5 points
  2. 2 days medicine to be taken home: 12 points
  3. 3 days medicine to be taken home: 20 points
- II. Partial payment of fees: Points will be accepted in the place of money for the payment of treatment fees at the rate of 10 points per one dollar.
- III. Progressing from one treatment class to the next where the patient will be required to come to the center less frequently to pick up his medicine.\*
  1. Class 1 (coming in seven days/week) to Class 2 (six days/week with Sunday's medicine taken home on Saturday): 20 points
  2. Class 2 (six day/week) to Class 3 (five days/week with Saturday and Sunday medicine taken home on Friday): 45 points
  3. Class 3 (five day/week) to Class 4 (three day/week Monday, Wednesday, and Friday or Tuesday, Thursday and Saturday with medicine for other days taken home): 60 points plus 3 points per week for being maintained on a Class 4 level.
  4. Class 4 (three days/week) to Class 5 (two days/week with medicine for other days taken home): 85 points plus 5 points per week for being maintained on a Class 5 level.

\*Note: Progressing from one treatment class to another is subject to staff approval and having the required number of points only entitles the patient to consideration for advancement, it does not guarantee it. If you would like to use your points to advance from one treatment class to the next, you should inform your counselor of this decision. He will check to see that you have enough points and if you do have enough points he will bring your request up at the next staff meeting. He will notify you of the staffs decision as soon as possible and if the request is approved he will deduct the required number of points from your total.

A patient may be moved from a higher treatment class to a lower treatment class without any point refund if the staff feels that the patients behavior does not warrant the amount of freedom and responsibility he has been receiving or that the patient's behavior constitutes a threat to the program.

Patients will be dismissed from the Methadone Program and placed on the Detoxification Phase for rapid withdrawal from addiction to Methadone for the following reasons:

1. Physical violence or threat of physical violence to staff or other patients.
2. Redistribution of medication for any reason or in any manner.
3. Possession of illicit drugs or alcohol on the premises.
4. Missing three consecutive doses of Methadone unless the patient gives prior notification to the staff that he will be unable to pick up his Methadone and provides a valid reason.
5. Theft or willful destruction of Center property.
6. Indictment for possession or sale of illicit drugs after being placed on maintenance.
7. Failure to participate in any therapeutic activity at the D.T.C.
8. Being intoxicated (from any substance) and unable to receive Methadone for any 3 consecutive days.

THESE PROCEDURES MAY BE CHANGED AS NECESSITY DICTATES.

#### HOUSE RULES

1. Regular dispensing hours are from 6:00 a.m. to 11:00 a.m. (morning) and from 4:30 p.m. to 8:00 p.m. (evening). Medicine will be dispensed during these times only.
2. All patients on the Methadone program must leave the premises by 10:00 p.m. unless attending a scheduled activity.
3. Patients who appear to be intoxicated (from any substance) will not be dispensed any medication until no longer intoxicated.
4. No patients are allowed in the Secretary's or any other Staff Member's office without their verbal permission. Knock before entering.
5. Medication not dispensed as take home medicine must be consumed in the presence of the dispensing nurse.
6. Patients will be expected to give urine specimens upon request. No medication will be given until the specimen is obtained.



## APPENDIX C

The following four pages contain a joint statement by the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs entitled "Conditions for Investigational Use of Methadone for Maintenance Programs for Narcotic Addicts". This statement sets forth the general guidelines for operation of a methadone treatment program.

## Title 21—FOOD AND DRUGS

### Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

#### SUBCHAPTER C—DRUGS

### PART 130—NEW DRUGS

#### Conditions for Investigational Use of Methadone for Maintenance Programs for Narcotic Addicts

A notice was published in the *FEDERAL REGISTER* of June 11, 1970 (35 F.R. 9014), proposing establishment (21 CFR 130.44) of acceptable guidelines for programs for the investigation of methadone in the maintenance treatment of narcotic addicts. The guidelines of the Bureau of Narcotics and Dangerous Drugs, Department of Justice, were also proposed June 11, 1970 (35 F.R. 9015).

In response, a substantial number of comments were received from the medical community through the American Medical Association, Student American Medical Association, American Psychiatric Association, National Academy of Sciences-National Research Council, known authorities in the treatment of drug addiction, and from individuals and municipalities currently operating methadone maintenance programs.

The majority of the comments are in the form of objections to provisions of the protocol and the regulation, as follows:

1. The criteria in the protocol for the exclusion of subjects from the studies: Pregnancy, psychosis, serious physical diseases, and persons less than 18 years of age.

2. The requirement in the protocol that no more than a 3-day supply be given to a subject at one time.

3. The necessity for making records available to the Food and Drug Administration and to the Bureau of Narcotics and Dangerous Drugs and the lack of a guarantee of confidentiality of patient records.

4. The requirement that one of the objectives of the studies be a return to the drug-free state.

5. The requirement that the dosage level be limited to 160 milligrams per day.

6. The necessity of obtaining prior approval from the Bureau of Narcotics and Dangerous Drugs.

7. The requirements for weekly urine analysis and other laboratory tests and examinations.

8. The classification of the use of methadone in the maintenance treatment of narcotic addicts as an investigational use.

9. The regulation being overly restrictive and not in the best interest of the public.

The Commissioner of Food and Drugs, having considered the comments and having met with representatives of in-

terested groups, associations, and individuals for further discussion, finds that:

1. The majority of the comments are a result of interested persons interpreting the proposal as restricting investigators to the suggested protocol. This is a misinterpretation since the protocol is intended only as a guide to assist the profession, municipalities, organizations, and other groups who are interested in sponsoring programs for the investigation of methadone in the maintenance treatment of narcotic addicts. It is not intended that every methadone program be confined to the limits of this protocol. Modification of the protocol and completely different protocols will be accepted, provided they can be justified by the sponsor. Modifications and completely different protocols consistent with public welfare and safety will be approved.

2. Since the suggested protocol is intended as an aid to those who wish to sponsor programs for the investigation of methadone in the maintenance treatment of narcotic addicts, it is recognized that it would be to the benefit of the Food and Drug Administration, the Bureau of Narcotics and Dangerous Drugs, and the sponsors of the investigations to have a suggested protocol that would be acceptable to the majority of sponsors while satisfying the requirements of the two aforementioned agencies. Accordingly, the following revisions have been made in the regulation as adopted below:

a. The provision of the protocol "Criteria for exclusion from the program" has been changed to "Patients requiring special consideration." Pregnancy, psychosis, serious physical disease, and being less than 18 years of age are not reasons for automatic eliminations from a program but are conditions that merit special considerations which are detailed.

b. A provision has been added to the protocol to permit the investigator to exceed the dosage of 160 milligrams per day when the investigator finds it essential to do so and describes the considerations leading to such dosage levels in his protocol.

c. The requirement for laboratory examinations at 6-month intervals has been changed to 1-year intervals.

d. The objectives of the study have been clarified.

3. The remaining comments concerning the protocol and not mentioned above deal primarily with problems that can be met by submission of a modified protocol to be judged on individual merit.

4. Regarding the objection that the recordkeeping requirements and the necessity for making records available to the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs could violate the confidential relationship between the patient and the physician: The Federal Food, Drug, and Cosmetic Act provides for promulgating regulations that require the sponsor of the drug investigations to maintain adequate records and that these records be made available to authorized

personnel of the Food and Drug Administration. These records must be adequate in the event that followup on adverse reaction information requires identification of the patient. The Bureau of Narcotics and Dangerous Drugs is authorized to have access to these records under the Harrison Narcotic Act.

5. Methadone used in the maintenance treatment of narcotic addicts is an investigational use drug because, despite recent research gains, there remains inadequate evidence of long-term safety and of long-term effectiveness for this use to permit general marketability of methadone for maintenance treatment under the Federal Food, Drug, and Cosmetic Act standards for new drugs.

6. It is necessary that prior approval for methadone maintenance programs be obtained from the Bureau of Narcotics and Dangerous Drugs as well as the Food and Drug Administration because of this drug's potential for abuse. The Bureau of Narcotics and Dangerous Drugs' approval will be based on the existence of adequate control procedures to prevent diversion of the drug into illicit channels. Since the applications will be submitted only to the Food and Drug Administration and reviewed simultaneously by the two agencies, the inconvenience to the sponsor and the delay of approval will be minimal.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052-53, as amended, 1055; 21 U.S.C. 355, 371(a)) and under authority delegated to the Commissioner (21 CFR 2.120), the following new section is added to Part 130:

#### § 130.44 Conditions for investigational use of methadone for maintenance programs for narcotic addicts.

(a) There is widespread interest in the use of methadone for the maintenance treatment of narcotic addicts. Though methadone is a marketed drug approved through the new-drug procedures for specific indications, its use in the maintenance treatment of narcotic addicts is an investigational use for which substantial evidence of long-term safety and effectiveness is not yet available under the Federal Food, Drug, and Cosmetic Act standards for the general marketability of new drugs. In addition, methadone is a controlled narcotic subject to the provisions of the Harrison Narcotic Act and has been shown to have significant potential for abuse. In order to assure that the public interest is adequately protected, and in view of the uniqueness of this method of treatment, it is necessary that a methadone maintenance program be closely monitored to prevent diversion of the drug into illicit channels and to assure the development of scientifically useful data. Accordingly, the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs conclude that prior to the use of methadone in the maintenance treatment of narcotic addicts, advance approval of both agencies is required. The approval will be based on a review of a Notice of Claimed Investigational Exemption for

a New Drug submitted to the Food and Drug Administration and reviewed concurrently by the Food and Drug Administration for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for drug control requirements.

(b) No person may sell, deliver, or otherwise dispose of methadone for use in the maintenance treatment of narcotic addicts until a study providing for such use has had the advance approval of the Commissioner of Food and Drugs on the basis of a Notice of Claimed Investigational Exemption for a New Drug justifying such studies.

(c) An abbreviated Notice of Claimed Investigational Exemption for a New Drug shall be submitted in four copies to the U.S. Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852. Forms entitled "Notice of Claimed Investigational Exemption for Methadone for Use in the Maintenance Treatment of Narcotic Addicts," suitable for such a submission may be obtained from the above address. The submission should be signed by the person in charge of the maintenance program who will be regarded as the responsible party and sponsor for the exemption. (If the sponsor is a manufacturer or distributor of the drug, the regulations as outlined in § 130.3 should be followed, except where the guidelines set forth below in this section are appropriate.) The notice shall contain the following:

(1) Name of sponsor, address, and date and the name of the investigational drug, which is methadone.

(2) A description of the form in which the drug is purchased (for example, bulk powder or tablet or other oral dosage form), the name and address of the manufacturer or supplier, and a statement that the drug meets the requirements of the United States Pharmacopoeia or the National Formulary if recognized therein. If it is in an oral form designed to minimize its potential for abuse, and is not recognized in the U.S.P. or N.F., assurance that the drug meets adequate specifications for its intended use should be provided. This information may be obtained from the manufacturer. If bulk powder is used, a statement detailing how it is to be formulated, the name and qualifications of the person formulating the dosage form, and the address of where the formulating will take place if it is to take place at any location other than the principal address of the sponsor.

(3) The name, address, and a summary of the scientific training and experience of each investigator, and all other professional personnel having major responsibility in the research and rehabilitative effort, and individuals charged with monitoring the progress of the investigation and evaluating the safety and effectiveness of the drug if the monitor is other than a physician-sponsor. An investigator, other than a physician-sponsor (and investigators immediately responsible to a physician-sponsor and named in his submission) who has signed a form FD-1571 or the form entitled "Notice of Claimed Inves-

tigational Exemption for Methadone for Use in Maintenance Treatment of Narcotic Addicts," is required to sign a form FD-1573, obtainable from the Food and Drug Administration.

(4) A description of the facilities available to the sponsor to perform the required tests including the name of any hospital, institution, or clinical laboratory facility to be employed in connection with the investigation.

(5) A statement regarding the number of subjects to be included in the program.

(6) A statement of the protocol. The following is an acceptable protocol; however, it is not to be construed that this protocol must be adhered to in order to obtain clearance by the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs. This protocol is intended primarily as a guide for investigators who wish guidance in what said agencies consider acceptable. Investigators who wish to do so may submit modifications of this protocol or other protocols; these will be judged on their merits.

#### Protocol

A. Objectives. 1. To evaluate the safety of long term methadone administration at varying dosage.

2. To evaluate the efficacy of oral methadone per se in decreasing the craving for other narcotic drugs and in minimizing their euphoriant effect.

3. To evaluate the efficacy of methadone as a pharmacological moiety in facilitating social rehabilitation of narcotic addicts.

4. To determine which addicts are capable of returning to an enduring drug-free state.

B. Admission criteria. 1. Documented history of physiological dependence on one or more opiate drugs, the duration of which is to be stated.

2. Confirmed history of one or more failures of treatment for their physiological dependence on opiates.

3. Evidence of current physiological dependence on opiates.

An exception to the third criterion (current physiological dependence on opiates) is allowable in exceptional circumstances for certain subjects for whom methadone maintenance may be initiated a short time prior to or upon release from an institution. This procedure should be justified on the basis of a history of previous relapses. In these circumstances, appropriate descriptions of the facilities, procedures, and qualifications of the personnel of the institution are to be included in the application filed by the sponsor.

Subjects who wish to do so may be transferred from one approved program to another.

C. Patients requiring special consideration—1. Pregnant patients. Safe use of methadone in pregnancy has not been established. There is limited documented clinical experience with pregnant patients treated with methadone, and animal reproduction studies have not been done. It is therefore preferable that pregnant patients be hospitalized and withdrawn from narcotics. If such a course is not feasible, pregnant patients may be included provided the patient is informed of the possible hazard. To minimize the risk of physiological dependence of the new born, or other complications, pregnant women should be maintained on minimal dosage. The investigator should promptly report to the Food and Drug Administration the condition of each infant born to a mother in a methadone maintenance program.

2. Patients with serious physical illness. Patients with serious concomitant physical

illness are to be included in methadone maintenance program only when comprehensive medical care is available. Such patients require careful observation for any adverse effects of methadone and interactions with other medications. The investigator should promptly report adverse effects and evidence of interactions to the Food and Drug Administration.

3. Psychotic patients. Psychotic patients may be included in methadone maintenance programs when adequate psychiatric consultation and care is available. Administration of concomitant psychotropic agents requires careful observation for possible drug interaction. Such occurrences should be promptly reported.

Investigators who intend to include in their programs patients in categories 1, 2, and/or 3 above should so state in their protocols and should give assurance of appropriate precautions.

4. Patients less than 18 years of age. It is imperative that adolescents be afforded the benefit of other treatment modalities whenever possible and that those with minimal histories of physiological dependence be excluded from methadone maintenance programs. Investigators who wish to include adolescents in the program are therefore required to submit special protocols for this purpose. These protocols should state in detail the number of such patients to be treated, the alternative treatment methods available, the criteria for selection, the screening procedures, and the ancillary procedures to be employed.

D. Admission evaluation. 1. Recorded history to include age, sex, history of arrests and convictions, educational level, employment history, and past and present history of drug abuse of all types.

2. Medical history of significant illnesses.

3. History of prior psychiatric evaluation and/or treatment.

4. Assessment of the degree of physical dependence on and psychic craving for narcotics and other drugs, and evaluation of the attitudes toward and motivations for participation in the program.

5. Formal psychiatric examination in subjects with a prior history of psychiatric treatment and in those in whom there is a question of psychosis and/or competence to give informed consent.

6. Physical examination.

7. Chest X-ray.

8. Laboratory examinations to include complete blood count, routine urinalysis, liver function studies (including SGOT, alkaline phosphatase, and total protein and albumin globulin ratio), blood urea nitrogen, and serologic test for syphilis.

E. Procedure—1. Dosage and administration. The methadone is to be administered in an oral form so formulated as to minimize misuse by parenteral injection. The initial dosage is to be low; for example, 20 milligrams per day. Subsequently, the dosage is to be adjusted individually, as tolerated and as required, up to 100 milligrams per day. In exceptional cases, investigators may find it essential to exceed this dosage to obtain the intended effect. If such cases are encountered, the initial protocol or an amended protocol should include the maximum dosage to be administered, the number of patients for whom such dosage is required, and a description of the considerations leading to such dosage levels. The methadone is to be administered under the close supervision of the investigator or responsible persons designated by him. Initially, the subject is to receive the medication under observation each day. After demonstrating adherence to the program, the subject may be permitted twice weekly observed medication intake with no more than a 3-day supply routinely allowed in his possession. Additional medication may

be provided in exceptional circumstances, such as illness, family crisis, or necessary travel, where hardship would result from requiring the customary observed medication intake for the specific period in question.

2. **Urinalysis.** Urine collection is to be supervised; urine specimens are to be analyzed for methadone, morphine, quinine, cocaine, barbiturates, and amphetamines; urine specimens are to be pooled or selected randomly for analysis at intervals not exceeding 1 week.

3. **Rehabilitative measures.** Rehabilitative measures as indicated may include individual and/or group psychotherapy, counseling, vocational guidance, and job and educational placement.

4. **Abnormalities.** There shall be adequate investigation and appropriate management (including necessary referral and consultation) of any abnormalities detected on the basis of history, physical examination, or laboratory examination at the time of admission to the program or subsequently, including evaluation and treatment of intercurrent physical illness with observation for complications which might result from methadone.

5. **Repeated examinations.** Physical examination, chest X-ray, and laboratory examinations conducted at the time of admission are to be repeated annually.

6. **Discontinuation and followup.** Consideration is to be given to discontinuing the drug for participants who have maintained satisfactory adjustment over an extended period of time. In such cases, follow-up evaluation is to be obtained periodically.

7. **Records.** Adequate records are to be kept for each participant on each aspect of the treatment program, including adverse reactions and the treatment thereof.

8. **Other special procedures.** Within the limitations of personnel, facilities, and funding available and in the interest of increasing knowledge of the safety and efficacy of the drug itself, the following procedures are suggested as worthwhile, to be carried out at baseline and periodically in randomly selected subjects: EKG, EEG, measures of respiratory, cardiovascular, and renal function, psychological test battery, and simulated driving performance.

9. **Voluntary and involuntary terminations.** Subjects who have demonstrated continued frequent abuse of narcotics or other drugs, alcoholism, criminal activity, or persistent failure to adhere to the requirements of the program are ordinarily to be terminated and their records should reflect that they are treatment failures. If they are continued indefinitely in the program, the reasons for so doing should be stated in the protocol.

10. **Results.** 1. Evaluation of the safety of the drug administered over prolonged periods of time is to be based on results of physical examination, laboratory examinations, adverse reactions, and results of special procedures when these have been carried out.

2. Evaluation of effectiveness or rehabilitation is to be based on such criteria as:

- ✓ a. Arrest records.
- ✓ b. Extent of alcohol abuse.
- ✓ c. Extent of drug abuse.
- ✓ d. Occupational adjustment verified by employers or records of earnings.
- ✓ e. Social adjustment verified whenever possible by family members or other reliable persons.

3. Withdrawal from methadone and achievement of an enduring drug-free status.

4. Evaluations are to be recorded at predetermined intervals; for example, monthly for the first 3 months, at 6 months, and at 6-month intervals thereafter.

5. **Evaluation group.** Whenever possible, a locally oriented independent evaluation committee of professionally trained and qualified persons not directly involved in the project nor organized by the sponsor will inspect facilities, interview personnel and selected patients, and review individuals' records and the periodic analysis of the data.

(d) The sponsor shall assure that adequate and accurate records are kept of all observations and other data pertinent to the investigation on each individual treated. The sponsor shall make the records available for inspection by authorized agents of the Food and Drug Administration. The Bureau of Narcotics and Dangerous Drugs is also authorized to inspect these records under the Harrison Narcotic Act.

(e) The sponsor is required to maintain adequate records showing the dates, quantity, and batch or code marks of the drug used. These records must be retained for the duration of the investigation.

(f) The sponsor shall monitor the progress of the investigations and evaluate the evidence relating to the safety and effectiveness of the drug. Accurate progress reports of the investigation and significant findings shall be submitted to the Food and Drug Administration at intervals not exceeding periods of 1 year. All reports of the investigation shall be retained for the duration of the investigation.

(g) The sponsor shall promptly notify the Food and Drug Administration of any findings associated with the use of the drug that may suggest significant hazards, contraindications, side effects, and precautions pertinent to the safety of the drug.

(h) The physician-sponsor or individual investigators in admitting addicts to the investigational treatment program

are required to give to the addict an accurate description of the limitations as well as the possible benefits which the addict may derive from the program.

(i) The physician-sponsor or each individual investigator of this program shall certify that the drug will be used and administered only to subjects under his personal supervision or under the supervision of personnel directly responsible to him; a statement to this effect shall be included in the notice. The signing of the form "Notice of Claimed Investigational Exemption for Methadone for Use in the Maintenance Treatment of Narcotics Addicts" by a physician-sponsor or the form FD-1573 by an investigator will satisfy this requirement.

(j) The physician-sponsor or each individual investigator shall certify that all participants will be informed that drugs are being used for investigational purposes, and will obtain the informed consent of the subjects and shall include a statement to this effect in the notice. The signing of the forms as indicated in paragraph (i) of this section will satisfy this requirement.

(k) Failure to conform to the protocol for which approval has been received from the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs will be a basis for termination of the claimed investigational exemption.

(l) The sponsor of a "Notice of Claimed Investigational Exemption for a New Drug" already on file with the Food and Drug Administration should review and amend his submission to bring it into accord with the acceptable protocol where appropriate within 60 days after the effective date of this section. All differences in his protocol from the suggested protocol should be justified.

(m) Provisions under the Harrison Narcotic Act enforced by the Department of Justice are applicable to this use of methadone.

**Effective date.** This order is effective upon publication in the FEDERAL REGISTER (4-2-71).

(Secs. 505, 701(a), 52 Stat. 1052-53, as amended, 1055; 21 U.S.C. 355, 371(a))

Dated: March 25, 1971.

CHARLES C. EDWARDS,  
Commissioner of Food and Drugs.

## TITLE 26—INTERNAL REVENUE

Chapter I—Internal Revenue Service,  
Department of the Treasury

SUBCHAPTER A—INCOME TAX  
[T.D. 7100]

[Treasury Decision 7076]

### ART 151—REGULATORY TAXES ON NARCOTIC DRUGS

#### Administering and Dispensing Requirements

On June 11, 1970, there was published in the FEDERAL REGISTER, 35 F.R. 9015, 9016, a notice of proposed rule making amending § 151.411 of Title 26 of the Code of Federal Regulations in order to make clear the conditions upon which practitioners may administer or dispense narcotic drugs in the course of conducting clinical investigations in the development of methadone maintenance rehabilitation programs. Essentially, the proposal would require that practitioners obtain approval prior to the initiation of such an investigation by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which would then be reviewed concurrently by that agency for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for drug control requirements.

This proposal was published in conjunction with a notice of proposed rule making published by the Commissioner of Food and Drugs for addition of a new section to Part 130 of Title 21 of the Code of Federal Regulations. Among other matters this notice contained acceptable criteria and guidelines agreed upon by the Food and Drug Administration and the Bureau of Narcotics and Dangerous Drugs for the conduct of clinical investigations of this nature. Since the original publication of both of these notices, two extensions of 30 days each have been granted for the receipt of additional written comments. After extensive review of the written comments received, both agencies have agreed upon certain alterations in the proposed criteria and guidelines which are designed to facilitate

further research and to accommodate the diverse needs and interests of the scientific community. These changes have been effected by appropriate modification of the new section to be added to Part 130 of Title 21 of the Code of Federal Regulations published elsewhere in this issue of the FEDERAL REGISTER. Inasmuch as the bulk of comments received concern the criteria and guidelines appearing originally in that proposal, no modifications of the proposed amendment to § 151.411 of Title 26 of the Code of Federal Regulations as published on June 11, 1970, have been undertaken.

As previously set forth, it is recognized that the investigational use of methadone, a class "A" narcotic drug requiring the prolonged maintenance of narcotic dependence as part of a total rehabilitation effort, has shown promise in the management and rehabilitation of selected narcotic addicts. In addition, it is a drug which has been shown to have a significant potential for abuse. The amendment which follows is designed to clarify the conditions under which it may be used for the specific investigational purpose indicated until such time as the results of present and future clinical investigations may indicate the necessity for reevaluation of current uses and control mechanisms. It does not authorize the prescribing of narcotic drugs for any such purpose, see 26 CFR 151.392. Moreover, it does not affect any other uses of narcotic drugs, or waive any requirements concerning the control, security, use, transfer, or distribution of narcotic drugs imposed by other Federal narcotic laws or regulations. The amendment shall become effective as of the date of this publication; however, those practitioners currently engaged in the operation of a bona fide clinical investigation shall have a period of 60 days in which to submit or resubmit a Notice of Claimed Investigational Exemption for approval.

Accordingly, under the authority previously cited in the notice of proposed rule making published in the FEDERAL REGISTER on June 11, 1970, 35 F.R. 9015, 9016, the word "Dispensing" preceding § 151.411 of Part 151 of Title 26 of the

Code of Federal Regulations is hereby deleted and § 151.411 is amended to read as follows:

#### § 151.411 Administering and dispensing.

(a) Practitioners may administer or dispense narcotic drugs to bona fide patients pursuant to the legitimate practice of their profession without prescriptions or order forms.

(b) The administering or dispensing of narcotic drugs to narcotic drug dependent persons for the purpose of continuing their dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be deemed to fall within the meaning of the term "in the course of professional practice" in sections 4704(b)(2) and 4705(c)(1) of title 26 of the United States Code: *Provided*, That approval is obtained prior to the initiation of such a program by submission of a Notice of Claimed Investigational Exemption for a New Drug to the Food and Drug Administration which will be reviewed concurrently by the Food and Drug Administration for scientific merit and by the Bureau of Narcotics and Dangerous Drugs for drug control requirements; and provided further that the clinical investigation thereafter accords with such approval; see 21 CFR 130.44. The prescribing of narcotic drugs is not authorized for any such purposes.

*Effective date.* This Treasury decision shall be effective when published in the FEDERAL REGISTER (4-2-71).

Dated: March 25, 1971.

[SEAL] JOHN E. INGERSOLL,  
Director, Bureau of Narcotics  
and Dangerous Drugs, De-  
partment of Justice.

RANDOLPH W. THROWER,  
Commissioner, Internal Revenue  
Service, Department of  
the Treasury.

Approved: March 25, 1971.

EDWIN S. COHEN,  
Assistant Secretary  
of the Treasury.

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