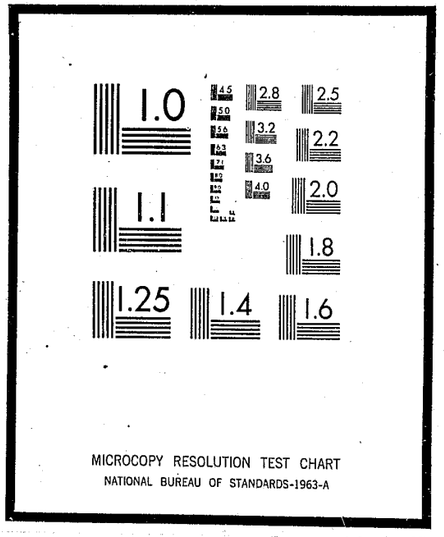

Proceedings

THIRD NATIONAL CONFERENCE ON METHADONE TREATMENT

November 14-16, 1970

New York City

Sponsored by
National Association for the Prevention of Addiction to Narcotics (NAPAN)

Co-sponsored by
National Institute of Mental Health

5600 Fishers Lane
Rockville, Md. 20852

PREFACE

The Third National Conference on Methadone Treatment provided a forum, as in previous years, for some reports of scientific studies and some communications which emphasized the organization of new programs. To a significant degree, however, this Conference gave relatively less time to anecdotal reports of the practical, everyday problems of administering methadone maintenance treatment programs. In thus departing from the prior—and historically understandable—conference emphasis, the program was able to be more diversified. Many new facts were added to the growing body of scientific knowledge, in evidence of which stands the panel on pharmacology. Special attention was given to other treatment issues in medicine, pediatrics, and obstetrics, possibly the first time such topics were treated together in such a gathering. This Conference also included reports from a more varied field of interests, than heretofore. For instance, included were papers on the complex issues of mapping out an epidemiology of heroin addiction, and the enormous task of developing large-scale systems for delivering clinical services to halt this plague.

A new area of clinical concern was reported: Treating adolescent addicts by methadone maintenance. The documented spread of heroin use among this age group has arrested the public concern and spurred responsible clinical interest.

In addition to the foregoing characteristics which mark as unique the Third National Conference on Methadone Treatment, the most obvious has to do with its size: With over 575 registrants in attendance, the Conference was the largest in this short annual series. Associated with the larger total of registered participants was greater diversity of attendees, giving the Conference yet another remarkable characteristic. Included were university and medical school professors in psychiatry, pharmacology, and related sciences; hospital, public health, and mental hygene administrators; operators of public and private clinics; counselors and various ancillary service workers, including former addicts; therapeutic community workers; and many others.

Some of the presentations and discussions gave evidence of an increasing reconciliation between therapeutic community "purists," who this year reported an increasing use of methadone, and methadone-oriented "theorists," who seemed to recognize increasingly the value of group encounter, counseling, vocational services, and the like.

Among suggestions spontaneously offered for future conferences are requests for activities to help counselors and other outpatient workers having direct daily contact with addict-patients, illustrating the abiding interest in the issues of direct patient care.

These published Proceedings are a result of excellent cooperative efforts of over 60 participants who helped to draft papers, served as panel chairmen, worked on arrangements and rendered other services, for which all participants must be grateful. The endorsements of the Council of Mental Health of the American Medical Association, the American Psychiatric Association, and the New York Academy of Medicine, provided encouragement which was most appreciated.

Thanks are due the sponsor, The National Association for the Prevention of Addiction to Narcotics, and the cosponsor, The National Institute of Mental Health, for the excellent help of their respective officers. The former are especially to be thanked for the inspiration to initiate the Conference as well as for so many of the arrangements.

The latter must be particularly thanked for funding the expenses of the panelists and for the prompt publication of the Conference Proceedings. With more precision, those who merit our thanks are Mr. Karst J. Besteman and Dr. Richard Phillipson of the National Institute of Mental Health and Dr. Sidney Cohen, formerly of NIMH; Mr. Nathan Strauss III and Mr. Harold Alksne of the National Association for the Prevention of Addiction to Narcotics.

One other body of important supporters and coworkers needs to be publicly identified and thanked. In a real sense the Beth Israel Medical Center was an unofficial cosponsor. Without the encouragement of Dr. Ray E. Trussell, General Director, I should not have accepted the assignment as Conference Chairman; without the consent of Mr. Charles A. Silver, President, and the Board of Trustees, the work could not have been undertaken. The burden of handling the many Conference details fell to my associate, Dr. A. Stauffer Curry, and the secretarial staff of Mrs. A. M. La Corte, both of the Department of Psychiatry in Beth Israel's Morris J. Bernstein Institute.

Finally, my own role as chairman was a most satisfying one, made so by an experienced and cooperative Planning Committee.

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INTRODUCTION: SOME TRENDS IN METHADONE TREATMENT

Marvin E. Perkins, M.D.

Since the occasions of the First National Conference on Methadone Treatment held June 21 and 22, 1968, (*1*) and the Second National Conference on Methadone Treatment held October 26 and 27, 1969,(*2*) interest in the methadone maintenance approach to treatment has resulted in a steady, if scattered, series of contributions to a variety of readerships, legal, lay, medical, and governmental. Reviews of the medical controversy and of the problems under Federal law are ably accomplished in *The Yale Law Journal* (*3*). For the popular reader, two articles appeared which attend to the controversial polarities of management: Abstinence or maintenance. The first of these describes, in a favorable presentation, the existential encounter concept of the Addiction Services Agency of New York City. (*4*). The other describes the struggle to establish methadone maintenance under the indicting title, "While Doctors Argue, People Die" (*5*).

Following the Second National Conference, the New York Academy of Medicine issued a statement noting the promising aspects of the technique and discouraging the inexperienced individual physician from its use (*6*). Earlier during the year, the State of New York Narcotic Addiction Control Commission made public a report of its advisory body which concluded that the methadone program deserved continued support and urged similar programs to that of Morris J. Bernstein Institute. The report also cautioned against a premature change in public health policy that might permit individual physicians to administer methadone "without the structure of a formal rehabilitative program" (*7*). A similar posture (to that of the academy and the commission) was assumed in the World Health Organization during the year (*8*). More recently, the Committee on Alcoholism and Drug Abuse of the Medical Society of the State of New York presented recommendations to the House of Delegates approving the Dole methadone maintenance treatment method, supporting expansion of facilities, and calling for efforts to remove legal restrictions which prevent use by qualified personnel of the method (*9*). On the latter point, a nonprofit publication, *The Medical Letter*, in a lead editorial, refers to "*ambiguities* in both Federal and State laws governing the *right* of physicians to prescribe narcotic drugs for the maintenance of addicted patients" (italic supplied) and concludes that agencies, private and governmental, should speed the extension of treatment facilities (*10*).

Public policy is being shaped by governmental action at local, State, and national levels, as events since a year ago most dramatically attest. A few well publicized actions will bear witness to the directions of these currents. The mayor of the city of New York, in May 1969, announced the establishment of a voluntary neighborhood clinic program to "test various approaches to methadone maintenance, with a goal of treating 5,000 addicts over a 5-year period" (*11*). Parenthetically, this new city program has no connection with the one at Bernstein Institute established under the former mayor and now supported by the State of New York (*12, 13*). A Federal grant of a million dollars to aid in the financing of the new city methadone research program was hailed by the mayor in July (*14*). In August, he vetoed a city council bill that would have mandated methadone treatment for heroin addicts in the city's prisons (*15*); and in September, the council overrode the veto. This was the first major legislative matter in which the mayor was overturned in nearly 4 years as chief municipal executive (*17*).

Interest and activity on the local scene are by no means confined to New York City. The very day the council overrode the mayor of the city of New York, an article datelined from San Francisco appeared in the columns of *The Wall Street Journal* on the methadone controversy (*18*); and the day before one could have read Walter C. Alvarez' column in Mexico City wherein he called the Dole-Nyswander treatment "most promising" (*19*).

The Governor of New York, in delivering his "State of the State" message to the legislature on

January 7, 1970, called for a greatly expanded methadone maintenance program. He sought a $15 million appropriation for expansion, which was promptly characterized by *The New York Times* as "an utterly inadequate attack on a tremendously complex problem" (*20, 21*). The legislature subsequently approved the Governor's request so that the State Narcotic Addiction Control Commission might increase the methadone maintenance program during the fiscal year under State auspices. In June, *Fortune Magazine* featured an article in which the $1,800 annual cost per methadone maintenance patient was identified as a "bargain from Society's standpoint" (*22*).

Not only are the chief executives at Federal, State, and local levels finding the means to support the methadone approach to heroin addiction, but another related matter appears to be under immediate review. Here, our reference is to the aim of the Department of Justice to establish regulations to prevent "diversions and abuse" of methadone, announced a little over a year ago (*23*). In January, the revelation was made that the new regulations of the Bureau of Narcotics and Dangerous Drugs were to be stringent in order "to reduce methadone overdose and to curtail illicit street sales" (*24*). More recent information suggests that another agency of the Federal Government, the Food and Drug Administration, in fact, may be preparing to ease restrictions on the prescribing of methadone by physicians for maintenance purposes (*25*).

Paradoxical concern are that the more "stringent" regulations of the Bureau of Narcotics and Dangerous Drugs might shackle programs of the type being recommended by informed medical opinion, while on the other hand "eased" guidelines of the Food and Drug Administration might pave the way for solo practitioners to engage in methadone treatment without benefit of other rehabilitative program structure, a form of practice eschewed by most of methadone's supporters at this time.

Two kinds of spectres may be discerned among those who support the development of methadone treatment, as well as among opponents. I referred to one of these in passing just a week ago (*26*), namely, the fear that the program will become the victim of forces that lead to such easy distribution of methadone that antisocial consequences obtain. Perhaps this grim possibility is not unlike the future described by Anthony Burgess in his novel, *A Clockwork Orange* (*27*). He describes a society in which teenage hoodlums take over the streets after dark, preparing themselves by stopping at a "Milkbar" where they imbide milk laced with one or another narcotic. To ward off this prospect, assurances are sought that developments will not take place to preclude provision of the required services (counseling and therapy) for encouraging individual choice of a new lifestyle and which the easy acquisition of the drug, perhaps alone could not accomplish. The second apparition which lurks ahead, is the elaboration of some monstrous bureaucratic organization built by inspired, but unwise advocacy, and doomed to collapse. Another British author, William Golding, has described this kind of dedicated pursuit in his novel, *The Spire* (*28*), in which an architectural impossibility is forced into the heavens by an ambitious man of the cloth. Too much is at stake to permit this to happen.

Because of the increased interest in methadone maintenance as a form of treatment of heroin addiction, in the formulation of medical opinion and policy, and in governmental action and public policy, conferences of this type are timely. We aim at such illumination that future developments—programmatic and organizational—may be as soundly based as possible, given the information and experiences at hand.

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I. EPIDEMIOLOGY

METHADONE MAINTENANCE: WHY CONTINUE CONTROLS?

Richard Phillipson, M.D.

I welcome this opportunity to take the chair at this session on epidemiology and methadone: Many of you may wonder what the title of my paper has to do with epidemiology which has been defined as "'a science that deals with the incidence, distribution, and control of diseases" and also as "the sum of the factors controlling the presence or absence of a disease or pathogen." I have chosen it because I feel very strongly that all physicians and others who are engaged in the present struggle to combat the problem of narcotic addiction have a great responsibility; a responsibility especially to see that the mistakes made in the second decade of this century, when morphine instead of methadone was dispensed in clinics in this country, are not repeated. Before we consider what these mistakes were let us look, albeit briefly, at events on the drug scene in the United States in the last decade of the 19th century.

In the 19th century our forebears were ignorant of 20th century biochemistry. Opiate use was perceived as a "will-weakening" vice instead of a biochemical disease. It was generally known that addicts deprived of their opiates would lie or even steal to get their drug; hence there was much talk of the moral degeneration caused by opiates.

There was nevertheless very little popular support for a law banning these substances. "Powerful organizations for the suppression of sale of alcoholic stimulants existed throughout the land," but there were no similar organizations against opiate use.

The reason for this lack of demand for suppression of opiates was quite simple: These drugs were not seen as a menace to society and physicians often referred to opium or morphine as "G.O.M." —"God's own medicine." Opiates were also widely prescribed, for asthma, for cough, for diarrhea and dysentery, and for a wide variety of other illnesses. Dr. H. H. Kane's 1880 textbook entitled "The Hypodermic Injection of Morphia. Its History, Advantages, and Dangers. Based on Experience of 360 Physicians," listed 54 diseases (including nymphomania) which benefited from morphine injections.

A remarkable fact is that for the great majority of these conditions, morphine really was of significant help. For morphine is a highly effective tranquilizer and the 19th-century physicians used morphine much as the physicians today use chlorpromazine, chlordiazepoxide, and other tranquilizers.

Opium in the 19th century was used as a substitute for alcohol and Dr. J. R. Black in a paper entitled "Advantages of Substituting the Morphia Habit for the Incurably Alcoholic," published in the *Cincinnati Lancet-Clinic* in 1889, said "opium is less inimical to healthy life than alcohol." It "calms in place of exciting the baser passions, and hence is less productive of acts of violence and crime; in short, the use of morphine in place of alcohol is but a choice of evils, and by far the lesser." Then he continued: "On the score of economy the morphine habit is by far the better. The regular whiskey drinker can be made content in his craving for stimulation, as least for quite a long time, on two or three grains of morphine a day, divided into appropriate portions, and given at regular intervals. If purchased by the drachm at 50 cents this will last him 20 days. Now it is safe to say that a like amount of spirits for the steady drinker cannot be purchased for 2½ cents a day, and that the majority of them spend 5 and 10 times that sum a day as a regular thing.

"On the score, then, of a saving to the individual and his family in immediate outlay, and of incurred disability, of the great diminution of peace disturbers and of crime, whereby an immense outlay will be saved the State; on the score of decency of behavior instead of perverse deviltry, of bland courtesy instead of vicious combativeness; on the score of a lessened liability to fearful diseases and the lessened propagation of pathologically inclined blood, I would urge the substitution of

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Figure 1

METHADONE MAINTENANCE TREATMENT PROGRAM

Rate of Discharge by Month for Patients Inducted on an Ambulatory Basis Versus In-Patient Induction and Van Etten as of June 30, 1970

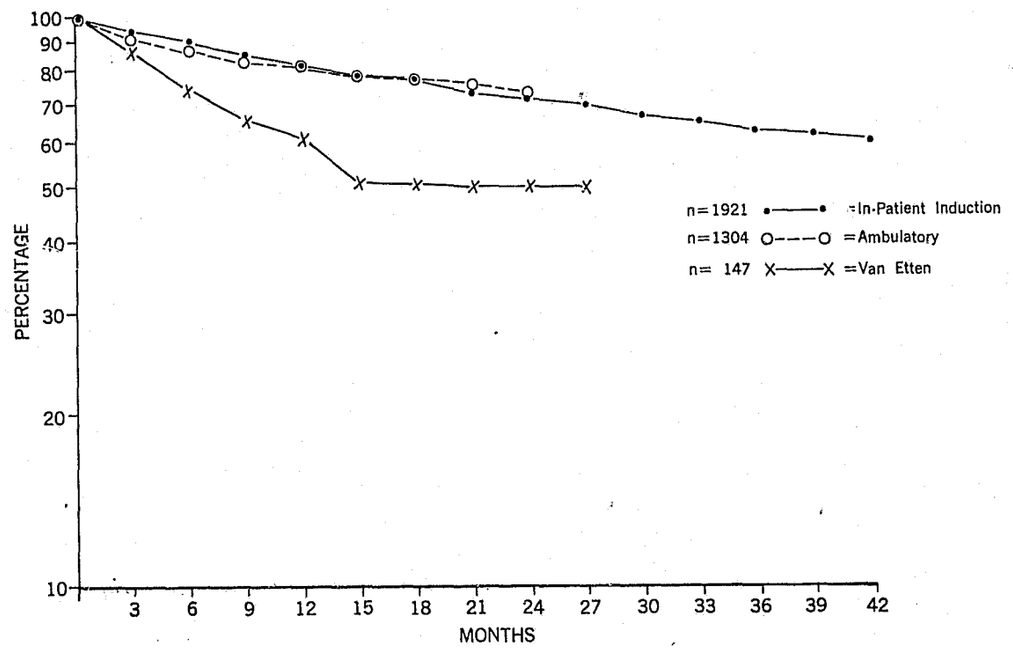


Figure 3 contrasts the discharge rate for men and women. The slight difference shown is not significant due to the much smaller number of women. The rate of discharge for men by age at time of admission is shown in figure 4 and once again shows no difference between younger and older patients. A small difference appears in figure 5 between the rate of discharge in the third year between black and white patients. This difference is not statistically significant at this point but bears monitoring in the future.

REASONS FOR DISCHARGE

As shown in figure 6, problems with alcohol abuse as a reason for discharge increases with age at time of admission for both men and women, drug abuse (primarily amphetamines and barbiturates) as a reason for discharge decreases with age and is more common among the women than among the men. Voluntary withdrawal from the program increases with age particularly among the men.

Discharge for behavior or psychiatric reasons is more common among the younger patients of both sexes. Deaths follow the pattern in the general population.

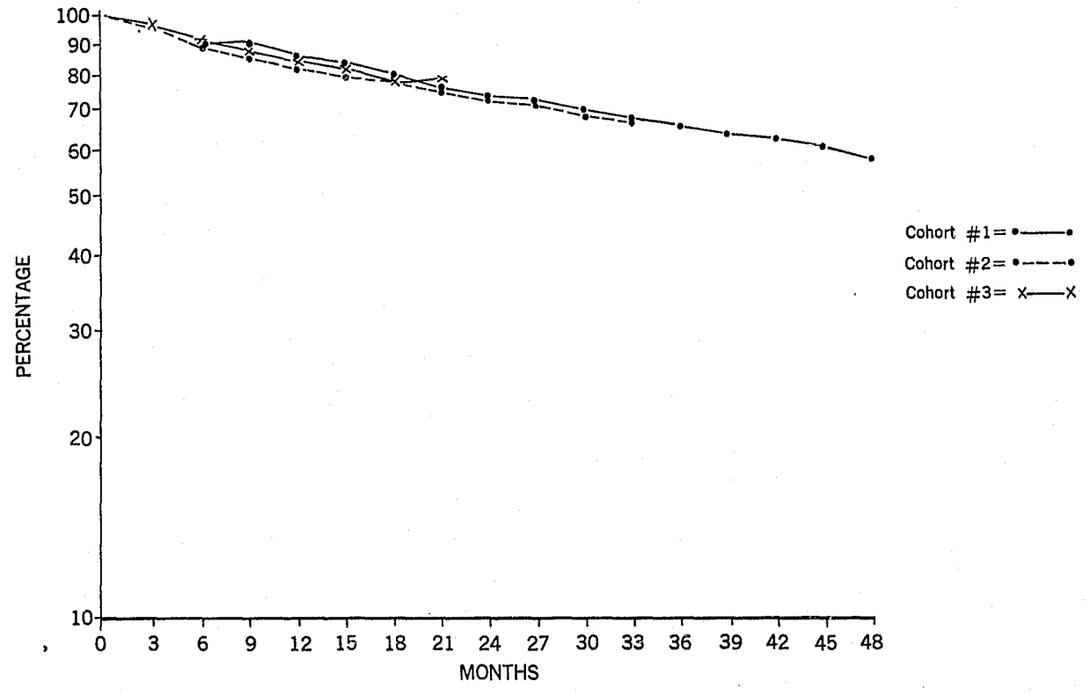
When we look at reasons for discharge by ethnic group as shown in figure 7, we note that alcohol problems are more common among the black patients and drug abuse is more commonly a factor among the white and Spanish patients.

Voluntary withdrawals and discharge for behavioral reasons account for the majority of dropouts in the first year. Chronic problems with alcohol abuse, and continued drug abuse were the major causes of discharge in the second and third year.

Figure 2

METHADONE MAINTENANCE TREATMENT PROGRAM

Rate of Discharge by Month for Three Successive Cohorts of 500 Patients By Date of Admission



FOLLOWUP OF DISCHARGED PATIENTS

With the assistance of two medical students[1] during this past summer, we completed an intensive followup on a sample of patients who had left the program. We selected all patients who were discharged alive by December 31, 1969, and who had been in the program 3 months or longer at the time of discharge. This gave us a pool of 562 persons. We divided this group into two segments: (1) those who had left the program voluntarily, and (2) those who had been discharged from the program for cause.

Our primary source of followup was the New York City Narcotics Register which receives reports from the police and correction agencies, hospitals and treatment programs, and from private practitioners. Another very useful source was a series of interviews with patients who left the program and have subsequently been readmitted. This was a major contribution by the medical students.

For the sample of 281 patients on whom we could obtain 6 months of followup the results are shown in table 2.

[1] Mr. Michael Lane, Downstate Medical School, and Miss Mary Hartshorn, Medical College of Pennsylvania.

Table 2.—METHADONE MAINTENANCE TREATMENT PROGRAM

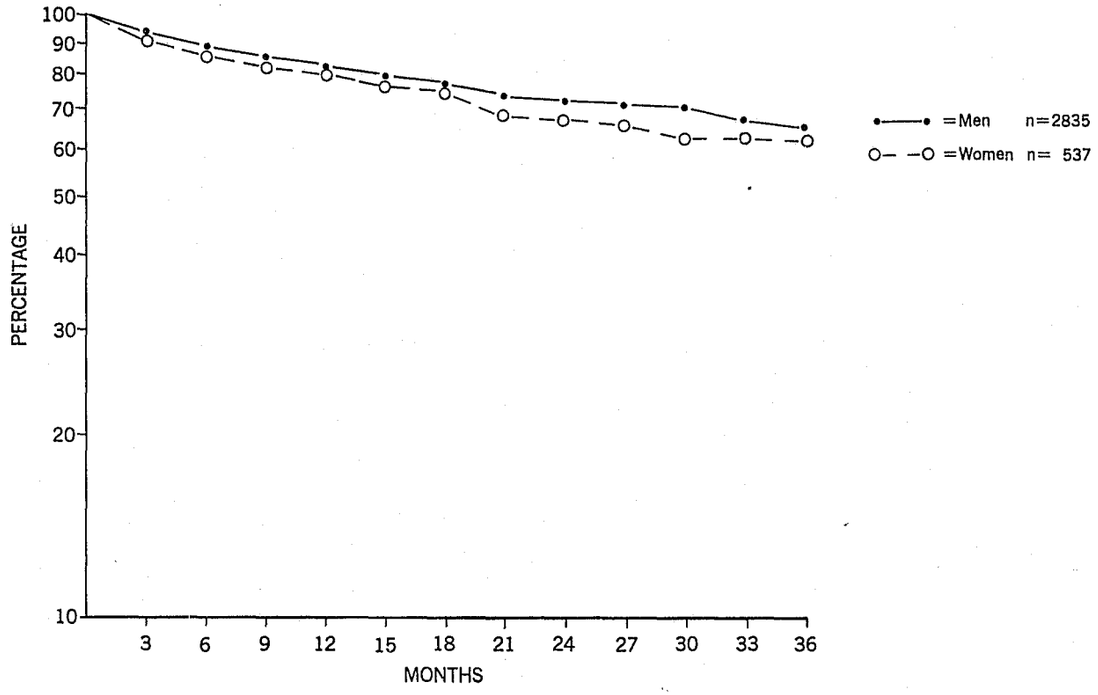
Followup of 281 patients 6 months following discharge from MMTP

	Left voluntarily (percent)	Discharged for cause (percent)	Total discharge (percent)
Arrest or jail	10	26	23
Dead	2	2	2
Detoxification	13	20	19
Other Rx program	11	4	7
Medical or psychiatric facility		3	2
Private M.D.	2	2	2
Moved	7	1	1
Readmitted	33	6	11
No reports found	22	36	33
Total sample	100 (45)	100 (236)	100 (281)
Total N	(90)	(472)	(562)

Figure 3

METHADONE MAINTENANCE TREATMENT PROGRAM

Rate of Discharge by Month for Men **versus** Women
as of June 30,1970



Those patients who left the program voluntarily had a lower arrest and detoxification record than the rest. They also had a larger proportion admitted to other treatment programs and one-third had been readmitted to the program, contrasted with only 6 percent of those discharged for cause. If one considers that no record found is roughly equivalent to remaining "clean," one-third of this group were still "clean" 6 months after leaving the program.

The same sampling procedure was followed for the 396 patients on whom we could obtain 12 months to followup. These results are shown in table 3. In this group only, 21 percent would be considered still "clean." The readmission rate was somewhat lower (13 percent). Except for arrests and deaths, those who left the program voluntarily are very similar to the other group.

Table 4 shows the results of the followup on our sample of 181 patients on which we had a followup of 1 year or more. Here the readmission rate is 22 percent and the proportion who appear to have

Table 3.—METHADONE MAINTENANCE TREATMENT PROGRAM

Followup of 198 patients up 1 year after discharge from MMTP

	Left voluntarily (percent)	Discharged for cause (percent)	Total discharge (percent)
Arrest or jail	13	28	25
Dead		2	2
Detoxification	34	23	25
Other Rx program	6	6	6
Medical or psychiatric facility	3	4	4
Private M.D	3	1	2
Moved		2	2
Readmitted	16	13	13
No reports found	25	21	21
Total sample	100 (32)	100 (166)	100 (198)
Total N	(64)	(232)	(396)

remained "clean" is only 18 percent and the death rate reaches 5 percent.

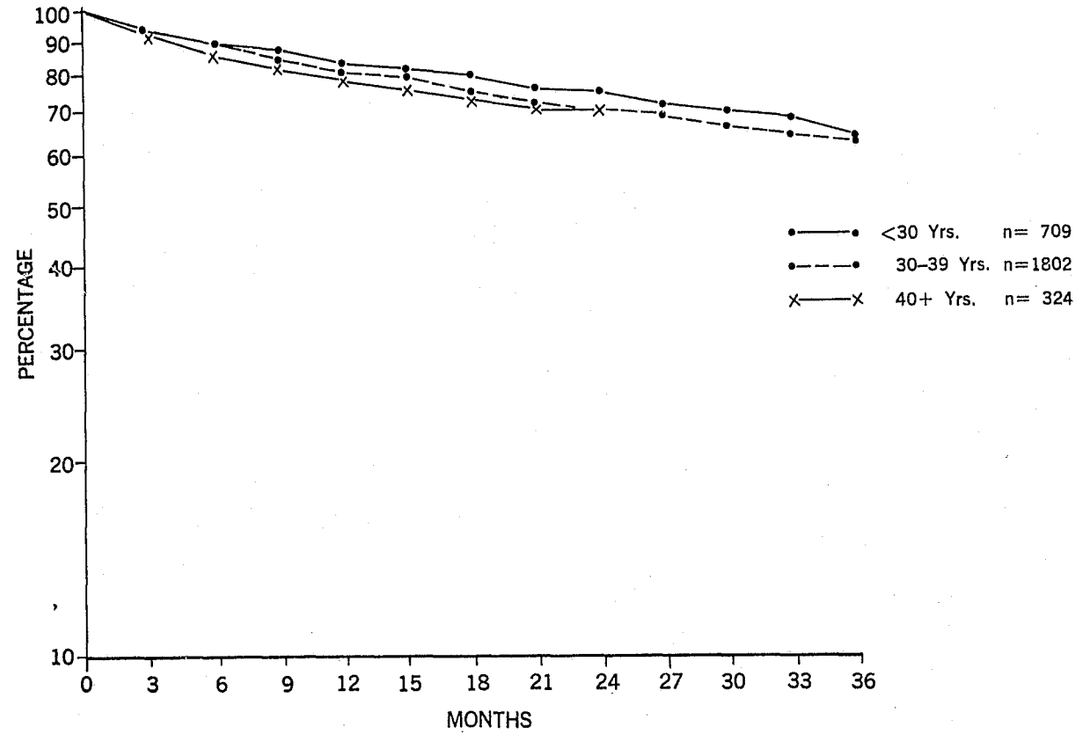
These data would tend to indicate that, among those patients who withdraw from methadone maintenance treatment, only a small proportion have been able to "make it" on their own.

Because of the tremendous current interest in "criminality" associated with addiction, we looked

Figure 4

METHADONE MAINTENANCE TREATMENT PROGRAM

Rate of Discharge by Month for 2835 Men by Age at Time of Admission
as of June 30, 1970



into the previous arrest records of those patients who have remained in the program, contrasted with those who left the program voluntarily, and those who were discharged for cause. We contrasted this, in a "before and after" picture, as shown in figure 8. It is interesting to note that

Table 4.—METHADONE MAINTENANCE TREATMENT PROGRAM

Followup of 181 patients 1 year or more after discharge from MMTP

	Left voluntarily (percent)	Discharged for cause (percent)	Total discharge (percent)
Arrest or jail	18	30	28
Dead		5	5
Detoxification	37	27	28
Other Rx program	11	11	22
Medical or psychiatric facility	6	7	7
Private M.D	6	3	3
No reports found	21	17	18
Readmitted [1]	[1] 29	[1] 21	[1] 22
Total sample	100 (28)	100 (153)	100 (181)
Total N	(56)	(306)	(362)

[1] Readmitted patients each had one or more reports of arrest or detoxification.

the past history of those who were discharged for cause with reference to arrests is worse than either of the other two groups—and that their behavior following discharge is as poor or worse than before admission. Those who left voluntarily demonstrate a short period of improvement but also tend to return to their previous arrest pattern. Those who remained in the program show a constant and accelerated decline in criminal behavior as measured by arrests.

Enough of failures. Now let's discuss successes.

CRITERIA FOR SUCCESS

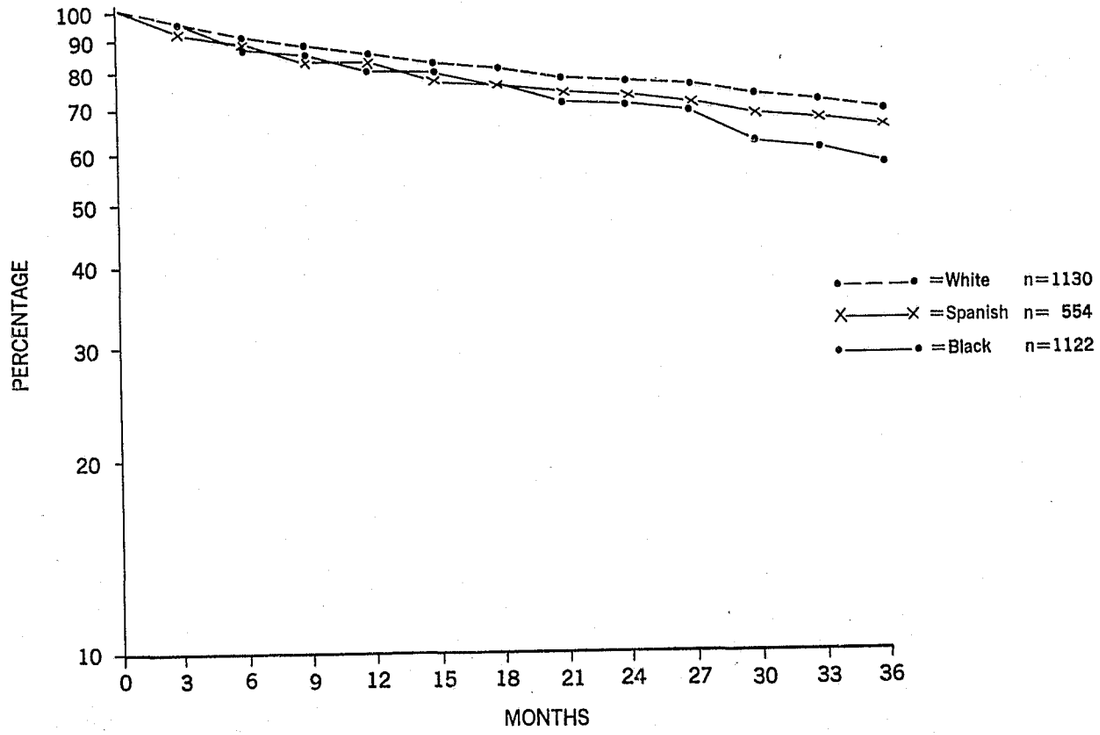
The criteria established by our evaluation unit with the approval of the evaluation committee for measuring success of the program has revolved around four basic measures:

1. Freedom from heroin "hunger" as measured by repeated, periodic "clean" urine specimens.

Figure 5

METHADONE MAINTENANCE TREATMENT PROGRAM

Rate of Discharge by Month for 2806 Men by Ethnic Group
as of June 30, 1970



2. Decrease in antisocial behavior as measured by arrest and/or incarceration (jail).
3. Increase in social productivity as measured by employment and/or schooling or vocational training.
4. Recognition of, and willingness to accept help for excessive use of alcohol, other drugs, or for psychiatric problems.

RESULTS

1. Although many of the patients test the methadone "blockade" of heroin one or more times in the first few months, less than 1 percent have returned to regular heroin usage while under methadone maintenance treatment.

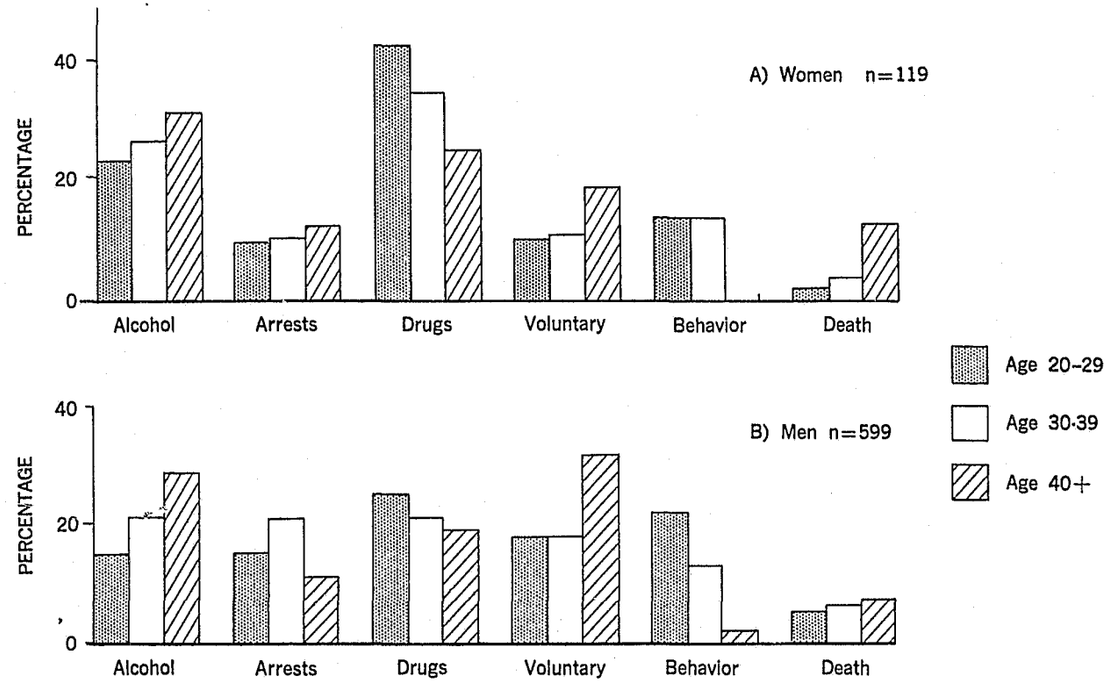
2. Antisocial behavior as measured by arrests and incarcerations (jail) have been looked at in several ways. First, the percentage of arrests among patients in the program during the 3 years prior to admission was compared with the percentage of arrests of these same persons following admission. This "before and after" picture is also contrasted with the proportion of arrests in a contrast group of 100 men selected from the detoxification unit at Morris Bernstein Institute matched by age and ethnic group and followed in the same manner. The results are illustrated in figure 9. The arrest records of these two groups are quite similar for each year of observation prior to admission. Following admission to the program, the contrast is striking for each period of observation with the methadone maintenance patients showing a marked decrease in the percentage of patients arrested, and the contrast group showing a pattern very similar to the earlier period of observation.

We have also calculated the arrests per 100-patient-years of observation for the 3 years prior to admission in contrast to the arrests per 100-

Figure 6

METHADONE MAINTENANCE TREATMENT PROGRAM

Percentage Distribution of Principal Reason for Dicharge of 718 Patients by Age at Time of Admission



patient-years of observation after admission. We have compared these data using the same computations for the contrast group. The results are shown in table 5. These results would appear to indicate that remaining in the methadone maintenance program does indeed decrease antisocial behavior as measured by arrests or incarcerations.

3. Increased social productivity can best be illustrated by the employment profiles shown in figures 10 and 11. There is a steady and rather marked increase in the employment rate with a corresponding decrease in the percentage of patients on welfare as time in the program increases. This is true both for the men and the women. These data include both ambulatory and inpatient induction groups. This accounts for the increased percentage of men employed at time of admission since this was one of the early criteria for admission to an ambulatory unit.

4. Figure 12 is an attempt to illustrate stability of employment among patients remaining in the program as contrasted with their previous employment experience. The shaded area might be considered as a measure of their increased social productivity since admission to the program.

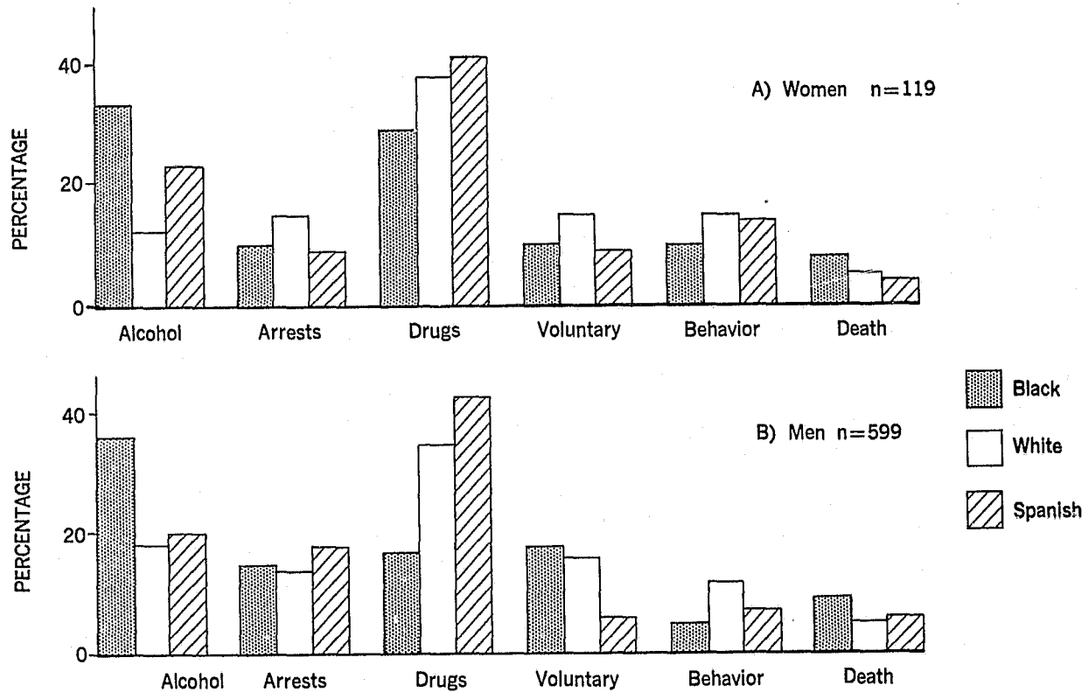
5. Although chronic alcohol abuse continues to be a problem for approximately 8 percent of the patients (both men and women), and for some becomes the principal reason for discharge, a majority of these patients show continued improvement in their ability to handle their alcohol problem with the support and assistance of members of the program staff who recognize the problem, and are willing and able to cope with it.

6. Problems with chronic abuse of drugs such as barbiturates, amphetamines, and more recently, cocaine, are evident in approximately 10 percent of the patients. There again, for some, it has resulted in discharge from the program. For many others, the patients are able to function satisfactorily, with the assistance and support of members of the program staff.

Figure 7

METHADONE MAINTENANCE TREATMENT PROGRAM

Percentage Distribution of Principal Reason for Discharge of 718 Patients by Ethnic Group



CONCLUSIONS

On balance, the successes in the methadone maintenance treatment program far outweigh the failures. The rapid expansion of the program during the past year, and the change in emphasis to include primarily ambulatory induction under the expanded admission criteria does not appear to have made any noticeable change in the effectiveness of this treatment for those heroin addicts who have been accepted into the program. A majority of the patients have completed their schooling or increased their skills and have become self-supporting. Their pattern of arrests has decreased substantially. This is in sharp contrast to their own previous experience, as well as their current experience when compared with a matched group from the detoxification unit, or when compared with those patients who have left the program. Less than 1 percent of the patients who have remained in the program have reverted to regular heroin use.

A small proportion of the patients (10 percent) present continued evidence of drug abuse involving use of amphetamines, barbiturates, and cocaine, and another 8 percent demonstrate continued problems from chronic alcohol abuse. These two problems account for the majority of failures in rehabilitation after the first 6 months.

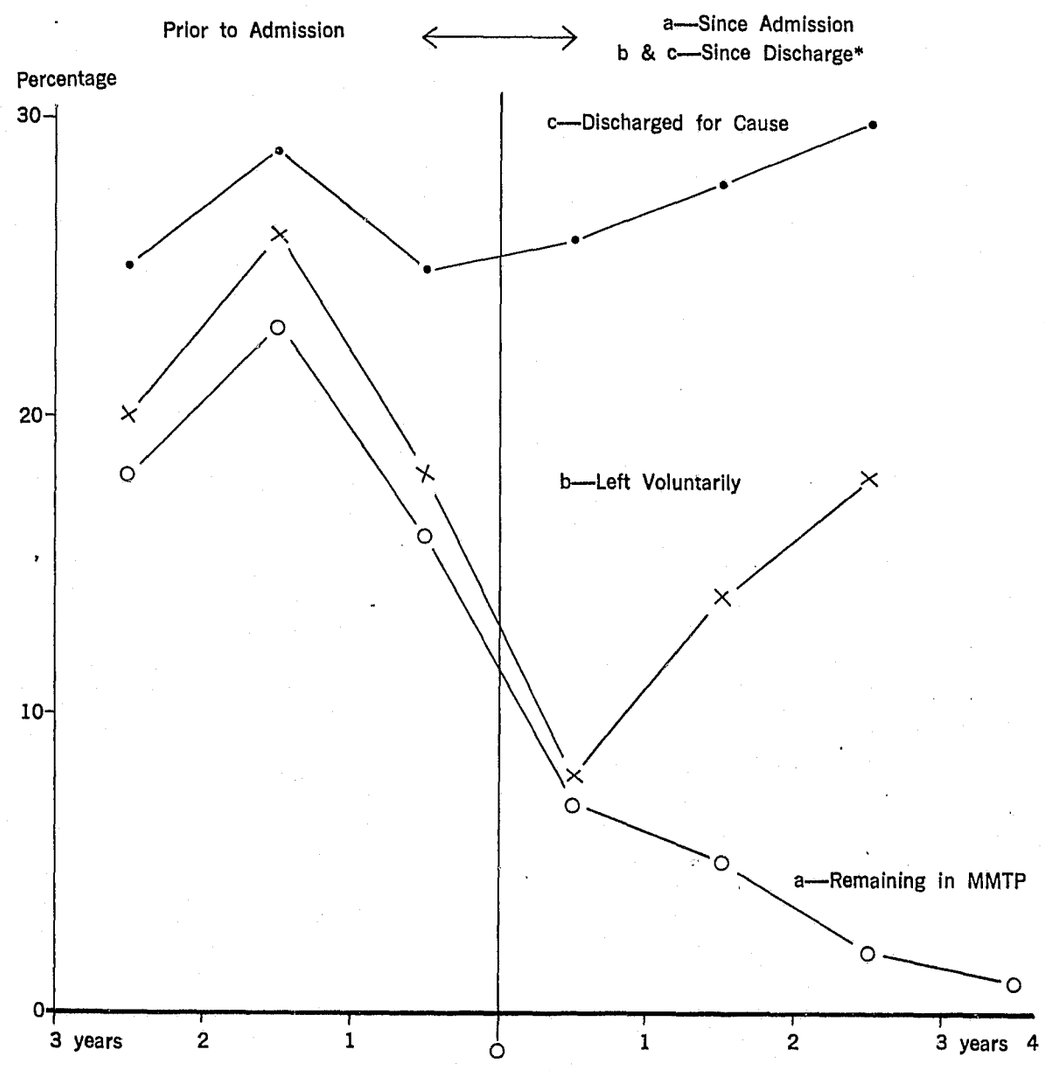
Methadone maintenance as a treatment modality was never conceived as a "magic bullet" that would resolve all the problems of patients addicted to heroin. For this reason, we believe that any treatment program using methadone maintenance must be prepared to provide a broad variety of supportive services to deal with problems including mixed drug abuse, chronic alcoholism, psychiatric or behavioral problems, and a variety of social and medical problems.

Many questions continue to remain unanswered with reference to the role of methadone maintenance in the attack on the total problem of heroin addiction; nevertheless the data presented on the group of patients who have been admitted to this methadone maintenance treatment program con-

Figure 8

METHADONE MAINTENANCE TREATMENT PROGRAM

Comparison of Arrest Records Among Persons Continuing and Discharged from Methadone Maintenance Treatment Program



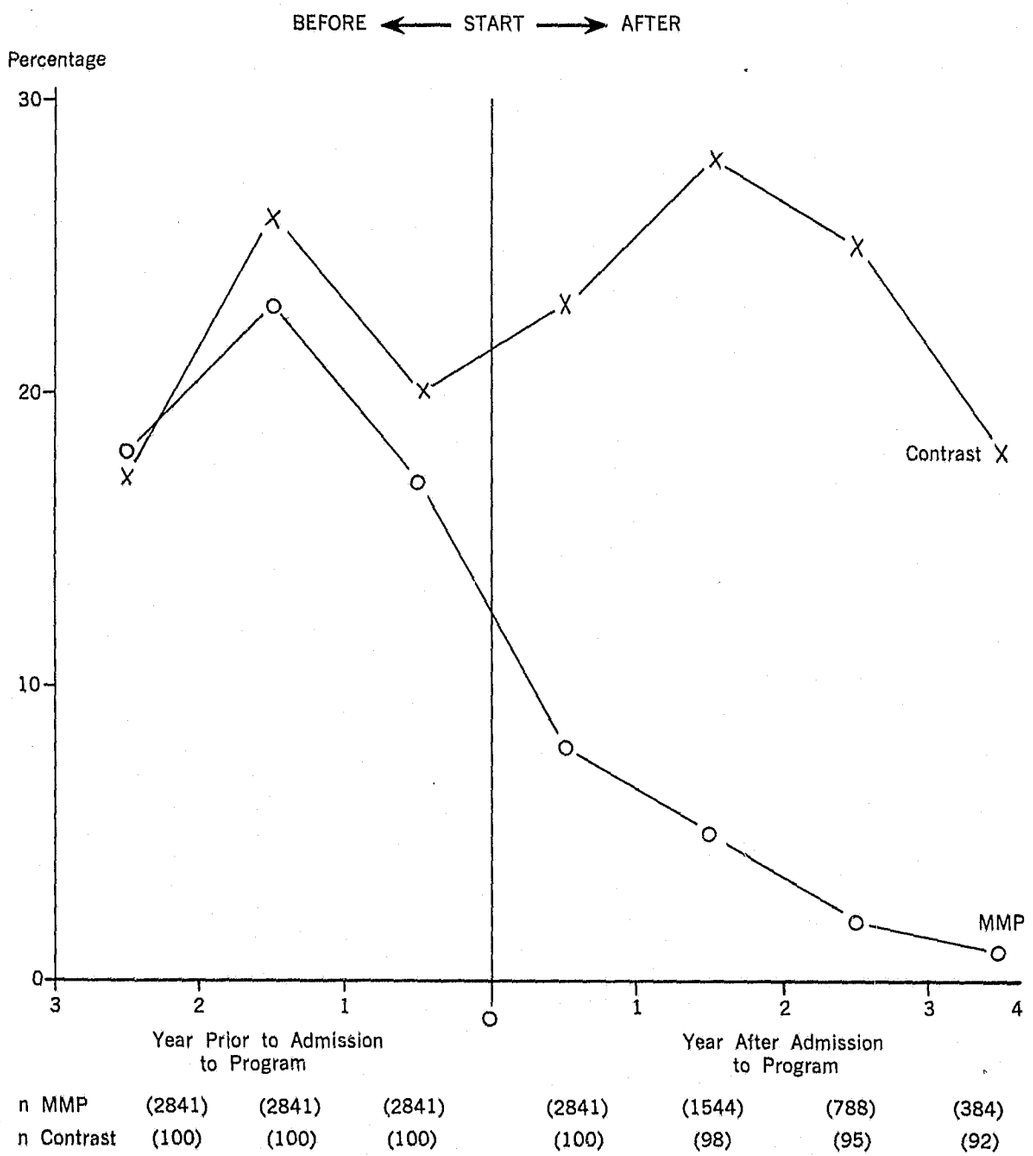
n MMP	(2560)	(2560)	(2560)	(2560)	(1544)	(788)	(384)
n Vol. Dis.	(45)	(45)	(45)	(45)	(32)	(28)	—
n Invol. Dis.	(236)	(236)	(236)	(236)	(166)	(153)	—

*All discharges had participated in MMTP for at least 90 days prior to discharge.

Figure 9

METHADONE MAINTENANCE TREATMENT PROGRAM

Percentage Distribution of Arrests for 2841 Men in Methadone Maintenance Program 3 Months or Longer as of March 31, 1970, and Contrast Group By Months of Observation

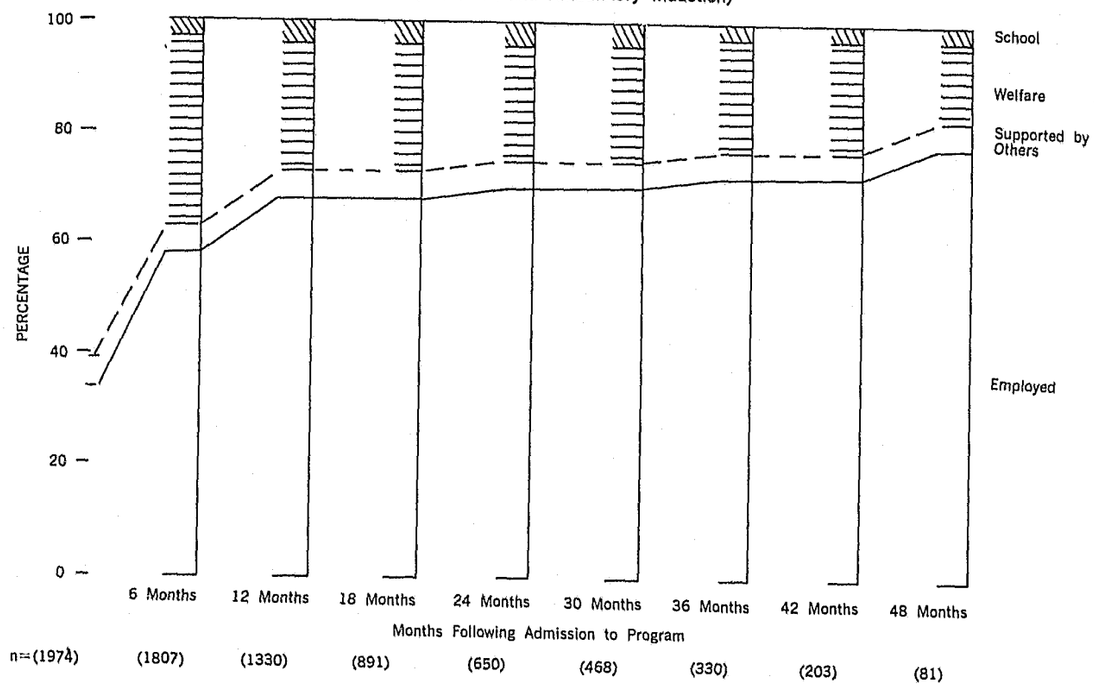


n MMP	(2841)	(2841)	(2841)	(2841)	(1544)	(788)	(384)
n Contrast	(100)	(100)	(100)	(100)	(98)	(95)	(92)

Figure 10

METHADONE MAINTENANCE TREATMENT PROGRAM

Employment Status and School Attendance for Men in Methadone Maintenance 3 Months or Longer as of March 31, 1970 (In-Patient and Ambulatory Induction)



n=	(1974)	(1807)	(1330)	(891)	(650)	(468)	(330)	(203)	(81)

tinues to demonstrate that this program has been successful in the vast majority of its patients.

After a careful review of the data related to successes and failures over the past 5 years, the Methadone Maintenance Evaluation Committee has submitted the following recommendation as of Friday, November 6, 1970:

RECOMMENDATIONS

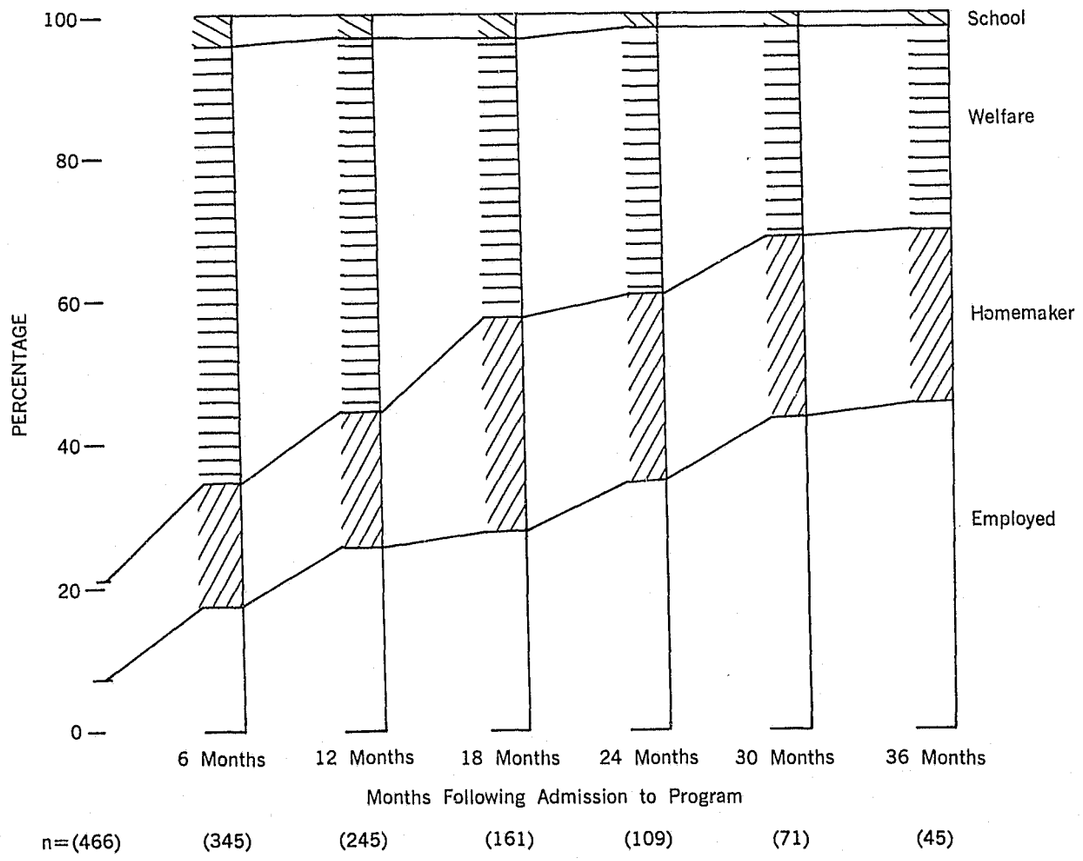
As a result of the continued encouraging results in the methadone maintenance treatment program through October 31, 1970, the Methadone Maintenance Evaluation Committee recommends:

1. That there be continued financial support for the methadone maintenance treatment program to allow continued intake of new patients using admission criteria including a minimum age of 18 years and a history of a minimum of 2 years of addiction with care in selection of patients to prevent the possibility of addicting an individual to methadone who is not physiologically addicted to heroin.
2. That there be continued evaluation of the long-term effectiveness of the methadone maintenance treatment program for the group stabilized on an inpatient basis, the group being stabilized on an ambulatory basis, and the group undergoing rapid induction.
3. That new programs which plan to use methadone maintenance should include all elements of the program including:
   a. Availability of adequate facilities for the collection of urine and laboratory facilities for frequent and accurate urine testing;
   b. Medical and psychiatric supervision;
   c. Backup hospitalization facilities;
   d. Adequate staff including vocational, social and educational support, and counselling;
   e. Rigid control of methods of dispensing methadone and number and size of doses given for self-administration in order to prevent diversion to illicit sale or possible intravenous use;

Figure 11

METHADONE MAINTENANCE TREATMENT PROGRAM

Employment Status and School Attendance for 466 Women in Methadone Maintenance 3 Months or Longer as of March 31, 1970 (In-Patient and Ambulatory Induction)



f. Staff members of potential new programs planning to use methadone maintenance be trained in this technique in a medical center which has been shown to use methadone maintenance effectively.

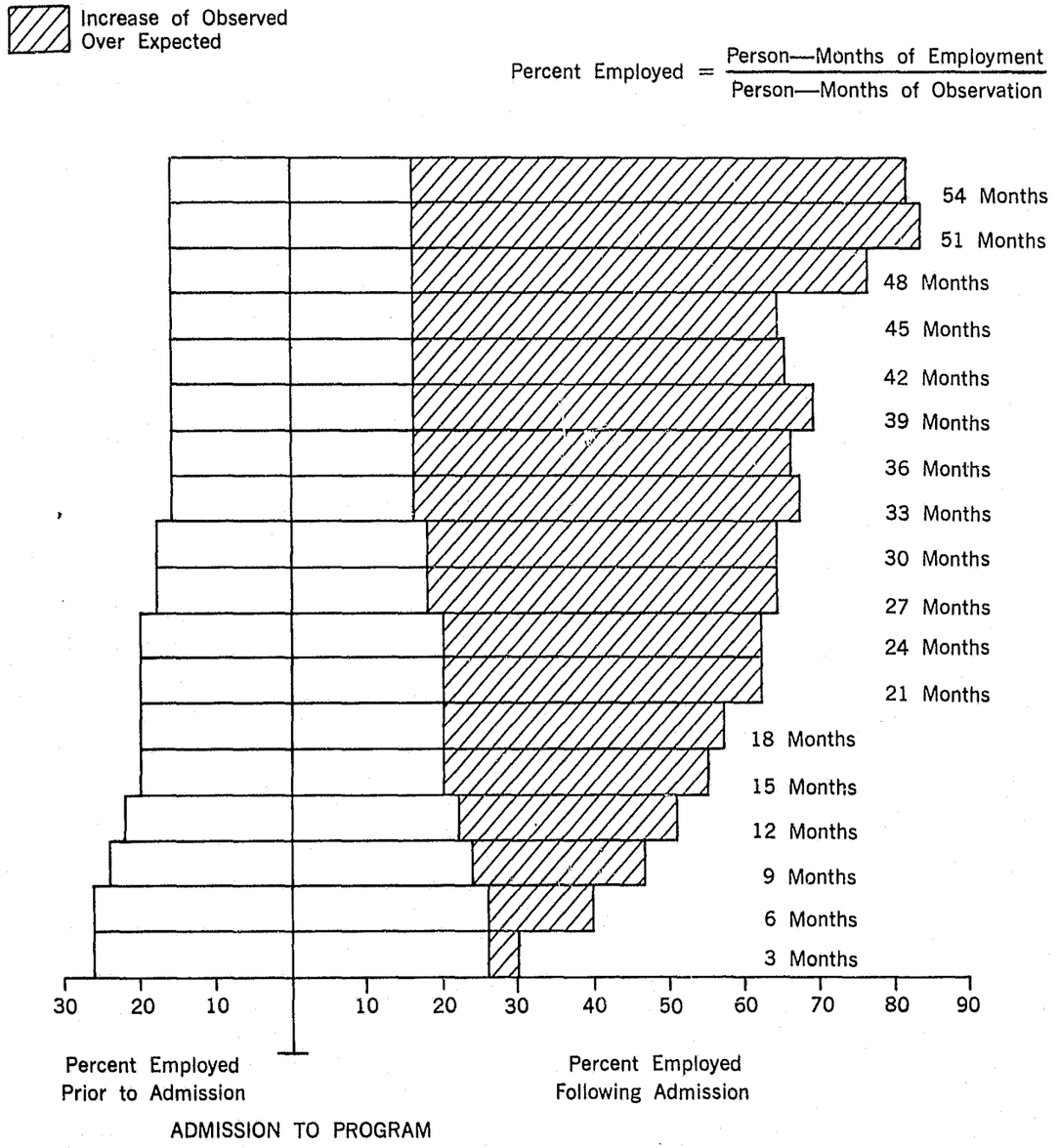
4. That continued research is essential particularly with reference to:
   a. The role of methadone maintenance in the treatment of young heroin addicts (under 18);
   b. Developing programs using methadone maintenance in combination with other approaches to the treatment of heroin addiction.

   Projects in these areas should be supported and encouraged, but must be considered new research studies, and should be subjected to the same surveillance and independent evaluation as the current programs.
5. That methadone maintenance not be considered at this time as a method of treatment suitable for use by the private medical practitioner in his office practice, because of the requirements for other program components including social rehabilitation and vocational guidance.
6. That a pilot or demonstration project be developed involving the use of properly trained practicing physicians as an extension of an

Figure 12

METHADONE MAINTENANCE TREATMENT PROGRAM

Percent of Person—Months of Observation During Which Men in Program Were Employed Before and After Admission by Duration of Employment as of July 31, 1969



organized methadone maintenance treatment program to treat those patients whose needs for ancillary services are minimal. These patients should be continued under the supervision of the methadone maintenance treatment program for periodic evaluation and urine testing.

ACKNOWLEDGEMENTS

1. The members of the Methadone Maintenance Evaluation Committee both past and present with particular reference to Dr. Henry Brill who has so aptly chaired that committee since its inception.

2. All the members of the methadone maintenance treatment program staff for their devotion to their job and for their cooperation whenever needed.

3. The staff of the Rockefeller Data Bank, especially Dr. Alan Warner and Mrs. Ellen Smith, for their willingness to make available to us, whenever requested, data which has been a crucial starting point of our evaluation.

4. Those medical students who have made substantial contributions to our efforts over the past 4 years.

5. The directors of the New York City Narcotics Register who have allowed us to use their data for validation and for followup. These listed in chronological order over the past 5 years are:

Dr. Florence Kavaler
Mrs. Zili Amsel
Miss Joy Fishman
Mr. Sherman Patrick

6. The diligence and devotion of my staff including:

Mrs. Dina D'Amico
Mrs. Angela del Campo
Mrs. Frieda Karen
Miss Elaine Keane
Mrs. Dorothy Madden
Mrs. Inge Mayer

7. And last but not least to the New York State Narcotic Addiction Control Commission for funding our efforts.

Table 5.—METHADONE MAINTENANCE TREATMENT PROGRAM

The number of arrests and incarcerations per 100-person-years for methadone maintenance patients before and after admission contrasted with patients from detoxification unit

	Methadone group	Detoxification group
Before admission:		
Arrests/100 person years	115	131.
Jail/100 person years	49	52.
n	17,500 person-years	600 person-years.
Following admission:		
Arrests/100 person years	4.3	135.
Jail/100 person years	1.0	63.
n	10,800 person-years	1,040 person-years.

Appendix A.—METHADONE MAINTENANCE TREATMENT PROGRAM

Inpatient induction units by county as of October 31, 1970

Manhattan
Gracie Square Hospital (M & W)
Harlem Hospital (M)
Morris J. Bernstein Institute (M & W)
Riker's Island (M)
Rockefeller University Hospital (M & W)
Roosevelt Hospital (M & W)
St. Luke's Hospital (M & W)

Bronx
Albert Einstein Medical Center (M & W)
Bronx State Hospital (M & W)

Brooklyn
Brookdale Hospital (M & W)

Westchester County
St. Joseph's Hospital (M & W)
White Plains Hospital (M & W)
Yonkers General Hospital (M & W)

Appendix B.—METHADONE MAINTENANCE TREATMENT PROGRAM

Outpatient and ambulatory induction units by county as of October 31, 1970

	Number of Units
Manhattan	
City probation	2
Gracie Square Hospital	1
Greenwich House	1
Harlem Hospital	5
Jewish Memorial Hospital	1
Morris J. Bernstein Institute	1
Lower East Side	1
Lower West Side	1
Rapid Induction	10
Mount Sinai Hospital	2
Rockefeller University Hospital	1
Roosevelt Hospital	1
St. Luke's Hospital	1
St. Vincent's Hospital	1
Bronx	
Bronx State Hospital	1
Lincoln Hospital	1
Van Etten Hospital	1
Brooklyn	
Brookdale Medical Center	1
Coney Island Hospital	2
Cumberland Hospital	2
Lutheran Hospital	1
Methodist Hospital	1
Queens	
Long Beach Memorial Hospital	1
Triboro Hospital	2
Westchester	
St. Joseph's Hospital	1
White Plains Hospital	1
Yonkers General Hospital	1
Yonkers Public Health Building (WCCMHB)	1

A SPECTRUM OF APPROACHES IN METHADONE TREATMENT: RELATION TO PROGRAM EVALUATION

S. B. Sells, Ph. D.
and
Deena D. Watson, M.A.

All observers of the drug abuse scene in the United States agree that it has undergone frequent and rapid change during the past 5 years, in magnitude, in substances abused, in population groups involved, in public concern, and in the organization of measures for prevention and treatment. One aspect of this change has been the rise of methadone maintenance as the most widely favored approach to the treatment of heroin addiction since the epochal work of Dole and Nyswander in 1964.

The recently published Directory of Narcotic Addicition Treatment Agencies in the United States, 1968–1969 (Watson, Sells, et al., 1970) listed information for 43 agencies in operation during those years that offered methadone maintenance as a treatment modality. Today there are a great many more and we hear of new ones almost every day. Indeed, despite cautions by expert committees of the World Health Organization (1966, 1968), the National Academy of Sciences (1966, 1967), and other authorities (Eddy, 1970, Gearing, 1970), that methadone treatment should continue to be regarded as experimental, the favorable results reported by those who have presented data on treatment outcomes have been difficult for the planners and sponsors of many new programs to resist and resistance has been even harder for many individuals to understand.

The dramatic results reported for methadone maintenance need to be interpreted in relation to the criteria employed. In the Dole-Nyswander program these involve blockaded heroin desire, decreased antisocial behavior, increased social productivity, and increased amenability to rehabilitative services during the period of maintenance on methadone. Very little data is available on these or related criteria for periods of time subsequent to completion of a methadone treatment program. Although positive behavior change under a maintenance regime is unquestionably rehabilitative, some critics have argued that this reflects to a large degree supportive prolonged withdrawal and that enduring change with narcotic abstinence is the appropriate goal.

From the standpoint of criterion design in evaluative research, there is no real conflict here, as the distinction reflects nonoverlapping periods on a time continuum. On the other hand, in our survey of treatment agencies and to some extent in the literature, there have been strong intimations that some workers either implicitly or explicitly make a contrasting dichotomy of *prolonged maintenance* as one goal versus eventual *narcotic-free rehabilitation* as the other. To the extent that these may reflect differences in philosophy, treatment approach, organization of therapy and supporting services, and therapeutic climate, this dichotomy may be important to investigate. Some preliminary data related to this question are presented later.

It has been reported, in hospital psychiatry, that patient behaviors that are effective in posthospital adjustment differ from those that are effective for adjustment in hospitals (Fairweather, 1964). Dole and Nyswander (1967) have commented on the danger of complacency of well-adjusted (phase 3) methadone patients, who may come to regard the continued taking of medication as an inconvenience. Contrast this with the deep concern of the patient in a therapeutic community who must face up to realities about himself in daily encounters with fellow patients. Effective evaluative research must eventually take into account not only the short-term changes, but also the factors related to long-term change as well, assuming that such changes occur.

Statistical studies of treatment effectiveness involve many problems, related principally to the large number of variables that may be considered relevant. Unfortunately, the relevance of many of these must remain questionable until they can be evaluated adequately. The design of an evaluation study requires consideration of at least five sets of variables, describing: 1. the patient sample, 2. the environmental setting, 3. the treatment program, 4. the time periods covered, and 5. the criteria. In the framework of our present understanding each set involves many variables requiring careful specification in order (a) to avoid ambiguity, (b) to facilitate comparison with other samples and other studies, and (c) to enable the evaluation of relevant factors contributing to outcomes. These are discussed briefly in relation to research on the evaluation of methadone maintenance programs.

Patient sample.—The NIMH Guidelines for patient selection mention a number of factors, in-

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cluding motivation, chronic alcoholism, drug history, medical and psychiatric history, age, and criminality. Such information is generally considered relevant and requires no further comment. In addition to detailed specification of demographic factors, which were understandably omitted from the Guidelines, it is important to note at least two additional points. First, as important as motivation is, it is even more difficult to measure, and casual certification of degree of motivation is pointless. A satisfactory analysis of motivation for treatment may be impossible under clinic conditions, but related factors, including measures of alienation, self-esteem, efforts to obtain help, and participation in program activities may be feasible and useful. Second, it is critically important to specify the definition of a patient. This requires an adequate intake procedure and record system, which are essential for accurate accounting of entry and exit times and circumstances. The importance of recording the detailed treatment program for each patient is discussed below. The cavalier manner of accounting for dropouts in many published reports (see Eddy, 1970), such as "of those who remained in treatment 1 year, 15 percent showed much improvement," is not only confusing, but interferes with accurate assessment of total outcome. For a group of 10 of the 16 programs that our Institute has been monitoring under an NIMH contract, the combined dropout rate for 602 methadone maintenance patients within 30 days of admission was 17.6 percent. This is considerably higher than comparable figures reported for the Rockefeller program and raises questions as to whether it reflects patient, program, or recordkeeping differences, or some combination of all.

The sample characteristics of the 43 methadone programs included in the Directory show mixtures of white, black, Mexican, and Puerto Rican patients primarily, of both sexes, with a small number admitting patients under age 21. Recently there has been a tendency to lower the age limits. Overall program statistics and univariate relationships are too gross to analyze the unique effects of age, sex, race, ethnic background, and other patient variables, in relation to treatment patterns and outcomes. It seems clear that sophisticated multivariate methodologies are needed to answer many of the currently urgent questions related to patient characteristics.

Environmental setting.—Deviance is not solely a medical, psychiatric, or psychological problem. The influence of sociological, economic, political, and ecological variables is generally recognized, but we have been reluctant to complicate further our already complex evaluative designs to take account of them. The work of Chein and his associates on juvenile heroin addicts in New York (Chein et al., 1964) and of Jessor and his associates (1968) on factors associated with alcoholism in a triethnic community in Colorado are compelling examples of research that has demonstrated that factors external to the individual are significant in the phenomena of substance use. Variations in social, educational, and economic opportunity, in the conditions of living, in community attitudes, and other facets of the epidemiology of addiction must be evaluated as moderators of the effects of treatment efforts.

Treatment program.—The publications of Dole and Nyswander (1965, 1967, 1968 a, b) and the NIMH Methadone Maintenance Guidelines (1970) have brought about much standardization of methadone programs. At this time, it seems reasonable to expect more attention to be paid to safeguards, methods of induction, dosage, patient screening, urine testing, and rehabilitative services than even 2 or 3 years ago.

Of the 43 methadone programs listed in the Directory, 31 were located in the East and of these, 14 were in New York City. Six were in Midwestern States (Illinois, Michigan, Ohio, Kansas, Missouri), four in the West (California, Oregon, Colorado), one in the Southeast (New Mexico), and one in Hawaii. We have included four additional programs, for which the information became available too late for Directory publication, in the present analysis.

The 47 methadone programs in this sample represent a wide range of organizational patterns and treatment approaches. Seventeen, or slightly over one-third, employed one or more staff members designated as research personnel. Apparently, the other two-thirds made no budgetary provision for research. Slightly over half (27) of the programs employed ex-addicts as staff members, but not necessarily assigned to methadone patients in multimodality programs. Six of the agencies had inpatient facilities only and 19 had outpatient facilities only; the remainder had both in- and out-patient units.

Table 1 lists 21 program activities characteristic of many treatment programs working with narcotic addicts and the number of agencies with methadone programs providing each. Group and individual psychotherapy were the most common auxiliary therapies to methadone, while therapeutic communities, not necessarily all available simultaneously to methadone patients, were found at only eight of these agencies. If the data of table 1 are accurate, some methadone programs administered the medication without detoxification, less than half provided no medical-surgical treatment;

Table 1.—PROGRAM ACTIVITIES. NUMBER OF PROGRAMS REPORTING EACH

	Number	Percent
Detoxification:		
Methadone	30	64
Tranquillizers and other drugs	6	13
Drug free [1]	4	8.5
Chemotherapies:		
Methadone maintenance	47	100
Cyclazocine maintenance	8	17
Naloxone and other	3	6
Group Work:		
Therapeutic community	8	17
Group psychotherapy	36	76
Group discussions and programs	9	19
Individual psychotherapy	35	74
Medical-surgical treatment	23	49
Educational classes	8	17
Religious counseling	5	11
Work assignments	3	6
Rehabilitation services:		
Vocational rehabilitation	20	42
Employment counseling	24	51
Social and family services	16	34
Occupational therapy	10	21
Recreational programs	8	17
Prevention	6	13
Research	17	36

[1] Drug-free detoxification is not a feature of the methadone program.

and supplementary services, such as education, vocational counseling, vocational rehabilitation, social service, and the like were provided by a minority of the sample.

Table 2 shows a distribution of the number of the 21 activities, listed in table 1, per agency. Not all of the activities were available for methadone patients, but the numbers do reflect the patterns of services provided for addict patients. The mean number of program activities was 7; 11 agencies had 10 or more, while 18 had five or fewer. Although not shown in the table, it was found that only eight of the 47 agencies provided chemotherapy not associated with any form of group work, while 39 provided both chemotherapy (methadone, cyclacozine, or other chemotherapy) in association with group work. For the first eight agencies, only one additional program service was offered, on the average, while for the 39, the average was four. Among the former group, at the time, were several very prominent in research on methadone maintenance.

Table 2.—DISTRIBUTION OF NUMBER OF PROGRAM ACTIVITIES REPORTED BY 47 METHADONE MAINTENANCE PROGRAMS

15	1
14	2
12	2
11	1
10	5
9	2
8	7
7	5
6	4
5	10
4	2
3	1
2	3
1	2
[1]	

[1] Mean number for sample.

Table 3 shows an interesting comparison relating the combination of group work with methadone treatment. The two most prominent therapy features of the programs monitored by the IBR in the NIMH reporting system are methadone maintenance and therapeutic community. Although the data available at present are incomplete for the 10 agencies on which this table is based, the dropout rate for methadone maintenance is lower than that for therapeutic community at all three time periods. Methadone maintenance associated with therapeutic community shows the lowest dropout rate at 1 month, but catches up with methadone maintenance at 5 months. More extensive data will hopefully be available in the near future to examine these relationships more adequately.

Table 3.—DROPOUTS FROM 10 METHADONE MAINTENANCE PROGRAMS AT THE END OF 1, 3 AND 5 MONTHS, FOR 3 THERAPY GROUPS: METHADONE, THERAPEUTIC COMMUNITY, AND METHADONE MAINTENANCE ASSOCIATED WITH THERAPEUTIC COMMUNITY-COMBINED DATA

Dropouts at	Methadone maintenance N=602		Therapeutic community N=305		Methadone maintenance and therapeutic community N=104	
	Number	Cumulative percent	Number	Cumulative percent	Number	Cumulative percent
1 month	106	17.5	95	31.0	12	11.5
3 months	40	24.2	22	37.2	9	20.2
5 months	15	26.8	12	40.2	6	26.0

A number of other relationships were examined in the survey data on which the Directory was based. For the sample of 47 agencies, a significant positive association was found between the employment of research personnel and the employment of ex-addicts. This suggests that methadone programs engaged in research were also innovative, during 1968 and 1969, in employing ex-addicts. This practice is more widespread today. Agencies employing research personnel also tended significantly to experiment with other newer therapies, such as cyclazocine, naloxone, and therapeutic communities.

Detailed interviews, program documents, and professional publications were available from our survey for 25 of the 47 methadone agencies in the present sample. From these, judgments were made that resulted in a two-fold classification concerning the philosophic outlook of the program leaders about methadone treatment. One category was labeled *narcotic-free rehabilitation* and the other, *prolonged maintenance.* This is admittedly a subjective classification, but was undertaken on an

Table 4.—RELATION BETWEEN TYPE OF REHABILITATION EMPHASIS AND PREFERRED DOSAGE LEVEL FOR 25 METHADONE PROGRAMS. NUMBERS IN PARENTHESES INDICATE PERCENT OF TOTAL OF 25 PROGRAMS

Preferred dosage level		
High (50–180 mg.)	8(32)	10(40)
Low (20–40 mg.)	6(24)	1(04)

exploratory basis. Fourteen of the 25 programs were classified as favoring narcotic-free rehabilitation and 11, prolonged maintenance. Of the same 25 agencies, 18 preferred high dosages of methadone (50 to 180 mg.) and seven preferred low dosages (20 to 40 mg.). An association between these was found, as shown in table 4, indicating a linkage between preference for low dosage maintenance and program orientation toward narcotic-free rehabilitation. The phi coefficient of 0.37 representing the correlation estimate for this fourfold table is significant at the 0.05 level.

As shown in table 5, a moderate correlation (phi=.28) was also found between rehabilitation emphasis and employment of research personnel. Agencies engaged in research tended to express the prolonged maintenance emphasis, as in Dr. Gearing's reports, which is certainly consistent with the realities of carrying out evaluative research under the real time constraints that have existed to date. Nevertheless this is a noteworthy relationship.

Rehabilitation emphasis was not significantly related to size of patient census or to employment or ex-addicts, nor was dosage level related to either of these factors. However, dosage level was marginally related to the employment of research staff. The phi coefficient for this relationship was 0.28, in the expected direction of high dosage associated with research effort.

Research involvement was moderately associated with number of program activities (phi=.23); it was found that agencies employing research staff tended to have fewer program activities, while those not engaged in research had more. A similar relation (phi=.30) reflected the tendency for programs with fewer different activities to have a "prolonged maintenance" emphasis, while those with larger numbers of activities tended to express the "narcotic-free rehabilitation" emphasis.

Table 5.—RELATION BETWEEN TYPE OF REHABILITATION EMPHASIS AND EMPLOYMENT OF RESEARCH PERSONNEL, FOR 25 METHADONE PROGRAMS. NUMBERS IN PARENTHESES INDICATE PERCENT OF TOTAL OF 25 PROGRAMS

Employment of research personnel		
Yes	5(20)	7(28)
No	9(36)	4(16)

Ambulatory induction of methadone patients was not enough of an issue at the time of our survey to provide data for this report. Results reported by Dr. Gearing, however, indicate that it will undoubtedly be an accepted procedure before long. Indeed, results reported for the Rockefeller program, along with dissemination of the NIMH Guidelines, may already have resulted in greater uniformity of program features than we found in the 1968–1969 survey.

Both the Rockefeller program and several impressive programs outside this group have engaged in a number of innovative practices. One direction taken in a number of programs involves experiments within the chemotherapy framework. These include variation of dosage levels, studies using new therapeutic drugs and new methods of administration. Related to these are studies of new urinalysis procedures. A second development of major importance has been the merging of chemotherapy with group work in various ways. One of these has been the combination of methadone maintenance with therapeutic communities, in several prominent programs. Another noteworthy approach has emphasized the involvement of members of the "square" community (as "big brothers") in the treatment arrangements for individual patients. Decentralized methadone administration, through neighborhood pharmacists was an innovative practice quite recently, but is rapidly being adopted in many cities. Keeping track of innovation in this rapidly developing field is a difficult task, but clearly worthy of the effort, particularly if innovative ideas can be checked out before receiving undue notice.

Time as a variable.—Time is important in the evaluation of treatment in at least three respects. First, it is necessary to consider the location of every treatment activity and sample in calendar time. As every epidemologist knows, data for one period may differ markedly from data for another period because of changes in the world, the economy, the drug scene, and numerous other significant factors. Our survey research has convinced us that changes within organizations, of major significance, may occur within a relatively short time. It would be ideal if every program contributing data to an evaluation enterprise could have a full-time historian and archivist, whose influence on the classification of data may often be of critical importance.

A second aspect of time as a variable involves the amount of time, per 24-hour period, that the patient participates in the treatment program and is under its influence. This is related to Goffman's (1957) concept of the total institution and is one way of differentiating between the essential aspects of inpatient and outpatient institutions. However, the issue of whether degree of participation and influence, measured in units of time, is related to intensity and effectiveness of treatment, is raised for consideration.

Finally, there is the time continuum from the beginning of treatment, time zero, to various landmarks, one of which involves completion of treatment, followed by various periods of post-treatment experience. We have already emphasized the importance of recording key events, such as admission, accurately, and equally important is the event of completion. It can be noted, for example, that direct comparison of patient behavior under a methadone maintenance program with the post-treatment behavior of patients discharged from treatment by other modalities is improper. The dismal record by other modalities in the past is known. However, little is yet known about the record of methadone patients over a sufficient post-treatment period.

Criteria.—The criterion issue has already been discussed. It is our belief that criterion decisions, like value choices, are not based on scientific considerations alone and that they must be responsive to practical concerns. The scientist may be satisfied to present his data objectively and to report what he finds. However, public demonstration of the effectiveness of treatment must take account of the expectations of responsible sources of public opinion as to what constitutes successful rehabilitation. It will soon be possible to follow substantial numbers of methadone patients from a wide range of programs and settings and the question of post-treatment narcotic-free adjustment, in relation to the variety of system patterns outlined above need no longer be an academic issue.

Concluding Note.—Rapid expansion of methadone treatment is occurring before many questions relevant to optimal program design can be answered by empirical test. The wide spectrum of approaches described could be utilized for investigative purposes if an organized approach, cooperative effort, and adequate funding were possible. As long as methadone programs are regarded as experimental it would seem to be a minimum requirement that a basic set of records be maintained and made available to qualified investigators.

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UTILIZATION AND REVIEW OF METHADONE PATIENT DATA

Alex Richman, M.D.

INTRODUCTION

This paper outlines the development and uses of an integrated data system within the department of phychiatry of Beth Israel Medical Center. Particular attention is directed to the utilization and review of several types of data for patients in the methadone maintenance clinics of the M. J. Bernstein Institute. It is intended to illustrate in this presentation various approaches to the uses of data, rather than to concentrate on one particular study.

Utilization review is defined as being concerned with maintaining consistent, high-quality patient care and with promoting the most efficient use of available health facilities and services. Utilization and review activities of our department of phychiatry include studies of the delivery, uses, and outcome of care. These studies are essentially concerned with providing information essential for evaluation and program planning.

BETH ISRAEL DEPARTMENT OF PSYCHIATRY

The department of psychiatry of the Beth Israel Medical Center includes the Morris J. Bernstein Institute with various inpatient and outpatient services for drug addicts, a psychiatric inpatient unit; mental hygene clinics at the Beth Israel Hospital and the Gouverneur health services program in psychiatry.

During 1969 the inpatient services of the M. J. Bernstein Institute had over 9,000 inpatient admissions and 500 transfers between the various inpatient services during the year. In addition to a large detoxification program and a specialized medical unit for addicts with major medical problems, inpatients could be admitted to a Phoenix House or the methadone maintenance program. The general psychiatric inpatient service admitted 400 patients; patients were cared for in the psychiatric day hospital.

At the end of 1969, the mental hygiene clinics of the Beth Israel Hospital had 800 patients; the methadone maintenance clinics of Bernstein Institute had another 790 outpatients under care.

BETH ISRAEL PSYCHIATRY COMPUTER LIAISON SYSTEM

A coordinated data system, Beth Israel Psychiatry—Computer Liaison System (BIPSYCL), has been developed with the following objectives:

1. Providing the information necessary for evaluation and program planning by our department of psychiatry.
2. Including patients from all programs of the Beth Israel department of psychiatry. This involves the various inpatient, outpatient, partial hospitalization and emergency care programs named above.
3. Supplying required statistical data to the multi-State information system of the New York State Department of Mental Hygiene, the methadone data system (Rockefeller University), and the New York City Narcotics Register (department of health).
4. Reducing redundancy and promoting efficiency in reporting.

BIPSYCL will be able to provide the statistical data essential for a comprehensive community mental health center. This involves:

1. The ability to include all clinical programs.
2. Recording data on applicants and waiting lists as well as admissions, terminations and patients under care.
3. "Tracking" patients transferred through a variety of programs within the department of psychiatry and providing cumulated accounts of such transfers and multiple contacts within these programs.
4. Recording information on the nature and date of staff contacts with individual patients (including missed appointments).

DATA SYSTEMS IN WHICH BETH ISRAEL DEPARTMENT OF PSYCHIATRY PARTICIPATES

This section describes various data system with which the Beth Israel department of psychiatry interacts. The needs of these separate data systems have been considered in developing BIPSYCL.

NEW YORK CITY NARCOTICS REGISTER

Within New York City, agencies are required by law to send reports of addicts to the narcotics register of the department of health. The Bernstein Institute has provided information on its 70,000 admissions, since January 1961, to the New York City Department of Health.

METHADONE DATA SYSTEM (ROCKEFELLER UNIVERSITY)

The Bernstein Institute has participated from the beginning in the methadone data system. This system has been described previously by Drs. Dole and Warner and future developments of this system are presented by Dr. Warner elsewhere in these proceedings. Applicants for the methadone maintenance program are assessed by the intake unit of the citywide methadone maintenance treatment program administered by the Beth Israel Medical Center. This assessment includes completion of a basic data sheet which is submitted to the methadone data system.

Patients accepted for induction as inpatients or outpatients at the Bernstein Institute are admitted through the Bernstein Institute admissions unit where further data is acquired (see below). Subsequent systematic data is supplied to the methadone data system on weekly and monthly reports.

SHARED HOSPITAL ACCOUNTING SYSTEM (SHAS)

The inpatient activities of the department of psychiatry have been computerized for admissions, patients under care, discharges and transfers within services. This component is part of the shared hospital accounting system operated by the Beth Israel Medical Center. This advanced group of IBM programs (SHAS) gives, in addition to accounting-type data, daily up-dated lists and statistical tabulations which are used in various parts of the Bernstein Institute.

1. Admissions, discharges, and transfers
   a. Alphabetized lists of admissions, discharges, and transfers.
   b. Statistical tabulations of census at beginning, admissions, transfers in, transfers out, discharges, discharges against advice, occupancy for the day, and occupancy for the month-to-date.
      1. by ward
      2. by service
2. Admissions, Patient Days of Discharges, and discharges Against Advice
   These daily statistical tabulations are cumulated from the start of each month to give, by sex and age group, by ward and service, the number of:
   a. Admissions
   b. Patient days of discharges
   c. Discharges against advice
3. Patients in Hospital at Midnight
   There are lists for each ward and for the Institute as a whole which show the names of patients in alphabetic order, their age, and the number of days since admission.
4. Monthly Tabulations of:
   a. Type of admission
   b. Patients in hospital listed by date of admission
   c. Days on waiting list before admission.

WAITING LISTS

In addition to providing types of data shown previously for the various inpatient services at Bernstein Institute, shared hospital accounting system has been modified to meet the specific needs of our waiting lists. The admissions unit of Bernstein Institute has contract with about 1,200 heroin users a month. At any one time, there are from 800 to 1,200 patients on the waiting list for detoxification. In addition, during the average month there are 200 to 300 patients who have failed to appear for admission on their guaranteed admission date, 200 persons referred for consultation from the New York City Department of Social Services with regard to their addiction status, and a number of other patients in less clearly defined categories.

SHAS has been modified to produce a waiting list which is updated each day. One list shows the names, in alphabetic order, of patients scheduled for future admission as well as those with whom we have had any contact over the past 2 months. Another list shows, for each service, the names, in chronological order, of patients scheduled for admission. We are now adapting both these daily updated lists to include patients accepted for admission to the citywide methadone maintenance program of Beth Israel Medical Center.

MULTI-STATE INFORMATION SYSTEM

Within New York State, all facilities licensed or financed by the department of mental hygiene are required to provide statistical reports on the characteristics of their admissions and terminations. These statistical reports are part of the multi-State information system (MSIS) which is an automated record keeping system used by psychiatric services in Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont.

MSIS is so programed that a user can install one part of the system at a time, starting with the basic admission/termination application and progressing to activity reporting. A facility is given the option of using either a portion or all of the available system. Consequently, it is possible for the facility to implement only those parts of the system that are appropriate to its own needs.

This system can generate unit rosters, periodic patient summaries and admission/termination statistics. These reports provide a total picture of the patient's clinical involvement with the facility during any time period. By making reports on patient activity available throughout the facility, the system shows where patients have been and what services they have received.

Additional reports to aid in the management of the complete facility are generated as by-products of the system. The reports show those patients who are receiving the services of more than one unit, the utilization of locations within the facility, and the services performed by individual staff members. The system can further aid in the administration of a facility by generating information for reports to county, State, and national agencies. The total system is intended to provide the detailed reporting, tracking, and counting essential for a community mental health center.

This system has been initiated within the inpatient services of the department of psychiatry. With the full cooperation of Mr. Abbott Weinstein of the Office of Statistics and Data Processing of the New York State Department of Mental Hygiene, the computer programs for the three phases of the multi-State information system have been installed at the management information center of the Beth Israel Medical Center; thus we are now able to operate the system entirely within the computer resources of our own medical center.

DATA FROM ADMISSIONS UNIT, M. J. BERNSTEIN INSTITUTE

We have attempted to integrate the various data systems described above in order to reduce redundancy, enhance the quality of the data, and provide a well organized systematic procedure for persons applying for detoxification and patients being admitted to the Bernstein Institute.

The admissions unit of the Bernstein Institute interviews applications for detoxification and sees people referred for consultation from the New York City Department of Social Services. Methadone maintenance patients being admitted to the inpatient or ambulant induction units of Bernstein Institute who have been previously accepted by the citywide methadone program of the Beth Israel Medical Center, also go through the admissions unit.

Similar procedures are used for these three large groups of patients, from whom we obtain:

1. Census questionnaires
2. Patient data sheets
3. Multi-State information system forms (MS-5)

Since the fall of 1969, all three groups have been completing a questionnaire based on the U.S. 1970 census form. This questionnaire contains the basic Federal census questions and is completed by the patient himself in the same manner as the 1970 Federal census. Recently we have been assessing the usefulness of a self-administered Cornell medical index.

As we keep detailed records of all individuals who cross the threshold of our admitting area, it is possible to mount special studies on a representative sample of applicants. Currently we are developing:

1. A drug profile to describe the nature, duration, and intensity of use of drugs other than heroin
2. A study of the addiction characteristics and M.M.P.I. responses of heroin users who are Vietnam veterans
3. A semantic differential method for assessing the attitudes of patients to various types of addiction treatment facilities.

I have described our admissions unit in detail in order to emphasize that standardized data is systematically obtained from various groups of heroin users or suspected heroin users attending the Bernstein Institute, as well as from patients in the methadone maintenance treatment program.

USES OF METHADONE MAINTENANCE PATIENT DATA

Within our Center, much data on methadone patients are available. In addition to material derived from the various systems described above, information is available regarding any previous admissions for detoxification at the Bernstein Institute, as well as clinical records maintained during the course of care in the methadone maintenance treatment program.

It is the aim of BIPSYCL to be able to correlate data obtained at different times and from different systems.

COMPARISON OF METHADONE PROGRAM PATIENTS WITH GENERAL POPULATION

We are very much interested in the demographic characteristics of our patient population, such as age, sex, color, birthplace. As well, we are concerned with social characteristics (schooling, occupation, household composition) for which there are comparable data from the general population.

On July 20 of this year, the Holding project was initiated with the intake of 100 patients from the waiting list at the rate of 32 per week. The objective of this project was to assess the feasibility of accelerated intake on a larger scale. The demographic composition of this group is of interest: 77 percent were male, 54 percent were between 25 and 34 years of age, and 47 percent were not white. However, when one considers these data in detail, one gets a different view of their demographic profile. Among the various age groups there is considerable variation in the distribution by sex and color.

These data were obtained from the self-administered census questionnaires and therefore represent the patients self-report of color. This form has been used over the past 15 months and was also completed during April 1970 by patients in the methadone maintenance treatment program who had been admitted prior to our initiating use of this form. We are now beginning to process these data, anticipating that we will have the numerators ready when the census denominators arrive for New York City. Some special substudies have already begun on these census questionnaires with regard to the 240 Vietnam veterans who were found among 12,000 applicants for detoxification.

Data from this census questionnaire permit detailed comparisons of the social characteristics of our patient population with those of the general population. Furthermore, use of these standardized questions enables systematic comparisons of patients in different clinical programs.

COMPARISON WITH APPLICANTS NOT ACCEPTED FOR THE METHADONE MAINTENANCE TREATMENT PROGRAM

Perkins and Bloch (1970) compared the characteristics of patients admitted to the methadone maintenance treatment program with applicants who were not accepted. Nonaccepted applicants, in comparison to admissions, had fewer patients who were white, or employed, or with previous hospitalizations at Bernstein Institute. However, nonaccepted applicants were more likely to use barbiturates, have a problem with alcoholism, or to have engaged in criminal activities during the 6 months prior to intake.

COLLABORATIVE STUDIES WITH NEW YORK CITY NARCOTICS REGISTER

We are now conducting six collaborative research studies with the New York City Narcotics Register. For these we adhere strictly to the essential stringent requirements concerning confidentiality. These studies include samples of patients from all clinical programs of the Bernstein Institute.

We have had over 30,000 individual admissions to the Bernstein Institute since 1961, while the Narcotics Register has had over 55,000 names of heroin users reported between 1964 and 1968. Our collaborative research studies are intended to provide perspective on:

1. What reports are received for patients after they have been discharged from Bernstein Institute or after they have applied for admission, but have failed to appear on their admission date (Richman et al., 1970).
2. How do heroin users who come to Beth Israel Medical Center compare to those who were initially reported to the register from other sources?[1] What is their demographic profile? What is the longitudinal pattern of these reported contacts? (Of a sample of 200 New York City heroin users first reported to the register in 1967, initial analyses indicate that about one-half were reported only by law enforcement agencies up to the end of 1968.)
3. What previous events described by our patients have not been previously reported to the register?

ATTENDANCE OF METHADONE PATIENTS

Individual visits to M.M.T.P. clinics are recorded. These forms are completed for each patient visit and describe the purpose of the visit, the date, and the name and profession of the person providing the service.

We have been studying the use of clinical services in terms of attendance and relating attendance to demographic and psychological characteristics.

Ninety-six of the 100 patients admitted to the Holding project between July and August 1970, were still in attendance during October. The following graph shows the distribution of visits during 4 weeks from October 5–30. Between 37 to 51 visits per day occurred from Monday to Thursday, while there were 69 or more visits on Fridays. During the 4 weeks there were 1,008 visits by 96 patients, an average of 10 visits per patient.

Patients attend daily until their drug taking, and their social and occupational circumstances are considered by the nurse in charge of their clinic to have stabilized. With increasing evidence of stabilization, the frequency of required attendance is reduced. The number of Holding project patients who attended 5 days during the week decreased from 42 patients in the week of October 5–9, to 29 in the last week, October 26–30. There were 27 patients who appeared every day during the month. In the Holding project clinic during October on the average, 44 Holding project patients attended on Monday, 45 from Tuesday to Thursday, and 73 on Friday. Consistent attendance (e.g. every Monday during October) amounted to 39 patients on Monday, 35 on Tuesday, 39 on

[1] Some comparisons of methadone patients with those known to the register have been described by Dr. F. Gearing in her reports to the evaluation committee.

Wednesday, 36 on Thursday and 68 on Friday. It is evident that consistent attenders make up a major portion of those seen on any given day.

The greater concentration of Friday visits for the Holding project clinic is obvious. The overall attendance pattern for patients in the other Bernstein clinics of the methadone maintenance program is different. For the 1,098 patients in the other Bernstein clinics during October, average attendance was highest on Mondays and lowest on Tuesdays and Wednesdays.

SOCIAL CHARACTERISTICS AND ATTENDANCE

Finally I would like to illustrate the correlation of data from various sources. First I would like to show for Holding project patients attending during October, the relation between social characteristics recorded some time before their admission in July 1970, to daily attendance during October 1970. As described above, daily attendance is required for those who are not considered to be stabilized.

Over one-fourth (28 percent) of the patients attending during October attended on 20 consecutive clinic days. The frequency of daily attendance was not uniform among groups of different social characteristics. Daily attendance was similar among those who lived with mother (27 percent) and those who lived alone (26 percent), while those living with a spouse were less likely to attend daily (21 percent).

Black patients more frequently attended daily (45 percent) and white patients less frequently (14 percent). Residence by borough show similar variations with more Bronx patients (39 percent) attending daily and fewer Brooklyn patients (18 percent). The most marked differences in attendance were shown by work history obtained at the initial intake assessment. Patients who were not working at the time of intake were four times (38 percent) as likely to make daily visits as those who were working at the time of intake (9 percent).

NERVOUSNESS AND ATTENDANCE

I have also considered daily attendance of Holding project patients in relation to symptoms self-reported by patients on the Cornell medical index on the day of their induction. Six of the 21 Cornell medical index questions which were answered by 25 percent or more of the patients related to "nervousness." Positive answers to five of these six questions were more frequently associated with daily subsequent attendance than were negative answers.

METHADONE MAINTENANCE HOLDING PROJECT FREQUENCY OF DAILY ATTENDANCE AMONG THOSE ATTENDING DURING OCTOBER, 1970 ACCORDING TO RESPONSES ON CORNELL MEDICAL INDEX AT INTAKE

Patient group	Percentage with daily attendance
All patients (N=9;)	28
Does worrying continually get you down? Yes, N=26)	31
Are you considered a nervous person? Yes (N=25)	32
Do you usually feel unhappy and depressed? Yes (N=29)	37
Do you usually have great difficulty in falling asleep or staying asleep? Yes (N=30)	40
Are your feelings easily hurt? Yes (N=21)	49

DRUG ABUSE AND RETENTION

I have shown the relations between attendance and demographic characteristics; and attendance and "nervousness." Finally, I would like to illustrate the use of data from different sources at different times. This combination of clinical observations and records of attendance gives a flowing perspective of the longitudinal course of care for our methadone patients.

During 1969, there were 587 persons (inducted as inpatients) who were cared for in methadone clinics of the Bernstein Institute. It is emphasized that these patients may have started M.M.T.P. during any part of 1969 as well as before 1969. During April 1970, 80 percent of the 587 patients were being cared for within Bernstein clinics, and in October 1970, 72 percent were still attending

One can group those 587 patients according to the drug abuse reported by the unit director during the 1 to 12 months the patients may have attended in 1969. There were no reports of self-administered drugs for 39 percent of the patients; heroin use was reported for 28 percent of the group at some time and another 33 percent had taken drugs other than heroin.

Among the 229 patients who were not reported as having used drugs during 1969, 198 (or 87 percent) were still in attendance during Ocober 1970. Among those reported using heroin during 1969, 75 percent were still in attendance during October 1970 and among those reported using drugs other than heroin, 67 percent were attending during October.

SUMMARY

I have attemped to outline some of the ways in which we are developing utilization and review data on patients in our methadone maintenance program. I have emphasized the need for relating information from multiple sources to give a longitudinal perspective. In addition, I have shown some types of analysis which allow us to study our methadone patients in relation to the general population, in relation to heroin users reported to the Narcotics Register, in relation to applicants for detoxification to us or patient populations of other facilities. Finally, I have illustrated some of the types of information essential for better understanding and management of clinical care.

We are now able to extend our perspective from dealing with cross-sectional information from one data system at one point of time to relating information from various sources at different times. Thus we will be able to better assess the working of our clinical services as well as extend our understanding of the longitudinal course of patients in the methadone program.

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A SURVEY OF PATENTS ATTENDING DIFFERENT CLINICS IN NEW ORLEANS

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Unlike most people here, I ame not a professional 'with years of experience in the field of addiction. I did not become interested until 1968 and then only because I felt that drug use and abuse were spreading like an epidemic, and should be tackled as such. A handful of people in New Orleans—a mere handful—had already recognized the fact: The leaders were Dr. James Nix, Judge Andrew Bricara, Dr. William Bloom, and Capt. Clarence Giarusso, Chief of the Police Narcotics Squad. Dr. Nix and Dr. Bloom had already started clinics for methadone rehabilitation. I felt that we should mobilize more effort to investigate causes and wider mechanisms of control. I was fortunate in obtaining support for the purpose from the National Institute of Mental Health and we formed a Drug Abuse Research Team with three full-time workers and a larger number of part-time workers and volunteers, including social scientists, physicians, attorneys, and many others on whose behalf I speak here today. We now have about 1,200 heroin addicts on methadone in eight clinics which are cooperating in our study.

METHOD

Our approach is by definition epidemiological, so we have to first arrive by computation at relevant denominators to accommodate the numerations which express our problem. We try, therefore, to obtain personal, psychological, and social data, not only about the addicts in our clinics but also about street addicts, about their families and contacts. Much of our effort is expended in interviewing in bars, cafes, on the street, in homes, as well as in the clinics. We use addicts, ex-addicts, students, and volunteers as interviewers, under the guidance of a small staff of physicians and social scientists. Data processing and some of the analysis is in the hands of Bernard Goldsmith, a methematician with training in epidemiology, who arranges storage of data cooperatively with the newly formed office of the Louisiana Narcotics Commission whose chairman, Dr. Chester B. Scrigna, and executive director, Mr. Luke Fontana, are members of DART.

Admission of patients is by voluntary enlistment, though some are refered to us, permissively, on "Methadone Parole" by the police department. This could be assumed to be a form of compulsion but, in the face of the current epidemic, we consider it an expedient option for hard-core addicts with criminal records. Few patients are refused admission, provided their urine contains opiate, their stated age is 18 years or older, and they are deemed, on interview, to be addicted. Each patient

is interviewed by a physician and, in the private and charity clinics, by a panel of ex-addicts who explain rules and procedure. All patients supply in some detail personal, family, social and drug history. A proportion is also asked to cooperate in psychological and psychiatric evaluation of their status at entry and response to treatment, for which purpose control data is being obtained from comparable populations of nonaddicts. Approximately 25 percent of the present series of 767 patients have been referred to Tulane Health Maintenance Service, or elsewhere, for tests of hepatic, cardiorenal, and respiratory function.

Each patient pays $10 per week to cover the cost of methadone and dispensing. Recreation facilities, group therapy sessions, cafeterias and social activities generally are available in the private clinics and are being developed in the others. No hospital facilities or beds are available, though we have occasionally used private suites as "kick-pads" for supervised detoxification.

RESULTS

Demography. Ninety percent of our addicts applying for rehabilitation are born in New Orleans, 4 percent elsewhere in Louisiana, and 2 percent in adjacent States. The problem is therefore, strictly local and indigenous: The factors concerning addiction reside in the city and locality. By counting the number of addicts visiting pushers, by taking the opinions of community workers, of addicts themselves and by other means, we think that there are about 2,500 strung-out addicts in Orleans Parish, which has a population of 600,000. They are more numerous in ghetto areas, but by no means confined to any one part of the city. Seventy-five percent are black males with a median age in 1969 of 29 years. In 1970, this median is dropping to about 26 because of the rapid spread in increase of drug abuse in young people. In whites, the 1969 median was 27 years, also falling currently. We have evidence from a school study by Charles J. Fleming, to be published separately, that experimentation and abuse of heroin are spreading very rapidly from the street to the high schools and junior high schools in and around the city.

METHADONE REHABILITATION

Of the estimated addict population of 2,500, 1,200 are now attending methadone clinics, and we have reasonably good data on 767 who have been attending eight clinics for 2 months or longer (table 1). This unselected clinic population contains a relatively lower proportion (66 percent) of black males with higher proportions of white

Table 1.—DRUG ABUSE RESEARCH TEAM (DART)
New Orleans, La.
Patients under surveillance in methadone clinics [1]

Clinic	Male		Female		Total
	Black	White	Black	White	
Algiers	138	3	27	2	170
Bloom	118	50	12	3	183
Nix 1	47	59	11	12	129
Nix 2	32	7	3	0	42
City	46	1	15	0	62
Desire	93	3	13	0	109
House of Bread	0	0	16	10	26
9th Ward	37	1	8	0	46
Total	511	124	105	27	767

[1] The total income of each clinic each week (City Clinic excepted) can be calculated by multiplying $10 by the figures in the last column.

males (18 percent) and females (16 percent) than our demographic estimate. The private clinics (Algiers, Bloom, and Nix), which operate at economic rates but without profit, accommodate 68 percent of the total clinic sample, while the City Clinic, which operates with public funds, accommodates only 8 percent.

Dosage proceeds conventionally, starting at 10–30 mg. daily and rising until heroin hunger is abated. Median dosage of all patients is 90 mg. but the range varies greatly, between patients and between clinics (table 2). Distribution curves, in all except one of the clinics, shows bimodality: The majority of patients receive doses of 50–100 mg. but a smaller number require much higher doses (140–230 mg.) for maintenance.

Table 2.—DART
New Orleans, La.
Dosage of methadone (mg.) in patients under surveillance

Clinic	Patients (number)	Median (mg.)	Range (mg.)	Distribution (mg.)
Algiers	170	90	40–160	Bimodal 89,130.
Bloom	183	100	20–130	Bimodal 90,130.
Nix 1	120	90	20–230	Bimodal 90,120.
Nix 2	42	80	20–190	Bimodal 70,110.
City	62	110	50–140	Bimodal 100,130.
Desire	109	60	10–130	Unimodal.
House of Bread	26	90	30–220	Bimodal 80,170.
9th Ward	46	80	30–100	Bimodal 50,90.
All patients	767	90	10–230	Bimodal 90,130.

In the Desire Clinic, the median dose is significantly lower (60 mg.) than in any other, the range relatively narrow (10–130 mg.) and the distribution unimodal and normal with the mean dose to the median dose. In the other community clinic, in the ninth ward, a similar low-dose range is practiced (30–100 mg.). In both of their clinics, the patients are exclusively black and mainly below 25 years of age. Detoxification is attempted in all clinics but with very little real success. Approximately 60 percent are estimated, by urine tests, to be avoiding opiates but usage of barbiturates and alcohol is frequent, marihuana and amphetamines less so. The cure rate in 454 patients who had been maintained on lower doses or detoxified was estimated at best to be 0.9 percent—four patients, who obtained regular jobs, left the drug-scene and stated that they had not used any opiate for 1 month or longer. These four patients came from two clinics.

The ranges of dosage in black and white, male and female patients, are similar (table 3). The highest doses (200–230 mg.) are required to maintain a few white males and females.

Table 3.—DART
New Orleans, La.
Dosage of methadone (mg.) in patients under surveillance

	Number	Median (mg.)	Range (mg.)	Distribution (mg.)
Males:				
Black	511	90	10–210	Unimodal.
White	124	120	10–230	Bimodal 80,150.
Females:				
Black	105	90	30–200	Bimodal 70,130.
White	27	110	30–220	Bimodal 80,170.
All patients	767	90	10–230	Bimodal 90,130.

Dropouts and reasons for dropout are reported separately (Adams et al., 1970). The dropout rate for all clinics except the charity clinic (15 percent) were fairly constant at about 25 percent. We define a dropout as a patient who leaves the program after receiving two or more doses of methadone. The methadone-failure rate is different, being: total dropouts — (transfers + returns). Reasons for dropping out (Adams et al., 1970) vary enormously between patients and between clinics. Of relevance here is the fact that administrative difficulties and complaints within the clinics accounted for many patients leaving the private clinics and that community influence seemed to be a factor promoting attendance at local community clinics. Approximately 30 percent of dropouts complained about side effects or dissatisfaction with methadone, and one-third of these admitted that they wanted to return to heroin even after increased dosage of methadone. The dropout rate was unrelated to dosage, race or sex. Of 70 who were traced or interviewed, at least 50 percent reverted to heroin though 32 percent quickly found themselves in jail without any notification to the police; 31 percent reentered the same clinic or another one; 4 percent died; 7 percent were admitted to hospital; and the remainder (8 percent) were drafted or left the area.

Side effects of varying severity were reported by patients attending all clinics and are detailed separately in this volume by Butcher and Bloom (1970). Symptoms or signs of hepatitis were reported by 80 out of 356 long-term addicts (22 percent), of whom 5 percent had given blood donations since their attack. A significantly higher proportion (PLO.001) of this group was female, mainly white, so the real figure may be higher.

The benefits of methadone maintenance are not the subject of this communication but it may be noted that, in all clinics, at least 70 percent remained on or returned to the program, lessening or abandoning the regular use of heroin as judged by interview and intermittent spot checks of urine passed on the premises under supervision. Sixty-five to eighty-five percent obtained employment of one kind or another within 6 weeks—against an adverse economic trend—and, in eight whose arrest records were obtained from the police department over the years 1964–69, arrests and charges were reduced threefold.

Among other factors studied in the different clinics (table 4), local support and recognition play important parts in maintaining attendance and morale in the two community clinics but administrative efficiency in their clinics is low because of frequent changes and absences of the volunteer staff. Political conflict arose, especially in the Desire Area, because we were accused by black militants of pursuing a genocidal policy. This attitude changed to one of approval and support after meetings between our research group, ex-addicts, and the black militants.

Table 4.—DART
New Orleans, La.
Differences between methadone clinics in New Orleans

	Private	City	Charity	Community
Official support	−	+	−	−
Official recognition	(+)	+	(+)	+
Community support	−	−	−	+
Community recognition	+	(+)	(+)	+
Political conflict	−	−	−	+
Administrative conflict	+	−	−	−
Administrative efficiency	High	High	High	Low
Cliques, powerplay	+	−	−	−
Dropouts	High	?	Low	Medium
Number of patients (N=767)	524 (68.3%)	62 (8.2%)	26 (3.3%)	155 (20.2%)

The pattern of drug abuse is changing in New Orleans, as in other cities, in that more and more adolescents are turning to heroin as a first or second drug. It is, therefore, of interest to compare the reasons for use of a drug as given by 77 confirmed younger addicts with those given by older addicts (table 5). This comparison suggests that the differences in the age groups 17–24 and 25–31 are minimal, and that curiosity about drugs was at least as strong a factor in persons who became

Table 5.—DART
New Orleans, La.
Reasons for starting drugs in heroin addicts on rehabilitation

Reason	Age group (years)			Total
	17–24	25–31	31	
Curiosity	29 (29.2)	42 (52.3)	62 (51.5)	133
Enticed by friend or gang	25 (22.8)	43 (40.9)	36 (40.3)	104
For kicks	15 (14.7)	31 (26.3)	21 (26.0)	67
All others [1]	8 (10.3)	22 (18.5)	17 (18.2)	47
Total	77 (77.0)	138 (138.0)	136 (136.0)	351

addicted in the 1950's or earlier when, according to our estimates, addiction did not usually begin until adult life. We hoped that our psychological and psychiatric evaluations, especially when correlated with attitudes and value scales, might have given us some predictors of response to rehabilitation but so far this has not been the case.

DISCUSSION

The results reveal many imperfections in the assessment and management of the drug problem in New Orleans, but serve nevertheless to show that about 50 percent of addicts of all ages, and including recently addicted young persons, can readily be recruited into methadone rehabilitation programs operated at economic rates in private, municipal, charity or community clinics. Each clinic is able to hold about 75 percent of its attending list with maintenance doses in the (median) range 60–110 mg. per day. A lower median (60 mg.) may suffice for the majority of young addicts but long-term addicts may require up to 280 mg. Even at this high dose, methadone is well tolerated for months on end.

Losses by dropout, including deaths, admission to hospital, recidivism, and disappearance, reduce the proportion remaining on the program to about 38 percent of the estimated addict population of the city. This proportion has largely abandoned the use of opiates, though not of other drugs nor alcohol, and has a greatly improved record of employment and social stability, and much less involvement in crime. A heroin addict in New Orleans who is "ripping and running" has to earn $30 to $150 per day to maintain his habit, since heroin costs on average $5 to $10 per bag, and support himself. Such sums cannot be earned legitimately by our addict population but an ex-addict on methadone, at $10 per week, can and usually does support himself and his new habit, which he is therefore reluctant to abandon if he has any appreciation for personal and social stability.

The dropout rate and methadone failure rate in New Orleans are high in comparison with some centers in New York and elsewhere. We have reason to believe that nonexpert supportive steps by community action personnel and peer groups would improve our performance at low cost. A way to secure greater administrative efficiency as well as to improve the quality of treatment and rehabilitation public funds on a much larger scale is urgently required. In this area, drug abuse has to compete with poverty, slums, unrest, and many other social problems for relief measures and appropriation, and also, in no small measure, with strongly polarized political and moralistic attitudes at all levels in the community. While these obstacles remain, it is encouraging and expedient to note that private enterprise and voluntarism can intervene effectively in the crisis of the contemporary epidemic of drug addiction in urban society, on a fairly large scale and yet at minimal cost.

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II. DOSAGE, DURATION, SIDE EFFECTS

BLIND CONTROLLED DOSAGE COMPARISONS WITH METHADONE IN 200 PATIENTS

Avram Goldstein, M.D.

The Santa Clara County methadone program is a research program authorized by the State of California Research Advisory Panel. This account is a summary of our experience in the first 8 months. One is sometimes asked how it happens that after 6 years of methadone maintenance we still have so many questions—and some of them quite fundamental—to answer. Let me point out in reply that favorable conditions for carrying out objective investigations in this area have only recently developed. Current changes in public attitudes toward heroin addiction and methadone maintenance are the direct consequence of the years of courageous pioneering by Vincent Dole and Marie Nyswander, against great odds. They showed that methadone works and that it can be used safely on a long-term basis. Now we need to apply the rigorous techniques of clinical pharmacologic experimentation to fill in the details, in order to optimize and standardize our methadone treatment procedures.

Our aim is to include all hard-core heroin addicts in our county of about a million population; we guess there are about 1,000. The criteria for admission are: (1) At least 2 years of addiction; (2) at least one attempt to withdraw, with subsequent relapse; (3) age at least 18; (4) residence in the county for at least 1 year. All addicts who met these criteria, without exception, were accepted, in the order in which they presented themselves. Neither psychosis nor alcoholism nor multiple drug abuse were grounds for exclusion, and no subjective prejudgments about the likelihood of success were allowed to affect an addict's admission or his subsequent treatment. Consequently, the outcomes reported here can be taken to apply to unselected heroin addicts voluntarily enrolling in a methadone program.

This report concerns the first 8 months of operation, during which 206 patients were admitted. Of these, 44 (21 percent) were women. The ethnic composition was: Mexican-American 55 percent, Black 6 percent, White 39 percent.

An important aim was to ascertain if good results could be obtained without extensive ancillary services, and thus to see how economically a successful methadone program might be operated. This approach, and the program policies, follow logically from our attitude toward heroin addiction. Whatever motivations may have led a person initially to the use of heroin, we postulate that the chief problem in the hard-core addict is heroin itself—that most of his difficulties are the result of heroin use, rather than the other way around. It follows that our primary aim is to stop heroin use. When this has been accomplished, we expect most patients to be able to proceed along the road to rehabilitation with such pragmatic counseling as seems appropriate, but without formal psychiatric interventions. Our program is structured accordingly. Patients in need of medical, dental, or psychiatric services are referred elsewhere for appropriate treatment. We estimate that some 10 percent of our patients require special psychiatric help; whether a matched group of nonaddicts would be different in this respect we do not know.

A clinic handling 200 patients is staffed by two psychiatric nurses, three addiction specialists aides (two male, one female), one vocational counsellor, and a clerk-typist. The addiction specialist aide is usually an ex-addict (often a stabilized patient on our own program) who acts as first-line liaison with the patients and their communities, supervises urine collection, and carries on a great deal of the day-to-day activity of the program. A Patient Council, elected from among the stabilized patients who have ceased narcotic use, is entrusted with responsibility in the area of discipline (e.g., infraction of rules, absences), public relations, and community drug abuse education. Stabilized patients lead group discussions with newer or less successful patients. We are establishing a demo-

cratic rather than an authoritarian mode of operation, in order to develop each patient's potential for responsible involvement in the welfare of others. Program policies (except for strictly medical ones) are discussed and modified, and new staff are interviewed and selected with participation of the stabilized patients.

Central supervision over the several methadone clinics in the county is provided by a medical director (who is a physician), a supervising psychiatric nurse, a supervising addiction specialist, and a supervising rehabilitation (vocational) counsellor. The total costs of such a program, embracing five clinics with 200 patients each, are estimated to be about $10 per week per addict.

To understand the successes and failures of any methadone program it is probably important to consider its "style," since so many different approaches are possible. Our program is built on a medical model of heroin addiction. Addicts come to us because they wish to be rid of their disease—a chronic relapsing disorder of uncertain etiology, characterized by compulsive use of a narcotic. Methadone can help them accomplish this by freeing them of the craving (narcotic drug hunger) and by making them crosstolerant ("blockade") to heroin, thereby diminishing the rewarding aspects of a "fix." From the first contact with the addict we assume a sympathetic and nonpunitive attitude toward heroin use. We establish a gradual ambulatory transition from heroin use to nonuse. Accepting in a matter-of-fact way that patients are using heroin when they start, we simply assure them that as the methadone dose increases, their use of heroin will decrease and eventually cease. We ask to be told frankly when and how much a patient has "fixed" so that we can follow his progress and help him more effectively. If a patient continues using heroin we regard this as a treatment failure and seek to understand why, patiently avoiding punishment or threats of discharge from the program.

As a patient "cleans up" and his urine test results become consistently negative, he is allowed to attend clinic less frequently, on a graduated schedule, so that after 3 "clean" months he visits clinic only once weekly.

Behavior that endangers the program (e.g., selling or giving away methadone, using the clinic to deal in illicit drugs, violence or threats of violence against patients or staff) is cause for discharge, but no one has been discharged yet. The Patient Council deals with such cases, and with the problem of flagrantly irregular attendance.

Although our basic attitude is nonpunitive, the program is not permissive. Certain rules are adhered to strictly, and staff is ever mindful of the fact that "coming" is a perfected element in the addict's lifestyle, indeed, is a component of the disease we are trying to treat. Examples of rules that are enforced to the letter are those concerning urine collection (see below), clinic hours (doors close at the specified time), and "take-home" methadone (none leaves the clinic except in a locked box).

Since a major objective was to secure information about methadone dosages, a blind design was absolutely essential. Dosage is never revealed to patients and is never discussed with patients. We discuss a patient's health, his physical and mental symptoms, and his heroin use, but never his methadone dose. Research on dosage would otherwise be impossible. We believe, however, that quite apart from this necessity, there are good reasons to conduct a program in this way. First, there is no "dose negotiation," and the methadone clinic is not seen as a "connection." The "dose game" is an integral part of the addict's lifestyle, which we wish to help him change. Second, as detailed below, symptoms are often unrelated to dosage. The situation in which a patient and a physician (or nurse) try to arrive at a new dose on the basis of symptom complaints is the epitome of "double-blind" design, i.e., the blind leading the blind. Only when we learn, through rigorously designed dosage comparison experiments, what the effects really are upon various symptoms will it be possible to make rational decisions about dosage.

EXPERIMENTAL DESIGN AND MEASUREMENT CRITERIA

A. *Urine testing.*—The only objective valid way to assess heroin use is to test urine collected under the strictest kind of direct observation. It is not necessary to test urine daily, and pooling of several urine samples is fundamentally incorrect because it reduces the sensitivity of detection. We test randomly at an average frequency of 1 day in 5. A set of patient I.D. numbers is generated by computer and posted daily. If a patient's number is on the list, he is required to produce a sample under direct observation that day or the result will be entered as an "automatic dirty;" there are no exceptions to this rule. The urine samples are analyzed by TLC and GLC (if necessary) for all narcotics, and periodic tests for barbiturates and amphetamines are also done. The statistical basis for random urine sampling is published elsewhere (A. Goldstein and B. W. Brown, J.A.M.A. 214: 311, 1970).

We are presently field-testing a narcotic detection system based upon an entirely new principle, employing free-radical technology.[1] The method requires no chemical manipulations whatsoever. A drop of urine is added to a small tube containing reagents. This is placed immediately in a specially adapted electron spin resonance (ESR) spectrometer, and read instantaneously as positive or negative for morphine or other narcotics. We believe the instantaneous feedback provided by such a device will greatly enhance the value of urine testing in methadone programs. The cost will apparently be no greater than that of the current procedure.

B. *Progress questionnaire.*—A 30-item checklist concerning body symptoms, mood, employment, illegal activities, and heroin use is administered just before entry onto the program, then again 2 weeks later, and at 1, 2, 3, 6, 12, 18, and 24 months. The patient marks his responses directly on an IBM Port-A-Punch card. A clerk later punches out the marked positions with a stylus, and the cards are entered directly into the computer. This procedure eliminates the need for a keypunch operator and precludes transcription errors. The administration of the questionnaire before methadone treatment begins has proved to be extremely important, for (as seen below) many symptoms experienced on methadone and considered to be methadone side effects are present even more prominently before the addict starts on the program.

C. *Assignment to dosage groups.*—It is axiomatic in clinical pharmacology that no dosage comparison can be meaningful unless patients are randomly and concurrently assigned to the dosage groups. We proved this very well, though inadvertently. In order to gain experience and confidence with the use of methadone before initiating comparison studies, we placed our first 35 patients on the same stabilization dose—100 mg. (All doses are given in terms of methadone hydrochloride.) Subsequently, random concurrent assignments were made. On every criterion of success, the first patients did better than any subsequently admitted. If one had compared them with later groups placed on lower doses one would have concluded unequivocally (but incorrectly) that the 100 mg. dose is vastly superior in all respects. Retrospective analysis of input data showed that the first patients to enter the program were older, had more stable lifestyles, and had longer histories of addiction than those entering later. Since they were at the head of the waiting list, they were presumably better motivated. All dose comparisons presented here are based upon patients assigned randomly and concurrently at the time of admission. Women and men were assigned separately, so the sex ratio was the same in all groups.

The most difficult part of conducting dosage comparisons is to resist pressures to alter dosage prematurely. In the experiments reported here we planned to make no changes until 3 months had elapsed, then to terminate the experiment and adjust doses according to our "best judgment." It is tempting to think that complaints have their roots in too-low or too-high dosage and to intervene accordingly. One feels that this is the ethical thing to do, since one obviously wants to put the patient's welfare first. But do we know what is best for the patient? If we did, there would be no point in conducting these experiments at all. The truth is that there is no reliable guide that would permit rational dose changes to be made in the knowledge that they would probably be effective. On the basis of our experience we feel that for the present the best thing for the individual patient as well as for methadone patients in general is to conduct experiments in rigorous adherence to the protocols, and forego interventions based upon "intuition." Despite our best intentions we sometimes yielded to our own prejudices, but for the most part we resisted. We were rewarded frequently by seeing symptoms disappear despite our making no dose change whatsoever, and we were often embarassed on such occasions to be thanked profusely for increasing (or decreasing) the methadone dose.

RESULTS

Results Irrespective of Dosage

After 33 weeks of operation, 206 patients had been admitted, for a total of 3,573 patient-weeks of experience. Twenty-nine patients (14 percent) had left the program involuntarily; most had been incarcerated for crimes committed prior to entering the program, a few had left the area to escape outstanding warrants or because their role as police informers had become known. The pattern we are observing is that all who are sent to jail reenter the program later, either upon their release, or through a work-furlough arrangement with the sheriff's department. Five patients (2 percent) left voluntarily, usually to move to another area; and two patients were officially transferred to methadone programs elsewhere. None were dropped from the program by staff action. At this particular time, therefore, we had 170 active patients, or 83 percent of the number admitted (excluding the official transfers).

[1] Free Radical Assay Technique (FRAT) developed by Syva Corp. (Synvar Associates), 3221 Porter Drive, Palo Alto, Calif. 94304, from whom further information may be obtained.

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A better measure of adherence to the program is a survivorship analysis at a given number of weeks after entry. The number of patients admitted 6 months or more prior to the date of this analysis was 58. Of these, 76 percent were currently active 6 months after their admission date, and 71 percent had not had a single interruption. Since the inactive 24 percent were mostly in jail and would reenter, it is evident that the true survivorship in this program is very high, at least for the first 6 months.

Of the 48 active patients with tenure of 6 months or longer in the program, 88 percent had stopped using heroin. This statement means that they had achieved a record of consistently negative ("clean") urines over a period covering at least the previous 4 weeks.

Heroin use drops very abruptly within the first 2 weeks on our program, to less than 10 percent of its initial value. Then a slower decline continues for a period of approximately 3 months. The majority of patients at that time have ceased using heroin entirely, and the majority of the remainder use only small amounts sporadically. A few continue a low level of daily use, although very much less than before they entered the program.

All the results cited above are influenced by the predominance of better-motivated, older, and more stable patients among the early admissions to the program, as discussed earlier. We may well see less favorable results as time goes on and patients admitted later enter the survivorship calculations.

Uniform Dosage

In 93 patients an absolutely uniform procedure was employed. The purpose was to ascertain the feasibility of a uniform dosage schedule, for this would greatly simplify the conduct of large-scale methadone programs. The procedure was ambulatory throughout. Methadone hydrochloride was diluted in Kool-Aid, sweetened with sugar, and given once daily in the morning. The starting dose was 30 mg., increased by 10 mg. daily, to a stabilization dose of 100 mg., reached on the eighth day. In only a single patient was it necessary to deviate from this plan, because of repeated vomiting of the medication; eventually she tolerated a slower buildup schedule, but other measures (milk, quiet rest) were also employed, so she might have tolerated the original schedule too.

The extent of drowsiness during the buildup period convinced us that a slower incrementation would be desirable. We therefore adopted a uniform buildup exactly one-half as fast, repeating each dose on 2 successive days, and taking 15 days to reach 100 mg. We have used this modified schedule in 13 patients from the start, and in 36 patients raised from 30 mg. or 50 mg. after their 13th week. Only mild drowsiness was encountered.

The point of all this is that with respect to both rate of buildup and stabilization dose it is possible to treat virtually all patients in exactly the same way. The rationale is well grounded in the pharmacology of methadone. The early studies at Lexington showed that patients could be made tolerant to at least 200 mg. daily (H. Isbell et al., Arch. Int. Med. 82:362, 1948). Whatever arbitrary does is chosen, therefore, the body should become tolerant to that particular dose. Provided the rate of incrementation does not exceed the capacity of the physiologic mechanisms to adapt, any arbitrary rate of incrementation should be possible. From our standpoint, the faster we break the pattern of regular heroin use without inducing disabling side effects, the better. Therefore, we conclude that to stabilize patients at 100 mg., the 15-day buildup is optimal.

We are aware that our colleagues directing other methadone programs have arrived at "individualized" doses for different patients. The question is whether or not these patients would do just as well on a uniform adequate dose. We had an opportunity to test this in another program that offered to coperate. Stabilization doses in effect in the program at Woodville, Tulare County, Calif., ranged from 80 mg. to 150 mg. daily in approximately 45 patients. Gradual blind adjustments up or down toward 100 mg. were instituted, at the rate of 10 mg. weekly. Eventually all the patients were stabilized at 100 mg. When complaints occurred they were unrelated to the dose manipulation. There appear to be cyclic fluctuations in body symptoms (especially those related to autonomic dysfunction) on a time course of days to weeks, even on constant dosage.

The choice of stabilization dose, according to our pharmacologic model, need not be determined by individual needs of different patients. If side effects do not interfere, it should be desirable, in principle, to choose an arbitrary high dose rather than an arbitrary low dose. There are two reasons for this. First, there is presumably some low dose that represents the threshold for suppression (satisfaction) of the craving for narcotics. We expect this threshold to vary from patient to patient and possible temporarily within a single patient, just as thresholds for efficacy of most drugs vary in the population. We must exceed the threshold by a safe margin to avoid treating some of the population with inadequate doses. Second, if the cross-tolerance ("blockade") plays a role in extinguishing the heroin-use behavior pattern, it is desirable to establish a sufficiently high level of tolerance, i.e., to force adaptation to a dose several times higher than threshold.

Dosage Comparisons

It remains to consider what daily dosage is optimal. We have compared single doses of 30 mg. (20 patients), 50 mg. (80 patients), and 100 mg. (106 patients). Data presented here relate to patients' first 3 months on the program. As measured by urine test results or by questionnaire data, we find a more rapid suppression of heroin use with 100 mg. than with lower doses, but the results in all three groups tend to converge after the first month. There was little difference between the doses by the third month, although what marginal differences there were favored the 100 mg. group There was also no evident influence of dose upon absenteeism, dropout rate, or the number of arrests.

The study of "side effects" yielded some surprises. We programed the computer to carry out a longitudinal analysis for each patient, comparing his response to a given questionnaire item after a particular time on the program with his response to that same item just before entering the program. These individual comparisons were then summated for each dose group, and subjected to statistical analysis.

Almost without exception the body symptoms complained of on methadone were present prior to starting on the program, when the patient was using heroin. Most of these improved on methadone, so that despite the natural tendency to blame all troubles on the drug one happens to be taking, it is difficult to classify them as side effects. Indeed, some of the most prominent ones are clearly withdrawal effects rather than side effects, for their frequency and severity are inversely related to methadone dosage, and they occur principally in the evening, 8 hours or more after the daily dose. Symptoms that fall into this category comprise the constellation recognized by addicts as "feeling sick," including insomnia, nausea and vomiting, musclepains, and anorexia.

There were also dose-related side effects. Dermatitis, constipation, impotence, difficulty achieving orgasm, and feeling "loaded" on methadone were the prominent ones. They all tended to improve after the first month, but constipation and the sexual dysfunctions persisted in a small fraction of patients. Drowsiness was troublesome during the first month; surprisingly, there was no difference between 50 mg. and 100 mg. although the 30 mg. dose was significantly better. In any case, severe drowsiness disappeared by the second month.

As compared with the status before methadone, many symptoms showed improvement, but without significant dose relationship. Examples of these are headache, joint pains, hiccups, diarrhea, loss of libido, nervousness, running nose, trouble urinating, and unhappiness. Also unrelated to dose were dramatic reductions in the frequency of theft, and the amounts expended for heroin. Suppression of craving for heroin and reduction in heroin use were achieved faster at the higher doses, but by the third month the doses were virtually indistinguishable in these respects.

Excessive sweating was a very common complaint but difficult to classify. It was present to some degree in three-fourths of the patients before methadone, and in moderate or severe form in 10 to 15 percent. By the third month it had become worse in 42 percent of the patients and better in about 30 percent, remaining unchanged in the remainder. There was no dose relationship.

A common and perplexing problem was numbness, tingling, and stiffness of the fingers, sometimes accompanied by pains radiating down the arms. This was present in one-fifth of the patients before methadone. Some improved on methadone, some first developed this symptom on methadone. The frequency of the complaint fluctuated with time, but never exceeded 30 percent. There was no dose relationship.

It is sometimes said that depriving an addict of the heroin "highs" to which he is accustomed must lead him to seek alternative sources of drug-induced satisfaction. Our findings lead us to conclude that this is a myth born of a distorted view of the heroin addict's motivation. Regardless of dose, excessive use of alcohol remained unchanged as compared with premethadone use (about 20 percent of patients), as did the use of amphetamines (5 to 10 percent) and marihuana (about 45 percent). Use of barbiturates, initially 20 percent, declined to 6 percent. Finally, the fraction of the patient group that before methadone abused no drugs other than heroin (about 30 percent) did not change during 3 months on methadone.

The most surprising outcome of our investigation thus far is the lack of major differences in the effects of methadone dosage between 30 mg. and 100 mg. daily. Clearly, a motivated addict can and will give up heroin even on a dose as low as 30 mg. However, there are advantages of the higher doses that seem important to us. The 100 mg. daily dose suppresses heroin craving and heroin use faster than the lower doses, and there are fewer adverse symptoms of the withdrawal type. On the other hand, it does produce certain uncomfortable side effects in a greater fraction of patients and at greater severity than do the

lower doses; and whereas most of these wane after the first few weeks, some persist. Finally, the 100 mg. dose presumably yields a higher level of cross-tolerance (heroin "blockade"). It is too early to conclude definitively that a particular dose is optimal for most or all patients. That conclusion, when it comes, will be based upon the traditional cost-benefit analysis that one makes for any drug. Of no relevance here is the moralistic concept that because methadone is a narcotic, the less we give the better.

Duration of Action of Methadone

The principal complaints, at all dosages, were those identified as withdrawal effects (see above). Usually the patient lumps them together in the phrase "The methadone doesn't hold me," meaning that withdrawal symptoms come on during the late afternoon and evening. Individual variation was very striking. Some patients had no such complaints ever. Others had these complaints at all doses we tried, although (as shown earlier) their frequency was lower at the higher doses. For patients in this category, upward dosage adjustment did not seem to be very effective; for example, in a given patient the problem may be just as troublesome after stabilization at 150 mg. as it was previously at 100 mg. or even at 50 mg. We are still carrying out experiments and gathering data on this point, but our tentative interpretation is as follows:

In the tolerant-dependent state, the total number of narcotic recaptor sites in brain is assumed to be increased, but the number of unoccupied sites is normal (A. Goldstein and D. B. Goldstein, Proc. Ass. Res. Nerv. Ment. Dis. 46: 265:, 1968). Withdrawal symptoms result from a decrease in narcotic concentration, exposing the excess of receptor sites faster than their number can be reduced by biochemical regulatory processes. If the time course of decline of methadone concentration is slow enough, no significant withdrawal phenomena will ensue before the next day's dose supervenes. Thus a steady state is maintained with but silght fluctuation. If, on the contrary, methadone is more rapidly metabolized or eliminated in a particular patient, withdrawal effects will be felt within the 24-hour period. In such a patient, regardless of the stabilization dose to which he has become tolerant, withdrawal effects will be manifested as the methadone concentration falls from its peak at midday to a much lower level at night. Direct measurements of methadone plasma levels are urgently needed to verify or falsify this hypothesis. We are proposing simply that in many people methadone is not as long-acting as has been supposed. If our speculation is correct, the solution to the problem is either to employ a longer-acting narcotic (perhaps acetylmethadol) on a daily basis, or to divide the methadone dose. On the basis of our findings we split the dose of 110 patients so that the same daily dose was taken in two equal parts, morning and evening. The preliminary outcome of this experiment was promising, 62 percent asserting a definite improvement—the methadone was found to "hold" better. Since in our experience, continuous or sporadic heroin use virtually always occurs in the evening, it is possible that split dosage may also contribute to solving the problem of the refractory heroin user.

CONCLUSIONS

I summarize here our tentative and preliminary results based on data obtained in various studies on patients who have been in our program from 3 to 6 months.

1. Good results are being obtained with unselected addicts in an economically operated program the total costs of which approximate $10 per week per patient. Our primary aim is to stop heroin use and find patients employment. Psychotherapeutic services, if needed, are obtained by referral.

2. A random urine testing system is described, as well as the use of symptom questionnaires readily adapted to computer analysis.

3. Dosage studies require randomized concurrent assignments to the dosage groups, patients must not know their dosages, and baseline data must be obtained before starting methadone. Many "side effects" were found to be at higher frequency and greater severity before methadone than later.

4. Symptoms come and go even on constant dosage. One should be restrained in attempting to deal with complaints by manipulating dosage until the effects of different doses have been more clearly defined.

5. Virtually all patients can be built up to a uniform stabilization dose without regard for individual differences. Our most successful method is to begin ambulatory induction at 30 mg. once daily and increase by 10 mg. every second day, stabilizing at 100 mg. after 15 days.

6. Comparison of 30, 50, and 100 mg. daily doses revealed surprisingly few differences. The 100 mg. dose caused certain side effects more frequently and at greater severity than did lower doses. On the other hand, symptoms of the withdrawal type were less frequent, and suppression of heroin craving and heroin use was faster than at lower doses. Heroin use, however, declined very sharply in all dose groups, with little difference between the doses after the first few weeks. There was no dose effect upon attendance or dropout rate.

7. Contrary to what is often said, we found no change in the use of alcohol, amphetamines, or marihuana, and a sharp decline in the use of barbiturates, as compared with the premethadone data.

8. In many patients the duration of action of methadone appears to be too short, causing withdrawal symptoms in the evening. We were able largely to alleviate this problem by splitting the dose. If a longer-acting narcotic than methadone became available, it should be tried on a daily basis to see if a smoother action with less fluctuation can be obtained.

ACKNOWLEDGEMENTS

I am indebted to the program staff—Elaine Kiviniemi, Marianne Morgan, Robinetta Wheeler, Cecilia Holland, Serapio Ortiz, and Jose Espinosa—and also to Robert Campos and David Hahn for their conscientious cooperation in all aspects of this research. Computer programing was skillfully and generously furnished by David Cummings and Joshua Goldstein. Valerie Cunningham's help was virtually indispensable. Certain relevant aspects of this investigation were supported in part by research grant MH 13963 from the National Institute of Mental Health.

METHADONE MAINTENANCE: VARIATION IN OUTCOME CRITERIA AS A FUNCTION OF DOSE

Jerome H. Jaffe, M.D.

The data presented here are taken from a series of studies that are being conducted as part of the Illinois drug abuse programs (IDAP). It is important to emphasize that some of the findings may be a direct outcome of the somewhat unusual context in which the studies are conducted. Essentially, the IDAP has attempted to create a multimodality treatment system for narcotics users that would permit patients to avail themselves (within a single administrative framework) of a number of distinct approaches to social rehabilitation. Long-term maintenance on methadone was only one of a number of available alternative pathways: others included residence in a totally drug-free therapeutic community, the use of narcotic antagonists, residence in a therapeutic community where methadone could be continued or discontinued, and withdrawal from drugs followed by outpatient or half-way house care. The availability of such alternatives has major advantages for program development, but also creates problems that may not be encountered in programs utilizing only methadone maintenance. Both the advantages and the problems are discussed in detail below.

There are several reasons (both practical and theoretical) for our interest in the role of dosage in treatment with methadone. In the original studies with methadone (Dole and Nyswander, 1965; Dole, et al., 1968) patients were stabilized on 80 to 120 mg. of methadone per day. Such doses seemed to produce two distinct effects: a reduction or elimination of a vague sense of abnormality, and a high degree of cross-tolerance to opioid drugs that has been called "narcotic blockade." Theoretically, both of these actions could be essential in bringing about the changed behavior and social rehabilitation that were observed. On the other hand, it was not entirely unreasonable to wonder if one action, i.e., reduction of the felt sent of abnormality, might not be more significant than the cross-tolerance induced "blockade." Work with cyclazocine—a narcotic antagonist capable of producing significant blockade (albeit by an entirely distinct mechanism), but no reduction in narcotics hunger—caused me to suspect that the alleviation of hunger might indeed be the more significant of the two actions of high doses of methadone (see Jaffe, 1967, 1968).

One way to test this notion would be with lower doses of methadone. Theoretically, it might be possible to maintain patients at lower doses where, although they might not experience narcotic hunger, they would not be sufficiently tolerant to be unable to feel the effects of intravenous heroin should they elect to use it.

A finding that some patients do not require "blocking" doses of methadone, but merely a reduction or alleviation of "narcotics hunger" could, in turn, be useful in determining the nature of this postulated state of abnormality. Such a finding could also be of some very practical significance if it should also turn out that patients can be maintained on low "nonblocking" doses and that such patients find it easier to withdraw from methadone entirely once some satisfactory level of so-

cial stability has been achieved. On the other hand, Perkins and Bloch (1970) recently reported that patients at Beth Israel who were maintained on doses above 140 mg. per day tended to show fewer dropouts from treatment than those maintained at lower doses.

Last year, at the Second Methadone Conference, I presented data from a study in which approximately 60 patients assigned to a single methadone outpatient unit had been randomly assigned to two groups: high dose methadone (where 94 percent of patients reached a dose of 100 mg. by the 14th week of treatment), and a low-dose group maintained on an average of 40 mg. during the entire study. This group was followed each week with respect to rates of employment, urine test results, arrests, discharge and dropout rates. Patients were eligible for this treatment if they had used heroin for more than 2 years: there was no other screening, stabilization on methadone was entirely ambulatory. The rationale for these admission criteria and the ambulatory stabilization techniques have been presented elsewhere (Jaffe, et al., 1969).

The data presented for the first 17 weeks showed that the differences between the high-dose and low-dose groups were not dramatic. A slightly higher percentage of the high-dose group remained continuously as outpatients in treatment and they tended to have fewer urine specimens positive for morphine. The difference in the number of positive urine specimens was statistically significant for a number of weeks—from the 10th to the 24th week of treatment. There was no significant difference in the number of patients who became abstinent over the first 24 weeks. However, in confirmation of our previous observations (Jaffe, et al., 1969), patients treated with methadone in this context did not not lose their motivation to become abstinent and several were able to withdraw from methadone entirely without relapse to heroin use. The followup period after withdrawal ranged from several weeks to several months. From our point of view, the most important result of this early study was the high attrition rate from both high and low-dose groups. By the 14th week, 40 percent of the patients were no longer in continuous outpatient treatment. By the 24th week, both groups had fewer than 50 percent of the original patients in treatment. Those who remained, however, seemed to be doing quite well, for by the ninth week, 90 percent of the patients in both groups had at least one urine specimen negative for morphine, and employment was over 60 percent among the males.

Examinations of the operations of the specific unit to which all of these patients were assigned revealed a great deal of confrontation between staff and patients over the issue of continued drug use or failure to seek employment. Furthermore, patients in the low-dose group often had difficulty in convincing the staff to increase their methadone dosage. In any event, the unexpectedly high attrition rate reduced the numbers in each group to a level that made statistical analysis difficult.

As director of the program, I must assume the responsibility for this degree of confrontation even though the zeal with which it was applied exceded both my expectations and preferences. The considerations that enter into the formulation of operating policies are complex and vary from community to community and from time to time within a given community. In our situation, treatment with methadone was viewed with considerable skepticism by law enforcement officials and others with a vested interest in more abstinence-oriented approaches. We were concerned, therefore, that patients participating in our programs "make a good showing" and that the treatment concept would not be jeopardized by any publicity that could arise from serious crimes committed by patients being treated with methadone. On the other hand, we were ourselves committed to the idea of diagnosing the needs of the greater Chicago area by using a policy of nonselection (any bona fide heroin user of more than 2 years' duration was eligible) and of a totally ambulatory stabilization procedure.

This dilemma was resolved by the clinicians (some of whom were ex-addicts themselves) who waited only a week or two after an individual entered treatment before conveying their strong sense of expectation that the new patient would conform to the unit norm by ceasing drug use, excessive alcohol use, and find legitimate employment. This had the effect of extruding from the "intreatment" group those patients most likely to commit crimes while in treatment and thus open the entire program to criticism at a vulnerable stage of its evolution.

The shape of the attrition curve forced us to conclude that a high percentage of unselected patients with an average of 14 years of heroin addiction, most of whom have not been employed, find it easier to return to "the street" than to continue to be subjected to such demands for conformity. A number of procedures were instituted to reduce the degree of zeal, one of which was a deliberate delay in returning urine test results to the clinic. Although the patients who remained in treatment did extremely well with respect to arrest rates, drug use, and employment, ultimately, it became necessary to change the personnel in the unit in order to change the shape of the attrition curve.

The data I will now present comes from a study which attempted to replicate the previous design. It was started about 6 months after the completion of the first study. It may be that the group studied here was less well motivated than the group studied earlier. All patients entering any one of three geographically distinct methadone treatment units over a 7-week period, from October 6, 1969 to November 24, 1969, were assigned to high- or low-dose groups on the basis of whether they had an odd or even program identification number. A total of 126 patients entered the study. As shown in table I, there were no significant differences between these groups along a number of parameters including self-reported arrest rates.

Table 1.—BACKGROUND INFORMATION OF ADDICTS GIVEN CROSS TOLERANCE DOSES (HIGH DOSE) AND SELF-DEMAND DOSES (LOW DOSE) OF METHADONE

	High Dose(N=50)	Low Dose(N=76)	Statistics
Sex:			
Female	12.0%	22.4%	x^2=2.17 NS
Male	88.0%	77.6%	
Mean age	36.2 years	35.2 years	t=.67 NS
Race:			
White	18.0%	27.6%	x^2=1.54 NS
Nonwhite	82.0%	72.4%	
Marital status:			
Single	46.0%	43.4%	x^2=.05 NS
Nonsingle	54.0%	55.3%	
Mean years of education	11.3 yrs.	10.8 yrs. (N=75)	t=1.49 NS
Mean years of addiction	14.7 yrs.	14.1 yrs.	t=.48 NS
Mean arrests/free man-weeks for the 2-year period prior to initial contact.	0.028 (N=44)	0.026 (N=67)	t=1.22 NS
Arrests per 100 man years	145.60	135.20	

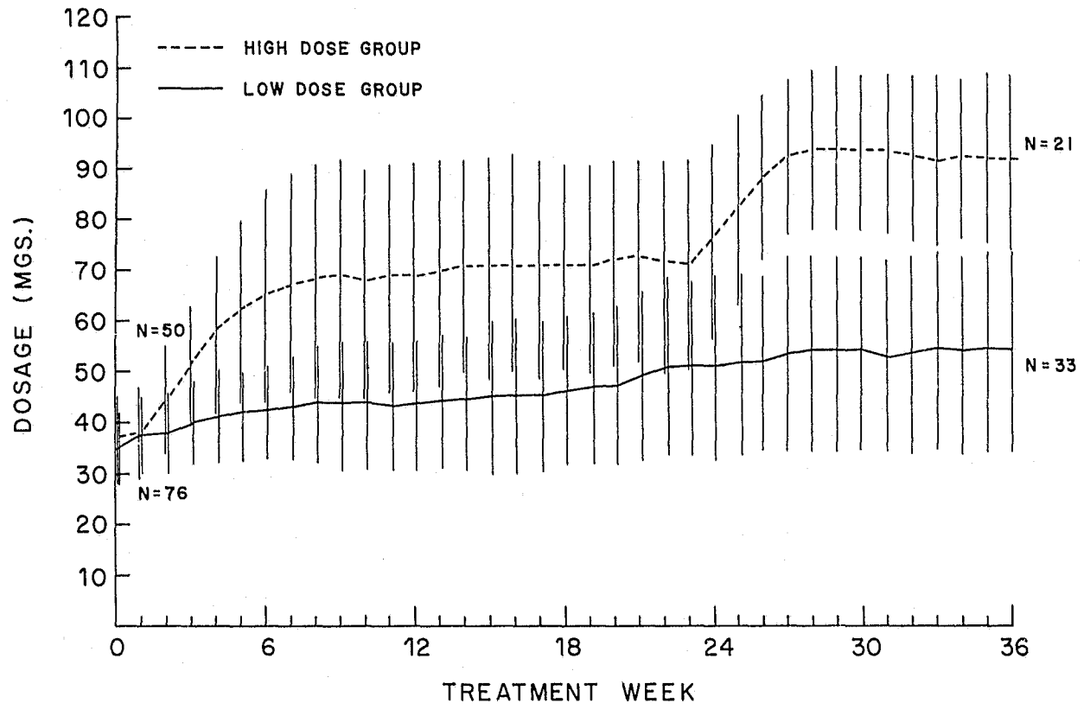
The daily dose of the high-dose group was supposed to have been increased by 10 mg. each week until a 100 mg. dose was reached. The low-dose group was started on an average of 35 mg. and was to have been given increases as requested by the patient or as thought appropriate by the staff of the unit. Three different physicians were involved in dosage adjustment. Patients were not aware of their own dosage. For the high-dose group, the orders for increments were made at the pharmacy by a member of the research staff. If the prescribing physician complained that the patient was too sedated, the dose was lowered. Thus, the final dosage for the high-dose group was based on a negotiation between research staff and prescribing physicians. Through an error, increases in dosage for the high-dose group did not take place for a number of weeks. The general picture of the difference in dose between the two groups is shown in figure 1. It is also apparent that the variation of actual dosage for each group was considerable. Our impression was that the staff had become quite concerned about the attrition rate of the previous study which had gradually become known over the period of the second study, and were more likely to increase the dose for low-dosage patients than they were the previous year.

Figure 2 shows the dropout and discharge rate over the first 36 weeks of the study for all three units. The curve for patients continuously in outpatient treatment is virtually flat between the 24th to 36th weeks with about 45 percent of patients remaining continuously on methadone in an ambulatory outpatient status. However, by the 36th week there is virtually no difference at all between the high- and low-dosage groups with respect to the percentage remaining continuously in treatment as outpatients.

The broken line indicates the percentage of patients still somewhere in the treatment system and in treatment continuously although they did not remain continuously as ambulatory outpatients. Using this criterion it appears that between the 10th and the 32d week there is a higher percentage of high dosage patients remaining in some form of treatment.

Figure 3 shows changes in employment for the two dosage groups. It is apparent that there is a change in the reported employment rates from about 45 percent to about 68 percent. However, given the dropout rate this might merely represent a dropout of the unemployed patients. The results, therefore, were reanalyzed to ask how many low- and high-dose patients employed at the beginning of the study obtained and retained employment at various times during the study. This analysis revealed that while 68 percent of both groups who remained in treatment were employed at the 36th week, the gains made by the higher dose group were greater than that for the lower dose group. Those remaining in the low-dose group had claimed a 54.5 percent pretreatment employment rate, while the high-dose group had claimed a 42.8 percent pretreatment employment rate.

In contrast to the first study where the high-dosage group had slightly more patients with all negative urine specimens, there were no obvious differences within the present study between the groups with respect to the percentage of patients using narcotics as measured by urine specimens positive for morphine. As shown in figure 4, by the 18th week at least 70 percent of patients in both groups had all available urine specimens negative for morphine. In most instances at least three urine specimens were to be collected from each patient each week. The lower curves show the results of the urine specimens analyzed according to a different and much more stringent criterion—it shows the percentage of patients with all (of three) specimens negative for morphine with any missing specimen counted as a presumed positive.

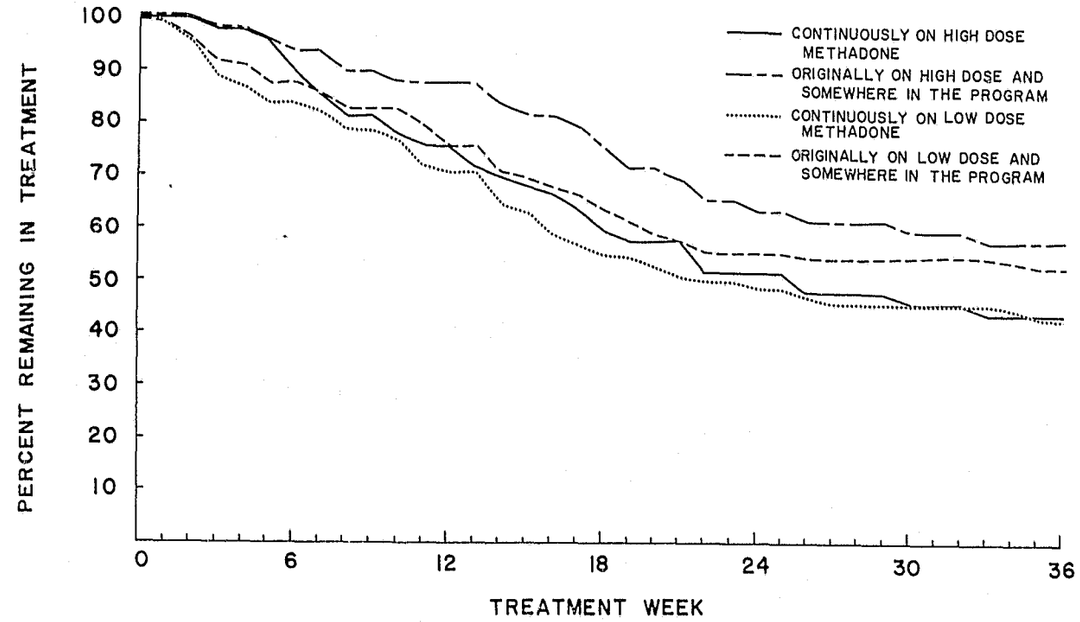


THE MEAN METHADONE DOSAGE LEVEL AND ± 1 STANDARD DEVIATION FOR PATIENTS STILL IN CONTINUOUS TREATMENT DURING A GIVEN WEEK IN THE METHADONE OUT-PATIENT PROGRAM.

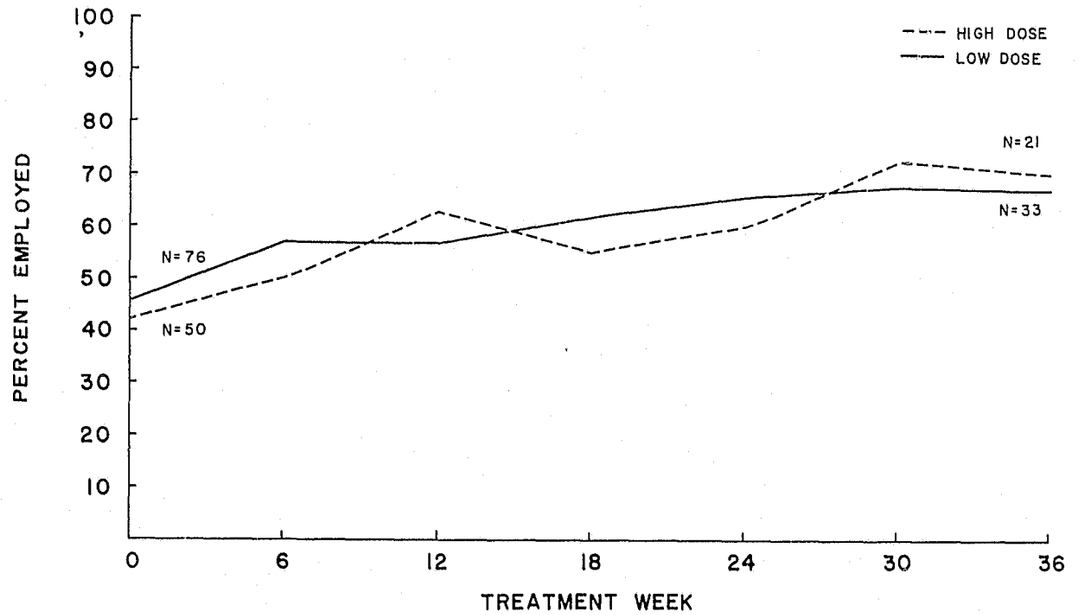
The fluctuations seen in the percentage of positive specimens are hard to explain on the basis of changes in laboratory procedures or failures by any given unit to collect three specimens. The data do not represent results coming from the lab during a given week, but rather, results obtained during different weeks corresponding to time in treatment for the patients. It may be that more high-dose patients had earned the privilege of coming to the clinic only two times a week, and that the assumption that a missing urine specimen would be positive is entirely without foundation.

As far as we can tell from the self-reports of patients, there is no significant difference between the two groups with respect to arrest rates. In the low-dose group there were 18 self-reported arrests; in the high-dose group there were 15. In addition, the arrest rates per free man week did not seem to show any dramatic decrease over the base expectancy rate. Viewed more optimistically, however, most patients did reasonably well over the 36-week period. Of those who remained continuously as outpatients 78 percent of the low-dose group and 71 percent of the high-dose group reported no arrests at all during this period. If we eliminated arrests occurring during the first 3 weeks of ambulatory treatment, the figures are even more encouraging with 85 percent of the low-dose group and 76 percent of the high-dose group remaining arrest free over the remainder of the observation period. It should be emphasized that an arrest includes arrests for loitering as well as for traffic offsenses. It is evident that a more detailed analysis of the type of offense will be required, as well as a verification of these data by inspection of arrest records, before any final conclusions can be drawn.

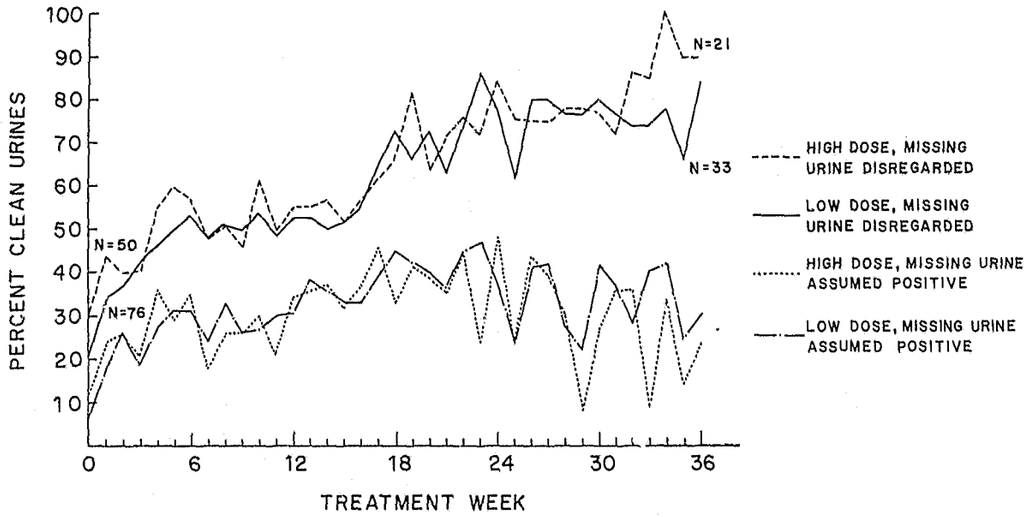
Figure 5 shows that in a complex system it is difficult to describe outcome in simple terms. It can be seen that by the 36th week approximately 70 percent of patients are somewhere in the treatment system for the high-dose group and 60 percent of patients are in the system in the low-dose group. Some of these patients have elected to be withdrawn from methadone. But as the figure shows, the percentage in each group is not dramatic nor



THE PERCENTAGE OF PERSONS WHO REMAINED EITHER CONTINUOUSLY IN THE HIGH DOSE AND LOW DOSE GROUPS OR TRANSFERRED INTO OTHER PARTS OF THE PROGRAM.



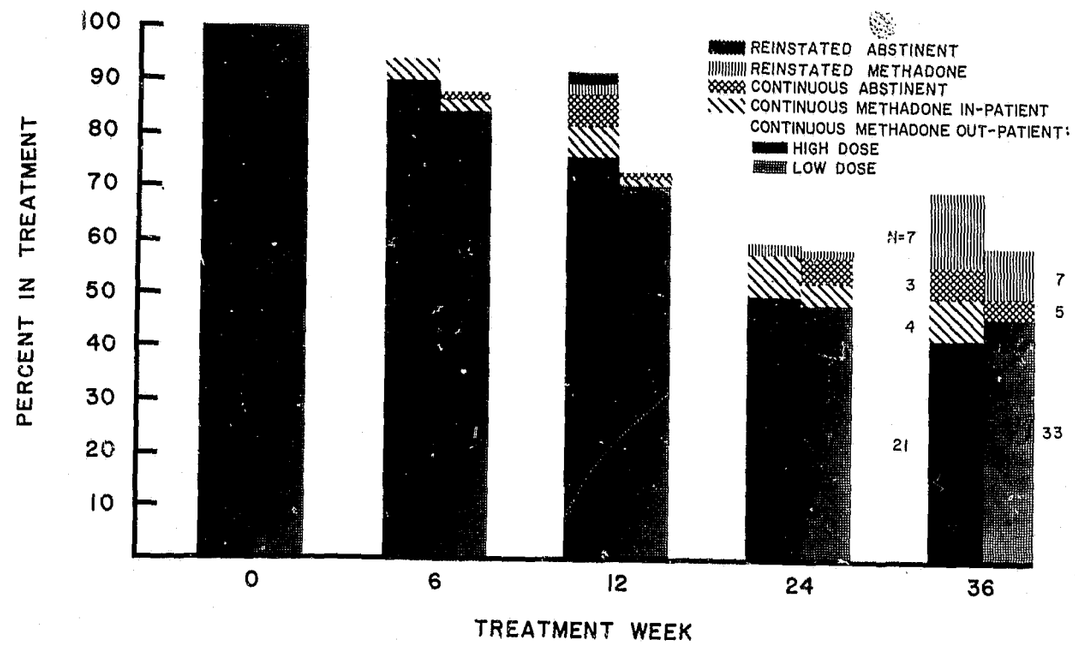
THE PERCENTAGE OF PERSONS WHO WERE EMPLOYED AND STILL IN CONTINUOUS TREATMENT DURING A GIVEN WEEK, AND WHO FILLED OUT A WEEKLY ACTIVITY SUMMARY FORM, IN THE METHADONE OUT-PATIENT PROGRAM.



THE PERCENTAGE OF PATIENTS FREE FROM MORPHINE IN THEIR URINES AT EACH TREATMENT WEEK FOR THOSE STILL IN CONTINUOUS TREATMENT DURING A GIVEN WEEK IN THE METHADONE OUT-PATIENT PROGRAM. PERCENTAGES ARE DETERMINED IN TWO WAYS, FIRST, FROM ONLY THE URINE SPECIMENS ACTUALLY PROVIDED AND SECOND, ON THE BASIS THAT 3 URINE SAMPLES A WEEK CONSTITUTE A COMPLETE WEEK OF DATA WITH A MISSING SAMPLE ASSUMED TO BE POSITIVE.

is there any significant difference between the groups. The data reported here are not easily compared with those from other methadone maintenance programs operating in other communities. Aside from the differences in selection criteria, in dosage and in the use of ambulatory stabilization techniques, the Illinois drug abuse program operated its methadone program in what may be a unique philosophical ambiance. Ascribing to the view that different individuals might be best served by different treatment approaches including abstinence-oriented techniques and therapeutic communities, we could not simultaneously subscribe to the view that all compulsive narcotics use was a manifestation of a drug-induced metabolic lesion. Patients who felt ready to attempt withdrawal from methadone were given the option for transfer to other units. Not investing the use of methadone with special or unique curative potential had its disadvantages. Many patients requested withdrawal prematurely (we think), and staff members seemed less reluctant to discharge nonconforming patients (since they were not depriving them of an essential medical service). Yet these negative factors (which we feel may have contributed to high attrition rates) had to be balanced against some very positive advantages of this philosophical position. For example, although Chicago has a number of highly organized and articulate minority group organizations, no community group has raised the issue of an establishment program dispensing medication that would permit it to control the behavior of minority groups. In our situation the medication was viewed as facilitating social recovery, not providing an essential element for the biology of the patient. The presence of former methadone patients, now abstinent, did much to underscore the reality of our commitment to this view. The criticism of abstinence-oriented groups has also been muted by our philosophical open-mindedness. Obviously not every community will find it appropriate to follow a similar approach. We present our situation merely to elucidate the factors that went into the evolution of our early treatment philosophy.

The data from this study can be interpreted in a number of ways. First, let me point out what, in retrospect, may be less than an optimal experimental design. In an effort to increase the dose so gradually that clinic physicians and staff would not notice, the increase was carried out over a number of weeks. Given the attrition rate, it might have been better to try harder to get the high-dose group to the 90 to 100 mg. stabilization dose within 3 to 4 weeks. Under such conditions, a greater difference between the high- and low-dose groups might have become apparent. Given the study even as conducted, however, it is difficult to avoid the inference that for some patients, at least, relatively low doses of methadone are sufficient to facilitate social rehabilitation, decrease heroin use, and increase productivity.



STATUS OF PERSONS IN THE IDAP WHO WERE ORIGINALLY METHADONE OUT-PATIENTS AND EITHER 1. REMAINED AS OUT-PATIENTS, 2. WERE TRANSFERRED TO OTHER MODALITIES, OR 3. LEFT AND RETURNED TO SOME FORM OF TREATMENT.

On the basis of the data generated thus far, there is no reason to believe that low dosage is in any way superior to high dosage although it may be that such side effects as constipation and sweating may have been lower in the low-dose group. However, our previous observations remain generally valid. If a patient is making a relatively good adjustment on a low dose (with respect to heroin use, employment, and there are no complaints of withdrawal) there is no imperative to increase the dose merely to induce cross-tolerance. While one cannot be certain that all patients had equal access to heroin in sufficient purity to produce effects, observation that some patients on high dosage continued to use heroin certainly indicates that heroin of reasonable quality was available in the general area. Thus, the absence of heroin use among a significant number of low-dose patients cannot be readily attributed to an "adequate level of blockade" relative to the quality of heroin available.

Expressed in a more theoretical way, it appears that, for a few patients at least, it is the alleviation of narcotic hunger and not "blockade" that is the essential feature of the maintenance program as it operates in Illinois.

Lastly, we have again observed that the availability of methadone does not invariably eliminate the interest in abstinence, and that a few patients do elect to undergo withdrawal from methadone and that a few of these are able to remain abstinent for considerable periods maintaining the social gains originally achieved while they were being treated with methadone.

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METHADONE SIDE EFFECTS AND RELATED SYMPTOMS IN 200 METHADONE MAINTENANCE PATIENTS

William A. Bloom, Jr., M.D.
and
Brian T. Butcher, M.S.

ABSTRACT

Earlier studies had indicated sexual problems apparently related to methadone use. To further evaluate this possibility a total of 209 patients—30 females and 179 males—were surveyed, using a questionnaire administered by trained volunteers to record the presence of sexual symptoms and other complaints before and during methadone use.

Overall, those complaints which increased most markedly after starting methadone treatment were weight gain, increased frequency of urination, increased use of alcohol and increased intake of fluids. Other complaints such as drowsiness and constipation were present but to a lesser degree.

When examined for influence of age, sex, time on program, and dose of methadone, these factors were also shown to influence the reporting of complaints. Complaints of sexual difficulties appeared only minimally related to methadone. Female patients are thought to become more fertile once stabilized on methadone.

A SURVEY OF COMPLAINTS OF METHADONE PATIENTS IN NEW ORLEANS

Problems of Obtaining Hard Data from Soft Information

This study grew out of a gradual realization of a need for greater objectivity in assessing side effects in methadone maintenance patients. This occurred when biases appeared as we became interested in evaluating certain complaints such as sexual impotence in our patients. Eventually, it became apparent that many of our patients cooperated to the degree of readily feeding back information for which we were looking; i.e., they tended to tell us what we wanted to hear.

In the early stages of our program several of our quite reliable patients complained of impotence. We then began questioning all our male patients about any diminished sexual desire, delayed ejaculation or impotence. Based on the patients' answers, we had by the time of our report last year to the Second National Methadone Conference concluded that at least 30 percent of the males on our program had sexual difficulties during the first 2 months of methadone maintenance; and thereafter, 20 percent continued to have difficulties. We had hypothesized that methadone was directly responsible for a significant level of sexual problems.

The first blow to what in retrospect appears to have been a falsely erected hypothesis was the result of a detailed home life study of a sample of our patients. Forty-five spouses were interviewed and home visits were made by the social worker making the study.[1] Many of the patients on the program reported their husbands to be much better able to function sexually after being placed on methadone than while using heroin. We concluded that either our approach to investigating the matter had influenced our results or the men's basic attitude about themselves and their "adequacies" was being reflected in the report of sexual functioning.

A form was developed which could be completed by trained volunteers or nonprofessional personnel to study somatic symptoms which the patients might have had before receiving methadone. These symptoms could then be compared to

[1] Personal communication with Miss June Clark, Drug Addiction Research Team of Tulane University.

complaints or problems reported during treatment with methadone. All factors were presented more or less equally to minimize any clues which might lead to biased reporting. Patients were questioned with respect to the following somatic complaints:

Runny or stuffy nose	Dryness of mouth
Blurring of vision	Chest pains
Sweating	Pain down left arm
Nausea	Vomiting
Drowsiness	Constipation
Diarrhea	Heartburn
Swelling of feet or ankles	Nervousness
Tingling in skin	Loss of weight
Increase in weight	Headaches
Bleeding gums	Numbness in hands and feet
Decreased sexual interest	Ejaculation (delayed)
Impotence	Hallucination
Confusion	Sleepwalking
Burns or fires from cigarettes	Increased use of alcohol
Increased intake of fluids (other than alcohol)	Difficulty in urination
Increased frequency urination	Loss of appetite
	Other (specify)

It should be pointed out that this is not a definitive study of "side effects," but rather, a survey to determine level of complaints before and after methadone maintenance. This might eventually be helpful in evaluating side effects in outpatient populations receiving methadone.

METHODS

The forms were administered by graduate students in various fields of study to all patients who visited the clinic during interview time, which varied from day to day. The dosages of methadone on the day of the interview were recorded along with the date the patient had begun the program. The patients were divided into two groups, depending on whether or not they had been on the program over 6 months. There were three classifications depending on age.

RESULTS

The distribution of patients sampled by age, dosage of methadone, and length of time on the program is shown in tables 1, 2, and 3, respectively. The complaints, in all patients surveyed, that showed the greatest percentage increase are shown in table 4. A comparison of these complaints in males and females is given in table 5. In the majority of cases there was little difference in reporting between males and females.

Table 1.—AGE DISTRIBUTION OF PATIENTS SURVEYED

	Age			Total
	≤ 24 years	25–34 years	>35 years	
N	36	112	61	209

Table 2.—DISTRIBUTION OF PATIENTS SURVEYED BY DOSAGE

	Dosage					Total
	80 mg.	90–110 mg.	120–140 mg.	150–170 mg.	180 mg.	
N	39	89	35	22	24	209

Table 3.—DISTRIBUTION OF LONG AND SHORT TERM PATIENTS

	Long term (≥6 months)	Short term (≤6 months)	Total
N	96	113	209

Table 4.—COMPLAINTS FROM 209 PATIENTS BEFORE AND DURING METHADONE MAINTENANCE

	Before (percent)	Methadone maintenance (percent)
Weight gain	2	80
Increased use of alcohol	15	49
Increased intake of fluids	38	63
Increased frequency of urination	11	37
Constipation	57	70
Numbness of hands and feet	12	32
Delayed ejaculation	49	60
Hallucinations	6	17

Table 5.—COMPLAINTS FROM MALES AND FEMALES BEFORE AND DURING METHADONE MAINTENANCE

	(N=179) (percent) male		(N=30) (percent) female	
	Before	Methadone maintenance	Before	Methadone maintenance
Weight gain	1	83	0	60
Increased use of alcohol	14	40	17	30
Increased use of fluids	38	64	20	43
Increased frequency of urination	11	35	3	40
Constipation	57	70	60	67
Numbness of hands and feet	12	31	13	20

Shown in table 6 is the percentage of reporting of symptoms of the three age groups for all patients. Increased use of alcohol is more marked in the oldest group, as is the reporting of hallucinations. The increased reports of delayed ejaculation were found in males 25 years or older, but blurring of vision was reported to increase most in patients of 24 years or less.

When patients were examined by dosage of methadone (table 7) blurring of vision was shown to increase in those patients receiving 90 mg. a day or more. Reporting of drowsiness increased in patients receiving 90–170 mg. per day. Surprisingly, however, reporting of drowsiness decreased in the group receiving more than 170 mg. per day. A decrease was also observed in those patients receiving less than 90 mg. per day. Swelling of feet and ankles increased in patients taking 120 mg. or more per day. Impotence was increased in patients receiving 90 or more mg. per day, as were hallucinations (defined as "seeing or hearing

Table 6.—COMPLAINTS FROM METHADONE MAINTENANCE PATIENTS ACCORDING TO AGE

	<24 years		25–34 years		>35 years	
	B[1]	MM[2]	B[1]	MM[2]	B[1]	MM[2]
	percent		percent		percent	
Weight gain	0	64	1	77	2	90
Increased use of alcohol	14	31	13	31	18	56
Increased intake of fluids	36	64	34	58	34	62
Increased frequency of urination	3	33	9	35	16	41
Constipation	61	75	51	74	64	64
Numbness in hands and feet	14	33	12	33	11	33
Hallucination	3	11	7	14	5	21
Delayed ejaculation	56	59	36	51	44	51
Impotence	31	22	21	22	23	26
Edema feet and ankles	6	6	5	6	13	25
Blurred vision	17	39	13	18	18	25

[1] B=Before admitted to methadone maintenance program.
[2] MM=While on methadone maintenance program.

Table 7.—COMPLAINTS FROM METHADONE MAINTENANCE PATIENTS ACCORDING TO DOSAGE

	Dosage									
	≤80 mg.		90–110 mg.		120–140 mg.		150–170 mg.		≥180 mg.	
	B[1]	MM[2]	B[1]	MM[2]	B[1]	MM[2]	B[1]	MM[2]	B[1]	MM[2]
	percent		percent		percent		percent		percent	
Blurred vision	10	8	18	25	17	23	27	41	0	24
Drowsiness	44	41	33	60	17	34	18	50	32	28
Heartburn	13	18	15	31	14	23	18	45	16	36
Swollen feet and ankles	10	8	10	10	6	14	5	23	0	8
Weight gain	3	64	2	80	0	83	0	77	0	52
Numbness in hands and feet	15	25	16	37	9	26	9	55	0	20
Delayed ejaculation	47	57	49	54	40	51	27	45	44	68
Impotence	81	26	22	28	20	23	23	32	16	20
Hallucinations	10	10	5	13	3	14	5	36	8	16
Increase in use of alcohol	13	31	15	42	28	46	5	32	8	32
Increased intake of fluids	41	59	38	60	26	54	27	59	28	48
Increased frequency of urination	13	33	12	34	11	40	9	41	0	40

[1] B=Before admitted to methadone maintenance program.
[2] MM=While on methadone maintenance program.

things that are not there.") Heartburn, weight gain, numbness of hands and feet, delayed ejaculation, increased intake of alcohol and other fluids, and frequency of urination were reported more frequently in all dosage groups.

While many other complaints such as constipation and drowsiness were frequently reported, an increase in reports of problems while on methadone maintenance did not markedly exceed the level existing prior to admission.

DISCUSSION

It should be emphasized that this study was based on self-reported complaints and not medical observations. However, certain of these complaints warrant further investigation because of the high percentage of patients reporting them. The complaints which increased most frequently after treatment with methadone were; weight gain, increased frequency of urination (most marked in the females), increased use of alcohol (primarily in the patients over 34 years of age), and numbness of the hands and feet (which were reported in the higher dosage group.)

Blurring of vision was more common in patients receiving higher doses of methadone and among the younger patients (less than 24 years of age). High dosage patients of both long and short term complained of swelling of feet and ankles.

Hallucinations were infrequently reported but there was a slight increase in the older age group and in the higher dosage groups.

SEXUAL PROBLEMS IN MALES

Although our earlier studies indicated impotence was a possible side effect of methadone, our present results do not support this. The change in reports if impotence after admission to the methadone program was insignificant. In a breakdown of the long-term and short-term patients it appeared the longer term patients and the older patients claimed an increase in impotence, while the short-term patients did not unless they were on high doses of methadone (over 140 mg. per day). In the short-term patients there was increased sexual interest, but there was also an increase in patients reporting delayed ejaculation.

PREGNANCY

The rate of pregnancy in our New Orleans methadone programs has been as high as 20 percent during the past year. Female patients of childbearing age appear to be more fertile once they are stabilized on methadone.[2] They should be informed of this and where appropriate, be afforded birth control information or measures.

LENGTH OF TIME ON PROGRAM

This did not appear to greatly influence the level of complaints with the exception of impotence, blurring of vision, swelling of the feet and ankles, all of which were increased in the long-term patients.

CONCLUSION

Obviously many factors can influence patient complaints. It is recommended more detailed and objective assessments be made of the somatic symptoms of patients before beginning methadone in order to evaluate the significance of possible methadone-induced problems. We have found it is more difficult to ask the "right" questions than to get the "right" answers.

[2] Communication with Dr. Frank Minyard, an OB–GYN specialist and director of the Bethlehem House program in New Orleans.

DRUG ADDICTION RESEARCH TEAM (DART) STUDY SIDE EFFECTS OF METHADONE INTERVIEW

Name_____ Age_____ Clinic_____

Sex: M F Race: W N Other Interviewer_____

Date of interview_____

Date commenced taking methadone: Month_____ Year_____ Dosage_____

KEY: 0=None
1=Little or moderate
2=Frequent or severe

SYMPTOM	BEFORE METHADONE			PRESENTLY		
1. Runny or stuffy nose	0	1	2	0	1	2
2. Dryness of mouth	0	1	2	0	1	2
3. Blurring of vision	0	1	2	0	1	2
4. Chest pains	0	1	2	0	1	2
5. Sweating	0	1	2	0	1	2
6. Pain down left arm	0	1	2	0	1	2
7. Nausea	0	1	2	0	1	2
8. Vomiting	0	1	2	0	1	2
9. Drowsiness	0	1	2	0	1	2
10. Constipation	0	1	2	0	1	2
11. Diarrhea	0	1	2	0	1	2
12. Heartburn	0	1	2	0	1	2
13. Swelling of feet or ankles	0	1	2	0	1	2
14. Nervousness	0	1	2	0	1	2
15. Tingling in skin	0	1	2	0	1	2
16. Loss of weight	0	1	2	0	1	2
17. Increase in weight	0	1	2	0	1	2
18. Headaches	0	1	2	0	1	2
19. Bleeding gums	0	1	2	0	1	2
20. Numbness in hands and feet	0	1	2	0	1	2
21. Decreased sexual interest	0	1	2	0	1	2
22. Ejaculation (delayed)	0	1	2	0	1	2
23. Impotence	0	1	2	0	1	2
24. Hallucination	0	1	2	0	1	2
25. Confusion	0	1	2	0	1	2
26. Sleep walking	0	1	2	0	1	2
27. Burns or fires from cigarettes	0	1	2	0	1	2
28. Increased use alcohol	0	1	2	0	1	2
29. Increased intake fluids (other than alcohol)	0	1	2	0	1	2
30. Difficulty in urination	0	1	2	0	1	2
31. Increased frequency urination	0	1	2	0	1	2
32. Loss of appetite	0	1	2	0	1	2
33. Other (specify):						
_____	0	1	2	0	1	2
_____	0	1	2	0	1	2
_____	0	1	2	0	1	2

Comments: _____

RESULTS OF LOW DOSAGE METHADONE TREATMENT

William F. Wieland, M.D.
and
Arthur D. Moffett, M.S.W.

Last year at the Second Methadone Conference we reported a method of treatment which we termed "Outpatient Detoxification." In general, the method consisted of prescribing low doses of methadone (50 mg. per day or less) in tablet form, with gradual reduction in dosage at an individualized rate. Supportive counseling and other services were provided for each patient. We reported 162 cases, few of whom had completed detoxification by that time. The overall response of these patients was favorable and was comparable to high dose methadone maintenance. Patients who responded poorly were usually transferred to high dose maintenance.

During the past year three problems were noted with this approach:

1. Many patients remained on a low dose indefinitely and could therefore, hardly be described as undergoing "detoxification."
2. The dropout rate from the "detoxification" program was excessive compared to high dose maintenance.
3. The incidence of continued heroin abuse was also excessive.

A fourth problem has been the recent promulgation of governmental regulations against the use of methadone tablets in the treatment of opiate addicts.

As a result, the method of treatment has been reconceptualized and its operation has been changed as follows:

1. The dispensing of methadone doses of 50 mg. per day or less is now called "low dose maintenance." The term "detoxification" is only used when a patient is actually undergoing a gradual dose reduction, usually at the rate of 10 mg. per week.
2. Patients are more rapidly transferred to "high dose maintenance" when their need becomes apparent.
3. All methadone is dispensed in liquid form mixed with Tang, just as it always has been for the high dose patients.

This report describes the status of 52 low dose maintenance patients as of September 1, 1970. These patients were under treatment at our largest clinic and represent 14.4 percent of the total of 360 active patients in that clinic.

POPULATION

All 52 low dose patients described in this report had been in treatment a minimum of 3 months. For purposes of comparison, a matched sample of 52 high dose patients was selected; the matching was done by race, sex, age, and length of treatment. All high dose patients were also selected for dosages of 100 mg. per day or more (range: 100–180 mg. per day).

Table 1.—DEMOGRAPHIC CHARACTERISTICS (N=52 IN EACH GROUP)

Characteristics	Low dose (50 mg. or less)		High dose (100 mg. or more)	
	N	Percent	N	Percent
Male	40	76.9	40	76.9
Female	12	23.1	12	23.1
Black	40	76.9	39	75.0
White	12	23.1	13	25.0
<30 years of age	25	48.1	26	50.0
>30 years of age	27	51.9	26	50.0
<12 years of school	33	63.5	35	67.9
12 years or above	19	36.5	17	32.1
Single	20	38.5	14	26.9
Married	21	40.4	19	37.3
Separated or divorced	11	21.1	17	31.6
Widowed	0	0.0		4.2
Work at admission	24	46.2	23	44.2
Not Working at admission	28	53.8	29	45.8
Probation/parole	16	30.8	18	34.4
Cases pending	6	11.5	7	13.2

Table 1 represents demographic data on the two populations. There were no significant differences in the two populations.

Table 2.—SELECTED DEVIANCY CHARACTERISTICS (N=52 IN EACH GROUP)

Characteristics	Low dose (50 mg. or less)		High dose (100 mg. or more)	
	N	Percent	N	Percent
Heroin addict	49	94.2	5	97.2
Other opiates	3	5.8	1	2.8
<8 years of use	34	65.4	27	51.9
8 years or above	18	34.6	25	48.1
Previous treatment	27	51.9	35	66.5
No previous treatment	25	48.1	17	33.5
No arrests	15	28.8	4	8.0
1–4 arrests	23	44.2	20	38.2
5–9 arrests	3	5.8	10	19.8
10 or above	11	21.1	18	34.0
No incarceration	21	40.4	4	8.5
1–3 years incarceration	11	21.2	23	42.9
4–7 years incarceration	20	38.4	10	18.9
8 years or above	0	0.0	15	29.7

Table 2 presents selected deviancy characteristics. There is a tendency for the high dose patients to have had longer addiction careers, more previous treatment, more arrests, and more incarcerations than low dose patients.

RESULTS

The results are based on a 60-day evaluation period in July–August, 1970. Table 3 presents data on employment, receipt of welfare, and arrests.

Table 3.—EMPLOYMENT, WELFARE, ARRESTS (N=52 IN EACH GROUP)

60 day period	Low dose		High dose	
	N	Percent	N	Percent
Working	28	53.8	23	43.9
Not working	24	46.1	29	56.1
Welfare	25	48.1	28	53.8
No welfare	27	51.9	24	46.2
Arrests	0	0	0	0
No arrests	52	100	52	100

Employment rates are lower than anticipated for both groups and are lower for high dose than low dose patients. This may partially be due to the general rise in unemployment. No arrests were known for either group, which is in keeping with the consistently low arrest rates of patients after entering our program.

Drug abuse patterns were also determined by urine surveillance* during the 60-day period in July-August, 1970. Patients had one to five tests per week by thin-layer chromatography. The results are presented in table 4.

Table 4.—DRUG ABUSE PATTERNS

Drug (60 day test period)	Low dose		High dose	
	N	Percent	N	Percent
1. Heroin (Q or M):				
a. None positive	2	3.8	5	9.6
b. 1–35 percent positive	10	19.6	26	50.0
c. 36–70 percent positive	14	26.6	12	23.1
d. 71–100 percent positive	26	50.0	9	17.3
2. Amphetamines (1 or more positive tests):				
Yes	36	69.7	38	72.2
No	16	30.3	14	27.8
3. Barbiturates (1 or more positive tests):				
Yes	14	26.9	10	19.6
No	38	73.1	42	80.4

*Performed by the Clinical Pharmacology-Toxicology Center at Philadelphia General Hospital under the direction of W. J. Russell Taylor, M.D., Ph.D.

It is apparent that drug use and abuse continues to be prevalent in both groups according to urine surveillance; however, the low dose patients more frequently show a high percentage of positive specimens for heroin than high dose patients. Apparently the methadone "blockade" is a partial deterrent for high dose patients; whether because it blocks the craving or the emphoria or both was not determined.

DISCUSSION

As a result of this study we conclude that low dose methadone maintenance in selected cases produces fairly similar results to high dose maintenance in selected cases. The low dose patients in this study had slightly better employment records on the positive side, but increased heroin abuse as a negative factor. Both groups showed a high incidence of amphetamine use and a relatively high incidence of barbiturate use. On the basis of clinical reports, it was found that much of the amphetamine and barbiturate use was in modern dosage, often for symptomatic relief of sluggishness or obesity (amphetamines) or relief of insomnia (barbiturates). Of course, some patients were fairly heavy abusers of these substances.

One might conclude that dosage per se is a less important variable than other factors, such as the typology of the patients, the ancillary services, and the attitude of the program regarding punitive discharge from treatment. We plan to reevaluate all low dose patients to determine which ones might benefit from transfer to high dose maintenance. We will then see whether any significant changes occur in their treatment outcome, particularly the frequency of heroin use.

Despite the unexpectedly high incidence of positive urines, criminal activity and arrest rates are markedly reduced. Both patients and families usually reported overall improvement under treatment, despite the lack of total rehabilitation. In both the fields of psychiatry and general medicine we often have to be content with achieving some measure of improvement in patients which may fall short of our more idealistic goals. There is no reason to expect anything different in the treatment of heroin addiction, traditionally one of the more difficult entities to treat.

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SEXUAL EFFECTS AND SIDE EFFECTS OF HEROIN AND METHADONE

William F. Wieland, M.D.
and
Michael Yunger

There is a paucity of data on the sexual effects of heroin addiction and an even greater deficit on the sexual effects of methadone use.

Lindesmith (*1*) claims that "particular ailments" of opiates "are associated with some incidental aspects of the addicts' way of life rather than with the drug per se. The same may be said of the depression of sex activity, since users sometimes report no such effect and may even regard the drug as an aphrodisiac." The U.N. Commission on Narcotic Drugs (*2*) in its annual report of 1953 reports "the reproductive system generally tends to become inactive in both males and females; opiates have a general tendency to reduce or obliterate sexual desire although there may be individual exceptions to this."

Blum and Associates (*3*) feel "a safe assumption is that chronic drug use (opiates) in fact reduces sexual interest and potency (it may, however, also increase the duration of the male erection)." Mathis (*4*) feels that heroin addicts "are less interested in sex, or less concerned with it than the average for their age group. Heroin . . . furnishes the ultimate in tranquilization. It leaves no anxieties to act upon—sexual or otherwise." Willis (*5*) found in a sample of 77 males and 31 females that libido was depressed while on heroin in 87 percent of the males and 55 percent of the females. He also found that 70 percent of males experienced impotence while on heroin.

One of the common patient concerns about methadone is whether its use decreases the sex drive. Dole and Nyswander (*6*) report that during treatment with methadone "sex drive is usually blunted in heroin addicts and they often joke about it."

Other commonly reported side effects of methadone include constipation, weight gain, nausea, vomiting, sluggishness, pruritis, sweating, and menstrual irregularity.

This report describes the results of a questionnaire administered by one of us (N.Y.). Patients were queried regarding the existence and severity of the common side effects of methadone, compared with these same effects while on heroin. In addition, a comparison of the sexual aspects of heroin and methadone included questions on sex drive, sex activity, sexual enjoyment, difficulty in achieving a climax, difficulty in obtaining an erection, and changes in activity occurring during sex, such as becoming more passive.

Population.—The subjects of this study were all former heroin addicts presently being treated on the methadone program of the West Philadelphia Mental Health Consortium. There were a total of 70 patients studied, all of whom were under the age of 36. Of these, 55 were male (40 white and 15 black) and 15 were female (eight white and seven black). The age distribution was as follows: 37 patients were less than 24 years of age (28 males, nine females); 19 were between 24 and 28 years of age (15 males, four females); and 14 were between 29 and 35 years of age (12 males, two females).

There was a fairly equal distribution of patients on a low dose of methadone (50 mg. or 1 ss), moderate dose (60 mg. to 100 mg.), and nigh dose (over 100 mg.) at the time of the interview. Eighteen males and seven females were low-dose patients; 20 males and six females were moderate-dose patients; and 17 males and two females were high-dose patients.

Results.—Constipation and weight gain were evaluated quantitatively. Moderate constipation was designated from 3/7, 4/7, or 5/7 of the normal bowel habit and severe constipation was designated from 1/7 or 2/7 of the normal bowel habit.

The remaining areas were evaluated qualitatively and comparatively between heroin and methadone. "Occasional" or "frequent" were designated as it related the perceived effects of heroin or methadone in the individual patient. If a patient experienced the side effect only in the first few weeks or months of use, this was designated by "initially."

There were no significant differences between males and females or between blacks and whites in the incidence of general side effects, so the data on all patients was pooled. The data on sexual effects are reported separately for males and females, since differences were noted by gender.

There were no significant differences in the frequency of side effects or in the sexual effects relative to the dose of methadone. However, there was a slight, but not significant, trend for high dose patients to be more severely constipated, to gain larger amounts of weight, and to have more menstrual irregularity.

GENERAL SIDE EFFECTS

The results obtained on constipation are given in the following table:

	Percent	
	Heroin	Methadone
Normal bowel habit	22.8	45.8
Moderate constipation	35.7	32.8
Severe constipation	41.5	21.4

Heroin is more associated with severe constipation than methadone. Also, about twice as many patients report a normal bowel habit on methadone than on heroin.

The results obtained on weight gain are shown in the next table. These results are with methadone use only, virtually no one reported any weight gain while taking heroin:

Weight gain	Percent	
	Males	Females
None	52.7	45.8
Initially only (greater or=5 lbs./mo.)	12.7	20.0
Initially only (less than 5 lbs./mo.)	3.6	13.3
Gradually (less than 2 lbs./mo.)	14.5	13.3
Gradually (greater than 2 lbs./mo.)	16.5	6.6

The results of weight gain are summarized in the following table of total weight gain:

Total weight gain	Percent	
	Males	Females
None	52.7	46.3
Less than 10 lbs.	5.3	13.8
10 to 20 lbs.	31.1	33.3
Greater than 25 lbs.	10.9	6.6

As was mentioned previously there was tendency for high-dose patients to gain more weight (six out of seven of those gaining greater than 25 lbs. were high-dose patients).

Appetite was reported as good in 100 percent of patients on methadone and only in 14.3 percent of patients on heroin. On heroin, 39.9 percent felt that their appetite was fair and 45.7 percent felt that it was poor on heroin.

The following table illustrates the results on nausea and vomiting, which indicate that these are very common in the initial period of heroin use:

	Percent	
	Heroin	Methadone
Nausea:		
None	48.5	84.3
Initially only	47.2	5.7
Occasional	4.3	10.0
Vomiting:		
None	47.2	91.5
Initially only	45.7	5.7
Occasional	7.1	2.8

The results on sluggishness, pruritus, and sweating are summarized in the following tables:

	Percent	
	Heroin	Methadone
Sluggishness:		
None	15.8	48.5
Initially only	27.1	4.3
Occasional	57.1	30.0
Frequent		17.2
Pruritus:		
None	35.7	75.7
Initially only	4.3	2.8
Occasional	45.7	14.5
Frequent	14.3	7.0
Sweating		
None	34.3	37.1
Initially only		5.6
Occasional	39.9	32.8
Frequent	25.8	24.3

These results indicate that both sluggishness and pruritus are associated more with heroin use than with methadone use. Sweating, on the other hand, is common to both heroin and methadone.

SEXUAL EFFECTS

Blinick (*7*) reports that "chronic opiate addiction in women is associated with amenorrhea, anovulation, and infertility." Eighty percent of females in the present study had regular periods while on methadone; in contrast, 26.6 percent of women had regular periods while taking heroin. Only 6.6 percent experienced persistent amenorrhea with methadone (this one patient was on a high dose) while 53.4 percent experienced amenorrhea when taking heroin. An additional 20 percent experienced late periods on heroin while 6.6 percent experienced this on methadone (this one patient was a high-dose patient). One patient (6.6 percent experienced shorter periods on methadone (a low-dose patient).

In this study 56.4 percent of males and 46.6 percent of females were never married. Of those that had been married, 62.5 percent of males and 25 percent of females felt that drugs definitely affected the marriage adversely while 37.5 percent of males and 75 percent of females felt that drugs had little or no effect on their marriage.

Patients were asked to rate their sex drive, their sex activity, and their enjoyment of sex on a 4-point scale consisting of above average, average, below average, and very low. These ratings were made for both heroin and methadone in each patient. The results with heroin are shown in the next table (by percent):

On heroin	Sex drive		Sex activity		Enjoyment of sex	
	Males	Females	Males	Males	Males	Females
Above average					5.5	
Average	18.2	26.7	20.0	26.7	27.2	33.3
Below average	63.6	73.3	61.8	73.3	60.0	66.7
Very low	18.2		18.2		7.3	

Heroin suppresses all three areas in the majority of patients, somewhat greater in males. Only three males stated that it enhanced their enjoyment of sex. The results are similar to those reported by Willis (*5*) in the males, but our sample showed greater suppression than his female sample.

The results on methadone are summarized in the next table (by percent):

On methadone	Sex drive		Sex activity		Enjoyment of sex	
	Males	Females	Males	Females	Males	Females
Above average						
Average	65.4	66.7	69.1	66.7	74.7	53.3
Below average	20.0	12.3	21.8	33.3	18.2	40.0
Very low	14.6	20.0	9.1		7.3	6.6

Methadone apparently produces less frequent suppression than heroin. However, further analysis of the data indicates that a few patients experience worse suppression from methadone. The next table demonstrates the change in sexual functioning from heroin to methadone (by percent):

Change from heroin to methadone	Sex drive		Sex activity		Enjoyment of sex	
	Males	Females	Males	Females	Males	Females
Improved	60.0	46.6	56.4	46.6	49.1	33.3
No change	21.8	26.6	32.7	46.6	36.3	60.0
Lower	18.2	26.6	10.9	6.6	14.6	6.6

Whether the improvement is due to the change in drug or to the change in life style is not determined by this data. About 20 percent of the males reported an initial suppression with methadone that improved over time.

The following table presents the results with difficulty in achieving a climax and difficulty in obtaining an erection (by percent):

		Difficulty with climax		Impotence, males
		Males	Females	
None	Heroin	15.4	13.3	34.5
	Methadone	52.7	33.3	54.3
Sometimes	Heroin	36.3	20.0	50.9
	Methadone	16.3	40.0	21.8
Frequent	Heroin	38.1	66.6	14.5
	Methadone	13.6	26.6	16.3
Initially	Heroin			
	Methadone	7.3		7.3

These results show that heroin produced more difficulty with climax and with impotence than methadone. The impotence findings with heroin are similar to those of Willis (65.4 percent *vs.* 70 percent). Promiscuity and changes in the availability of partners are shown in the following table (by percent):

	Males	Females
Availability of partners:		
No effect	60.0	53.4
More available on heroin	21.8	13.3
Less available on heroin	20.0	6.6
Promiscuity—desire for new partners:		
No effect	58.2	40.0
Decreased with both	14.5	6.6
Decreased with methadone	3.6	6.6
Decreased with heroin	9.1	
Increased with heroin	14.5	6.6
Increased with methadone		

These results show that heroin use is associated with a tendency to increase promiscuity in some patients and a tendency to decrease promiscuity in others, while methadone treatment has virtually no effect on promiscuity. Feelings of sexual inadequacy such as loss of manliness, and loss of womanliness are shown below (by percent):

Sexual inadequacy	Males	Females
None	76.3	85.6
Yes, on heroin only	1.8	13.3
Yes, on methadone only	5.5	
Yes on both	7.3	
Yes, on methadone initially as well as heroin	9.1	

The following table illustrates the results of change in activity during sex (by percent):

Passivity	Males	Females
No change	47.2	80.0
More passive on heroin	12.7	13.3
More passive on methadone	1.8	6.6
More passive on both	20.0	

These results show that both males and females tend to deny any feelings of sexual inadequacy, although males have a slightly higher incidence. Males also tend to admit becoming more passive with heroin and methadone during sex while the vast majority of females do not. Passivity is, of course, more acceptable to the female sexual role.

None of the females admitted to homosexuality and 81.8 percent of males denied any homosexual activity. Fourteen and a half percent of males admitted to homosexuality only during heroin use and 3.7 percent of males admitted to homosexuality throughout their life.

Only 13.3 percent of females admitted to prostitution to help support their habit while 18.2 percent of males admitted to male prostitution to help support their habit.

Only 23.7 percent of males abstained from heroin on the street for longer than a week as did 13.4 percent of the females. Of those who did kick heroin longer than a week on the street, 53.9 percent of males and 100 percent of females felt their sex drive increased, while 46.1 percent of the males felt there was no effect.

Each person was also questioned as to whether there were other factors that may have influenced their sexual life such as lack of time, poor mood or a suitable partner not being available. Eleven percent of males felt that time was a limiting factor while taking heroin, and 7.3 percent of males and 20 percent of females felt there were other factors involved such as poor mood or unsuitable partners.

Discussion.—This was a retrospective study and, therefore, subject to falsification or distortions of memory. However, according to the patients' subjective reports, it would appear that most side effects are less on methadone than on heroin, or at least they are perceived as being less severe. None of the side effects were incapacitating and they were seen more as an annoyance than a source of serious dissatisfaction. When sexual side effects were present, they tended to be more annoying than the other side effects. None of the patients planned to terminate treatment because of side effects.

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A COMPARISON BETWEEN SUBCUTANEOUSLY ADMINISTERED MORPHINE AND SUBCUTANEOUSLY AND ORALLY ADMINISTERED METHADONE ON PUPILS AND SUBJECTIVE EFFECTS

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The potency of orally and subcutaneously administered methadone was determined in relation to subcutaneously administered morphine in 12 prisoner patients who were serving sentences for violation of Federal narcotic laws. Ten and 20 mg. of orally or subcutaneously administered methadone were compared with 10 and 20 mg. of subcutaneously administered morphine. The study was conducted in two groups of six subjects using a latin square design in which the order of the doses was randomized. On each test day, which were at weekly intervals, subjects received both a subcutaneous injection and 30 ml. of an orange flavored drink. One or the other of these vehicles contained the active drug. Observations, which consisted of the measurement of respiratory rate, blood pressure, pulse rate, rectal temperature and pupillary diameter, were made at 0700 and 0730 prior to receiving the medication at 0800, and again at 0830, 0900, 1000, 1100, 1200, 1300, 2000 and 0800 the following morning. After the administration of medication, patients completed at these same times the Addiction Research Center single dose questionnaire and a subjective drug effects questionnaire, and the observers completed their version of the single dose questionnaire.

Using changes in pupillary constriction, opiate signs and observers' liking scores, subcutaneously administered methadone was found to be approximately equipotent to subcutaneously administered morphine, and orally administered methadone about one-half as potent as subcutaneously administered methadone. Using subjects' liking scores, opiate symptom scores and scores on the MBG scale, subcutaneously administered methadone produced higher scale scores, and for this reason was adjudged to be somewhat more euphorogenic than morphine; however, valid potency estimates were not obtained. Twenty mg. of orally administered methadone produced scores that were comparable to or greater than those produced by 20 mg. of subcutaneously administered morphine on the subjects' liking, opiate symptom and MBG scale scores.

With regard to the miotic effect, the effects of subcutaneously administered methadone on pupils were maintained for approximately 24 hours, as were the effects of orally administered methadone. The effects of morphine on pupils decayed to about 50 percent by 24 hours.

Most of the measures of subjective effects indi-

cated that the euphorogenic action of methadone was only slightly less than peak effect at 12 hours and greatly diminished at 24 hours. The duration of action of morphine was less than that of either subcutaneously or orally administered methadone.

It is concluded that both orally and subcutaneously administered methadone have potent euphorogenic actions that are entirely commensurate with their ability to constrict pupils. The duration of action of methadone is well sustained on pupils for 24 hours, which is in keeping with the findings of Isbell; however, subjective effects exhibit a marked decrement between the 12th and 24th hours.

DURATION OF METHADONE INDUCED CROSS TOLERANCE TO HEROIN*

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With the rapid proliferation of methadone maintenance programs for the control of opiate dependence, the need to define the clinical pharmacology of this agent becomes urgent (*1*). A major problem in these programs is the delivery of medication. Because of the unreliability of the patients and the salability of methadone, it is desirable to give the patient the least amount of medication for self-administration. The requirement that the patients attend a clinic daily to receive methadone, however, interferes with vocational and educational programs. An accepted compromise is for the patient to receive methadone in the clinic two or three times per week, as well as a supply for self-administration on the intervening days. Such a compromise, however, allows seepage of methadone into the community, with its abuse including the accidental ingestion of methadone—a possibility that has led to six reported deaths in New York City in 1969 (*2*).

A more ideal situation would allow the administration of the maintenance medication as infrequently as possible, each administration under observation, allowing none to be dispensed directly to the patient. This study was undertaken to investigate the dose-time relationships of cross-tolerance to heroin induced by methadone.

METHOD

Male narcotic addicts admitted to the Metropolitan Hospital narcotic addiction treatment facility volunteered for this study. The population is similar to those reported in earlier treatment studies from this laboratory, with an average period of opiate abuse of 14.8 years, and an age range of 22 to 48 (mean, 34.9) years (*3–6*).

Each patient was detoxified, using reducing amounts of methadone. After a minimum of a 1 week without drugs, each subject received an intravenous "challenge" of 25 mg. recrystallized diacetylmorphine (heroin) in 2cc saline, administered in 2 minutes (*6*). The subjects were interviewed and completed a 14-item questionnaire drawn from the Addiction Research Center Inventory (ARCI) (*7*). The quality of the euphoria, pupillary constriction, voice change, and reduction in the respiratory rate were observed. This data provided a baseline for the subject's response to heroin.

Twenty-nine subjects participated in the study. Twenty-one were stabilized at 100 mg., five at 150 mg., and three at 300 mg. daily. To determine the degree of cross-tolerance, challenges with 25, 50 or 75 mg. heroin or placebo were repeated at different times. Patients stabilized on daily doses of 100 mg. methadone were challenged at 6, 24, 48, and 72 hours following the last dose of methadone. Those stabilized on 150 mg. and 300 mg. methadone per day were challenged 72 hours after a dose of methadone. Patients challenged after 48 hours received an identical tasting placebo substitution instead of methadone at 24 hours after methadone; while those challenged at 72 hours received placebo at both 24 and 48 hours.

After each heroin challenge, each subject again completed the drug effect inventory. A research assistant, unaware of what the subject had received, rated the subject's physiological and behavioral reactions. A global rating combining the self-assessments and the interview ratings was obtained. Cross-tolerance ("blockade") was defined as the absence of euphorogenic effects following an injection of heroin.

*This paper was accepted for publication in the *British Journal of Addiction* prior to presentation in New York and the sponsors of the Conference are grateful for permission to reproduce it herein.

RESULTS

The results of the heroin challenges in patients maintained on 100 mg. methadone daily are summarized in figure 1.

Challenged at 6 hours after a methadone dose, five subjects experienced no behavioral effects of heroin.

At 24 hours postmethadone, four subjects demonstrated complete blockade to 25, 50, and 75 mg. heroin. One patient showed no response to 25 mg. and 50 mg. challenges, but exhibited euphoria following 75 mg. heroin.

At 48 hours, no subject experienced the effects of the 25 mg. challenge, but two of six responded to the 50 mg. dose. Seventy-five mg. heroin produced euphoria in four of six subjects.

At 72 hours after the last dose of methadone, each of five subjects responded to the 25 mg. heroin challenge with euphoria.

We attempted to extend the duration of cross-tolerance by increasing the maintenance dose of methadone. Five subjects were brought to a daily dose of 150 mg. All became tolerant to the effects of methadone and were challenged 72 hours following the last dose. Each subject in this group responded to a 25 mg. heroin challenge.

Three subjects were stabilized on a daily dose of 300 mg. methadone. They showed no response to 50 mg. challenges of heroin 72 hours after a methadone dose.

There was consistency between the different measures of subjects' reactions to heroin. In those challenges where some euphoria was experienced, the average score on the inventory was 3.4. Where blockade was present the mean score was 0.6.

In premethadone challenges, all patients exhibited pupillary constriction to pinpoint size. Subjects who showed no behavioral response to heroin also failed to show pupillary constriction except in a few instances when pupils were reduced in size, although not to pinpoint size.

To test whether high dose methadone could be clinically useful each subject received 300 mg. methadone on Monday, Wednesday, and Friday, and placebo on the intervening days. Each subject developed withdrawal symptoms about 40 hours following the last dose of methadone.

DISCUSSION

Subjects receiving a daily schedule of 100 mg. methadone exhibited cross-tolerance to heroin which persisted for at least 48 hours following the last dose of methadone. This observation extends the reports that subjects maintained on 100 mg. methadone exhibited cross-tolerance to 30.0 mg. morphine parenterally given (*8*).

Increasing the maintenance dose of methadone to 300 mg. daily did extend cross-tolerance to 72 hours. Attempts to maintain patients on this dose administered three times per week, however, were unsuccessful as the onset of withdrawal symptoms precluded the practical use of this schedule.

The desirability of administering methadone in a clinic, with none dispensed for self-use, is clear. Such a procedure would overcome the objection that these programs may serve as a source for the introduction of narcotics into the community. Recent reports of the successful maintenance of patients by using alpha-acetylmethadol administered three times per week suggests that other synthetic narcotics may provide a longer duration of pharmacological cross-tolerance, useful in the treatment of opiate dependence, and studies of these agents are urgently needed (*9*).

This paper was accepted for publication by the *British Journal of Addictions* prior to its presentation at the 3rd National Methadone Conference and we are grateful for their permission to publish also in these Proceedings.

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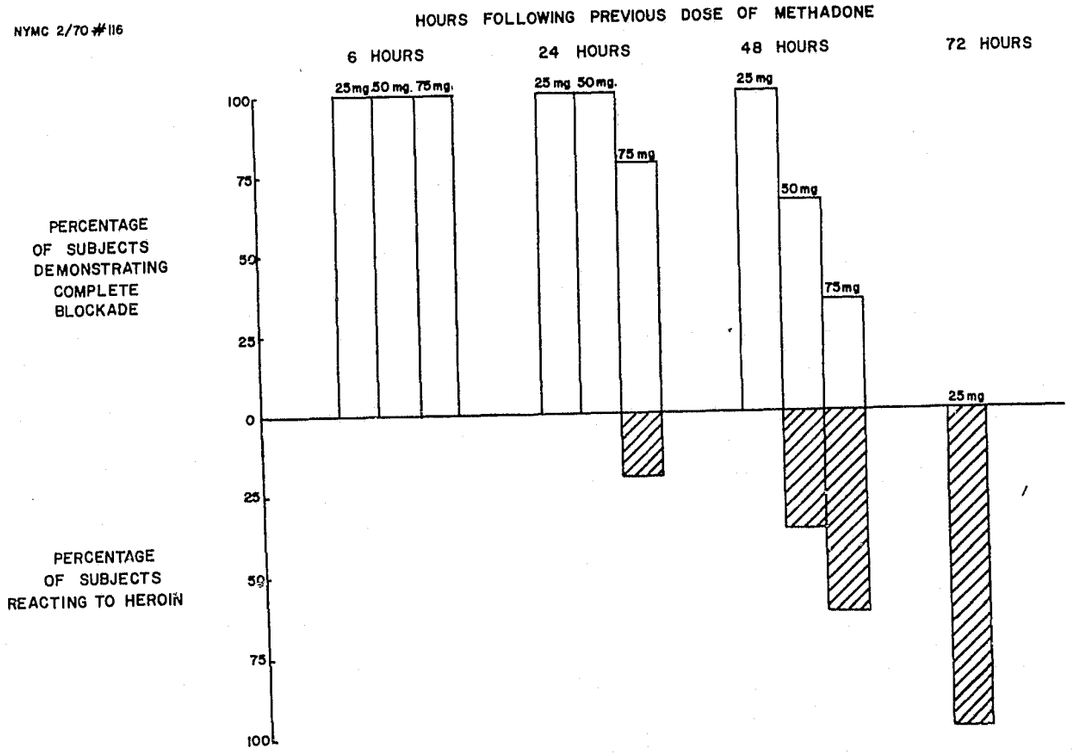

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PREGNANCIES IN METHADONE MAINTAINED MOTHERS

A Preliminary Report

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The effect of maternal narcotic addiction on the newborn infant has been widely reviewed in the literature with case reports dating back to 1875 (*1*, *2*). To these reports, which deal almost exclusively with heroin and morphine addiction, it now seems appropriate to add our findings and to raise several questions regarding the effects of methadone on pregnancy and the neonate (*3*, *4*, *5*).

Methadone is a synthetic narcotic which was developed in Germany during the Second World War as a byproduct of research on meperidine. Conceived originally for its analgesic property, methadone is now being used widely in this country to maintain or blockade former heroin addicts so that heroin becomes neither necessary nor desirable, and the addict can return to a normal, more productive life (*6*, *7*). Recently, guidelines for methadone maintenance treatment programs were established by the FDA, thereby increasing the probability for the continued growth of this modality of therapy.

Because of the frequent use of methadone in women of child-bearing age the questions of placental transfer, teratogenicity, and neonatal effects as they pertain to methadone treatment are relevant.

There is now ample qualitative evidence that methadone and other narcotics cross the placenta (*8*, *9*, *10*, *11*, *12*, *13*, *14*), but there are few quantitative data relating to this (*15*, *16*). Eisenbrandt et al. (*17*), while in the process of examining the excertion of methadone using C (*3*) labeled-methadone, found large amounts of radioactivity in both the placenta and fetus of a rat found to be pregnant at autopsy. Davis and associates (*2*) demonstrated methadone in the urine of nine babies born to mothers who received methadone analgesia during labor. However, the circumstances under which these observations were made differ markedly from those existing in methadone treatment centers, and placental transfer under these conditions has not yet been described.

Fear of the possible teratogenic effect of methadone has been mentioned by one author (*5*) as reason for a temporary reduction in methadone dosage given during pregnancy. This possibility has been pondered by many other persons involved in methadone treatment programs. Nevertheless, no human teratogenic effect of methadone has been reported to date. An increase in congenital malformations was found in hamsters when large quantities of methadone were given subcutaneously during pregnancy (*8*). Interestingly, much larger quantities of heroin were required to produce the same incidence of malformation.

The development of abstinence symptoms in infants delivered of narcotic-addicted mothers has received considerable attention in the literature and constitute a characteristic syndrome. Most authors report that the infants appear normal at birth, but that a progressive restlessness and irritability ensue within 24 to 72 hours. Concomitant with the restlessness is a protracted shrill cry, sometimes lasting for hours at a time. The infants generally feed poorly. This, coupled with frequent diarrhea and vomiting, may cause inanition (*2*). Yawning, sneezing, excessive perspiration, and convulsions have also been noted. A variety of medical regimens have met with varying degrees of success in attempting to treat this syndrome. The possibility of a similar withdrawal occurring in infants born to methadone-treated mothers has been anticipated. Thus far there has been so significant evidence of "withdrawal syndrome" in these infants. The reasons for this remain to be explained, since methadone does have a characteristic withdrawal associated with its discontinuance in adults.

The opportunity to further examine the pharmacology of methadone as it relates to pregnancy and the neonate has been provided through the cooperation of several addicts currently participating in two Minneapolis methadone programs.

MATERIAL

The two major Minneapolis methadone treatment programs [1] are concerned with the voluntary rehabilitation of the "hard core" addict. Although criteria for admission and continued participation in the programs differ, both use liquid methadone to produce narcotic blockade. Comprehensive medical and social service facilities are also available to the patients. At the time of this study there were 26 women in the programs, of which 25 were of child-bearing potential. Six pregnancies were seen, of which five were conceived on high dosages of methadone; in one, therapy was initiated following heroin addiction during the first trimester. There have been three live deliveries and one abortion. Two women are currently pregnant and undelivered.

CASE STUDIES

Case I

Maternal addiction and obstetric history.—Patient A was a 25-year-old Caucasian female gravida IV, para 3–0–0–3, blood type O negative. She had negative serology and pap smear during the pregnancy of interest. Her last pregnancy occurred prior to narcotic addiction and terminated with the delivery of a viable 2900 gm. male infant. At that time the patient was using large quantities of amphetamines. She had a 2-year history of heroin use prior to her admission to the methadone program in May 1969. Her habit was estimated at five bags a day, and she had attemped other forms of therapy (*4*). Her methadone dosage during pregnancy is shown in table 2.

Labor and delivery.—A 2355 gm. female infant was born at 36–38 weeks gestation by normal, spontaneous vaginal delivery. One-minute and 5-minute Apgar scores were 6. The placenta was grossly normal and the cord had three vessels.

Infant hospital course.—Infant A was admitted to the newborn nursery of Mt. Sinai Hospital on May 6, 1970. Physical examination was not remarkable and gestational age was estimated at 38 weeks using criteria outlined by Lubchenco (*19*).

[1] Pilot City Health Center, Mt. Sinai Hospital.

The first 4 neonatal days were not remarkable; however, on day 5 the infant began to feed poorly and was noted to be "fussy." On day 9, because of continued poor intake and weight loss, the infant was begun on gavage feedings. On day 10, the infant was noted to be extremely irritable, with a loud cry and rapid respirations. On day 11, the infant was admitted to the pediatric special care unit and extensively evaluated. The workup revealed X-ray evidence of minimal pneumonitis and clinical suggestions of congestive heart failure. Subsequently, a positive urine culture of E. Coli 10 (*8*) was obtained. The infant was treated appropriately for these clinical entities. Nevertheless, respirations continued at about 110, and there was some temperature spiking to 102° and 103° from days 12–15. Excessive perspiring, prolonged crying, and thrashing of the arms and legs were also noted during this interval. The infant began gaining weight on day 15 and steadily improved from then to her discharge on day 26. A urine obtained for qualitative methadone analysis on day 17 was negative.

The infant is now 3 months old and has continued to thrive without further difficulty since her discharge.

Case II

Maternal addiction and obstetric history.—Patient B was a 25-year-old Caucasian female gravida 5, Para 1–0–3–2, blood type A positive. She had negative serology and pap smear during the pregnancy of current interest. She had an abnormal obstetric history in that she had two babies born, one at 6 months and one at 7 months, both of whom died. Her last two pregnancies terminated with the deliveries of viable female infants. Both occurred prior to narcotic addiction. She had a 2½-year history of heroin addiction prior to admission to the methadone program and was using an estimated three bags a day (table 2).

Labor and delivery.—A 2580 gm. male infant was born at 38–40 weeks gestation. Labor was induced by amniotomy and delivery accomplished vaginally. The 1-minute Apgar score was 9. The placenta was grossly normal and the cord had three vessels.

Infant hospital course.—Infant B was admitted to the newborn nursery of Mt. Sinai Hospital on May 16, 1970. The baby appeared to be about 38 weeks gestation by physical and neurologic examination. About 2 hours after birth the infant had rapid respirations (65) with concomitant flaring and grunting He was admitted to the pediatric special care unit. Chest X-ray was suggestive of pseudorespiratory distress syndrome; however, respirations decreased by 8 hours at which time the examination was normal. On May 18, day 3, the infant appeared jaundiced. Bilirubin was 17 mg. percent and phototherapy was initiated. On day 4, Bilirubin was 25 mg. percent with 1.1 direct, and the infant was exchanged with whole blood. The infant tolerated the exchange well; however, the Bilirubin persisted at 23–24 mg. percent on the following day, and a second exchange with 330 cc. of whole blood was done through a supraumbilical cutdown. The baby appeared to tolerate the second exchange well, was constantly vigorous, and fed by mouth. However, an unusual amount of irritability, characterized by a persistent shrill cry and rigorous thrashing of the arms and legs, was noted during the first 4 posttransfusion days.

The infant was examined on day 11, found to be active and alert, feeding and gaining weight normally, and was discharged to his home. He has thrived without complication since then.

	5/18	5/19	5/20	5/21	5/22	5/23	5/24	5/25
Bilirubin	17.5/ .8	25.1/ 1.0	23.0/ 1.0	17.6/ 2.1	19.2/ 2.8	17.5/ 2.1	17.0/ 2.6	13.4/ 2.0
(Pretransfusion)		25.5/ 1.1	24.5/ 1.2	17.6/ 1.0	19.0/ 3.3			
Bilirubin		14.0/ 1.2	17.8/ 1.1					
(Posttransfusion)		24.3/ 1.1	10.0/ 0.6					
Hemoglobin			16.4	15.1	15.0			
Hematocrit			50	46	46	42		

Cord blood values: Hgb. 17.6 gms., Hct. 60, Normoblasts 37, Reticulocytes 10.6%. METHADONE 85 μg%, by thin chromatography.
Infant's blood Coombs negative.
Infant's urine for qualitative methadone—negative at 7 days.

Case III

Maternal addiction and obstetric history.—Patient C was a 19-year-old gravida 2, para 0–0–1–0, O positive Caucasian female. Her only other pregnancy ended in abortion at 16 weeks' gestation when the patient was 15 years old. At time the patient's illicit drug use included methedrine (1 ounce/week), mescaline, psilocybin, and cocaine. She began using heroin (3 bags/day) and LSD in the first trimester of her second pregnancy and was admitted to the methadone program at 22 weeks' gestation. Near term the patient had a positive VDRL; however, a later FTA was negative (table 2).

Labor and delivery.—A 3015 gm. female infant was born at 38 weeks' gestation by spontaneous vaginal delivery. The 1-minute Apgar score was 8. The placenta was grossly normal and the cord had three vessels. Microscopic sections of placental tissue showed what appeared to be a mature placenta with minor degrees of degenerative change. Sections of umbilical cord showed normal cord structure free from inflammatory change.

Infant hospital course.—Infant C was admitted to the newborn nursery of St. Paul Ramsey Hospital on June 28, 1970. Physical examination was not remarkable and gestational age was estimated at 39 weeks. The neonatal course was complicated by an initial positive VDRL. A repeat VDRL and FTA were negative. The infant was kept in the hospital for 1 week and was discharged as a normal female infant. No manifestations of withdrawal were observed.

	Days						
	1	2	3	4	5	6	7
Maternal serum methadone level*	178 ug.%						
Infant serum methadone level	210 ug.%						
Infant urine methadone level			116 ug.%	118 ug.%	10 ug.%	80 ug.%	75 ug.%

*Used thin layer chromatography accurate to less than 5 ug.%.

Case IV

Maternal Obstetric history.—Patient D was a 36-year-old Negro female gravida 4, para 3–0–0–3. Patient had a spontaneous rupture of membranes at 20 weeks in her pregnancy and required I.V. Pitocin induction and vacuum curettage because of imminent abortion and elevated temperature. The patient had been hospitalized and treated for acute pyelonephritis earlier in the pregnancy and urinalysis at the time of abortion revealed 35–40 white blood cells, and 1+ albumin. No positive cultures were obtained from the uterus or the urine.

The gross consisted of a male infant measuring 11 cm. from crown to rump. There did not appear to be any congenital abnormality. A 6 cm. umbilical cord and sections of an immature placenta were also observed.

Maternal addiction history.—Patient D had more than a 2-year history of known heroin addiction preceding her admission to the methadone program. She entered the methadone program several months before conceiving her aborted pregnancy and successful blockade was accomplished using 120 mg. liquid methadone a day. At about 16 weeks in the pregnancy it was decided to reduce her methadone dosage by 10 mg. weekly decrements in an attempt at detoxification. She was receiving 80 mg. a day at the time of the abortion.

COMMENTS

Evaluation of the tropic under study is made difficult both by the series size and some unexpected, compounding variables. Nevertheless, several findings consistent with those of other studies (*3, 4, 5*) have appeared and answers to several pertinent questions more thoroughly elaborated.

Previous reports have indicated that narcotic (*1, 20*), and, indeed, methadone (*8*) usage during pregnancy has been associated with the delivery of low birth weight infants. Our findings would tend to substantiate those observations. Additionally, the discrepancy between gestational age, as calculated by the date of the LMP and physical and neurologic examination and the expected birth weights would indicate that these low birth weights were due to more than just early labor. Perhaps, placental and/or nutritional factors are involved here.

The absence of any life threatening withdrawal activity was a second finding. This concurs with reports of other neonates conceived and delivered under similar circumstances (*3, 5*). Although both infant A and B did demonstrate activity consist-

ent with abstinence symptoms, the presence of other more objective pathology requiring treatment and complicating the diagnosis of withdrawal preempted treatment for withdrawal. The relationship of methadone to this other pathology remains undefined.

The presence of a transiently positive VDRL in infant C and her mother is a provocative finding. The role of methadone and/or unknown liver disease as a cause of a biologic false positive serologic test for syphilis, in this population, should receive further investigation.

The absence of congenital malformations in the three viable infants and in the one aborted fetus, despite reliable documentation of significant placental transfer and accumulation of methadone, is an encouraging finding. It should be remembered that the fathers of infants A and B were receiving methadone.

It is our hope to follow these infants to try to determine if there are any latent consequences associated with the use of methadone in pregnancy.

SUMMARY

1. Placental transfer of methadone has been shown.
2. No teratogenic effect of this transfer was observed in our four subjects.
3. Minimal withdrawal activity, not requiring medical intervention, was observed in the two infants whose mothers received the highest methadone dose during pregnancy.

Table 1.—FEMALE PATIENTS IN METHADONE TREATMENT PROGRAM

Currently active	26
Capable of pregnancy	25
Pregnancies	6
Delivered	3
Current	2
Abortions	1

Table 2.—METHADONE DOSE IN Mg./Day

Patient	0–12	12–16	17	18	19	20	21	22–26	26–38	38–40
A	140 mg. QD	70–80 mg. BID							80 mg. BID	
B	60–70 BID		70–80 mg. BID						100 mg. BID	
C							30 mg. QD			
D	120 mg. QD			110		100		90	80	

Table 3.—DATA RELATING TO PREGNANCIES IN THE METHADONE PROGRAM

	A[1]	B[1]	C	D
Age	25	25	19	36
Parity	3-0-0-3	1-0-3-2	0-0-1-0	3-0-0-3
Birth weight in grams	2354	2578	3015	
Estimated gestational age by dates	36–38 wks.	38–40 wks.	38 wks.	20 wks.
Estimated gestational age by exam	38 wks.	38 wks.	39 wks.	
Infant withdrawal symptoms	Present	Present	Absent	NA

[1] Husband in methadone program.

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ABSTINENCE-RELAPSE PATTERNS AMONG HEROIN ADDICTS RECEIVING METHADONE TREATMENT ON AN OUTPATIENT BASIS

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The Narcotic Addiction Foundation (NAF) of British Columbia has been offering prolonged methadone treatment to addicts since 1964. During this time over 1,000 addicts have been treated with methadone maintenance and social counseling. Results with many of these patients under treatment have been excellent. In any particular month, with an average caseload of 337, between 65 and 70 percent of patients are working regularly and are not using heroin. It has been noted however, that many leave after a period of successful treatment to return to the use of heroin. Some of these return for treatment, while others never come back.

The NAF had 337 patients on methadone maintenance as of January 1, 1970. Table 1 shows the retention rate at the end of 3-month periods, along with the average age.

Table 1

	Patient number	Percent of original group lost in interim	Mean age
Jan. 1, 1970	337	34.7	30
Mar. 31, 1970	220		37
June 30, 1970	157	18.7	39
Sept. 30, 1970	128	8.6	39

Approximately one-third stopped treatment during the first 3 months. In the months that followed, the dropout rate was steadily smaller. A high percentage of those who stopped treatment were in the younger age group. This occurrence has always been noted at the NAF. Our experience has been that many young addicts still enjoy the excitement of the life which addiction produces. They apply for treatment to reduce their habit or to see what the program is all about. With daily urine testing and pickup of medication it becomes a drag for many and they drop out. This paper proposes to examine the abstinence-relapse pattern of a small group of addicts who remained on methadone maintenance treatment for over 2 years.

PROCEDURE

Patients were selected for the project who met the following criteria:

1. They must have first come to the Narcotic Addiction Foundation for treatment on or before December 31, 1966.
2. They must have been in treatment on a methadone maintenance program for at least 50 percent of the time between January 1966 and March 1970.

Forty-nine patients were selected who met the above criteria (34 males, 15 females). One-third of this group could be diagnosed as having severe psychiatric disorders as well as dependency on narcotics. Their average age was 45.3 years (range 28 to 75), and they had been addicted to heroin for an average of just over 20 years (range of 2 to 57 years). The data for this paper were collected solely from each patient's file, and the following information was obtained:

1. Basic data (age, sex, marital status, etc.).
2. Addiction history data.

3. Length of time between 1966 and 1970 spent in treatment.
4. Amount of daily methadone prescribed.
5. Number of relapses to heroin use during their time in treatment (a relapse was defined as a period of 2 weeks or longer during which the patient had dropped from treatment voluntarily and returned to heroin use).
6. Reasons for the relapse(s) as stated by the patient to the social worker.

Before presenting the results, it should be pointed out that not all patients in this study were receiving blocking doses of methadone. Up until 1968, the average amount of methadone prescribed was between 30 and 40 mg. daily. With the introduction of the high methadone maintenance program in that year, patients were offered levels of methadone up to 150 mg. a day for those who continued to show heroin in their urine. Only a few were tried at levels of 180 mg. daily. It was decided that with those who still used heroin at levels of 150 mg. a day of methadone, little would be achieved by increasing their medication. All had stated at that level they got no effect from heroin. Their continued use seemed to be related to association with users or the ritual of the needle.

Table 2 presents information on daily dose of methadone for the 49 subjects:

1. When they began treatment, and
2. As of March 1970, or their most recent period in treatment.

Table 2.—DOSE LEVELS

	Mg./day					
	20	30–40	50–60	70–80	90–100	Over 100
Dose when starting treatment	11	21	9	3	3	2
Dose as of March 1970	3	15	8	4	7	12

The 49 patients received an average dose of 44 mg. of methadone per day when they began treatment, and were averaging 73 mg. a day as of March 1970, or their most recent period in treatment. Dosage increased for most patients, either because they were doing poorly in treatment, or because they requested more medication. Those who remained at the lower doses were generally older patients who were doing well in terms of drug abuse.

RESULTS

Of the 49 patients involved, only eight had no relapses in the period under study. Table 3 presents data on the number of relapses by the number of years under study for the 49 subjects.

Table 3.—NUMBER OF RELAPSES BY YEARS UNDER STUDY

	Years			
	2	3	4	Total
No relapses	0	2	6	8
1	0	3	6	9
2	1	1	6	8
3	1	1	2	4
4	0	2	7	9
5	1	1	3	5
6	0	0	2	2
7	0	1	1	2
8	0	0	1	1
9	0	0	1	1
Total	3	11	35	49

The group averaged 2.9 relapses each in the period under study, which worked out to 0.79 relapses per patient-year in treatment, or one relapse every 15 months in treatment. The rate held the same for both sexes.

Table 4 shows the relation between age and number of relapses for the 49 subjects.

Table 4.—AGE VS. RELAPSES

	Under 40	40–49	50–59	60+
Number in age category	14	18	9	8
Total relapses in category	51	63	16	11
Average per person	3.6	3.5	1.8	1.4
Average per year in treatment	1.0	1.0	0.53	0.34

Those subjects who were under 50 relapsed about once every year, those in their fifties about once every 2 years, and those 60 and over about once every 3 years.

While both males and females relapsed once every 15 months on the average, the females tended more toward the extremes in terms of actual number of relapses per person, as table 5 indicates.

Table 5.—SEX VS. NUMBER OF RELAPSES

	None or 1		2 to 4		5 to 9	
	Number	Percent	Number	Percent	Number	Percent
Males	11	32.4	18	52.9	5	14.7
Females	6	40.0	3	20.0	6	40.0
Total	17	34.7	21	42.9	11	22.4

Females under 50 averaged one relapse during every 10 months of treatment, while females over 50 averaged one relapse in every 39 months of treatment.

Generally, those who received high doses of methadone were doing the poorest in treatment. Patients who abused heroin regularly usually had their daily dose of methadone increased. Table 6 relates dose level as of March 1970, to the number of relapses for each subject.

Table 6.—DOSE VS. NUMBER OF RELAPSES

	Mg./day							
	20–40		50–60		70–90		100+	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
None or 1	12	66.7	2	25.0	2	40.0	1	5.6
2 to 4	2	11.1	5	62.5	3	60.0	11	61.1
5 to 9	4	22.2	1	12.5	0	0.0	6	33.3

Those receiving 30 to 40 mg. relapsed about once every 21 months, those receiving 50–90 mg. relapsed about once every 19 months, and those receiving 100 or more mg. relapsed about once every 11 months.

Correlations between relapse and marital status were found. Of the 24 married subjects, 19 had addict spouses (the patient sample in this study contains two husband-wife pairs). Table 7 shows the relation between relapse rate and marital status for the group.

Table 7.—RELAPSE VS. MARITAL STATUS

	Widow(er)	Nonaddict spouse	Addict spouse	Single	Divorced
Number in category	4	5	19	13	8
Total relapses	3	10	60	36	32
Average relapses per patient	0.74	2.0	3.2	2.8	4.0
Months in treatment per relapse	60	22	15	15	11

Divorced patients tended to relapse more than any other group. Patients whose spouses had died or were nonaddicts relapsed far less frequently than did the others.

Data on reasons given to social workers for 100 of the 141 recorded relapses are given in table 8.

Table 8.—REASONS FOR RELAPSE

Marital problems	Yen for heroin	Job problems	Holiday relapse	Psycho-social problems
26	7	7	4	56

As the table shows, most of the relapses were the result of psycho-social or marital problems (82 out of 100). Only seven relapses were directly related to a yen for heroin. Psycho-social problems included difficulties with the law, friendship problems, difficulties with welfare agencies, and association patterns. The association pattern was considered by the treatment staff as the major factor for relapse.

Altogether, 2,148 patient-months were examined, 432 months of which were spent in relapse to heroin use (20.1 percent of the time). The average relapse lasted just over 3 months.

CONCLUSION

This paper has attempted to point out the occurrence of relapses in treatment of patients on the methadone maintenance program. In our opinion these relapses appear to be due to association patterns, boredom aggravated by lack of employment, and a desire to once more experience the effects of heroin. We have found in a number of our patients that alcohol is sometimes a predisposing factor in the return to heroin usage. There is no question in the effectiveness of the methadone program, however, perhaps more must be offered than medical and social work intervention if we are to decrease the number of relapses from the program. There is also a need for a greater effort in followup studies for dropouts from the program. These studies are costly and difficult to do. However, only by such studies will the long-term effect of the methadone program be evaluated.

III. ANCILLARY SERVICES

THE BERNSTEIN EXPERIMENT

Harold L. Trigg, M.D.

The current staffing pattern for the Bernstein Institute methadone maintenance treatment program is rooted in the history of the Bernstein Institute's Drug Addiction Service, which latter service concerns itself primarily with short-term detoxification.

In the process of setting up the Drug Addiction Service itself, in the early months of 1961, there occurred a rapid realization that staffing with psychiatry and other medical specialties, nursing, and social service, though perhaps adequate for simple pharmacological detoxification, was not adequate to cover other needs. One almost has to "entertain" the patient undergoing detoxification to assist him through a 2- to 3-week period of hospitalization and to control the number of premature signouts against medical advice.

At that point in 1961, the author was teaching in a local graduate school of psychology, and without any previous experience, with a nontraditional staffing pattern, selected two graduate students, both young men, with no previous experience in working with the addict population, and employed them in the capacity of general "troubleshooters" (officially named "counselors"). Their areas of functioning, though broad, did not include traditional medical and nursing responsibilities, but did include such areas as recreational therapy, issuing of phonograph records and recordplayers, defusing difficult relationships between patients before any altercation might occur, checking locked screens to make sure that locks had not been tampered with, and many other details.

The period of time up to February 1965 might be considered a thoroughly bleak one for any opiate addict, since the therapeutic community-abstinence programs were barely being whispered about, and one hardly knew, except through private conversations, that Dole and Nyswander were doing the initial research at Rockefeller University during the year 1964 on the high dosage Dole-Nyswander methadone maintenance treatment approach as we know it today. After spending the year 1964 doing the aforementioned initial research, Dole and Nyswander approached the officials of what is now the Bernstein Institute (then Manhattan General Hospital) stating that they needed space in which the work with more patients on the embryonic methadone maintenance treatment program. The Bernstein Institute answered in the affirmative, thus establishing a relationship with Dole and Nyswander that has led to what is today the largest methadone maintenance treatment program in the world.

However, going back to February 1965, which is the actual beginning of the Bernstein methadone maintenance treatment program, it was natural for the parents of the newborn methadone program to take meticulous measures to insure the growth of their child. I was privileged to have many discussions with Drs. Dole and Nyswander in those early days—in fact, it was Dr. Nyswander who worked so hard with me in launching the Drug Addiction Service in 1961. She was, therefore, familiar with the staffing pattern used on the Drug Addiction Service.

Drs. Dole and Nyswander had brought with them from Rockefeller a staff discipline known as the research assistant. The research assistant, as many of you know, is, by definition, a former heroin addict who has been under treatment on a methadone maintenance treatment program for a minimum of 1 year and who is deemed suitable for helping patients make the transition from the behavior of the "street addict" to that of "patient" on a medically supervised and controlled treatment program. However, during the early days and months, one of course could not have the more refined and, at the same time, relaxed view of today as to the role of the research assistant. One had no clear idea in those days as to the extent of the strength of the research assistant and whether one was simply being burdensome in asking the research assistant to undertake certain work with patients. In view of many such uncertainties, we reached a decision to introduce the

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category of staff referred to as counselor on the Drug Addiction Service.

Counselors, in this context, are, by and large, relatively young people, most of whom have a bachelor's degree in one of the behavioral sciences. In order to effect a smooth relationship between these two disciplines (i.e., counselors and research assistants), it became necessary to carve out some areas of responsibilities. One of the things agreed upon at the very outset, for example, was that only the research assistants would speak to patients about contaminated urine specimens in the first 6 weeks of hospitalization. It was our opinion, at that time (and still continues to be mine), that only the research assistant, by virtue of his own experience, had enough finesse to speak to such patients, during this early phase, without having the patients heighten their security operations and isolation techniques. In the early days, I might add, counselors were viewed as staff members who could keep the patient launched once the research assistant got the patient off the ground. After 6 years, we now know that the latter distinction does not seem to be warranted. What seems to me to be true is, that although the research assistant seems to be the most potent vehicle for launching the patient, once the research assistant really settles into the program, he often becomes as "square" as someone who has never used heroin and can become as effective with advanced patients as any other category of staff. In Phase II, primarily, the distinction between the counselor and the research assistant in their day-to-day functioning has undergone considerable blurring over the years, and it seems to me, all for the good.

The social service component of the Bernstein methadone program has undergone considerable change over the years, in view of the fact that all staff members, regardless of professional discipline, function more generically than otherwise—each staff member being expected to provide as wide a range of services for his patients as is possible within the limits of skill and legality; chiefs of the various disciplines are functioning primarily as resource people.

The vocational rehabilitation component of the Bernstein methadone program, which had considerable difficulty getting off the ground, has been an invaluable program component for the past couple of years. Our patients are now able to avail themselves of special vocational and educational training programs which were previously not open to them; or, if open to them, really did not understand the needs of an individual who had spent many years of his life using heroin, but who was now on methadone maintenance and had a different set of needs. Many new job areas have been opened.

In terms of the internal medical, obstetrical, gynecological, pediatric components and the ancillary services of the Bernstein methadone maintenance treatment program, there are three experts to cover those areas in more detail, later this morning. I would simply like to note, at this point, that we take great pride in these specialty services and hope to be able to expand them, not only to be able to provide continuity of services within the same medical center setting, but in order to enable us to do further evaluation and research for many years to come.

Having been asked repeatedly for the staffing pattern for a Phase II methadone outpatient clinic, the following is based on a census of approximately 100 patients:

- Half-time psychiatrist
- Half-time administrative support
- 2 full-time counsellors
- 2 full-time research assistants
- Quarter-time vocational rehabilitation counsellor
- 2 full-time nurses
- Half-time social worker
- Full-time secretary

ANCILLARY SERVICES IN METHADONE TREATMENT: THE BEDFORD-STUYVESANT EXPERIENCE

Beny J. Primm, M.D.

The Bedford-Stuyvesant experience has been a harrowing, frustrating, and thoroughly rewarding experience for me at this time. What Dr. Trigg has said is indeed true. I don't know now, when I look back, why I really took the assignment, because it was fraught with so many difficulties and frustrating patterns. There were three things, though, that I think were gleaned out of the Bedford-Stuyvesant experience that I could share with you. One of them is the political part of starting a program in an area where you are not necessarily welcome in the first place. The area itself

was rather hostile to methadone maintenance. People there decided that I was the black man who had been chosen by the white man to deliver the white man's poison to that community, which sort of alienated me completely from the segment of the population that I had been identified with in the past. The medical community did not know what my feelings were about methadone as a modality of treatment. They, too, were somewhat reluctant when they heard that Dr. Beny Primm was going to take on the task of the Addiction Research and Treatment Corporation.

Politically, I was in something of a no-man's land, and this no-man's land included the community. It has welcomed us after 1 year. The medical community has presently laid out a welcoming carpet for me, and that's probably why I'm here today delivering to you some of those experiences. This is heartening. With the encouragement of Dr. Dole and Dr. Taylor, visiting from Philadelphia, we instituted in the pharmacological portion of our program technicians rather than nurses, which has helped us considerably in cutting down on expenses and, of course, in rendering a much better service. I have been encouraged as well by Dr. Lowinson's regular telephone communications and, of course, Dr. Nyswander's warm greetings and well wishes yesterday. Also heartening has been my contact with Dr. Jaffe, whom I visited in Chicago, who helped me rid myself of many frustrations, and whom I later saw in San Diego, where he shared with me a number of experiences that guided us a little better.

The Lexington experience, which no program director should exclude from his agenda, was also invaluable. And I mention all of these because initially I had not realized that all of these were important for the success of the program. The exchange of ideas among professionals is the most important aspect of starting a methadone maintenance program and making it function adequately. I think the lesson that is gleaned, the political lesson that is, out of the Bedford-Stuyvesant experience, is that we must not allow the politicians, the oft-times sensational news media, nor a frightened society and even petty jealousies, to make us look, act, or seem like enemies—especially enemies— of the community. We are together for a common cause: Curing addiction.

Administratively it is an area where it is most difficult to run a program of such enormous design as we have at the Addiction Research and Treatment Corporation. I cannot go piece by piece on the administrative chart to show you just what happens but we set the program up in a corporate manner, as seen on the lighted board to your right—during intermission you can go there and see how the program is set up in an administrative fashion. We had to go out and canvass industry for the kind of individual who would be a good administrative director, who would be welcomed by the community, and who had the skills to coordinate all the disciplines that you see listed on that board.

We have extramural based research and evaluation teams. The Harvard Law School for the Betterment of Criminal Justice does criminal evaluation; the Yale Medical School does our medical evaluation; and the Columbia School of Social Work does our social evaluation. These institutions determine the kind of impact we have in these three areas in the community in which we are located. This ongoing research and evaluation is rather unique to ARTC. We receive continual feedback from these institutions regarding their areas of concern so that we can change our program structure as the program evolves in order to be more meaningful to the patient population that we are serving. There are weekly meetings with the Board of Directors of ARTC to keep them abreast of developments so that if we have any difficulty in securing funds or problems in locating property—and the many, many other problems that I know all of you are faced with—they can be of assistance to us in getting these things done. So it is a very coordinated effort, working together to deliver the service.

The delivery of ancillary services requires dedicated, compassionate, certificated professionals from all disciplines. Their skills must be finely coordinated and their departments interrelated. The program's administrative director has this sensitive task. He must create and direct systems of communication between departments to deliver these ancillary services effectively.

We have a Department of Prevention and Education, which the community really had dire need for and requested. This department communicates with every department, feeding back gathered information from the community, i.e., how they were received, etc.

We have a Department of Job Development, where we go out to sensitive industry to take on addicts who have been rehabilitated. We help the medical professional who works in that industrial complex with problems that he might face in the industry when treating an employee who might be addicted to drugs. We follow that individual while he is working with vocational counseling, constantly talking back and forth with the medical department where he is working.

Let's take the other areas, such as social service, which is in constant communication with job development. When program participants are not doing well in their family situation, the job development people know about it. We have a combined counselor-therapist. Rather than have the therapist outside the arena of social services, or the counselor outside social services, we have combined these two job slots. And the counselor and the therapist work together, so that the patient cannot manipulate two people, one person against the other, with the manipulative attitude that addicts often have.

The medical department is rather unique, in that we deliver the kind of care from head to toe that you would see in any major private medical clinic. But what is particularly unique about ARTC is the entire podiatric medical care and, of course, full-time dental care on an outpatient basis.

The podiatric medical care takes place right at ARTC, on the spot. Bert Brown made an interesting observation when he came to visit ARTC and went to a local barbershop in our area to get a haircut. The barber said to him that addicts have a tremendous "milage" problem, because they are constantly "chasing the horse." Therefore, they have very, very bad feet, and he wondered how they even continue to do this. So, when Bert came over that morning, he was going to suggest to me that maybe we should have a podiatrist to take care of the addicts' feet. Well, I told him we had a podiatrist working there for the last year. And, we also have the senior students of the M. J. Lewi College of Podiatry, who come on a daily basis to take care of the simple foot problems. If there are operative problems of the feet, we send them to the College of Podiatry. This has a tendency to make the addicted individual feel that we are concerned with treating him as a whole, and not just with his problem of addiction. Many of them come in with feet that are filthy, and our podiatry students show them how to care for them, teach them proper hygiene, and generally dignify their medical care. The other day we had a television performance on the relationship of podiatry to a narcotics treatment program.

We have a legal service that employs two full-time lawyers. In this system we have taken one patient who was at the Bronx State Hospital, who was on their methadone program, and who was known as a "jailhouse lawyer." We call him a Legal Advocate. He works constantly in this capacity, relieving our two lawyers of a great deal of their responsibility. He is doing considerably well. We are thinking of creating an additional position in this department when we expand to the Bronx.

We started a Therapeutic Community—we now have two—for our most incorrigible patients. A patient becomes incorrigible at ARTC when he fails to respond, after many trials, to the rules and regulations we have established. Presently we have a dropout rate that is very, very small. We have lost only about 27 out of a total of 577 that we have on the program. This is because we feel that we should measure our program's success by how well the most incorrigible patient does on the program. The Therapeutic Community was established after consultation with our research and evaluation team and executive staff. The Therapeutic Community concept in an outpatient methadone maintenance program was copied after Jerry Jaffe's in Chicago. We presently have 18 people in our therapeutic community. If they don't do well there, we do not dismiss them from the program. We may suspend them for a period of 3 months, or 6 months, until their attitude becomes a little bit better or they're more positively motivated. We then take them back on the program, to try to let them function again.

There is a great deal of difference between a program that is located in an area such as Bedford-Stuyvesant and a program located, let's say, in midtown or lower Manhattan. There, in Bedford-Stuyvesant, I consider what we have a very natural laboratory. Right next door to my building is the biggest dope drop in Brooklyn. And people can walk out of my building and walk right next door and "cop." For example, across the street is also a big dope drop. I have done my damnedest to try and get the responsible authorities to come into the area and close these people up. It is impossible. They can't find the drugs within these two places of business, so they can't do anything about it.

This makes program success a limited program success. It creates an abstinence barrier for people on the program. Oft-times they have nowhere to go, and addicts who are not on the program congregate outside of the building. And the kind of peer pressure that takes place when an individual walks outside of the building makes it very difficult to look for the kind of success you might look for everywhere else.

I propose to this Conference that when you run into that kind of situation, e.g., when the program is located in a natural laboratory, that you should not use the same yardstick to measure a program as you would a program in another situation. Because you can't look for the same kind of success rate, and the patients are indeed more incorrigible.

There are a number of gleanings from the Bedford-Stuyvesant experience. On the basis of them I would like to recommend to this body that a resolution come from this Conference that gives a carte blanche for program directors to communicate effectively. That is, whenever they have a problem or are in need of information from another program. This communication should be welcomed—whether the program is located in New York or whether it is in California.

You would be surprised at how much lack of confidence I had when I saw certain things with people using illicit drugs in the program, after they were properly blockaded. I did not believe what I saw. I had subscribed to certain theories in going into a modality like methadone maintenance. I felt that once you blockaded a patient, the patient did not need drugs anymore. This is not always true. Illicit drug use was seen everyday, and I was terribly frustrated. When I talked with Dr. Jaffee and people throughout the country, particularly the people in Lexington, they reassured me that this does occur. When patients come on a program initially, especially an outpatient methadone maintenance program, 95 percent use illicit drugs, 20 percent drop out initially, another 20 to 30 percent continue to be poor program performers. They reassured me that these were statistics similar to their own and not to be frustrated. This information can only come from other experienced investigators. I think this is a most important factor: When programs are designed, provisions should be made for the technical assistants capable of communicating that kind of experience from one program to another. For example, I think funding should include a position of this sort.

We must design a new yardstick to measure a program's effectiveness and success in a natural laboratory setting, i.e., drug assessment is different in an asimilar milieu, it is different in a different ambiance. A drug's effect is different when administered in a Taj Mahal like Columbia Presbyterian than a storefront in the South Bronx or Bedford-Stuyvesant. The kind of aura that surrounds a Taj Mahal—the columns, the organized efficiency and order in the way things are done—have a tendency of predispose to good program performance by a participant in that program. A good deal of the success of a program depends upon the director, i.e., whether he is black or brown or white, professional or nonprofessional. In the climate today, the black director has to answer to the community on a one-to-one equal basis. He is confronted, threatened, and often insulted. The white program director is rarely if ever approached by the black community rebel on a one-to-one basis. I doubt seriously if Dr. Dole has ever been confronted as I have in the Bedford-Stuyvesant community. My life has been constantly threatened face to face, i.e., "We are going to cut your head off," "We are going to blow up your car, etc. Programs outside of communities like Bedford-Stuyvesant are very insulated, and of course a different yardstick should be designed by a forum like this to measure that program's effectiveness.

COMPARATIVE STUDY OF THREE GROUPS OF PATIENTS AT THE BRONX STATE HOSPITAL METHADONE MAINTENANCE PROGRAM

Beatrice Berle, M.D.
and
Joyce Lowinson, M.D.

The methadone maintenance program located at Bronx State Hospital has been in operation since December 10, 1968. At the time of writing, it consists of an inpatient facility (capacity 28 beds), three outpatient departments (OPD's) at Bronx State and Lincoln Hospitals and a recently established residential therapeutic community. The program is being expanded through a grant from the New York State Narcotic Addiction Control Commission (NACC) to the Albert Einstein College of Medicine (AECOM).

The expanding program will be financed through the AECOM grant. It is expected to take care of some 2,000 patients residing in the Bronx. Under terms of the grant, the Albert Einstein College of Medicine will coordinate the programs at nine Bronx hospitals, including Bronx State, Montefiore, Morrisania, Jacobi, Soundview-Throgs Neck Community Mental Health Center, Lincoln, Lincoln Community Mental Health Center, Fordham, and Misericordia. These facilities will be responsible for the medical care which these patients require as well as for the management of the methadone maintenance program with supportive services. The methods developed by Dole and Nyswander (*1*) will be followed in the

new OPD's according to the protocol established by the methadone maintenance program at Bronx State Hospital.

The following report deals with 125 patients selected from 335 patients at the Bronx State Hospital methadone maintenance program as of October 30, 1970. No distinction has been made between patients stabilized in the hospital and those stabilized on an ambulatory basis. Patients at the Lincoln Hospital OPD are not included. Three groups will be discussed:

Table 1.—NUMBER OF MONTHS BETWEEN ADMISSION AND DISCHARGE FOR 54 BRONX STATE PATIENTS WHO WERE DISCHARGED FROM THE PROGRAM

N=54	Months
Mean number of months between admission and discharge	5.5
Range	0–24
Median number of months	4

Note.—Patients (31 percent) were discharged after 1 month or less on the program.

N=335		Number	Percent
Group I	The discharged	54	16
Group II	The nearly discharged	36	11
Group III	Successful patients	35	10

Group I are those patients who have been discharged from the program. Group II consists of those patients whose behavior and lack of progress would have made discharge mandatory in a less flexible program. For purposes of this discussion, the successful patients (group III) are defined as follows:

(a) One year on the program with once-a-week pickup of medication.
(b) Steady employment verified by monthly inspection of pay stubs.
(c) Stable home.
(d) No ascertainable drug use after first 2 months on program as determined by observation, urinalysis, patient's own statement.

We hope to answer the following questions through an examination of demographic data on admission in all three groups and comparing reasons for discharge or near discharge in groups I and II.

1. Can patients in group III be identified upon admission?
2. Why is one patient who breaks the rules discharged while another may be retained?
3. How can the number of discharges be reduced?

Both a more liberal admission policy and a more flexible discharge policy than those enforced on some other programs were in operation at Bronx State. Patients were admitted at the age of 18 with a 2-year history of heroin addiction. Applicants with a history of diagnosed mental disease, emotional instability, or mixed addiction were not necessarily excluded. Patients manifesting disruptive behavior, drug abuse, and apparent lack of progress were frequently given another chance before being finally discharged.

In an attempt to particularize the reasons for discharge, the following list was devised:

1. *No progress.*—If after a period of 3 or 4 months, an individual continues to use heroin or other drugs intermittently, maintains a drug oriented attitude toward life and appears to have made no attempt to secure a job, he may be discharged under the heading of "No Progress." This is usually associated with other reasons.

2. *Disruptive behavior.*—This is defined as creating disruption on the ward, on the hospital grounds, in the OPD or in a public place where the disruptive individual may try to involve other patients, i.e.: Bowling alley, movie theater. This may involve physical and verbal abuse of staff.

3. *Alcoholism.*—Appearing frequently and obviously intoxicated at the OPD. Lack of response to attempts to treat this condition.

4. *Selling drugs, resulting in arrest.*—This is self-explanatory.

5. *Bringing drugs on ward or OPD.*—This is self-explanatory.

6. *Criminal behavior* (e.g. assault, robbery, homicide) resulting in arrest.

7. *Self-discharge.*—Individuals who failed to report for medication for 8 days without adequate explanation were considered to have detoxified and discharged themselves.

8. *Psycho-social pathology beyond the reach of this program.*—This includes individuals who appear to require intensive phychiatric care as inpatients or outpatients but for whom such care is not available. They also include individuals whose personal lives have been so disrupted, due to their past drug history, criminal activities and personal handicaps, that the services existing within the program are not sufficient to provide rehabilitation. Incidentally, these people are known among professionals as the multiproblem patients. They become multiple-agency problems on whom many man-hours may be spent, alas, to no avail.

9. *Mixed addiction.*—This is self-explanatory.

In reviewing the discharged and the nearly discharged, we note first that 31 per cent of the patients were discharged before 1 month on the program. This category includes individuals discharged immediately for bringing drugs on the ward. Among early discharges we find individuals admitted at the request of a housemate, (relative, spouse, friend) already on the program. The individual thus coerced by a relative or friend on the program frequently turns out not to be willing or able to commit himself to the program. At the same time, the 24-month range indicates that a number of patients were carried as nearly discharged for a considerable period of time. We can produce the record of a male patient on whom the therapeutic efforts of the staff individually and collectively were expended for the 24 months with little progress. During his third admission to the ward, he went out on a pass and was arrested for possession of drugs. This incident led to his final discharge. To try to establish a statistically significant difference between the reasons for discharge and nearly discharged would be stretching the data. These are clinical observations. Looking at table 2, one can infer that the program does not tolerate drug traffic, is not equipped to deal with severe and persistent phycho-social pathology, expects a degree of progress, endeavors to deal with alcoholism, disruptive behavior, and mixed addictions (table 2).

Table 2

Reasons for discharge or near discharge	Discharges N=54	Discharges Percent	Near discharges N=36	Near discharges Percent
No progress	17	32	8	22
Disruptive behavior	7	13	13	36
Alcoholism	6	11	8	22
Selling drugs resulting in arrest	14	27	1	3
Bringing drugs on ward or OPD	4	8	6	17
Criminal behavior	7	13	5	14
Self	2	4	0	0
Moved	6	11	0	0
Psycho- or sociopathology	16	30	8	22
Mixed addictions	9	17	10	28
Total	87 (An average of 1.6 per discharge)		58 (An average of 1.6 reasons per near discharge)	

Table 2A

Multiple reasons	N=54	Percent	N=35	Percent
1 reason	30	55	17	49
2 reasons	20	37	13	37
3 reasons	4	8	5	14
Total	54		35	

The discharged and nearly discharged frequently merge into each other. Eight of the discharged were readmitted. Six are making satisfactory progress, two have been discharged after readmission (table 3).

In a clinical review of the nearly discharged, we can pick out a number of patients who may soon fall into group I. Others for whom discharge orders were written 6 months ago and retracted at the last minute are doing well.

Table 3

Dispositions on discharges	N=16	Percent
Transferred	2	13
Transferred to other agency	0	0
Incarcerated	4	25
Readmitted	8	50
Discharged after readmission	2	13
	N=54	Percent [1]
Unknown	18	34
No data	20	38

[1] "Unknown" and "no data" responses have been excluded from the percentages but their percentage of the total is shown.

At present, we have only clinical impressions as to the circumstances which may intervene in favor or against a patient near discharge. These are listed in the hope that a more systematic evaluation of these factors will be made in the future.

1. *The therapeutic urge.*—A staff member may be challenged by the difficulties encountered with a particular patient whom others have failed to reach. The new approach may or may not succeed. As far as we know there is no yardstick to measure reasons for success or failure in a particular personal endeavor of this sort. While staff are encouraged to "try their hand," the physician must set a time limit for the experiment as a counselor should not spend 90 percent of his time on one patient, neglecting the other 30.

2. *Life circumstances.*—A lucky or unlucky break in a job or family situation may tip the balance either way in the marginal patient.

3. *A supporting family or employer* may help to rehabilitate a patient at a critical moment.

4. *Patient intervention.*—On the ward, a group of patients may intercede for a patient about to be discharged and carry him through a crisis. On the other hand, a patient dealing in drugs may corrupt a marginal patient leading to the discharge of both.

Since the discharged and nearly discharged become clinically indistinguishable at a time of crisis on the program, how do they differ from each other and from the successful patient on admission?

Basic data collected on the three groups on admission and processed through Rockefeller University are shown in table 4.

The three groups are similar in age, years on drugs, age when addicted. A greater proportion of white males are found in group III than in either of the other two groups. Marriage is reported as highest in group I but the quality of marriage is not estimated. The noteworthy variables may be summarized as follows: In the Bronx State Hospital program, as constituted at present, the applicant most likely to succeed is white, is or is not married, has a high school education or better, is more

Table 4.—BASIC DATA—PREADMISSION [1]

Variable	Discharged		Nearly discharged		Doing well	
	N=54	Percent	N=36	Percent	N=35	Percent
Sex:						
Male	47	87	30	83	33	94
Female	7	13	6	17	2	6
Ethnicity:						
Black	12	22	10	27	4	12
White	35	65	19	53	25	71
Puerto Rican	7	13	5	14	6	17
Other	0	0	1	3	0	0
No information	0	0	1	3	0	0
	N=54		N=36		N=33	
Age (years):						
Median	32		30		29	
Range	21–50		25–48		27–49	
	N=54		N=16		N=21	
Longest job held (months):						
Median	16		18		21	
Range	0–72		0–120		4–60	
	N=54	Percent	N=36	Percent	N=35	Percent
Marital status:						
Single	15	28	17	47	13	37
Married	32	59	14	39	16	46
Separated	4	7	4	11	5	14
Divorced	2	4	1	3	1	3
Common-law	1	2	0	0	0	0
No information	0	0	0	0	0	0
Education:						
Grades 1–7	2	4	1	3	1	3
Grades 8	3	5	3	9	2	6
Some high school	39	72	12	35	12	38
High school graduate	9	17	15	44	11	34
Some college	1	2	3	9	6	19
College graduate	0	0	0	0	0	0
Other	0	0	0	0	0	0
No information	0	0	2	6	3	9
Vocation:						
Laborer	26	50	5	14	7	21
Semiskilled	8	15	9	25	7	21
Skilled	6	12	7	19	2	6
Clerical	8	15	7	19	7	21
Professional	1	2	0	0	3	9
Sales	1	2	3	8	1	3
Other	2	4	6	16	6	6
None	0	0	1	3	1	3
No information	2	4	1	3	1	3
	N=54		N=17		N=14	
Months since last job:						
Median	13		10		12	
Mean	22.4		19.7		12.4	
Range	1–60		3–60		2–60	
	N=54		N=35		N=34	
Age when addicted:						
Median	17.5		18.5		18	
Mean	20.3		18.2		19.2	
Range	12–30		13–27		14–30	
	N=54		N=34		N=34	
Number of criminal convictions:						
Median	6		5		3	
Mean	8.4		6.7		3.9	
Range	0–30		0–30		0–22	
	N=54		N=34		N=33	
Number of times in treatment for addiction:						
Median	2.5		2		1	
Mean	3.5		2.8		2.2	
Range	0–20		0–10		0–20	
	N=54	Percent	N=36	Percent	N=35	Percent
Work history:						
Never worked	3	6	1	3	0	0
Working now	4	8	7	21	17	49
Worked in past	44	86	25	76	18	51
No information	3	6	3	8	0	0
Welfare:						
On now	14	27	8	25	4	11
On previously	24	46	13	40	9	26
Never on	14	27	11	35	22	63
No information	2	4	4	9	0	0

[1] "No information" responses have been excluded from the percentages.

apt to be laborer, clerical, or semiskilled worker, is currently employed, has never been on welfare, has become addicted between the ages of 14 and 30, has a median of three criminal convictions before coming on the program, and a median of one previous treatment for drug abuse. Previous residence in a therapeutic community is in his favor. Five of the successful patients had spent time in a therapeutic community.

In groups I and II, there is a greater proportion of females and blacks. The same proportion of Puerto Ricans is found in all groups. Only one member of group I had some college experience although nine claimed some college in group II. The proportion of laborers (50 percent is greatest in group I. The median number of previous criminal convictions in group I is double that in group III, as is the number of previous treatments for drug abuse. One quarter of patients in group I were receiving welfare at the time of admission. Only 6 percent of group I were working and 3 percent of group II.

CONCLUSION

1. Groups I and II present many similarities in reasons recorded for discharge and nearly discharged.

2. Group III at time of admission present a number of noteworthy differences in demographic variables compared to group I and II. Patients in group III are better educated, possess more skills, have a history of continuing employment, fewer criminal convictions, fewer treatment failures than their counterparts in group I or II.

RECOMMENDATIONS

1. Criteria need be established for selection of potential group III patients for rapid induction centers where supportive services are minimal.

2. Special rehabilitative services for group I and group II patients should be instituted as soon as possible after admission. These should include:

(a) A therapeutic community (eight of our nearly discharged patients have been selected for this experiment).

(b) Dispensing of methadone should be provided by the social or medical agency assuming primary responsibility for the care of the severely disturbed patients. A psychotic patient should be able to receive methadone while under psychiatric treatment on the psychiatric ward just as the tuberculous patient has received methadone while on a tuberculosis ward.

ACKNOWLEDGMENT

The authors wish to acknowledge Mr. John Langrod's assistance in gathering the data for this paper.

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USE OF PHENOTHIAZINES AND ANTI-DEPRESSANTS IN THE TREATMENT OF DEPRESSION AND SCHIZOPHRENIA IN METHADONE-MAINTAINED PATIENTS

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Insufficient attention has been paid to psychiatric diagnosis in opiate dependent patients. While there has been recognition that some addicts are psychotic or depressed, it is customary to view most addicts as having character disorders, and further exploration is usually devoted to determining various demographic or behavioral characteristics.

In the course of treating heroin addicts in an outpatient methadone program, the authors were impressed with the large number of borderline patients, many of whom also exhibited symptoms of depression, anxiety, and intermittent psychosis. Other patients had significant depressive reactions or schizophrenia. The recognition of these symptoms becomes particularly important today because of the availability of a wide range of psychotropic drugs which are fairly specific in treating these symptoms. Furthermore, the recognition of a borderline state has implications for psychotherapy and prognosis.

The present report is a study of 126 patients, the full caseload of a satellite clinic which opened in April 1970. The study was done during the last 2 weeks in October 1970 by two psychiatrists in collaboration with the counseling staff of the clinic. All patients were on methadone, with a dosage range of 10 to 180 mg. per day, all were receiving individual counseling, some were attending group therapy, and some were receiving various psychotropic drugs in addition to methadone.

Population.—Table 1 shows the race, sex, age range, and marital status of the 126 patients.

The age range is 17 to 52 with a mean of about 30. The racial breakdown is 61 percent black, 39 percent white. Only 10.7 percent are females. The most striking data is the high percentage of single patients (53.2 percent), the high percentage of separated black males (33.3 percent) and the low percentage of currently married patients (23 percent).

Table 1.—SELECTED CHARACTERISTICS OF 126 PATIENT

	Black (N=77)		White (N=49)		Totals
	Males	Females	Males	Females	
Single	27	8	31	1	67
Age range	19–52	19–35	17–35	23	
Married	14	3	11	1	29
Age range	17–50	33–49	20–47	22	
Separated	21	3	3		27
Age range	21–47	23–50	22–50		
Divorced	1		2		3
Age range	33		21–25		
Total	63	14	47	2	126

At the time of the study, 50 percent of the patients were employed, in training, or homemakers. The remainder were dependent on parents, spouses, or welfare.

Method.—One of us (R.F.T.) interviewed each patient and the patient's counselor to establish a diagnosis and to determine the current response to treatment. The other author (W.F.W.) has interviewed most of the patients and frequently consulted on diagnosis as well as prescription of psychotropic drugs.

Result.—A total of 64 patients (50.8 percent) had a recognizable pyschiatric disorder which was more serious than the usual personality adjustment problems seen in addicts. Of these, 36 were black (46.7 percent of all black patients) and 28 were white (57.1 percent of all white patients). More whites than blacks were diagnosed as suffering from borderline states or depression, while more blacks than whites were diagnosed as suffering from personality disorders and schizophrenia.

Borderline states were diagnosed by the criteria of Grinker et al., namely, anger as the main affect, defect in affectional relationships, defect in self-identity, and depressive loneliness. Whenever other significant symptoms were present, a secondary diagnosis was made. Table 2 presents the diagnoses of these 64 patients.

Table 2.—DIAGNOSES OF 64 PATIENTS

Diagnosis	Number of patients
Depressive reaction	11
Borderline	3
Borderline with depression	18
Borderline with personality disorder	17
Borderline with conversion	1
Borderline with alcoholism	3
Schizophrenia	11

Of these 64 patients, 17 are married (25 percent), 25 are employed (39 percent), and nine are both married and employed (14 percent). By contrast, of the 62 patients without a psychiatric diagnosis, 12 are married (19 percent), 37 are employed (60 percent), and six are both married and employed (10 percent). It would seem that the psychiatric disorder does not decrease the incidence of marriage compared to other addicts, but it does decrease employment. This data is summarized in table 3.

Table 3.—EMPLOYMENT AND MARRIAGE

	Employed	Married	Both	
Psychiatric diagnosis	25 (39%)	17 (25%)	9 (14%)	N=64
No psychiatric diagnosis	37 (60%)	12 (19%)	6 (10%)	N=62

Response to Methadone Plus Counseling

All patients receive individual counseling and some also attend weekly group therapy sessions. A global rating of response to treatment without psychotropic drugs was made by R.F.T. in consultation with each patient's counselor. The main interest for this study was change in psychiatric symptoms with only a secondary interest in employment, etc. The global ratings were good (marked reduction in symptoms), fair (moderate reduction in symptoms), and poor (little or no reduction in symptoms). For convenience in reporting, good and fair responses are classified as improved. These results are summarized in table 4.

Table 4.—RESPONSE TO COUNSELING AND METHADONE WITHOUT PSYCHOTROPIC DRUGS

Diagnosis	Number of patients	Total	Improved
Depressive reaction	2	11	1 (50%)
Borderline	0	3	
Borderline with depression	4	18	2 (50%)
Borderline with personal disorder	11	17	6 (54%)
Borderline with conversion	1	1	0
Borderline with alcoholism	2	3	1 (50%)
Schizophrenia	6	11	4 (66.7%)
Total	26	64	14 (53.8%)

Twenty-six out of 64 patients received only methadone plus counseling. Of these, 14 (53.8 percent) were rated as showing improvement in psychiatric symptoms.

Response to Methadone, Counseling, and Psychotropic Drugs

Three classes of drugs were prescribed in the remaining 38 psychiatrically-diagnosed patients, namely, major tranquilizers, minor tranquilizers, and antidepressants. These were prescribed to treat appropriate target symptoms, and sometimes two or three agents were prescribed to individual patients in an effort to improve multiple target symptoms. The response of these patients is shown in table 5.

Table 5.—RESPONSE TO COUNSELING, METHADONE, AND PSYCHOTROPIC DRUGS

Diagnosis	Number of patients	Total	Improved
Depressive reaction	9	11	8 (88.8%)
Borderline	3	3	1 (33.3%)
Borderline with depression	14	18	11 (78.5%)
Borderline with personal disorder	6	17	4 (66.7%)
Borderline with conversion	0	1	
Borderline with alcoholism	1	3	1 (100%)
Schizophrenia	5	11	3 (60%)
Total	38	64	28 (73.7%)

Of the 38 patients receiving one or more psychotropic drugs, 28 (73.7 percent) were rated as showing improvement in phychiatric symptoms. Of the total of 64 psychiatrically-diagnosed patients, 42 (65.6 percent) of patients were rated as improved.

Discussion.—It is important to stress that this is a retrospective, clinical study, not a controlled prospective study. Drugs were prescribed according to clinical assessment and severity of symptoms. Nevertheless, it would appear that about 50 percent of unselected cases reporting to a voluntary methadone program have concomitant psychiatric disorders of a serious type. A significant number responded favorably to methadone plus counseling, and an even greater number responded to these modalities plus psychotropic drugs.

Two further precautions are in order:

1. Since the total caseload was studied, some of the patients had only been in treatment for a short time, and none had been treated for more than 6 months.
2. Many of these psychiatric disorders are of a chronic or relapsing type and may require prolonged supportive and/or drug therapy. Borderline patients are notorious for their liability and their inability to tolerate stress. Most require prolonged or repeated therapeutic intervention.

It is our hope that this preliminary report will stimulate others to examine psychiatric diagnoses more carefully and to experiment further with the judicious use of appropriate psychotropic drugs.

REFERENCE

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DEPRESSION IN OPIATE ADDICTS MEASURED BY OBJECTIVE TESTS

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and
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Previous studies of opiate addicts vary widely in their interpretation of the extent of psychopathology. Yet, a determination of the nature and extent of psychopathology in opiate dependent individuals is vital information if we are to have a scientific foundation for treatment. This becomes particularly relevant now that we have a wide range of psychotropic drugs which are fairly specific in their ability to effect certain target symptoms. Furthermore, to the extent that treatment of opiate addicts becomes more effective, the more likely it is that treatment will replace penal methods as the primary means of control.

Perhaps the reasons for such widely divergent opinions concerning the personality and dynamics of the addicts are to be found in the methods of study utilied by their respective proponents. With the few exceptions outlined below, these theorists have based their opinions on case study material, psychiatric reports, and epidemiological data. Although interesting and relevant to the formation of hypotheses, such data do not constitute adequate verification of psychopathological theses. Such verification can only come from objective measures of personality and psychopathology which have both adequate reliability and validity.

Previous objective psychological studies of narcotic dependent individuals have found elevated *D* and *Pd* scales on the Minnesota multiphasic personality inventory (MMPI) (Hill, et al., 1960), which were interpreted as indicating the presence of depression and psychopathic deviancy (Razor, 1969). Lombardi et al. (1968), found in a cross-validated item analysis of matched prisoner controls and heroin addicts, 19 discriminating MMPI items, of which seven were on the *D* scale, and eight on the *Pd* scale, adding further confirmation to the results of the Hill et al. study. Unfortunately, the *D* scale of the MMPI does not discriminate between "state" or "trait" depression. (Comrey, 1957), O'Conor, Stefis, and Gresock, 1957), Consequently, the correct interpretation of the Hill et al. findings of depression cannot be made.

The Minnesota multiphasic personality inventory might be considered the psychometric equivalent of a broad-range initial psychiatric interview. It enables the skilled user to define the areas that need further elaboration in subsequent sessions. However its very broadness, multidimensionality and comprehensiveness limit its specificity. Once an area is defined for further investigation, more delimited, but specific procedures are called for. Self-reports, in the form of check lists and inventories, have the highest validity and reliability in comparison with other psychological evaluation techniques in specific delimited areas (Mischel, 1968, pp. 106 ff.).

The purpose of this study is to determine the nature of the depressive symptomatology of narcotic addicts and to compare their pattern of symptoms with normals, neurotics, and psychotics. The measures of psychopathology we have chosen are all objective, highly specific, self-report inventories:

1. The Zung self-rating depression scale (SDS) is devised directly from the clinical psychiatric diagnostic indicators for depression (Zung, 1965). It has been found to be robust with respect to confounding by age, sex, social class, and so forth (Zung, 1967).
2. The Beck depression inventory (BDI) has a large amount of normative and research data (Beck, et al., 1961; Beck, 1967). It differentiates well between depression and anxiety (Beck, 1967); correlates highly with clinical ratings (Beck,

1962), and is not very subject to response sets (Beck, 1967, pp. 206–207).

3. The 35 symptom check list (SCL) is used in psychotropic drug evaluation research and was originally derived from a set of items used for the assessment of therapy as well as diagnosis (Frank, et al., 1957; Parloff, et al., 1954; Lipman, et al., 1968; Williams, In Press).

Method

The SDS, BDI, and SCL were administered to 196 outpatients, constituting approximately 80 percent of the active caseload (253 cases) on the methadone program of the West Philadelphia Mental Health Consortium during the week of October 10, 1969. All the outpatients were undergoing substitution therapy with methadone. (Wieland, et al., 1969. Demographic data was collected by interviews at the end of the previous month as part of our regular monthly evaluation.

Table 1.—SELECTED CHARACTERISTICS OF PATIENTS UNDER TREATMENT ON SEPT. 1, 1969—MEAN AGE 31 YEARS

	Percent
Program distribution:	
Low dose (<60 mg.)	56.0
High dose (>60 mg.)	44.0
Race distribution:	
White	44.8
Black	55.2
Sex distribution:	
Male	83.0
Female	17.0
Age distribution:	
Less than 20	3.2
20 to 29	43.3
30 to 39	34.7
40 to 49	13.4
50 and more	5.4
Education distribution:	
8 years or less	11.2
9 to 11 years	54.5
12 years (H.S. graduate)	27.1
13 to 15 years	5.4
16 years (college graduate)	1.4
More than 16	0.4
Current occupations of those employed (60%):	
Executive—professional	0.6
Manager—proprietor	
Administrator—supervisor	3.9
Clerical—sales	8.4
Skilled manual	31.6
Semiskilled manual	20.6
Unskilled manual	34.8
Total	100.0

All subjects were individually tested by one of the authors (S.S.). In addition to the 196 subjects successfully tested, 15 subjects (5 percent of the total narcotics unit) were tested, but their scores are not reported because of obvious invalidities in their protocols, such as gross inconsistencies in their responses and evidence of hurriedly and inadequately completed forms. No test protocol was accepted unless it contained answers to all test items.

Population.—Social and demographic characteristics are presented in table 1. Low dose refers to patients who were taking less than 60 mg. of methadone daily. High dose refers to patients on 60 to 200 mg. daily.

Results

The 35 symptom check list was included in the battery of instruments as a measure of the importance of repression vis-a-vis other symptomatology. The total scores are shown in table 2.

Table 2.—35 SYMPTOM CHECK LIST (N=196)

Mean	S.D.	Range	Mean+1 S.D.
59.039	16.955	35–112	42–76

The separation of the symptom check list into its components factors by Rickels, et al., (1969) was utilized to yield mean scores for each factor in the sample. Mean scores and standard deviations of the ranked factors of this instrument are presented in table 3. The results indicate that depression is the most important factor, with fear-anxiety and cognitive performance difficulty next in order. The lowest factors are somatization and general neurotic feelings. Hence, the notion that opiate dependent individuals tend to be depressed is borne out in an atmosphere where restrictions of freedom, such as an inpatient setting, is not a confounding variable.

Table 3.—35 SYMPTOM CHECK LIST FACTORS RANKED IN ORDER OF DECREASING MEAN SCORES

Factor Number	Label	Mean	S.D.
V	Depression	1.747	0.607
IV	Fear-anxiety	1.737	0.607
III	Cognitive-performance deficit	1.706	0.545
II	Somatitization	1.550	0.500
I	General neurotic feelings	1.497	0.462

The total scores for the Beck depression inventory are presented in table 4, along with comparative scores from three other nonaddict populations.

Table 4.—COMPARATIVE SCORES ON BECK DEPRESSION INVENTORY

Group	Mean	S.D.	Range	Mean ±1 S.D.
1. This study (N=196)	12.852	9.740	0–40	3.1–22.5
2. Beck ("hospitalized psychiatric . . . clinically judged 'not depressed'") (N=115)	10.9	8.1	N.A.	2.8–19.0
3. Beck (ibid.) (". . . clinically judged as depressed mildly") (N=127)	18.7	10.2	N.A.	8.5–28.9
4. Beck (ibid.) (". . . clinically judged as depressed moderately") (N=134)	25.4	9.6	N.A.	15.8–35.0

Three separate factor analyses of the Beck depression inventory (Beck, 1969; Pichot, 1964; Weckowicz, 1967) were combined to yield six factors. These factors were obtained by the criterion of taking the highest loadings on each item on the separate factor analyses. Factor analysis of our 196 patients is presented in table 5 ranked in order of severity. The predominant factors are irritability, disturbances of appetite, weight, and sleep, and performance difficulties.

Table 5.—BECK DEPRESSION INVENTORY FACTORS RANKED IN ORDER OF DECREASING MEAN SCORES

Factor Number	Label	Mean	S.D.
IV	Irritability	0.934	1.043
II	Appetite, weight, and sleep loss	0.757	0.713
III	Performance difficulties	0.732	0.724
I	Depression, guilt, sense of failure	0.601	0.559
V	Social withdrawal	0.520	0.868
VI	Body—image change, crying, loss of libido	0.495	0.573

The total scores for the self-rating depression scale (Zung) are presented in table 6, along with comparative scores from nonaddict populations.

Table 6.—COMPARATIVE SCORES ON SELF-RATING DEPRESSION SCALE (ZUNG)

Group	N	Mean	S.D.
1. This study	196	42.35	10.07
2. Zung (1965) 100 Normals	100	26.50	14.11
3. Rickels, et al., Anxious Neurotic Outpatients: in a clinic (In Press)	36	48	N.A.
4. Ibid . . . in general practice	59	53.6	N.A.
5. Zung (1965) diagnosed as: psychoneurotic depressed reaction.	39	64	N.A.
6. Ibid. Psychoneurotic anxiety reaction	28	54	N.A.
7. Ibid. Personality disorder	41	55	N.A.
8. Ibid. Transcient situational adjustment reaction	19	53	N.A.

The factor analysis of the SDS completed by Rickels, et al (1969) was utilized to obtain factor scores which were then ranked in order of severity. These are shown in table 7. The predominant factors are performance difficulties, depressive outlook, and appetite disturbance.

Table 7.—ZUNG SELF-RATING DEPRESSION SCALE FACTORS RANKED IN ORDER OF DECREASING MEAN SCORES

Factor Number	Label	Mean	S.D.
V	Performance difficulties	2.628	0.756
I	Depressive outlook, negative feelings	2.385	0.802
III	Appetite disturbance	2.054	0.860
II	General depression and agitation	1.808	0.559
IV	Somatic complaints	1.695	0.720

Discussion.—According to the SDS (the only scale on which there is data on a normal population), our patients are significantly more depressed than normals ($p=0.005$), despite the fact that they are in treatment with methadone and counselling. However, according to the BDI they are not as depressed as hospitalized patients judged as mildly depressed ($p=0.005$) or "moderately depressed" ($p=0.005$).

The factor analysis of the SCL indicated the three dominant symptoms to be depression, fear-anxiety, and cognitive-performance deficits. In order to determine the nature of these symptoms and to compare them with populations of nonaddict patients, the factor analyses of the BDI and SDS were utilized. The BDI revealed that irritability was the predominant factor, followed by disorders of appetite, weight, and sleep, and performance difficulties. The SDS indicated performance difficulties as the dominant factor, followed by depressive outlook and appetite disturbances. It is noteworthy that our patients exhibited low scores on loss of libido and somatization, similar to neurotic patients.

These findings present objective evidence that opiate dependent patients under treatment in a methadone program tend to continue to experience dysphoria. It is more severe than "normals" but less severe than neurotics or psychotics. Furthermore, the nature of the dysphoria differs qualitatively from neurotics and psychotics in that opiate addicts experience more irritability, performance difficulties, and negative outlook, whereas neurotics and psychotics experience more of a depressive mood with guilt or agitation.

Of course, there is a considerable overlap in this data, and individual patients vary widely from one another. We have found that some patients exhibit clinical depressions similar to other psychiatric populations and respond equally well to antidepressants and supportive therapy. This clinical recognition, which was confirmed by the present study, has improved the prognosis in these patients, who might otherwise have shown little or no improvement in a methadone program alone.

We have presented summary data on the total population. Further analyses can be performed to isolate subgroups in the population and to determine whether there is a differential response to treatment in these subgroups.

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MEDICAL EVALUATION AND CARE OF THE METHADONE-MAINTAINED PATIENT

Morton I. Davidson, M.D.

The substance of my talk today will be medical care of the methadone maintenance treatment program patient. We have under our care at the Medical Center, several thousand (2,000 plus) patients with tentacles stretching to all parts of the city, giving advice regarding our experience.

The care begins with the initial workup. The evaluation entails a complete history and physical; blood work is done by the SMA–12 multichannel method, blood count, serologic evaluation, urinalysis, chest X-ray, and electrocardiogram. From this point on, our medical clinic handles problems that are referred by the outlying clinics, which do not take care of the specific medical problems, but refer the patient with his complaint to our facility. At this facility, we have several internists, who during the day will see the patients for their specific complaints and direct their diagnostic and treatment programs. Night and weekend coverage is by telephone; advising nurse, patient or physician.

There are inherent difficulties in this type of system because of the nature of our total responsibility. We refer a patient back for followup, and this requires close supervision of this population of patients because many of them have had poor relations with the medical profession and are unable to keep appointments. We have assumed the responsibility of reminding and assisting our patients in followup.

On the intake physical, we have on numerous occasions picked up significant pathology. Recently, we had one man, in his fifties who underwent a routine physical and during the rectal examination, a carcinoma was revealed. Presently, he is under surgical care at the Beth Israel Medical Center for this disease.

At this point, I would like to discuss problems most inherent in our patient population. Pulmonary problems are seen regularly and probably take up most of the time of our physicians. Heroin addicts have chronic lung disease because they are chronic smokers and, too, because their lungs have for many years had to act as filters for intravenous injections. Many of our patients have had pulmonary function studies, which have revealed obstructive and ventilatory abnormalities; some have also had diffusion problems. To our clinical eye, it seems that out of this population this has been a significant problem. The patients have a propensity for developing pulmonary infections more readily than the normal population. An upper respiratory infection followed by fever and cough is a very common complaint and the X-ray findings usually reveal an infiltrate. We have had success in treating these patients as outpatients with close followup. Hospitalization has not been needed in most instances. We know that many of these patients harbor tuberculosis and, from the public health standpoint, chest X-ray is imperative. Methadone has given stabilization to these patients so that they wouldn't leave treatment before it's completed. (Note Van Etten studies.)

The second large area of disease is in those patients who have liver disease. Most patients, who have had a chronic use of intravenous drugs, have incurred at least one bout with hepatitis and/or its variants. On the program, we do see significant chemical abnormalities in patients who are symptom free. The finding of a slightly enlarged liver is also a common event.

The problem of alcohol abuse should be discussed because of its significant medical implications. Alcohol has become a problem in our patient population. The idleness and the return to a very similar environment without the support of heroin makes alcohol that much more desirable. This is inexpensive, apparently socially acceptable and so we see the rapid deterioration of our patients. Over a short period of time, these people will begin to gain weight and very frequently will get quite obese. Hepatomegaly, icterus and deranged chemistries make it evident that hepato-cellular injury has taken place. These people have been instructed and warned of the problems with alcohol, but then we begin to face the very difficult problem of treating alcoholics. It is a strikingly common event to see the rapid deterioration of these patients, who having had several months to a year on drinking, and begin to have serious liver deterioration. Several episodes of pancreatitis have been seen in this group of patients. Dermatologic problems are seen frequently. They are characteristically multiple infections, skin breakdown, and edema. It's our feeling that much of the edema of the extremities has been caused by chronic injury to lymphatics and the venous system. This is obvious when one looks at the scars on the arms and legs of these patients, particularly those who have been "skin popping." We have been fortunate in not having seen tetanus in our patient population. We immunize our patients on admission with toxoid. The Medical Center has, in a period of 2 years seen four patients with tetanus. Our success was quite good in their treatment and three survived, but this has had nothing to do with the methadone program.

Gastrointestinal complaints are another area that we see quite frequently. Certainly, constipation and the inevitable problems associated with this—anal difficulties, fissures, hemorrhoids, etc.—have become a common complaint. As time goes on, the patients become more adjusted to methadone and, with mild laxatives and stool softeners, the problems are well handled. The upper gastrointestinal compaints such as ulcer disease are common complaints. We see patients with a previous history of ulcer disease who, when continued in their evaluation, will eventually find an organic cause for their frequent complaints.

In discussing the management of patients with pain, it has been our observation that these patients are able to be managed in a relatively routine fashion. Perception of pain, has been *no* problem. There has never been a problem of masking symptomatology. They have experienced dental problems and perceive pain normally. One can see by the number of patients that are seen for aches and pains that this is not the case. However, when it comes to relieving pain, we have had experience with the use of superimposed narcotics such as morphine and demerol. These have been successful. Patients have been relieved of their pain. The explanation for this has not been worked out. These are empirical observations in the management of patients who have had pain—anywhere from abdominal-type pain, (visceral pain,) to patients with fractures etc. It does not seem to be that methadone, in itself, handles the pain, nor does it dull the patient's perception of the pain. "We refrain from using barbiturates, sedatives, tranquilizers and, certainly Talwin."

We have had patients who have undergone surgery varying from abdominal to orthopedic surgery to chest surgery. The patients have been managed with no particular difficulty regarding anesthesia. Again, these are empirical observations.

These patients are usually premedicated with a smaller divided intramuscular dose of methadone, and using other usual premedications or barbiturated or atropine derivatives. In the post-operative state, when they are more fully aroused (in the recovery room), they receive another divided dose of methadone and pain medication over and above this, if necessary. The patient will be given divided doses of intramuscular methadone while "N.P.O." When they are able to begin to ingest, their doses are put back to a normal once-a-day dose. We have no difficulty with this approach. These patients seem to handle their anesthetic quite well. There does not seem to be any specific increase in resistance to inhalational anesthesia.

In managing these patients, it has come to our attention that they are very much an immigrant population. We have brought about a new influx of people and are trying to integrate them into a foreign community. The integration into a community is the greatest difficulty and the offshoots of this are problems with housing, health management and jobs and, as a practicing doctor managing these patients, one gets the feeling that we have turned them back into a society that is in no way ready to accept them.

The problem patients (socially) will be seen over and over again; the patients with problems that lead to drinking, drug abuse, and deteriorating health. These are the people who may be socially or emotionally immobilized to begin with, and methadone is just keeping them off the streets regarding the heroin. Deterioration begins when these people start to use other drugs and this must be managed. There is a certain significant group which, I believe, has always been and most probably will continue to be the other drug abusers. These are the people who cannot in any way adjust to living in a usual life setting without some kind of intoxicant. To manage these people, if one is to keep them on the program, raises enormous problems. If one discharges them from the program . . . the program has settled its problem. However, these people are not back in the community, probably worse off than they were when they were using heroin. This is a problem that we begin to face and, as the doctors who see these people, our concerns are great. We at Beth Israel are now trying to review this situation to see what is happening and what we can do to offset and help the failures. At the present time, you have heard the statistics regarding the favorable percentage of our patients being rehabilitated, but the great concern is with those people who are failing and why they are failing.

I would like to reiterate that we are dealing with a patient population that is not physically well. We have all heard that addicts are a young and healthy population. Well, this is not so from our experience. We have patients who range in age from the "teens to the eighties." We have a patient population who are faced with the problems of the aged—such as heart disease, lung disease, neurologic impairment, and senility. Drug addiction has hit all generations and we have these people on the program. Medical evaluation and care are an absolute necessity. The physical examination, to begin with, should be an integral part for any program to be successful. These patients, like any other population, should undergo their physical examination at regular intervals. If this is not feasible, because of the program size, these patients should be seen as often as is possible. The admitting physical, blood work, and followup in a drug addiction treatment program are a necessity.

I'd like to take this opportunity to state that the methadone program should not deteriorate into a methadone dispensary program. It is a treatment program in a multifaceted fashion and to do things in a less than desirable way for political expediency would actually reduce the success rate substantially.

OBSTETRICAL ASPECTS THROUGH THE DELIVERY ROOM

George Blinick, M.D.

I think that one of the most frequent questions asked is, "What is the affect of addiction on pregnant women and their offspring?" Dr. Blatman and I will try, sequentially, to answer this in part. This is a very widespread concern. I regret that I was not able to be here yesterday, but I wasn't here because I was attending a symposium on differential reproduction in individuals with mental and physical disorders. This was sponsored by the American Eugenics Society, Bio-Medical Division of Population Council. To my surprise, I found that we were discussing the fertility of narcotic addicts and the effects of addiction on the offspring. This group was primarily a group of genetic psychiatrists or psychiatrists interested in genetics, and they came from all over the world—all over the country—and their interest was as great, wherever they came from, in what was happening in pregnancy, and what was happening to the offspring of women who are addicted or in the methadone maintenance programs. I learned much from this diverse experience. They were from all over the United States.

People captured me from Memphis, where they said it came late. But there it was in Nashville, England, Denmark, etc., etc. In any event, to get down to the paper, a survey of the literature would indicate that the female addict has amenorrhea, anovulation, and infertility. Addicts, themselves, believe this; although their retrospective histories are often contradictory and unreliable. In any event, the observed number of pregnancies of chronic addicts lends itself to this concept. Nevertheless, a number of investigators have found that heroin interferes with the normal menstrual cycle, ovulation; that under experimental conditions, not exactly like that of chronic addiction, it has been shown that morphine depresses ACTH and adrenal function. In actual fact, we do not really have very good endocrinological data on what happens to the addict. Dr. Paul Cushman of St. Luke's Hospital is in this room and, perhaps afterwards, he can tell us of his findings in the endocrinology of the addict world. In addition, studies of addiction complicating pregnancies, severe withdrawal symptoms in the baby, resulting in a characteristic syndrome of high pitched cry, restlessness, twitching, irritability, and convulsions have been described. At the same time, a high incidence of maternal complications such as toxemia, abruptio, postpartum hemorrhage have been reported. As you know, this study originated in the Bernstein Institute, and to this sophisticated audience, I am sure I need not explain that there are two types of programs at the Bernstein Institute. One is the detoxification and one is the methadone maintenance. However, to a less sophisticated audience this becomes very confusing because we are using the same drug in both programs. So Dr. Chryssanthou of our Department of Pathology drew me a little cartoon, which I find very helpful, and some of you may find helpful too. This shows a center block of methadone detoxification as you know it. The addict gets out into the world and at 16th Street he meets the pusher. His doses begin to increase, he can't afford to have it any more, and he's thrown into Bernstein for detoxification. This is obviously the revolving door approach, as compared to methadone maintenance, which, beginning (you know these are arbitrary figures) with low dosage, is gradually increased until an average of about 80 to 100 mg. is taken daily and continued daily.

I think you might like to know what has happened in the detoxification program, very briefly. Thus far, we have delivered 211 mothers who have undergone detoxification. Forty percent of these mothers returned to heroin between the interval that that they were detoxified and the interval that they were delivered. Ten percent of them took heroin immediately before entering for the relief of pains of labor. So a substantial number of them had heroin going despite the detoxification. We had nine prenatal mortalities and the two significant complications were that one-third of the babies in this detoxification group were premature by weight and one-third had old meconium in the amniotic fluid. The meconium in the amniotic fluid seemed to be related to intrapartum stress; not stress at the time of delivery itself. Prematurity is a serious problem. Dr. Blatman will tell you we don't know the fate of these children, but it's obvious that the low birth weight infant has many more developmental errors, than the normal birth weight. The maternal complications included an extremely large number of women with malnutrition and positive serology; but other complications such as bleeding, toxemia, diabetes were uncommon.

In the methadone maintenance treatment program, which is the program that we're interested in today, we have had 230 female admissions, 42 discharges, six deaths, leaving a current total of 188 patients. In these 188 patients, 20 pregnancies have been delivered. Of these 20 pregnancies, seven are premature by weight. We know that they're premature by weight, low birth weight babies, rather than premature by date, because in this stabilized group of patients, we know when their last menstrual period was. There was one stillborn, not related to methadone; a stillborn who had an intrapartum death because of strangulation by the umbilical cord, and a very careful autopsy did not reveal any congenital anomaly. There were four abortions and one ectopic pregnancy in this group of patients. The first 120 patients in the methadone program were closely observed, since they were all concentrated in the Bernstein Institute, as compared to the present and and desirable decentralization of the maintenance treatment centers. Of these patients, 83 were in the childbearing age and all but one began to menstruate normally, usually within 1 to 2 months, occasionally as late as 8 months. There were 20 deliveries; 13 of these pregnancies were initiated when the patient was on large doses of methadone in the treatment program. Seven conceived while they were on heroin and, because they were the

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wives of husbands in the methadone program, were accepted into the program when 4 to 5 months pregnant, and then built up as the ordinary methadone patient is, so that they were taking anywhere between 80 and 100 mg. of methadone.

In the beginning, because of the fear that a synthetic narcotic such as methadone would be tetragenic, we attempted to reduce the dose and as we reduced the dose in our first two patients, they promptly went back to heroin, and we promptly went back to giving them the same amount of methadone that is necessary to keep them free of symptoms. The antipartum course in all cases was uneventful, with not toxemia or undue weight gain. One patient had the stillborn vaginal delivery, which I described as the strangulation with the umbilical cord, and this is the only fetal death in our series. There were two cases of placenta praevia; one with a partial abruptio—a baby who weighed 2 pounds 14 ounces and was the only small, really small birth weight in the series. All babies, except two, had Apgar scores of 8 to 10, which means they were responsive and alert 1 minute after delivery. No congenital anomalies were noted. You all know that the patients in this group were specially selected, so that schizophrenia, alcoholism, multiple drug abuse of a severe nature excludes such a patient when detected. Furthermore, the pharmacological effect of methadone on menstruation may differ from heroin. We don't know. Two, and I think very important, the program stabilizes the life of the addict; three, it corrects the severe malnutrition which most addicts have and finally, as you learned from Dr. Davidson, these patients are under medical surveillance. The placental transfer of methadone is no less a problem in evaluation then the transfer of heroin and morphine. I think you know, at least until very recently, and now only in the experimental stage, that the minute amounts of morphine that pass the placental barrier cannot be detected by ordinary biochemical methods. This is really quite different from trying to detect morphine in the urine or blood, for that matter, of an adult male who is taking a fix, because the amount of drug that we're dealing with (fetal blood, fetal tissues, placenta and amniotic fluid) is really very minute. Little is known about the rate and extent of the passage of morphine across the placenta. Recently, in the laboratories of Beth Israel Hospital, it has been shown that morphine is bound to the proteins and therefore, not able to be detected by ordinary biochemical methods. If we can split morphine off the protein, then we think we can detect the small amounts of morphine and determine something about its placental transfer and this is in the process of investigation. In summary, in women treated with large doses of methadone, a synthetic narcotic drug, regular menstruation, ovulation, and a normal pregancy take place. One-third of the babies weight less than 2500 grams and are, therefore, premature by weight. No congenital anomalies have been found. Followup visits, as Dr. Blatman will demonstrate, so far have shown normal physical and intellectual development.

NEONATAL AND FOLLOWUP

Saul Blatman, M.D.

Since February of 1965, the Department of Pediatrics of the Beth Israel Hospital has cared for approximately 230 babies born to women who use heroin. These babies were delivered in the hospital's Department of Obstetrics under Dr. Blinick's direction. Almost all of the mothers came to us directly or indirectly from the Morris J. Bernstein Institute, a division of Beth Israel Medical Center. Almost 100 percent of them had received either one or more short courses of methadone during pregnancy in the Center's methadone detoxification program. Of great interest are 20 mothers who were treated in the methadone maintenance treatment program and who had conceived while on high dosage of methadone or who had started high dosage of methadone or who had started high dosage of methadone at some time during pregnancy, usually 100 mg. per day. It is this latter group of babies born to women maintained on methadone during pregnancy upon which I should like to focus most of my attention today. But I would like to tell you something about the other group. The large group of heroin users, who had received one or more short courses of methadone (for approximately 7 days) during pregnancy, gave birth to babies with a lower incidence both of frequency and intensity of symptomatology than has been observed generally elsewhere in babies born to heroin addicts. I would just like to review some of the symptomatology which is referred to frequently in the literature and to say that in our experience, even in the large group of women who were not maintained on high doses of methadone, we did not see as much serious pathology in the newborn baby as is reported by others.

The signs and symptoms with which many of you are familiar are hyper-irritability, tremors, sustained Moro reflex, shrill high-pitched cry, flushing, excessive crying, poor feeding, excessive mucous and lacrimation, excessive sneezing, vomiting, diarrhea, tachypnea, convulsions, cyanosis, vasomotor liability and areas of excoriation of the skin at points of contact with the surface of the crib. It has been important for pediatricians who treat these babies to consider in their differential diagnosis other kinds of pathology, notably neonatal tetany, intracranial bleeding, respiratory distress syndrome, infection-producing diarrhea, sepsis, and meningitis. In our group of patients, numbering about 230, birth weights were generally lower than in the rest of our population. Apgar scores mentioned by Dr. Blinick, which were measured at 1 minute after birth, a test of the overall condition of the baby, and particularly a clue or index to asphyxia, showed the babies to compare favorably with the rest of our newborn population. Only two babies demonstrated congenital malformations in the whole large group. I should also bring to your attention the fact that one of the babies who was considered to have an extreme form of symptomatology did, in fact, have neonatal meningitis, quite apart from the fact that the mother had been on heroin and was a member of the detoxification group. When babies in our large group of patients were symptomatic, medication was administered on an individual basis. Standing orders were not given. The medications used were phenobarbital, chlorpromazine and in some instances paregoric. Medication was titrated according to the baby's need. Those of you who are familiar with the care of infants born to heroin users are probably aware of the fact that many of these babies are often "snowed under" by depressant medication starting soon after birth.

Observations of the symptomatology of the baby in the neonatal period, laboratory results, and followup evaluation of physical status and mental development are as follows in brief: With regard to the problem of infant followup, of importance is the fact that it is relatively easy to make contact with methadone maintenance mothers after the delivery of their children, and although bringing these mothers and babies for repeated clinic visits is often more difficult than with the rest of the population (that is nondrug users), it has certainly been far easier to bring these children into a program of medical care, than in the case of methadone detoxification babies, or babies born to heroin addicts who have not had methadone at all. We have been almost uniformly unsuccessful in bringing into continuous medical care infants born to the methadone detoxified mothers or infants born to untreated heroin addicts. We have made many attempts employing the services of medical students, nurses, social workers and so on, but the only ones with whom we have almost complete success are the methadone maintenance mothers. With regard to duration of hospital stay, the disadvantages of long stay for babies in newborn nurseries or on an acute pediatric hospital inpatient service are obvious. It certainly is not a good idea to keep a baby in the hospital unnecessarily. Even though an attempt may be made at mothering in such a setting, the problems of nurse staffing prevent assignment of nurses in such a way as to provide adequate mother substitutes. For infants born to women who remain on the methadone maintenance program, the range of hospital stay for the infant was 7 to 30 days. This excludes one infant, who stayed for 112 days because the parents removed themselves from the methadone maintenance treatment program, and it was necessary to place this child elsewhere through the Bureau of Child Welfare of the city of New York. This, of course, happens very frequently with nonmethadone maintenance heroin users. Also excluded is a baby who was transferred to a premature center in the first 24 hours. The average hospital stay for infants born to methadone maintenance mothers was 15 days. The range of hospital stay for 200 babies (methadone detoxification babies) was 4 to 154 days with an average stay of 40 days per baby. This 40 days compares to 15 days for babies born to methadone maintenance mothers. I would like to point out that we make an attempt to keep these babies for at least 10 days so that we can observe them.

With regard to disposition of the babies after hospitalization on the pediatric service, all infants of mothers remaining on the methadone maintenance program were discharged from the hospital to the mother's home and care with the exception of one baby, who was premature by weight. Home in the case of methadone maintenance mothers is found to be generally stable and adequate. Of infants born to the first 180 mothers, who had participated in methadone detoxification, only 128, or 60 percent were discharged "home," and "home" in this group was not a stable, desirable place, but was frequently the residence of a friend, a grandparent or anybody at all and when hospital clinic visits for the babies were scheduled, it was often difficult to find them. With regard to birth weight, which Dr. Blinick commented on, infants born to methadone maintenance treatment patients had a birth weight of 2700 gms. compared with a mean

birth weight of 2600 gms. for the infants born to the first 175 methadone detoxification patients. This difference is not significant. I would repeat again as Dr. Blinick pointed out, that one-third of the babies born to methadone maintenance treatment mothers were premature by weight, that is, under 2500 grams.

With regard to congenital malformations, of 19 babies born to methadone maintenance treatment mothers, none demonstrataed congenital malformations. This is extremely important; 19 is a sizable number. In the large detoxification series of over 200 babies, two did, in fact, have congenital malformations. But we are not comparing the two groups. I think that the concern which we have had that methadone administered to the pregnant woman may produce a deformed baby, at least based on these 19 babies, is not confirmed. I think, too, that I should point out again that even in the large group, we have had only two babies with congenital malformations. This is quite different from the reports in the literature. It is said that women on heroin produce babies with congenital malformations beyond expectation in the general population. This has not been the case with our large detoxification group either.

With regard to the Apgar scores (the clue to the babies' overall condition), of the first 13 infants born in the series of methadone maintenance treatment babies, 85 percent had scores which were considered very satisfactory. This is about the same as in the large group. With regard to the symptomatology in the baby during the neonatal period, the term applied so frequently is "withdrawal symptoms" and I think this is an unsatisfactory term, which we should eliminate. When we talk about symptomatology in the baby, we should not label these babies as addicted, because we have no real indication that they are. It is rather difficult to do objective evaluation of the symptomatology of babies. Newborn babies are frequently hyperactive, jerky in their behavior in large part because their nervous systems are not completely myelinated soon after birth. The lighter the birth weight of the baby, the more apt he is to have some symptomatology suggestive of immaturity of the nervous system. In 19 infants born to women on the methadone maintenance treatment program, the following distribution or assignment of terminology has been made. The babies were divided into four categories: Mildly symptomatic, moderately symptomatic, severely symptomatic, and asymptomatic. Eight of the 19 were completely asymptomatic. Six of the 19 babies were in the mild category, characterized by twitching of the extremities and mild irritability but without a clinical need for medication to control these symptoms. Five babies of the 19 had moderate symptomatology characterized by more marked irritability than in the former group with some twitching and with diarrhea, without evidence of infection causing the diarrhea, and with apparent need for medication, which was given. None of the babies were severely symptomatic. For the methadone detoxification group, there was a higher proportion of moderately and severely symptomatic infants compared with the methadone maintenance group.

With regard to laboratory results, of the first 17 babies born to methadone maintenance treatment mothers, liver enzyme studies were within normal limits. This suggests that methadone does not interfere with conjugation of bilirubin in the baby. In addition, electrolyte studies in these babies were all within normal limits. Serum calcium and phosphorus, too, were within normal limits, so that the twitchiness of the babies could not be attributed to hypocalcemia or hyperphosphatemia. Peripheral blood examination showed hemoglobin and white blood cell counts to be within normal limits. Therefore, from the point of view of laboratory measurements, we can say that of the 19 babies, all showed normal laboratory determinations.

With regard to followup for purposes of evaluating physical and mental development, 14 of these babies have been followed for from 4½ to 42 months of age depending upon when the baby was born in the period of the last few years. Each child seen by us has been found to be developing physically within normal limits without exception. Psychometrics performed during these visits using the Knobloch-Modified Gesell Test or the Bayley Scales of Infant Development showed the following overall range: A normal or average test for 11 of the 14 babies; a below average test, as far as development of intelligence is concerned, in one baby; and a high normal or high average intelligence in one baby. One normal baby, who is average in all other respects, showed poor language development at ages 23 and 33 months. Overall, the impression is that this group compares favorably with other children of similar age.

In brief summary, the followup of babies born to women maintained on high dosage of methadone could be carried out satisfactorily and it was relatively easy to gain cooperation of the mothers. The duration of hospital stay was more brief than it was for the rest of the heroin or detoxification population, averaging 15 days compared with 40 days for babies born to nonmethadone maintained mothers. The added stay was required for social reasons most of the time. Most of the babies born to mothers on methadone maintenance, who went

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home with their mothers, came back for care. The birth weights were similar in the maintenance group compared with the detoxification group. Of great importance is the fact that there were no congenital malformations in babies born to mothers in the methadone maintenance group. Apgar scores compared favorably with the rest of the population. Rather minimal symptomatology was seen in the immediate neonatal period. Normal laboratory results and followup for physical development were found. Mental development was satisfactory.

It is important for us to continue long-term followup on these babies to see how they make out as they grow older. So much of the course will be influenced by the environment, but it appears to us at this point, that if mothers remain in the methadone maintenance program, the environment is a more stable one than if they are out of the program.

Before I sit down, I would like to remind you that children get into all kinds of medication and although this is not connected directly with my presentation, as a pediatrician I must tell you that measures to prevent the accidental poisoning of children in the homes of methadone maintenance patients should be taken. Methadone must be kept out of reach of small chidren and should be kept in secured containers. Thank you very much.

DISCUSSION

(Discussion following Dr. Dole's comments on Dr. Blatman's paper)

Dr. Blatman:

I just wanted to amplify an aspect of what Dr. Dole said, which is extremely important. First of all, that children who have ingested methadone be admitted to a hospital for observation. Secondly, that they be placed in a location on the hospital ward or on a pediatric service where they can be watched continuously. For us, the place of preference is in the hall, directly in front of the nurses' station, so that the child can be observed closely for at least 24 hours. Even though he may wake up and respond, he may lapse into coma again since the depressant effect of the methadone may outlast the antagonist effect of the antidote, narcan or nalline.

Dr. Dole:

I would like to amplify a very important statement that Dr. Blatman made at the end of his remarks—namely, the danger of poisoning by methadone. This has been of great concern to us, and there have been, in the past 2 years, two instances of patients' medication being consumed by infants, that I know of, and being either improperly treated in the hospital or brought to the hospital too late for treatment. This is not a large percentage of the approximately 2 million doses which have been dispensed in New York City since the beginning of the methadone maintenance program. At the present time in New York City there are well over 1 million doses of methadone being taken per year. Nonetheless, any poisoning is a tragedy because it should be avoidable.

We must be concerned with both prevention and treatment of methadone poisoning. As to the treatment, there is insufficient knowledge in the medical profession as to how to treat an overdose to nontolerant persons taking methadone. The critical requirement is to maintain respiration. If respiration is depressed, then artificial ventilation should be instituted immediately, using the best means available. There are specific antidotes for the respiratory depressions. They should be made available and the people in the emergency wards should be instructed in the proper use of them. I have prepared a statement on the treatment of methadone poisoning and will distribute it to all who are interested after I have it reviewed. I hope to have available from my office, for anyone who wants it for any treatment program, a standard treatment procedure to be delivered to the emergency room in each hospital, with recommendations for the medication and equipment to be in the hospital inventory.

The only point I want to stress here, so that no one will go away without knowing this fact, is that methadone has a 24- to 36-hour span of depression, depending on the size of the dose, and if naloxone or nalline, each one a specific antagonist, is given and the patient responds and the doctor thinks he has won the battle, the patient could die because the antidote lasts for 2 hours, while the underlying depressant persists much longer.

Now, as to prevention, in our research unit at Rockefeller, for the past 3 years, we have been developing a number of noninjectable capsules or tablet preparations, which are far less attractive to children than the Tang preparation customarily used. With several million doses per year being dispensed as methadone programs grow in size, the danger of a child ingesting a liquid methadone preparation will increase proportionately.

So, I have recommended to our program director, that in the very near future, every patient be put on one of our noninjectable tablet preparations. These will be generally available because the latest model of this has been manufactured by a pharmaceutical house and will become available on a national scale. Thank you.

IV. TREATMENT OF ADOLESCENTS

TREATMENT OF DRUG ABUSE IN ADOLESCENTS

William J. Vandervort, M.D.

A methadone maintenance program was begun at the Wilmington Medical Center in April 1968. It started with 12 patients, $2,000 in contributions, and the backing of the State Department of Correction, the Department of Mental Health, and the Attorney General's Office. The first patients were black, over 21, and usually on parole. They had been on heroin 3 to 10 years and a drug-free existence seemed unlikely.

With the drug scene revolution involving younger patients and a multitude of drugs, methadone maintenance is too rigid a method to cope with this new, fast-moving phenomenon. Thus, in May 1969, the clinic was changed to a drug abuse clinic. We now had 112 patients and $15,000 in funds. The staff was expanded to provide individual and group therapy, social work, counseling, and other services.

The ever-expanding problem became an epidemic in Wilmington in the spring of 1970. State laws were passed to encourage rehabilitation over punishment. A statewide program was initiated with a full-time director. Three additional drug abuse clinics were started in the State of Delaware.

By September of 1970, we had seen 420 patients at the clinic in Wilmington. About 32 percent of these were 13 to 19 years of age. Most started taking drugs at age 14, 15 or 16. In the case of 58 percent, the first drug was marihuana. Forty percent of these patients were still in high school, 50 percent were white, 90 percent male, and most were from the suburbs. This was in contrast to the past experience with black patients from the center city.

The psychopathology ranges from schizoid to sociopathic to simply a dependent, narcisitic-type personality. Group therapy, individual therapy, and psychologic testing are provided. Counseling is also available. The two social workers aid in job and school placement. Eighteen patients received no drug therapy. The rest were given methadone. Sixteen patients were lost to followup, and 14.7 percent of the patients dropped out. Twenty patients, or 4.78 percent, were off all drugs and accepted as 2-year cures.

Two hundred forty-four patients, or 60 percent, are now in active treatment. Forty-four of the patients have been transferred to clinics in nearby States. Sixty-eight patients are (1) just off methadone, (2) applying for a second course, or (3) in special treatment groups. One hundred thirty-two patients are receiving methadone on a daily basis. In addition, 47 patients are in their second course and eight are in their third course.

Each adolescent arriving at the clinic sees the nurse, a social worker, the psychiatrist, psychologist, or the doctor of the clinic. Then the treatment pattern is determined, methadone is prescribed if indicated, further appointments are made and the patient is given an appointment for a medical examination and laboratory studies.

Orientation sessions have recently been added for better patient cooperation. Most patients are started on 30 mg. methadone. This is increased 10 mg. every 3 days to 50–80 mg. and then the dosage is descreased 5 mg. every 3 to 5 days to zero. Vocational, psychiatric, and counseling efforts are made during this interval. As the patient decreases his dosage of methadone towards zero, problems and failures occur. The crucial level is below 30 mg. The patient begins to feel uncomfortable, insomnia and bone pain are common, and much reinforcement is needed. Group therapy with our clinic-psychologist has now been added to this effort.

It is frustrating to see a patient on 20 mg. of methadone and so near to total narcotic withdrawal suddenly have positive urines once again. Though he seems unable to tolerate discomfort, he does not have the determination to fight. He insists on drug assistance—like the obese patient on diet pills. The pleasure principle is stronger than the motivation to be rehabilitated.

I believe that fewer than 50 percent of the patients I see want to be off drugs. They seek help because a loved one demands it, or parole requires it, or the price of drugs at the time causes it. But the adolescent feels so much better on drugs that

he would not consider stopping. With drugs, the insecure adolescent becomes more secure. Painful daily events become tolerable. Depression lifts and its return will not be tolerated.

So, the treatment of adolescent drug problems is not medical but sociologic. Only society in general can reverse the trend to drugs. The music and idols of adolescents must be turned from drug orientation to nondrug, or all of our future young people will turn to drugs. The Brave New World will be a reality and soon. If the Establishment is thoughtful and wise, it will be helpful. If the necessary changes in society are made, there will be less need for drugs and a separate drug culture. It is up to us to see that these changes occur. If they do not, drug abuse clinics will be unable to stop the turn to drugs and the Brave New World will indeed be here.

SLOW DETOXIFICATION OF ADOLESCENT HEROIN ADDICTS IN NEW YORK CITY

Robert B. Millman, M.D.
and
Marie E. Nyswander, M.D.

There are no good estimates as to the extent of adolescent heroin addiction in New York City. We know that several hundred adolescent heroin users go through the courts monthly, and one prison in the area has limited itself to offenders in this age group. It has been reported that 60 percent of the enrolled students at several New York City high schools have used heroin. These facts are not surprising. Adolescents in this city with few cultural or educational options, given the exposure, might be expected to turn to heroin in increasing numbers.

The primary focus of agencies working with this age group has been education and prevention. To date, few successful treatment facilities exist in this city. Many of the street programs have terminated their services and the ongoing therapeutic communities have been unable to cope with the large number of young people requiring help.

Two years ago, in response to this problem, our group at the Rockefeller University began a study of adolescent heroin addicts, combining rehabilitative services with slow detoxification, using low doses of methadone. Beginning with two boys, the research program has admitted a total of 25 patients. The number has been kept low to permit us to make detailed observations concerning the problems of the patients and the rehabilitative process.

Patients were admitted to the program on an individual basis, with the stated aim of the protocol being to consider only so called "hard-core addicts." In general, patients were under 18 years of age and had a history of 1 to 2 years of continuous mainline heroin addiction. They had failed on other recognized treatment programs and had had previous arrests. All patients were selected from the metropolitan area; explicit parental consent was required in each case.

Patients were treated as outpatients at the Rockefeller University Hospital. Upon admission, all patients received a complete physical examination, X-ray of chest and laboratory workup. In selected cases, psychological testing has been performed. When necessary, further medical treatment was provided as well.

At the onset of treatment, the dose of methadone was low (10–20 mg./day in most cases), and was subsequently brought up to a maximum of 20–50 mg./day. Medical complications of the medication have been negligible. A number of patients experienced constipation, relieved in all cases with a laxative, Several complained of drowsiness early in their course. One patient developed an allergic skin reaction when begun on the medication, though this was found to be due to the Tang vehicle.

Initially, all patients were required to come to the clinic each weekday to take their medication and leave a urine specimen. They were given medication on Friday to take home for Saturday and Sunday. Five of the patients were hospitalized at Rockefeller University for short periods of special observation. The program undertook to provide a situationally oriented form of counselling, vocational and educational guidance, and recreational leadership.

Of the original 25 adolescents, 23 are currently in the program. One left because his home was in Connecticut, the other, a 13½-year-old, failed to keep his regular appointments and was therefore discharged to a treatment program providing residential control. We have continued to follow both these patients.

In the present group, the average age is 17, with a range between 13 and 22. Of these 23 patients, 11 have remained heroin free, seven have used heroin occasionally (1 to 3 times per month), and five are using the drug several times weekly. In no case, however, has a patient become readdicted to the regular daily use of heroin.

We plan to withdraw methadone from all patients who are socially stable and appear to have a reasonable chance of doing well without medication. Two patients in our group have already been detoxified. They continue to come to the clinic for consultation and to leave urine specimens. Whereas both of these patients have used heroin occasionally in the 7 months since detoxification, neither has become readdicted.

Interestingly, there has been little problem with abuse of other drugs. Two patients used amphetamines intermittently, one patient used barbiturates on weekends, and another has used cocaine on several occasions. Two patients reported single experiments with LSD.

As in the adult program, we are interested in defining the essential components of an effective rehabilitation program. To this end, we are analyzing the roles of different staff members with a view toward expansion of the program. At present, we have a staff of two full-time counselors, an ex-addict research assistant who is on the methadone maintenance treatment program, a secretary, and two physicians. The ratio of staff to patients is high because of the research nature of this program; in a service program, the same staff could provide treatment for at least twice as many patients.

Coupled with the problem of drug dependence and its disabilities, our patients also face the very real problems of deprived adolescents in an urban society. Adults being treated by the standard methadone maintenance treatment programs are encouraged to get jobs and support themselves. In most cases, the formal education of these patients was interrupted quite early, and they have little opportunity to return to school. Similarly, adolescent addicts generally have left school, yet they are too young to obtain regular employment. We feel that whenever possible, patients should be encouraged to return to school or equivalently take jobs that provide vocational training.

Of the 23 patients presently being studied, 10 are attending school regularly, whereas three were attending prior to admission to the program. Seven patients are working full time. Of the six remaining patients, three are registered in school but do not attend regularly, and three are seeking employment.

We have established liaison with schools the patients attend, so as to be able to provide support when necessary, as well as maintain adequate followup. One of our counselors, a former New York City schoolteacher, frequently visits individual teachers and administrative personnel to this end. Volunteer tutors, generally Rockefeller University graduate students, have provided some individual help to the patients. Similarly, one of the counselors concentrates on vocational guidance. Contacts have been made with vocational agencies as well as individual firms. It has frequently proven helpful to accompany the patients to an interview.

As in the regular methadone maintenance programs, we have found that an ex-addict, himself on a maintenance program, may play a crucial role in counseling other patients. This may be particularly true in an adolescent program where the patients are able to identify with him. Frequently, it is this staff member who makes the initial contact with a prospective patient. One of our counselors also serves as the liaison with the probation office and courts. A good number of the patients had cases pending when they were admitted to the program, and we elected to take an active interest in these.

ADOLESCENT HEROIN ABUSE IN SAN FRANCISCO

David E. Smith, M.D.
George R. Gay, M.D.
Barry S. Ramer, M.D.

San Francisco has the dubious distinction of being the focal point in our Nation for youthful drug abuse. Those patterns of drug abuse which started in San Francisco have spread rapidly to neighboring California communities and have ultimately spread out across the country in a "ripple" effects. Today in San Francisco, we find ourselves in the throes of a full-blown heroin

epidemic, and 1970 is labelled the "year of the middle-class junkie." There has been an alarming increase in deaths due to narcotics abuse in San Francisco. In 1965, the coroner recorded four deaths due to narcotics overdose, and in 1970, there have already been 47 deaths.

The Haight-Asbury Free Clinic has witnessed a shift in the abuse pattern of their clientele who use marihuana and LSD in the 1967 "Summer of Love," then on to Speed and barbiturate use in 1969, and now to heroin in 1970. At the San Francisco Center for Special Problems, we are witnessing an increase in the number of adolescents seeking treatment for narcotics addiction since the inception of our methadone maintenance treatment program. Our population of addicts has more than tripled in the past year with 250 new cases a month seeking treatment. An estimated 20 percent of these are under 18.

The combination of extensive rehabilitative services with slow detoxification using low doses of methadone appears to hold promise in the treatment of adolescent heroin addiction. We have demonstrated the ability to wean patients off heroin, and we think it is significant that no patients have become readdicted. Two patients have been detoxified to date, and though both patients have used heroin on occasion, neither has used regularly. More data is required before a statement may be made relative to the feasibility of detoxifying the majority of adolescents on the program. We will continue to explore staffing patterns and the provision of more effective ancillary services.

There are only two programs in San Francisco which provide outpatient nonnarcotic detoxification: The Center for Special Problems and the Haight-Ashbury Free Clinic. Both utilize combinations of phenothiazines, sedative-hypnotics, antispasmotics, and mood-elevators during outpatient detoxification. Only 10 percent of those individuals withdrawn without methadone complete the withdrawal process, and the recidivism rate is almost 100 percent.

Today's addict is using heroin as a social anesthetic to make life tolerable in a society that clearly rejects him. Whereas, just a few years ago during the "Kennedy era" the young addict liked what he saw and turned to psychedelic drugs to intensify that vision, his counterpart today is depressed and alienated and uses heroin as the ultimate pharmacological "copout."

The demographics of the addict population are changing rapidly. Addicts are younger, more of them are female, and more of them are white middle-class dropouts. They have been using heroin for less than 3 years and have an average daily habit of $75. Nearly all of them are unemployed. In our community where 16 percent of the population are oriental, less than 1 percent of the young people seeking treatment for heroin addiction at the Center for Special Problems and oriental. This might be attributed to a feeling of suspicion and mistrust toward non-Chinese physicians on the part of the ethnically conscious young Chinese-Americans, or it could be consistent with the Chinese tradition of keeping trouble inside—inside the individual, the family, or the community. All we know for certain is that there are oriental addicts. The one Chinese addict on our methadone maintenance program has told us that many of his friends are hooked.

California law prohibits the use of methadone or other narcotics for outpatient detoxification. The new young addict exhibits a low tolerance for pain and he comes looking for a painless way to withdraw. He is saying to us, "Give me methadone or forget it. I don't want to mess around with other junk."

Complicating matters further is that California law makes the addicted minor ineligible for methadone maintenance treatment. Our inability to meet the needs of these young people forces them to become their own physicians. They self-medicate with appalling combinations of alcohol, barbiturates, marihuana, cocaine, and Speed. It is bad enough that there are so many young heroin addicts; what is worse is that most of them are not being treated. They reject what they feel are the authoritarian and punitive approaches of traditional medicine and mistrust even the indigenous sources of self-help. San Francisco has several halfway houses which offer treatment to young addicts. Too often, however, the halfway houses are poorly funded, keep few, if any, statistical records, and have meager scientific data to report on their treatment effectiveness.

Until September of this year, it was illegal to treat addicts outside of penal institutions or State mental hospitals. An addict could get treatment only in public agencies and then usually behind locked doors. At the California Rehabilitation Center in Corona, a costly prison center, $16 million is expended each year in the alleged "curing" of addicts. Corona's recidivism rate is equal to that of most outpatient detoxification programs—92 percent. In September, Governor Reagan signed two bills which made methadone maintenance treatment programs feasible on a fairly comprehensive basis. The problem is that no money was appropriated for the programs, so we find ourselves in virtually the same place we were before the new law was passed.

All methadone treatment in California is under the supervision of the California State Research Advisory Panel which is appointed by the Governor. This panel is empowered to set up guidelines for operating methadone maintenance treatment programs. The chairman of the panel, an attorney in the State attorney general's office, believes in strict adherence to the letter of the law and he has insisted that the Federal guidelines drafted last June be followed with no deviation. Those guidelines prohibited the treatment of addicts under 18 years of age. Even if it were legal to treat these addicts with methadone, it would have to be done in most cases with parental consent. This legal stricture would prevent many adolescent addicts from seeking treatment voluntarily. Obviously, most addicted children need to keep their addiction secret from their parents.

Rehabilitation programs for young addicts have reported some degree of success. Spokesmen from programs such as Phoenix House, Daytop, and Reality House have said that their dropouts ran into trouble in their inability to control their craving for heroin. Since methadone eliminates the craving and the symptomatic discomfort of withdrawal, it allows the addict opportunity to derive a greater benefit from the psychosocial rehabilitation. We believe that a combination of methadone maintenance and rehabilitative programs offers the best opportunity for helping the adolescent addict. Many investigators have expressed concern over potential lifetime methadone maintenance for the adolescent addict. We feel that after substantial gain has been made in the addict's rehabilitation, gradual methadone detoxification should be attempted. This addict would then have a chance to lead a life free of chemical dependence. Should he not remain nonaddicted, a second attempt at methadone maintenance over a longer duration should be considered.

ADOLESCENTS ON METHADONE: PRELIMINARY OBSERVATIONS

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In summary, then, our experience shows that heroin abuse among the adolescent is on the rise. With the rapidly changing abuse patterns, young addicts continue to seek medical help. Many physicians, however, are frightened by the addicts and are made nervous by the narcotic agents who pursue the addicts. The young addict is either turned away from or declines help at the traditional sources of treatment. Nonnarcotic medical detoxification is not sufficient for the young addict. Unless legal restaints on treating minors and operating methadone maintenance programs are removed, the young drug addict will turn away from traditional sources of help and will go underground. Methadone maintenance treatment should not be unilaterally condemned in regard to the adolescent addict. As has been indicated, initially it can be used to get him under treatment and into a more constructive life style. Later, methadone can slowly be eliminated, Since the young addict tends to reject traditional forms of medical treatment, ancillary treatment modalities must be restructed so that the young addict will accept them. Without these changes, our treatment will be rendered ineffective and we will lose our fight against heroin addiction.

The widespread abuse of narcotics by school-age children and the vast increase in heroin-related deaths among teenagers, have recently caused much attention to be focused on the problems of drugs and youth. Educational programs in schools and elsewhere aimed at preventing teenage drug use are proliferating. Attacks on the drug distribution system are daily heralded in the press. Little attention, however, is being paid to the treatment of currently addicted adolescents. There is much popular support for intensive counseling, therapeutic communities, and, more recently, inpatient detoxification units specifically for adolescents. There is, as yet, little information available on the long-term followup of patients treated on such programs. Prior attempts at rehabilitation of adolescent addicts through prolonged detention have generally proved unsuccessful and detoxification alone has been disappointing.

Those of us involved in treating "hard-core" addicts with methadone maintenance have been discouraged by various governmental and medical

groups from taking adolescents into our programs. Federal and local guidelines relating to admission criteria for methadone maintenance programs have, in fact, proposed minimum age limits and lengths of addiction which, alone or together, would preclude the institution of any type of maintenance for the majority of narcotic-addicted adolescents.

The purpose of this paper is to describe and examine in detail the course of the 31 adolescent narcotics addicts who came to our Drug Abuse Center for help. Most (29) received methadone and the majority (23) of these patients were, in fact, at some time or other on methadone maintenance. For the 12 adolescents presently on methadone maintenance at our Center, the following data are based on clinical records and exploratory interviews focused on attitudes to treatment and on self-perceived changes in outlook, lifestyle, and life-situation. Documentation of these forced us to consider certain basic issues which must be faced not only by those involved in planning the care of drug addicted adolescents but also by anyone establishing criteria for intake and successful treatment in a methadone maintenance program. These issues are: What is a "hard-core" addict and can a teenager fit this description? Should an arbitrary minimum age limit be imposed in a treatment program? Should criteria for success on methadone maintenance be the same for adolescents and older addicts? Should separate clinics for teenage addicts be established as they are for many medical problems in this age group? Finally, should adolescents be placed on methadone maintenance at all? If so, should a prior trial at detoxification be mandatory?

THE JOHNS HOPKINS HOSPITAL DRUG ABUSE CENTER

The Johns Hopkins Hospital Drug Abuse Center offers a multimodality treatment approach for narcotics addicts of all ages. The programs include abstinence, ambulatory detoxification, and methadone maintenance. Urine surveillance and individual counseling are basic elements of each. Where appropriate, group counseling and individual psychoterapy are added. The overall goals of treatment are abstinence from illicit drug use, social rehabilitation, and the preparation of the individual to deal effectively with the problems of daily life.

The Drug Abuse Center initially opened on March 1, 1969, with only an abstinence program. Because of an obvious failure to retain patients in this program, an ambulatory detoxification program utilizing methadone was added on May 15, 1969. At first the duration of detoxification was 10 days, but this was expanded to 4 to 6 weeks because of excessive dropouts. Even with the addition of this prolonged detoxification, however, the dropout rate was close to 90 percent. By November 1969, and IND number was obtained so that methadone maintenance could be instituted. Marked improvement in clinic attendance and retention in treatment were noted when the methadone maintenance program was added. The decrease in illicit drug use, increased social acceptability, and improvement in individual life-situation documented in other methadone maintenance programs were observed (*1*, *2*). While, in general, this program was patterned after the Dole-Nyswander approach (*3*), our only major criteria for admission to maintenance initially were opiate addiction for 1 year and stated motivation for treatment. Age, multiple drug use (including alcohol), and psychiatric disease were noted, but did not affect admission to the maintenance program. Also, all narcotics addicts were either initially encouraged to undertake detoxification with followup care (abstinence program) or were offered methadone maintenance with the option of later detoxification on request with followup as described. Similarly, failure on the abstinence program following maintenance could be countered with the institution of methadone maintenance, provided program rules were not violated. (Violations consist of failure to give urine specimens, failure to appear at counseling sessions, and "no shows" for methadone when on maintenance.) Implicit in this approach is the philosophy that the patient is better off in treatment of some kind than entirely away from the Center. "Discharge with medical advice" was given only to those who had done well on the program and felt able to function "drug-free" in the community without counseling of urine surveillance. Throughout the history of the Drug Abuse Center there has been a high rate of interprogram transfer. The general understanding on the part of the patient when entering any type of program was that he could be detoxified on request and remain in good standing at the Center if he adhered to Center policy.

For all programs,[1] the intake evaluation includes a drug abuse history, employment and school status, and arrest and incarceration record and often a psychiatric evaluation. Methadone dosages vary, but the majority of maintenance patients receive in the range of 70–80 mg. orally once daily in fruit juice. Detoxification regimens are variable with reported prior heroin use serving as a guide. Both programs are entirely ambulatory. Patients must come to the clinic daily for medication. Maintenance patients may take home methadone on weekends only after 3 months free of illicit drug use documented by urine surveillance. Urine specimens are collected on an average of three times per week under direct supervision. The specimens are analyzed for morphine, codeine, amphetamines, barbiturates, cocaine, and quinine by the method of Kokoski (*4*) at the Drug Abuse Laboratory, Friends Medical Science Research Center, Inc.

As of June 1970, the median age of all patients in treatment was 22.9 years. Sixteen percent of these were 16 to 19 and 51 percent were 20 to 24 years old. The age range was 16 to 54 years. Nine percent of the total active and discharged patient population of 370 was under 19 years old.

[1] "Short-term detoxification" (6 weeks), "long-term detoxification" (3 months), "temporary maintenance (3 months or 6 months), and "unlimited maintenance" (at least 6 months).

ADOLESCENTS ON METHADONE

Between April 1969 and October 1970, 29 heroin-addicted adolescents (defined for the purpose of this study as under 19 years of age) were admitted to the various treatment programs at the Drug Abuse Center. Their age distribution is shown in table 1. Slightly less than half were under 18 years old. The demographic data, length of narcotics addiction and amount spent per day on heroin are listed in table 2. None of the 29 adolescents had ever been successfully detoxified on an outpatient basis, although many had tried this on their own and/or had gone to a private physician for this purpose. Many instances of involuntary detoxification had occurred in institutions (e.g., jail) but these were obviously ultimately unsuccessful. This group of 29 represents the total number of adolescents admitted to some type of methadone treatment program at the Drug Abuse Center who actually received methadone for some period.[2] Three-quarters of the patients were white and slightly more than half came from the city. While they had been addicted for an average of 1½ years, a number were addicted for less than 1 year. They spent an average of close to $30 per day on heroin. All adolescents were encouraged to enter the detoxification program with followup. However, if they were addicted for longer than 1 year and felt unable to adhere to this regimen, they were placed on one of several methadone maintenance schedules based on length of addiction. Those addicted for 1 to 5 years would receive "temporary maintenance" and those addicted for more than 5 years were placed on "unlimited maintenance." This scheme based on length of addiction was utilized only for the initial orders, and subsequent interprogram transfer was dictated by failure on the entering program. Thus an adolescent addicted for less than 1 year might go from incompleted "detoxification" to "temporary maintenance" or even "unlimited maintenance." It should be reemphasized that no one was encouraged to leave any program merely because he had passed some predesignated point in time (e.g., 3-month temporary maintenance or even 6-week detoxification). The average stabilized methadone maintenance dose was close to 60 mg., somewhat below the average for all maintenance patients.

Table 1.—AGE OF 29 ADOLESCENTS AT ADMISSION (LAST BIRTHDAY)

Age	Number	Percent
16	2	7
17	10	34
18	17	59
Total	29	100

Table 2.—CHARACTERISTICS OF 29 HEROIN-ADDICTED ADOLESCENTS

Age at admission:	
Average	17.5 years.
Range	16 to 18 years.
Sex:	
Male	90 percent.
Female	10 percent.
Race:	
White	76 percent.
Black	24 percent.
Residence:	
City	55 percent.
Out of city	45 percent.
Months addicted:	
Average	19.8 months.
Range	5 to 60 months.
Daily heroin cost:[1]	
Average	$29.
Range	$10 to 125.
Status on Oct. 14, 1970:	
Active	41 percent.
Closed	59 percent.

[1] Based on 26 cases; 3 unknown.

RESULTS

I. Initial Treatment Program and Course at Center

The initial treatment program offered each of the 29 patients at the Center is shown in table 3.

[2] Excluded from this group are two other patients: One heroin-addicted patient accepted for maintenance did not return to the Center to receive his first dose of methadone and was subsequently lost to followup. Another patient was referred to aftercare from the U.S. Public Health Service Hospital at Lexington, Ky. He was placed on an abstinence program (NARA III) and then relapsed to drug use. Orders were written for methadone maintenance, but he disappeared without ever receiving medication.

Table 3.—INITIAL TREATMENT PROGRAM OF 29 ADOLESCENTS

	Number	Percent
Short-term detoxification	14	48
Long-term detoxification	3	10
Temporary maintenance	11	38
Unlimited maintenance	1	3
Total	29	[1] 99

[1] Less than 100% because of rounding.

More than half (58 percent) of the adolescents were begun on some form of detoxification. Six of those dropped out prior to completing detoxification and never again applied for admission to any treatment program at the Center. Six more were transferred directly to a maintenance program without ever completing detoxification. Five others dropped out either during or after detoxification (on abstinence) but returned at some later date (days, weeks, or months later) and were then placed on methadone maintenance. Table 4 shows the variability in the interval between admission to the Center and institution of maintenance for the latter two groups. The intervals shown represent time spent in detoxification and/or abstinence (average 1 to 4 months) and for some were marked by arrest, jail, and the medical complications of addiction. Of the 29 adolescents, 23 (79 percent) were admitted to some form of methadone maintenance treatment at the Center initially or were eventually placed on methadone maintenance. Of this group of 23, 12 patients are currently (as of October 14, 1970) on methadone maintenance at this Center. The 11 patients who are no longer on maintenance have all been discharged from the Center.

Table 4.—TIME INTERVAL BETWEEN ADMISSION AND INSTITUTION OF METHADONE MAINTENANCE—11 PATIENTS NOT STARTED ON MAINTENANCE

	Number
Less than 1 month	2
1–2 months	4
3–4 months	3
5–6 months	2
Total	11

The active and discharged cases on maintenance were similar in age, race, residence, amount spent per day on heroin, and average methadone dosage when on maintenance. Of the 23 patients placed on maintenance only two were women and these are both currently active. Substantial differences were found in average length of addiction (27.1 months) for closed cases (range 6 to 60 months) as opposed to 15.8 months for the active cases (range 6 to 36 months). The percentage of positive urines was much higher in the cases closed (more than double the active patients). The average total stay in all forms of treatment at the Center was 8.2 months for the active cases (range 3 to 11 months) as opposed to 3.3 months for the discharged group (range 0.1 to 12 months). Significantly, the average duration of methadone maintenance treatment was 6 months for the active cases, but only 2 months for the cases closed (see table 5). Similarly a marked difference in total patient-months experience on methadone maintenance was noted between the active cases (74 months) and the cases closed (27 months).

Table 5.—DURATION OF METHADONE MAINTENANCE THROUGH OCTOBER 14, 1970 (23 PATIENTS)

	Active	Closed
Less than 1 month	0	3
1–2 months	1	5
3–4 months	2	1
5–6 months	4	0
7–8 months	1	1
9–10 months	3	0
11–12 months	1	1
Total	12	11

II. Patients currently on methadone maintenance: Change in status

The 12 active patients on maintenance have been at the Center for an average of 8.2 months (vide supra). Table 6 shows longitudinal positive urine rates for successive months while on methadone maintenance only (average of 6 months). The results indicate a generally progressive decline in illicit drug use related to months on maintenance. Table 7 shows the comparative status of these patients before admission to the Center and after admission (as of October 14, 1970). A trend toward self-improvement and decrease in antisocial behavior is noted. Most of these changes, although not yet very impressive, occurred after the institution of methadone maintenance.

Table 6.—AVERAGE POSITIVE URINE RATES BY TREATMENT MONTH WHILE ON MAINTENANCE—12 ACTIVE PATIENTS

Note: Units are calendar months through September 1970. "1st"=each patient's first full month in treatment, and so on. Quinine counted positive.

	Treatment month								
	1st	2d	3d	4th	5th	6th	7th	8th	9th
Average percent positive	29	25	20	11	16	8	20	5	0
Number of patients	12	11	9	9	5	5	4	4	1

Table 7.—COMPARATIVE STATUS OF 12 ACTIVE PATIENTS BEFORE AND AFTER ADMISSION

	Before		After [1]	
	Number	Percent	Number	Percent
In school	2	17	3	25
Gainfully employed	4	33	8	67
On public assistance	3	25	3	25
One or more arrests	11	92	7	58
One or more jail terms	7	58	1	8

[1] As of October 1970. Average time in treatment=8.2 months.

III. Cases closed: Reasons for discharge and followup status

The reasons for discharge for all closed cases (17) are listed in table 8. The vast majority of patients (13) dropped out of treatment without notice. To this date none of the patients who left maintenance or detoxification programs did so "with medical advice" and none were discharged for drug abuse per se. Table 9 shows the available posttreatment followup data on all patients treated with detoxification and/or maintenance. These data were obtained by telephone and personal interview with either the patient, his family, friends, or staff of the various treatment centers in Baltimore and Annapolis, Md., and Washington, D.C. While obviously "hearsay," these techniques are the most definitive ones available [3] short of daily urine surveillance and are now being utilized by other investigators (*5*). Five ex-patients are currently in treatment at other centers or with private physicians and three are in jail. One claims to be using drugs but is not in treatment. We presume that a relapse to drug use has occurred in the interval following discharge for these patients. Thus, most (9) of the the 13 ex-patients for whom data are available have relapsed to drug use. Only four patients claim abstinence. No information is available for the other four patients. Our best followup, of course, is with those currently in treatment with us. The facilities for both the detoxification and maintenance of adolescents on methadone have given our Center the unique opportunity to followup "detoxification failures" in this group and to observe how adolescents function on methadone maintenance.

Table 8.—CLOSED CASES (N=17): REASON FOR DISCHARGE, BY TREATMENT PROGRAM

	Detoxification	Maintenance	Total
Voluntary:			
Dropped out	6	7	13
Discharged with medical advice	0	0	
Other	0	[1] 1	[1] 1
Involuntary:			
Drug abuse	0	0	0
Violation of program rules	0	3	3
Total	6	11	17

[1] Planned to move out of State.

[3] A Narcotic Register will soon be in operation in Baltimore.

Table 9.—STATUS OF 17 CLOSED CASES AT FOLLOWUP, NOVEMBER 1970, BY TREATMENT PROGRAM

	Detoxification	Maintenance	Total
Abstinent [1]	2	2	4
Using drugs, untreated [1]	0	1	1
In treatment elsewhere	2	3	5
Incarcerated	2	1	3
No information	0	4	4
Total	6	11	17

[1] Self-reported.

IV. Adolescents compared with older patients: Termination rates and positive urine rates

Of all 370 patients admitted since the Center's inception, the 31 adolescents have had a slightly lower termination rate than have the older patients (table 10). To make the termination comparison a fair one, it was necessary to include two closed adolescent cases who never received methadone and are therefore not considered except in table 10.

Table 10.—COMPARATIVE TERMINATION RATES OF ADOLESCENTS AND OLDER PATIENTS

	Adolescents		Older patients		Total	
	Number	Percent	Number	Percent	Number	Percent
Active	12	39	113	33	125	34
Closed	[1] 19	61	226	67	245	66
Total admitted	31	100	339	100	370	100

[1] Includes 2 cases not counted elsewhere.

In urine tests while on methadone maintenance, adolescents appear to have better records than older patients. Thus far we have examined urine records in detail for the clinic as a whole only for April 1970—a representative treatment period during which six adolescents and 84 older patients were on methadone maintenance for the entire month. Results of the comparison are shown in table 11.

Table 11.—COMPARATIVE POSITIVE URINE RATES OF ADOLESCENTS AND OLDER PATIENTS ON METHADONE MAINTENANCE, APRIL 1–30, 1970

	Adolescents	Older patients
Number of patients	6	84
Number of urine tests:		
Average	12.5	12.0
Range	10–13	1–15
Percent positive:		
Average	15.7	31.9
Range	0–40	0–100

Note:—Quinine counted positive.

INTERVIEWS WITH 12 ADOLESCENTS NOW ON METHADONE MAINTENANCE

Recent interviews with the 12 patients active on maintenance have revealed certain themes not re-

flected in the data or tables. The large majority had no "drug craving" and claimed not to miss the "high" induced by heroin. The most consistent response to the question: "Has your relationship with your parents changed since starting on methadone maintenance?" was that they were now better able to communicate with them. They felt that it was better to be "drug-free" than on methadone (maintenance), but only a few were concerned with and none preoccupied with "getting off" methadone. This seemed to be related to their knowing that they could be detoxified from maintenance at will. It also became obvious that there was no significant parental or peer pressure to be off methadone maintenance. Indeed, only one patient seemed to have been confronted with the proposition that "when you're on methadone you're still an addict, just substituting one drug for another." This patient claimed he had heard this from heroin-addicted friends in reply to his suggestion that they seek this type of treatment for themselves. The patients' gratitude for being on the program appeared to be based on two important components: The first and most significant in all cases was the availability of methadone in a stabilized dose, and the second, the role played by the counselor. The latter was particularly significant in that counselors were assigned at random, were not young, were mostly not ex-addicts, and did not set up specific therapy aimed at adolescents. In short, teenage patients were not treated differently from other patients because of their age. In view of the stated importance of the counselor to the patient it was not surprising to find that none would have preferred to have been maintained by private physicians. In fact, most felt that they would not have done as well under private care. They did not feel that special clinics for teenage addicts should be established because they felt that the problem of their addiction was the same as that of adults.

While almost all (92 percent) of those who are now active on maintenance had been arrested and more than half had had one or more periods of incarceration, these adolescents do not fit the usual picture of the "down and out" addict. Indeed, in regard to their lifestyle we found a significant paradox. On the one side, most lived at home with their parents while addicted and many continued at work or attended school almost until admission to the Center. On the other side, it became obvious in interviewing these adolescents now active on maintenance that they had been emotionally "absorbed" by heroin: The pursuit of the drug and the "high" as well as the fear of withdrawal engrossed these young people to the exclusion of all else. While in outward appearance and in their own eyes they were not "hard-core" addicts, their "internal" lifestyle was as "hard-core" as that of adults with a 10- to 20-year addiction history.

DISCUSSION AND IMPLICATIONS FOR TREATMENT

We have observed and believe with others that the adolescent is not significantly different in regard to his addiction from the adult addict. As stated by Chein (*6*): "The adolescent addict is not typically seduced by vicious adults; he does have an addiction problem; he is an active bearer of the traits and attitudes of the adult addict. In fact, statistical studies in the 1920's and 1930's had already pointed out that the majority of adult addicts began their addiction in their adolescence or in early adulthood."

In spite of the basic similarities, the adolescent is different in several ways from the adult addict. Nyswander observed in 1967 (*7*) that although it would seem that adolescents (having been addicted for less time) should have a better prognosis in treatment than adults, the opposite is unfortunately true. Among obstables to treating adolescents noted by Nyswander are the antisocial attitudes of most adolescent addicts and the often total lack of motivation for drug withdrawal. She observed that adolescent addicts often feel no anxiety about their addiction and frequently associate pleasure with the use of drugs.

There are, however, certain factors favoring the potential successful treatment of adolescents. While the adolescent may have a "hard-core" addiction problem, his outward lifestyle is usually more normal than that of adult addicts. He is less criminalized and generally was either recently in school or gainfully employed. Periods of incarceration, if any, were mostly few and short-term. The great majority live with parents who are generally deeply concerned. The parents are often mobilized as an effective force to keep the adolescent doing well in treatment once progress has occurred. (They appear much less effective, however, in initiating treatment or motivating their child for treatment.) We feel that heroin-addicted adolescents deserve treatment if they request it. The type of treatment is less important than the actual initiation of ongoing involvement at a treatment center. Methadone maintenance has been successful in bringing about a significant improvement in the total life-situation of many adult addicts of varied backgrounds. This regimen should be made available to adolescents when appropriate.

In fact, some of our data indicate that adolescents do as well as, if not better than, older patients in our treatment setting. We favor the "drug-free" state if this is obtainable and feel that adolescents should be offered a trial at detoxification. Failure at detoxification, however, should not be a prerequisite for entrance to a maintenance program. There are several reasons for this. By definition, such requirement would necessitate detoxification plus some period of abstinence, followed by readdiction or at least significant illicit drug use. This would imply and indeed encourage those incapable of ceasing drug use during detoxification to risk arrest, incarceration, and death from overdose or infectious complications prior to becoming acceptable for maintenance treatment.

We no longer use length of addiction as a guide to an arbitrary treatment regimen. We recognize that the terms "long-term detoxification" and "temporary maintenance" are interchangeable and can be considered euphemistic for what is really "methadone maintenance." Similarly, we realize that the direct transfer from detoxification to maintenance at our Center might not be construed as true changes in programs. We believe, however, that those were indeed detoxification failures. A failure to reclassify these patients might have meant their loss forever from any form of treatment. To offer such a flexible approach to adolescent addicts, a drug abuse center should provide both ambulatory detoxification and methadone maintenance facilities including urine surveillance and counseling. Our approach is buttressed by the findings of Jaffe (*8*). He observed that "the availability of methadone maintenance does not inevitably destroy the motivation of patients to achieve abstinence." We do not feel that our approach hinders those who truly wish to be drug-free. Preliminary experience with adolescents at our Center has been encouraging. Some of our active patients now on maintenance have failed detoxification in some sense and have been in treatment at the Center for long periods of time. Others, similarly doing well, have been on maintenance continuously. We associate retention at the Center (regardless of program pattern) with improvement as documented in our data and interviews.

We feel that the usual status comparisons applied for the evaluation of patient progress on methadone maintenance programs are particularly inadequate for the adolescent. Paramount are the quality of his relationships with his parents and friends as well as development of the ability to deal realistically with current problems. These areas are not reflected adequately in tables which stress vocational rehabilitation and the avoidance of antisocial behavior. It must be noted that many adolescents are at school by convention only or remain to indulge in heroin "trafficking." On the other hand, some work in a family business which approximates a sheltered workshop environment. Often they would not have been hired or retained in the free market.

CONCLUSIONS

We believe that the adolescent can be classified as a "hard-core" addict in every sense if he meets the proper criteria. These latter are not based on length of addiction, size of habit, or externally observed variables, but on "internal" lifestyle and life-situation as experienced by the individual. We believe, moreover, that the term "hard-core" is not particularly useful in describing any addict or in constructing guidelines for intake in a treatment program. Its value is especially dubious in the latter sense when it is applied to exclude youngsters from a specific type of program. This is so whether that program is considered "experimental" or "approved for general use." We have observed remarkable improvement in the total life-situation of many adolescents treated with methadone maintenance who would have been ineligible for this treatment at most other centers. This pattern was most striking when observed following "detoxification failure" at our own Center. When an adolescent addict seeks help at a treatment center he should not be denied aid either because he is below an arbitrary age or has not been addicted long enough to satisfy a predetermined minimum limit.

We have found methadone in ambulatory detoxification and maintenance useful to attract and retain addicted adolescents in treatment. While strict short-term ambulatory detoxification is probably of limited value in itself, it does expose the addict to the concept of concern for him and his condition and does introduce him to the possibility of functioning without the fear of withdrawal or the need to pursue criminal ways to obtain drugs. The outcome, of course, is related to motivation for rehabilitation as well as the available treatment programs. Motivation varies with time and is influenced by many factors, not the least of which appears to be the overall philosophy of the treatment center as manifested by intake criteria, treatment modalities offered, program management, provisions for interprogram tansfer, and discharge and readmission policy.

We, as others, are concerned with the recent increase in adolescent drug use and heroin-related deaths; conditions which have sparked public outrage over the so-called "heroin epidemic." Our interest in adolescent addicts, however, is especially keen because we see a chance to assist them in the avoidance of following a well-documented

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pattern. We hope to keep them from irrevocably pursuing the down-hill course which will make them into what society currently knows by the term 'hard-core" addicts. The years of criminality, incarceration, and misery might be avoided by involving adolescents with methadone-based programs such as those described.

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SOME PSYCHOLOGICAL COMMENTS ON PREJUDICE AGAINST METHADONE MAINTENANCE

Leon Wurmser, M.D.

This may be the place to add a few impressionistic and provocative thoughts about several forms of prejudice against methadone maintenance treatment because we usually see them in bolder relief in regard to adolescents than to adults. We have encountered these forms in many discussions with patients, relatives, community groups, administrators, and politicians. We may also frankly admit that we ourselves have shared some of these prejudices at one time or another, but have been taught gradually and the hard way to view the problem differently.

(a) The first type of prejudice is indicated by the statement: "But methadone treatment is just another addiction." This is of course true. But the implication is: it is morally bad to be addicted. If we look at the value philosophical implications of this prejudice we can paraphrase it: It is bad to be dependent on, to be enslaved by a drug; it is good to fight any form of dependency and weakness. One connotation of this is: It is masculine, and with that admirable, not to be dependent; it is a sign of weakness, it is feminine, it is contemptible and shameful to be dependent. Narcotics addiction of any type serves as a symbol of dependency and arouses the same scorn as other forms of passive-dependent behavior, e.g. effeminate, homosexual, or coward attitudes.

We may then go one step further, as many opponents of methadone treatment do, and say: It is better to impose compulsory abstinence with a high risk of return to jail than to support this self-indulgence of drug dependency. What does this philosophical choice mean in sober reality? It means that we prefer to hound addicts on the streets as criminals over offering them generous opportunities to remain addicted, though under supervision. Our premise then is: we value compulsory abstinence higher than voluntary addiction; yet it means also: we value freedom from drugs higher than civil liberty. The practical consequence is that we consider the criminalization of the addicts, their roaming the streets, their fantastic depredations of society and their crowding together in the jails as the lesser of two evils, and the medical condoning as the greater one. This

prejudice expressing profound abhorrence of dependency and weakness can be called the "pseudo-masculine protest."

(b) The second type of prejudice is very akin to the first; it is the one particularly expressed in regard to young patients: "Addiction is a self indulgence, a shortcut to pleasure, and thus counteracts and paralyzes the drive towards maturity." Again there is much to be said for this view. Yet again we can find the prejudicial implications if we view this statement against the attitude towards other forms of compulsive behavior, since any psychopathological symptom fits that description of veiled or open self-indulgence. A harsh treatment in form of not going along with such a wish fulfillment makes sense only if we are willing and able to offer a detailed program of removing these road blocks to maturity, in other words an intensive treatment approach which allows the patient truly to work through and resolve the deeper problems which underlie his symptoms of irrationality; it would make at least theoretical sense e.g. to hospitalize juvenile drug abusers and subject them to a combined regime of therapeutic community, intensive psychotherapy, abstinence, and a firm and consistent structure. Practically, however, this is usually impossible, and the consequence of this prejudice boils again down to a value philosophical alternative: A treatment regime combining some counseling or psychotherapy with supervised addiction versus the pious hope that the sociopathic career downhill into a more and more fixed deviance and into a criminal identity somehow stops by itself. There is another fallacy in this same premise: that addiction is a shortcut to pleasure and therefore should be condemned. We all know that the social and inner motives for addiction are far more complex and intricate than an expensive search for cheap pleasure. Moreover and particularly in regard to adolescents we find hidden in this argument the same indignation many felt about Freud's discovery of infantile sexuality. Just as he was vilified as the despoiler and defiler of the innocence of little children, the physician using methadone in youngsters—or, as I witnessed a long time ago, the psychiatrist using Thorazine in a 13-year-old schizophrenic—is accused of stifling the growth potential of his poor victim. What is overlooked is that it is not the drug, but the illness at question which blocks the road to maturity and that in our context the judicious use of this drug can be in some cases of juvenile pathology again the lesser of two evils. It is the drug which can give the patient more of a chance to grow towards maturity than no use of such an auxiliary means. I would call this second type of prejudice "the revenge of the Puritans."

(c) The third prejudice is radically different again based on a fallacy: "Methadone is a means of genocide." The assumption is that methadone stifles libido and thus prevent—temporarily or forever—child bearing and sexual potency. Deeper down it implies: all potent drugs poison the body and therefore their use must be part of a conspiracy. This type of prejudice we might name "the paranoid fears of the discriminated."

(d) The fourth and last type is the most secret and hidden form. We have not heard it directly—but we believe we can infer its content from a number of conversations: "It puts us out of business." If we look at what an enormous economic loss is caused by illicit narcotics addiction—we find e.g. that it leads to a yearly property damage through shoplifting, stealing, conning and robbery of $100 million to $500 million in Baltimore City alone—we must assume that there is a considerable interest and complicity in keeping this business going. Whoever profits from this vast black market of drugs and stolen goods—pushers, buyers and, as Earl Warren just said, corrupt officials obviously cannot have must interest in the partial legalization of narcotics addiction represented by methadone treatment. This fourth inferred type of prejudice we may dub the "rationale of the entrepreneur." So much about the prejudice against methadone; it is wiser for me today not to speak about prejudice for methadone.

To sum up: We advocate neither a promiscuous permissive use of methadone nor a vindictive, punitive enforcement of abstinence but—in adolescents and adults alike—we are in favor of a judicious use of well supervised addiction combined with a comprehensive treatment program as the lesser of two evils. We know, the word "judicious" is derived from "judgment" (judicium), the opposite of prejudice, and the judgment we refer to is a weighing of conflicting values.

V. PRISONS, PROBATION, POLICE

PAROLE, PROBATION, POLICE AND METHADONE MAINTENANCE

John C. Kramer, M.D.

In 1961 the State of California enacted and initiated a civil commitment program for people who were judged addicted to the use of narcotics as well as those in danger of becoming so addicted. Though civil commitment procedures for addicts had been enacted in California and elsewhere prior to 1961, they lacked the force of the new California law and the determination of the State government to utilize the process. Upon its initiation, and for several years thereafter, the California civil addict program was often described as the most progressive and effective technique to treat and control narcotic addiction that had till then been tried. The limited amount of information which was forthcoming from the program tended to emphasize the objectives of the program, provided anecdotal experiences from the program and offered scattered and selective statistics about the program. In the late sixties an examination of the results of the program showed that, in fact, few patients succeeded in the program and that a large proportion of those who did were not heroin addicts. There was, at first considerable reluctance to accept this judgment but as time proceeded the reality became inescapable. Nevertheless there did not appear to be any suitable alternative to this massive program. Methadone maintenance was at that time prohibited by State law until 1969 could not even be undertaken as a research procedure in California. Until about 1969 methadone maintenance was viewed by many correctional and enforcement authorities in the State and by many physicians and attorneys as well as an interesting but questionable procedure which someone back in New York was trying. With a few notable exceptions correctional officials were either inadequately informed or misinformed regarding the nature of the treatment and its results.

Over the years the State of California had evolved some of the most restrictive laws in the Nation in regard not only to the illegal distribution of narcotics but even in regard to their legitimate prescription. Research which required the use of narcotics in human beings was illegal; law, recently rescinded, required that physicians treating addicts, whether or nor a narcotic was used, were to report the patients' names, addresses and condition to the State narcotics police. State statute still requires that every addict who is prescribed a narcotic must be reported to the same State narcotics police. Still prescribed by law are limitations on the location at which withdrawal treatment may take place, the amounts of drug a physician may use for withdrawal treatment and the length of time during which the narcotic may be prescribed for withdrawal treatment. In addition, some influential physicians in the State had expressed themselves in the past, prior to the methadone era, in violent opposition to the maintenance approach. More recently, physicians in private practice who attempted to offer informal methadone maintenance were approached by the State narcotic police who insisted that they desist. Some physicians in the employ of the department of corrections published letters to the editors of medical journals expressing a violent opposition to the methadone maintenance approach.

Since mid-1969, under the auspices of a bill which permitted research in the use of narcotics, several methadone maintenance programs have been initiated. Through the presence of the programs and the interest and publicity which they generated, and through the prominence given a letter from the Governor of Oregon to the Governor of California, methadone maintenance has become an immediate rather than a remote issue to correctional, judicial, and enforcement people. Probationers and parolees, erstwhile and current, have been seeking places on methadone maintenance programs and willy-nilly their parole officers must consider the possibilites.

In one highly publicized case, a patient in the Orange County program who was also a parolee from the California civil addict program, was told that he must remove himself from the methadone program or face return to the institution. He responded by making application for a writ of habeas corpus. During the first of two court hear-

ings he was arrested by his agent and returned to the institution. Though technically charged with violations other than being on a methadone maintenance program, it was, in fact, his refusal to discontinue the methadone treatment which angered the parole board. The judge who heard the writ studied the arguments for about 1 month before deciding that he would not infringe on the judgment of the parole board. An appeal of this decision was sought from the appellate court and a brief was filed. Though setting a date for oral arguments, the court vacated the writ a few days prior to the date set for argument, in effect, upholding the previous decision. Appeal to the State Supreme Court or to Federal court was under consideration when the parole board of the civil addict program, its most vehement methadone opponent having retired, indicated that its policy toward methadone maintenance for its parolees had changed. They decided that appropriate parolees, if participating in a legitimate methadone maintenance program would not be considered in violation of their conditions of parole; they added however that time spent on a methadone maintenance program would not count toward the 3 consecutive "good years" on parole which would permit termination of the commitment. During the regular 1970 session of the State legislature a bill was passed permitting parolees from the civil addict program or from a penal institution, to participate in methadone maintenance programs, and stating that such treatment shall not be construed to break the abstention from the use of narcotics. Though this bill was vetoed by Governor Reagan, the policy of allowing parolees from the department of correction to participate in methadone maintenance still stands.

The department of corrections itself, with support from the director, Mr. Ray Procunier, and the superintendent at Corona, Mr. Roland Wood, is planning its own methadone maintenance program. The current plan is to use the central nalline testing center in Los Angeles for the initial program which will be limited to 150 volunteers who have a history of 5 or more years of opiate involvement.

During the 1970 session, the legislature passed and the Governor signed two bills permitting methadone maintenance treatment. Each program must, however, be sponsored by the official county mental health program and each is subject to the approval of the department of mental hygiene. Though these restrictions will limit the rate of development of methadone maintenance programs, at least the legitimacy of these programs has been established, and participation by the State has been promulgated.

Despite the fact that California law places regrettable restrictions on the medical treatment of addicts, the State correctional system, its parole division and the probation departments of the various counties, have a well deserved reputation for being among the most progressive in the country. Despite my criticisms of the civil addict program, I must acknowledge that when it was established in 1961, and during the early years of its operation it represented the most ambitious and earnest treatment program for addicts anywhere in the world. My major criticism of it has not been that it failed, but rather that it did not acknowledge its failure when it had already become abundantly clear. To its credit the department of corrections has initiated and is moving ahead with plans for methadone maintenance albeit with the deliberate and ponderous movement of major bureaucratic operations. Within the county of Orange informal arrangements between the methadone program and the probation department has led to the special placement of seven probationers in cooperation with a judge of the superior court and the probation department. The early evidence of good results among those men placed on the program, men who were in serious danger of being violated for recurrent use of heroin, has led to a request for special placement of 12 additional probationers as well as an examination of the possibility of offering methadone maintenance to 70 additional probationers whose cost of treatment would be met by the probation department. Though problems exist regarding the feasibility of transferring funds from one county operation to another, the interest of the probation department and the courts in this program have been registered.

The official position of State agencies in regard to methadone maintenance is well represented by a letter from the Governor to interested physicians in the State.

MY DEAR DOCTOR: I recently signed SB 1271 (Way) and AB 232 (Vasconcellos), which permit methadone programs on a larger scale than under present law.

I thought you would be interested in the administration's policy on methadone. It is:

1. Methadone will be permitted under strict security controls with admission criteria which insure that other therapeutic methods will have been attempted previously.

2. Each program will have a research aim and an evaluation component.

3. Each program will be approved by the research advisory panel and comply with its criteria for such programs.

4. Each program should be accompanied by or have readily available ancillary services which seek to treat the cause of the addiction and to assist the individual to reenter the community as a normal, productive citizen.

5. All scientific and drug control requirements of the Federal Food and Drug Administration and the Federal Bureau of Narcotics and Dangerous Drugs must be complied with.

6. We will continue to encourage other rehabilitation programs which seek to totally eliminate and strike at the cause of drug dependence.

7. The department of corrections will continue its efforts to establish a methadone program within an institution of the department and to provide for parole participation in methadone programs outside of correctional facilities.

Our position, in short, is that while methadone has very bright possibilties for reducing heroin addiction and crime attending such addiction, there are many questions, both scientific and social, which remain to be answered. Therefore, while methadone will be made available in programs throughout the State, it must remain under research and security controls sufficient to insure that the programs will be responsibly operated by qualified persons and with the ultimate aim of eliminating entirely any dependency on narcotics, drugs, or other chemicals.

It is important to emphasize that methadone is not a panacea. It treats only the symptom, not the cause. But it does enable a sizeable percentage of addicts to avoid the asocial and criminal behavior of heroin users. Thus, the narcotic-dependent person has a greater potential for successful therapy designed to strike at the root cause of his addiction.

The bills which the Governor refers to in his letter were passed unanimously in the State assembly and with only one and two dissenting votes respectively in the State Senate. Though each was passed with an emergency provision making the law effective at midnight following the day the Governor signed them rather than 2 months later, the very nature of the limitations imposed and the fact that no special moneys were appropriated for these programs will insure that the thousands of eager candidates will wait months or even years before they are accepted.

My first professional publication resulted from an experience as a Navy psychiatrist in which I was asked to act as a probation officer to a man found guilty of theft. During the course of several months while the probationer was visiting me regularly and while I was functioning presumably both as a psychiatrist and a probation officer, the man again committed a theft which ultimately resulted in an additional conviction and expulsion from the service. In the dual role I found myself in an anomalous position. As a probation officer it would have been my duty to arrest him had I learned of any additional misbehavior. As a psychiatrist such information might provide material for therapy, or perhaps termination of therapy, but not disclosure of the fact to the authorities. I concluded that an attempt to function both as a psychiatrist and a probation officer presented serious difficult if not insurmountable obstacles. Since that time, and with more acquaintance with real probation officers I might modify my position somewhat. In general I have found that probation officers have a sufficient concern for their clients and enough optimism that they often show considerable flexibility. It was once the motto of the parole agents of the civil addict program that "If you use you lose." This view changed gradually and over time it has become generally accepted that parolees can be given an opportunity to "cleanup" on their own. Certain kinds of misbehavior in a purely medically run methadone maintenance program might, at the worst, result in expulsion from the program, while in a probation program similar misbehavior might result in a return to incarceration. Should an addict participate in two parallel programs, one a methadone program and one a parole program so long as no privileged information was transmitted from the medical program to the parole program, no ethical problems would likely arise. However, should a methadone maintenance program be operated as part of a parole or probation program some information, urine analysis results at the very least, would be available to the agent who might then act on this information. Serious evaluation of these ethical considerations should be made before plans for such combined programs are carried out.

There are many advantages of combining a probation or parole program with a methadone maintenance. A large proportion of opiate dependent people will sooner or later find themselves on either probation or parole. These agencies have people for counseling and facilities suitable for the operation of an outpatient methadone maintenance program. Should a client be on probation as well as on a separate methadone maintenance program some duplication of effort would be involved. A combined program would minimize such duplication. The double jeopardy of return to incarceration as well as removal from the methadone program might provide an enhanced motivation for some of the otherwise more recalcitrant candidates. The presence of a methadone maintenance program within probation and parole agencies will bring some candidates into contact with methadone programs who might not otherwise have sought them out.

Though I do not at this time know of any instance an absolute mandatory participation in a methadone maintenance program, the procedure in which methadone maintenance is offered in lieu of incarceration or prosecution makes methadone maintenance virtually mandatory in those in-

stances. One of the recently passed California bills referred to above states:

The department (of mental hygiene) shall also establish guidelines for the arrangements between local mental health facilities and county probation departments enabling methadone maintenance to serve as an alternative to commitment to the California Rehabilitation Center at Corona.

Since commitment to the California Rehabilitation Center at Corona may be an alternative to imprisonment and since incarceration at the California Rehabilitation Center itself is not particularly desirable, the logical outcome of this provision may be to force large numbers of opiate dependent individuals into methadone maintenance programs. Frankly, I doubt that more than a small minority will object. One paradoxical result may be that people with a short or sporadic history of heroin use will be incarcerated because they do not qualify for methadone maintenance programs, while those with substantial histories of opiate use will be placed directly on a methadone maintenance program.

The issue is already upon us. I have already had letters from men in jail who indicated that a judge would place them on probation if they entered a methadone maintenance program.

As combined methadone and parole programs because more widely used, it will be interesting to discover, when the parolee is finally released from his parole, whether he will remain voluntarily on the methadone program and what arrangements can be made for continuation of a parole or probation operated methadone maintenance program after the man completes his term.

Another issue of importance centers on the reluctance of some to initiate patients on methadone maintenance who are not currently addicted. Does one then wait until the man starts using before starting treatment?

I have not yet spoken of the relationship between police agencies and methadone programs. Anecdotal reports suggest that there is considerable variation from community to community in regard to the level of cooperation or opposition by police. My own experience has so far been free of serious problems. In general the idea of methadone maintenance has been accepted by those enforcement people I have spoken to, though acceptance ranges from considerable enthusiasm to profound skepticism. In only a few instances, and then generally from those police with many years in narcotics, have I heard outright opposition. The only problem worthy of mention we have until now encountered has been the refusal of the sheriff of Orange County to allow methadone maintenance patients to receive their medication in jail. He has indicated however that he would accede to a court order. When the Orange County methadone maintenance program was first initiated I went to the monthly meeting of the Orange County narcotics officers. Following an informal presentation, the officers asked questions. The one member of that group who had been offering the most probing questions raised his hand and stood at the very end of the meeting and asked, "What can we do to help you, Doc?"

I responded, "Just don't do anything to hurt the program."

In 1969 and early 1970 I felt apprehensive about the future of methadone maintenance programs in the State of California and I sought every possible opportunity to speak out for methadone maintenance. I am much less apprehensive these days. I have found that methadone maintenance speaks for itself and it is hard for anybody not to listen.

COURT SERVICES AND METHADONE TREATMENT: THE NEW YORK CITY PROBATION PROGRAM

Herman Joseph

The problem of heroin addiction has reached a crisis level in the operation of New York City's courts, jails, probation and parole departments.

In 1969:

—33,934 drug related felony and misdemeanor arraignments were reported. Perhaps 60 percent of all cases known to criminal court were drug related.

—15,146 prisoners were either sentenced or in detention in city jails for drug related crimes. Correction authorities estimate that 25 percent of the daily prison census of 14,000 are addicts.

—Approximately 2,000 heroin addicts were under supervision to New York State Parole. Addiction cases comprised about 25 percent of the parole caseload.

—An analysis of 1,977 cases active with the Bronx and Manhattan Supervision Branches of New York City Probation showed that 40 percent were involved with heroin.

As of October 13, 1970, 8,834 addicts were certified to intramural and aftercare facilities of the New York State Narcotic Addiction Control Commission. These statistics present a minimal estimate, as a coordinated method of accurately identifying heroin addicts known to the courts, jails, and affiliated agencies does not as yet exist.

During the past two decades, probation and parole departments in New York attempted to deal with the growing heroin addiction problem:

—In 1956, New York State Parole established small caseloads for heroin addicts. The goals were normal community functioning and abstention, using the authority of parole coupled with casework techniques. As a result the Narcotic Offender Treatment Unit was created.

—The Probation Department of Brooklyn Supreme Court was instrumental in the establishment of Daytop Village.

—In 1963, the New York City Office of Probation collaborated with the Washington Heights Rehabilitation Center in a joint management program. Addicts while under probation supervision were also treated by social workers and public health nurses. Again, normal functioning and possible abstinence were the goals.

Probation and parole status, casework techniques, civil commitment and therapeutic communities in and of themselves or in combination do not appear capable of returning a substantial number of addicts known to our court system to normal functioning within the community. Only a minority of the hard-core addicts known to court affiliated agencies or civil commitment programs are capable of abstinence, crime-free lives, and employment over prolonged periods of time. Available studies indicate that three out of every four addict probationers, parolees or those on aftercare in commitment programs either relapsed to drug use, were rearrested, or reinstitutionalized on violations over varying periods of time despite legal constraints.

The emergence of methadone treatment in the past 6 years presented a viable alternative for addicts who failed in other treatment methods. A study of 2,205 methadone patients admitted to the program over a 6-year period (January 1964 to September 1969) showed that 82 percent, or 1,800, remained in treatment. Approximately two-thirds of the patients were employed, in school, or functioning as homemakers. Also, the rate of arrests for 1,870 patients had dropped 96 percent during the 3-year period following methadone treatment as compared to the 3-year period before admission to the program. From January 1964 through December 1969, 269 patients were known to the probation and parole departments in New York City. Approximately 72 percent, or 193 patients, from this subgroup made good adjustments and were retained in treatment. The reason for the lower retention rate is that some of the patients on probation and parole were among the most difficult in the program, including patients who were arrested while in treatment. With these validated results, the application of methadone maintenance to the practice of probation and parole appeared to be the next logical step.

ESTABLISHMENT OF THE CITY PROBATION PROGRAM

Successful methadone patients have been known to probation and parole in New York City since the inception of the Dole-Nyswander program. Many officers are frustrated in their supervision of potentially eligible addicts as the waiting period for methadone treatment after application is approximately 12 to 18 months. Furthermore, methadone patients on probation and parole are also under supervision to a methadone program counselor with the counselor and probation or parole officer duplicating essentially the same service—the rehabilitation of the patient in the community.

Examination of a Dole-Nyswander methadone clinic showed that it is possible to create a workable program employing court affiliated personnel in conjunction with a medical center. Beth Israel Hospital was approached with the idea. They agreed to participate in a pilot project offering the necessary medical backup service, the medication, urine testing, a nurse and research assistant.

The director of the psychiatric clinic of the courts of New York agreed to be the medical director, to assist in intake screening, to assume responsibility for stabilizing patients, and to help solve medical and psychiatric problems as they arise. Subsequently, a second court clinic doctor volunteered her services; both are now affiliated with Beth Israel. The court psychologist agreed to examine patients before entering treatment, and after 1 year's participation in the program. All probationers receive psychological projective tests during the intake process. The probation department provided officers to act as counselors and a coordinating director for the pilot project.

Probation and the court clinic undertook the admission screening process.[1] The officer discusses the program with potentially eligible probationers and those who request treatment. If methadone maintenance is agreed to, the probationer is referred to the court clinic for completion of screening, which involves projective tests, psychiatric evaluation, and establishing the addict's drug history. Completed material is submitted to the hospital, and the probationer is then notified of dates for his physical examination and the beginning of treatment.

STAFF TRAINING AND ACCEPTANCE OF PROGRAM

Two important factors in the success of a methadone program are staff training and acceptance of the concept of maintenance treatment.

The court clinic physicians were trained at Beth Israel Medical Center, with which they are now affiliated. The court psychologist had participated in the methadone program at Brookdale Medical Center in Brooklyn.

The probation staff was oriented by the writer through staff lectures, individual conferences, and the distribution of methadone literature.

Subjects covered were the metabolic theory of addiction, the concepts of narcotic craving, euphoria, tolerance, physical dependence, narcotic blockade, and the use of methadone as prescribed by Dole and Nyswander. Statistical material, the medication's side effects, medical safety, the stabilization process, and criteria for screening were reviewed.

Although the metabolic theory challenged embedded ideas, the program was welcomed by the staff. However, philosophical differences arose in the case of probation officers who preferred the therapeutic community type of program and participated in various encounter groups and marathon sessions. These officers were honest, hard workers, and were initially repelled by the idea of maintenance. They also verbalized the opposition's arguments—"just substituting one drug for another." However, the good adjustments on methadone of some of their own addicted probationers convinced them that the program had an important place in treatment. One previously resistant worker is now successfully supervising four patients.

I cannot overstate the need for understanding in the training of persons who were saturated with opposing viewpoints and antimethadone propaganda. Many have invested years of their professional lives espousing traditional theories about addiction, addicts, and treatment. Some with patience can be retrained, others with deeply built-in emotional biases must be kept out of programs because of their destructive potential with patients. Unfortunately, this is not only applicable to probation and parole officers, but to doctors, nurses, psychologists, social workers, researchers, etc.

TREATMENT RESULTS AND METHODS

Twenty patients were accepted into our pilot study between February and October of 1970. Of the 20, two were discharged because of rearrests within the first 3 months of treatment. Of those remaining in treatment, 14 are working, in school or both, and four are either looking for jobs or waiting to enter a vocational training program. Prior to methadone treatment, only five were able to maintain steady employment. Almost all of the patients tried other treatment methods such as detoxification and programs which emphasize abstention; five patients had been in therapeutic communities for periods ranging from 3 months to 2½ years.

Histories of mixed drug abuse were reported by 15 of the patients, upon entering the program. Although there have been isolated instances of amphetamine and barbiturate findings in urine tests for six patients, no consistently serious mixed drug abuse pathology has been observed or reported. One probationer with a serious history of alcoholism and heroin addiction did have an acute episode with alcohol and is currently being considered for antiabuse treatment.

Six patients experienced difficulty in giving up heroin euphoria although narcotic craving was relieved. This group needed a great deal of supportive help from staff. At present, there are three patients who occasionally abuse heroin. However, reports from families, probation officers, and hospital staff show that there is an improvement in functioning, and heroin abuse appears to be subsiding.

Criminal activity as measured by arrest records has ceased except for the two discharged patients. In general, the patients' lifestyles have changed in a remarkably short period. This is a relatively young methadone census group with a mean age of about 24 and an age range of 18 to 29. All had heroin histories of at least 3 years before entering the program. Five of the patients are black, 10 are white and three are of Puerto Rican extraction.

A few patients have emotional problems and were seen by the court psychiatrist. Aside from individual counseling, group meetings were organized for the patients to discuss the program, problems of community adjustment, and drug abuse. Although these meetings have been temporarily suspended, they will be reconvened under the direction of the court psychologist. Some patients have requested continuation of the groups, while others find them a waste of time.

At the present time the probation program is operating from three separate offices—the doctors located at the court clinic, the probation officers at the Manhattan Supervision Branch, and the staff at the hospital clinic. This is a workable but not ideal arrangement.

Two problems arose. The patients find traveling to the hospital clinic for their medication, and then to the probation office, inconvenient and expensive. Communication between probation personnel, the hospital, and the physicians is made more difficult than necessary. We expect these difficulties to be resolved as Beth Israel will eventually provide a clinic for the probation program.

At present, we are accepting patients into our program at the rate of one per week. After the clinic is opened, we hope to accommodate 125 patients. Plans will then be made for future expansion depending on our needs, successes, and resources.

Nine probation officers participated in the pilot project supervising the methadone patients, in addition to their regular work. Within the next month a probation officer will be assigned to the methadone patients. Eventually three officers will be working full time at the proposed clinic. After patients are discharged from probation, they will enter the regular Beth Israel program.

RESEARCH

Medical evidence accumulated over the past 6 years has shown that the Dole-Nyswander method for the use of methadone is the most effective medical treatment for the hard-core addict. Therefore, all of our patients are assured of the proper daily dosage (80 to 120 mgs.), so that heroin craving is relieved and a narcotic blockade is generated.

Experiments dealing with variations of dosage which may lessen the effectiveness of the blockade, or double-blind studies involving the use of a placebo, or removal of the medication after a period of time to test whether the patient can abstain from heroin, or other biochemical and psychosocial investigations which would interfere with the validated findings of the evaluation unit at the Columbia University School of Public Health and Administrative Medicine have no place in probation, parole or court affiliated services.

What will be studied are the adjustments of our patients over the course of a treatment year and the effectiveness of our counseling methods. In the future, the clinic doctors and psychologist will reexamine our patients, and their findings will be reported.

DISCUSSION

Methadone maintenance is basically a medical procedure and should not be mandated by law nor made a condition of probation by the court. Addicts enter the probation program voluntarily. If they want to withdraw from methadone treatment, they are free to do so without fear of violating conditions of their probation. Therefore, possible temptations to use the medication as a means of control are eliminated or minimized. This helps to create an atmosphere of dignity which is essential if the patient is to overcome the liability of his addiction experience.

So far, none of our patients have requested to be withdrawn from the medication. They realize that methadone maintenance is a long-term treatment and have entered the program with a full knowledge of what it entails. However, an addict may be placed on probation with the condition that he enter a drug treatment program. Ideally, all referrals for drug treatment should be made in consultation with a physician. However, the limited availability to court affiliated agencies of relevant medical services and the enormity of the problem precludes this type of screening except in special cases such as the probation methadone program. Otherwise, the choice of treatment is currently being made by the probationer or parolee in consultation with his supervising officer. The final decision depends on availability of treatment, criteria for admission, plus the needs and wishes of the addict.

Recently there has been discussion about the creation of a special narcotics court in New York City. This suggestion may have some merit but, at the present time, it will only transfer the court congestion to a new legal structure without solving the basic problem—the availability of effective treatment.

There are over 1,000 probation and parole officers in New York City. Except for the few who participated in the pilot study, not one has been

[1] Admission criteria for probation program:

1. Over 18 with a 2-year heroin addiction history.
2. Mixed addictions are usually ineligible but will be considered.
3. Psychotic patients or those with histories of mental illness must be approved by the clinic.
4. Probationer must voluntarily agree to treatment, keep appointments and follow the program's procedures.
5. Probationers with addicted spouses (common-law and otherwise) are not eligible unless both can receive treatment.

directly involved in the medical treatment of their addicted probationers and parolees. Yet, they are faced with an unprecedented addiction epidemic. Many of these skilled professionals can be effectively brought into the treatment process. The probation-methadone project has demonstrated that a quality service can be created if court affiliated agencies pool their resources and work with a medical center. With proper planning by public health doctors and court affiliated personnel, an impact can be made on the "revolving door" which is the fate of many addicts known to our courts and jails.

Our pilot study can easily be duplicated in other locales with variations, depending on resources and the deployment of staff. Furthermore, the use of existing personnel is economical, since each participating agency contributes an aspect of treatment. Therefore, the creation of expensive treatment bureaucracies may be avoided. At the present time, our major concern is the rapid expansion of our program, so that it reaches the large number of eligible addicts on probation within a reasonable period of time.

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COMBINED TREATMENT OF THE CRIMINAL OPIATE ADDICT BY MEDICAL AND LAW ENFORCEMENT PROFESSIONALS

Gerald H. Starkey, Jr., M.D.
and
Donald J. Egan, M.D.

In December of 1969, Denver district attorney Mike McKevitt and I met to discuss a possible pilot study for the treatment of the criminal opiate addict.

Denver is a city with a population of approximately 750,000, whose narcotic arrests have risen 120 percent over the last 4 years. Various estimates by experts in the Denver area place the number of hard-core opiate addicts anywhere from 500 to 2,000. A realistic figure seems to be around 1,000; of this number approximately 85 percent of whom are under the age of 25.

Statistics obtained from Denver Narcotic Squad Lt. Donald McKelvy indicate that the criminal opiate addict, once released from jail, suffers at least a 90 percent recidivism ratio.

Funds were available from the Omnibus Crime Control and Safe Street Act bill of 1968. Discretionary funds were allocated under the Law Enforcement Assistance Administration (L.E.A.A.) for demonstration grants. Our program was designed to be aimed at the hard-core heroin addict, with a criminally supported habit. Persons charged with simple possession of heroin or persons facing sentence for simple possession and other related nonviolent felonies would be offered the option of "voluntary enrollment" in the methadone maintenance program in consideration of the district attorney's office to defer prosecution of the case, or the district court for sentencing of the defendant during his successful participation in the rehabilitation program. All persons presently on parole and probation in the Denver metropolitan area would also be eligible for treatment on the program for the duration of their legal supervision by these offices.

Defendants facing prosecution were referred to the director of the program, from either the district attorney's office, district court, probation or parole.

A threefold attack on the problem of opiate addiction was thus designed:

1. Chemotherapeutic block by methadone maintenance.
2. Coercion by law enforcement agencies; i.e., district attorney, probation and parole, and
3. Psychotherapy, which would be offered to all participants in the program, including weekly group therapy and/or crisis intervention or both.

In April of 1970, the grant was accepted by John McIvor, Executive Director, Colorado Law Enforcement Assistance Administration, for $36,556 to cover 50 heroin addicts over a 6-month pilot study program. These funds were matched in kind by present existing local moneys.

Dr. Donald Egan, a psychiatrist, was offered and accepted the position as cocoordinator of the program. Additional staff was hired, plus volunteer psychiatric residents from the University of Colorado School of Medicine and, on July 1 of this year, we accepted our first addict on the L.E.A.A. program.

Since the program was instituted, Dr. Egan and myself, working with the Denver Kiwanis Club, have established an Employment Committee Council, which places all of our criminal addicts in jobs in the Denver metropolitan area.

The psychiatric nurses were sent into the Denver city and county jails to ask for "volunteer patients" to come on the program. There are, currently, 30 addicts participating in the program; none of the addicts who have been placed on the program have been dropped; seven more have been accepted and still remain in jail; a total of 67 have been interviewed and 31 rejected.

PREREQUISITES OF THE PROGRAM

1. All patients must be 18 years of age.
2. Must have parental consent or be emancipated from family.
3. A 2-year addiction history for opiates.
4. The patient must be charged with possession, use, disorderly person, and/or with other related nonviolent crimes.
5. Patient must be incarcerated in jail or out on bond for an opiate offense, or be under active parole or probation.

METHODS OF OPERATION

The initial interview is staged by the psychiatric nurses. If, in their judgment, the patients are truly motivated, they are referred to Dr. Egan and the other volunteer psychiatric staff for final approval of the program. If the psychiatrists think the patients are acceptable, they are then brought into Ward 18 of Denver General Hospital, a prison ward, for a complete medical evaluation, including a serum 12-channel autoanalyzer, CBC, urinalysis, and chest films. The patients are gradually started on methadone and daily doses are increased from 60 to 120 milligrams of methadone, given on a once-a-day basis.

At the time of discharge from the hospital, charges have been deferred by the district attorney's office and/or the patient placed on probation or parole by the courts. Deferred sentencing is also possible by the district courts in Denver. In the interim, the Denver Kiwanis Club interviews the patient and places him in an appropriate job, commensurate with his education and abilities.

The patient is seen on a daily basis by at least one member of the group and given methadone under direct supervision, orally. Urines are taken on the patients every Tuesday and Thursday and dirty urines, of which we have had approximately nine since coming on the program, are dealt with in the group therapy sessions. Repeated dirty urines by a specific addict is reason for return to jail facilities.

There are presently 25 males and five females on the program. Three of the females were accepted on the program because the husband was on the program and it was felt that husband-wife addicts must both be blocked with methadone and included in group psychotherapy. The average age of all addicts is 32.3 years. There have been three arrests since the program started, all for misdemeanants; one for shoplifting a pair of $7 glasses, one for shoplifting a $4 hat, and one for driving without a license.

Twenty-one of the addicts have remained clean to the urinalysis examination since coming on the program. Nine addicts have had dirty urines on one or more occasions. Thirteen of the addicts are presently employed, two are housewives and two are in school. Thirteen are unemployed.

On paper, the program looked ideal and it seemed that all avenues of treatment were being utilized and every possible social and environmental pitfall was also being covered. However, approximately a month after the program started, the district attorney's office suggested that the deferred prosecution route in dealing with the addict

was not the proper legal procedure. The district attorney's office complaint was that the addict could go back to his heroin abuse after deferred prosecution and then the district attorney's office would have to reassemble his case, call witnesses that had previously been around the Denver area that have either died or have moved out of our area. They stated that it was causing extensive work.

The Denver Police Narcotics Squad also complained that deferred prosecution psychologically frustrated their efforts as addict enforcers and suggested that the defendant plead guilty to possession or use and then be placed on the program. We were advised by legal sources that this was coercion of the patient's inalienable rights to plead guilty to offenses they had been charged with, without proper due course of trial.

We met with the district court judges in Denver city and county and it was finally determined that the addicts would, in each case, be handled in an individual manner. If the addict had a good past record and it was felt by the district attorney's office, probation and parole, to be a fairly well motivated candidate, he would be offered deferred prosecution in a few individual cases.

For the most part, the addict was to go on to trial and either to plead guilty or not guilty and, at the time of sentencing, L.E.A.A. personnel would be present in the court room to offer to the judge an alternate method of disposition, rather than incarceration again in jail. It was also felt by law enforcement personnel that crimes of violence, even though related to opiate addiction, would automatically nullify the addicts, in terms of coming on the L.E.A.A. methadone program.

In spite of the numerous and sundry problems we have encountered in dealing with three or four different agencies, the program is operating and the psychological and social changes in the criminal addicts involved is most rewarding. Patients who have had up to 40 arrests are now out in society. Many who have been unable to remain arrest free for a 90-day period have been arrest free for a 4-month interim. Patients who have not held a job in the past for any length of time are gainfully employed, supporting their families and off of welfare roles.

VI. DELIVERY OF LARGE SCALE TREATMENT

PLANNING FOR THE TREATMENT OF 25,000 HEROIN ADDICTS

Vincent P. Dole, M.D.

Methadone maintenance programs in the United States and Canada are now treating about 9,000 former heroin addicts. The data from these studies amply document the safety of this medication and its efficacy in stopping heroin addiction when it is given under good medical control.

Detailed statistics have been collected in New York City by our central data office and made available to the independent evaluation committee directed by Dr. Frances Gearing. This committee has recommended continued support and expansion of the maintenance programs. The New York State Narcotics Addiction Control Commission has allocated an increased proportion of its next year's budget to maintenance treatment, and political leaders have called for an immediate expansion of maintenance programs in New York to a caseload of 25,000.

It would seem from all this that the only remaining problems of the methadone programs are to live with prosperity, and forget old arguments, now obsolete. The future, however, will not be this easy. The projected expansion of methadone programs to 25,000 in the next 3 years, or sooner, will confront us with difficulties of greater magnitude than any that we have met during the first 6 years of this work. The problems will be administrative, not medical. The larger the programs become, the more they will interact with other social agencies and political interests.

For example, if the programs in New York City grow to 25,000, they will be responsible for twice as many individuals with antisocial problems as the total present caseload of the Department of Corrections. How are criminal addicts to be treated and under whose control? General rules for bringing 25,000 criminal addicts into methadone treatment certainly do not exist at present. Is it proper for a judge to force treatment on an addict by sentencing him to a maintenance program? Is it advisable for a physician to accept patients on these terms? I would say definitely no to both of these questions. The rights of addicts must be respected, and the importance of abstinence programs must be recognized. I would object to the imposition of methadone maintenance treatment just as strongly as I have objected in the past to its unavailability when the needs of motivated volunteers could not be met.

Our responsibilities will also have common ground with the duties of narcotics control bureaus. With a caseload of 25,000, methadone programs will be dispensing approximately 9 million doses per year of a potent narcotic. We know that this medication is therapeutic when taken by the right person in a good medical program, but we also must recognize the need for adequate control of its usage. Law enforcement agencies of Federal, State, and city governments quite properly have been concerned with the dangers of diversion and misuse of this medication. We must work with them to reduce this danger to a minimum.

So far, we have done well in our programs to insure good medical control, but I am not sure that we have solved the problem for 25,000 patients. We have efficient, computerized record systems with continuous accountability for all patients, and treatment units that are small enough for all patients to be known personally. We would welcome suggestions from concerned agencies as to how our system of followup and data control could be improved without diminishing the effectiveness of the rehabilitation program. As to the medication, we have always insisted that it be dispensed in a form suitable for oral use only, and in the past 3 years we have been testing various noninjectable tablets which, in addition to medical advantages, can be more accurately controlled by identifying code numbers.

We have given much thought to the quantity of medication that should be dispensed to patients to take at home. Unreliable patients obviously should be required to take all medication under direct observation, but to impose this rule on all patients would be counterproductive. Crime reduction is correlated with rehabilitation. Certainly it would be against the public interest to make the dispensing rules so restrictive that a re-

sponsible patient could not hold a full time job. Here again is a need for communication between law enforcement agencies and medical treatment programs.

We have in common the goal of enabling previously criminal persons to lead socially acceptable, crime-free lives. This will not be done simply by dispensing methadone. If crime is to be reduced significantly, we need an effective rehabilitation program, and this includes specifically the authority to dispense a week's supply of medication to responsible working patients whose conduct in treatment has shown that they merit this trust. At the same time, we must use this authority with good judgment, and recognize the concern of law enforcement agencies that this medication be used only as prescribed.

Under the best circumstances it will be difficult to maintain effectiveness of the rehabilitation services with a rapid expansion to 25,000. How can we be sure that the programs will continue to be as effective as they are now when the number is five times as great? Methadone programs could grow into cumbersome bureaucracies treating more patients than are now being treated by all of the Federal, State, municipal, and private programs combined; or, alternatively, methadone might be dispensed without any attempt at rehabilitation. Neither extreme would provide good treatment for addicts. How are quality standards to be maintained?

At the moment, methadone programs are subject to controls exercised jointly by the Bureau of Narcotics and Dangerous Drugs and by the Food and Drug Administration, their authority being based on the proposition that the treatment is still only experimental. Privately, officials of these bureaus concede that the inherent safety and efficacy of the medication are no longer in doubt, but hold that the fiction of experimental status is needed as a legal basis for preventing misuse. There is some merit in their contention, but in any event, the IND permit which now serves as a license for methadone treatment cannot be retained indefinitely as a control device. Expansion to a caseload of 25,000 in New York, and an equal number elsewhere in the country, is inconsistent with the concept of experimental status. Either the treatment is experimental or it is ready for large scale use—but not both.

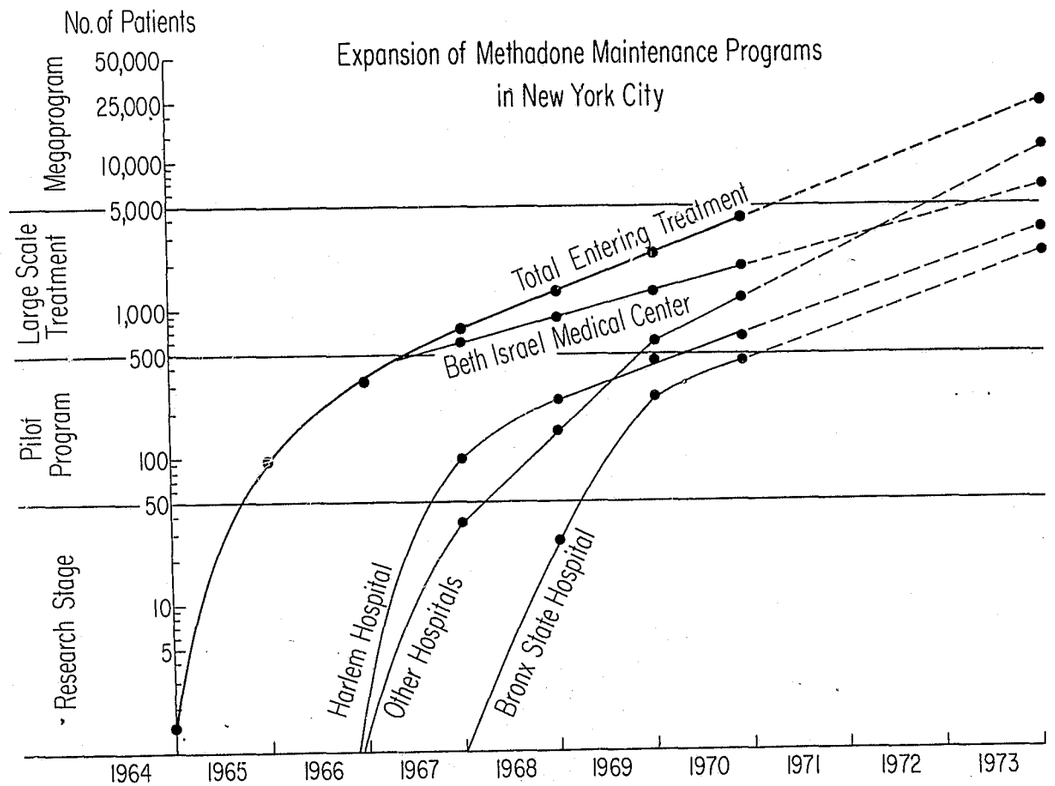
Methadone programs have already brought out strong differences in opinion as to how the treatment should be regulated, and even as to the capacity of the medical profession to define its own standards. The pessimists see only disaster if private physicians are allowed to prescribe methadone, and therefore insist upon controls by governmental agencies with power to prosecute offending physicians. The optimists see addiction becoming part of the inventory of chronic diseases, like diabetes and arthritis, some cases needing institutional care, while other cases are treated by physicians in general practice. It is futile to argue the assumptions that underlie these positions, but this much is clearly before us: Either the leadership of the medical profession and administrators of methadone programs will work together to guide an orderly expansion of methadone services, or the pessimists that view the medical profession as incompetent will win by default.

Let us review the evolution of methadone treatment in New York to learn what we can about the administrative problems in expansion (fig. 1). During the first 2 years, a few of us working together informally provided good medical services for a small, research-sized group (10–50 patients). Like teachers in a one-room school, we knew each patient personally. The ones in trouble were seen more often; the successful ones, less often; all were followed closely enough to know what they were doing. With growth to the pilot program stage (50–500), and even more so on becoming a large service program (500–5,000), our administrative structure changed. No longer could any single person know all of the patients or have time to hear their problems. Administrators, by necessity, delegated the actual treatment to other physicians and gave their own time to budgets and the details of staff work, laboratory services, data control, and public relations.

The net effect has been a healthy decentralization of the program into small treatment units (50–150) which retain the personal qualities of the original research-sized group. The theater for the patient's rehabilitation is his own clinic. These are small enough for him to be known as an individual and independent enough for him to respect the authority of the physician in charge (fig. 2).

With decentralization, the rehabilitation techniques have also become diversified in details—another healthy trend. While general standards of medical practice have been maintained by the sharing of administrative services—data control, central laboratories, staff meetings and consultations—local units have developed their own styles of counseling. The data and laboratory services could easily be extended to private practitioners affiliated with institutional programs. if administrators of existing programs and officials of government wished to encourage this trend. Many rehabilitated patients now being carried on publicly funded programs could pay a reasonable fee for continued treatment by private practitioners.

Figure 1



The problem before us is that decentralization of methadone programs, and specifically the inclusion of private practitioners in the system, would diminish the power of governmental agencies to regulate the treatment. At stake is control over a large program with a growing budget—for the country as a whole, perhaps $100 million per year by 1973—and with political significance at all levels of government. Decentralization of services might bring treatment to more addicts, but it would weaken the bureaus. History fails to disclose a precedent in which any bureau has cooperated in a reduction of its power.

Another concern for the future—this one internal to the medical profession—is the rivalry that has existed between different theories of addiction and different modalities of treatment. With growth to 25,000-patient size, methadone programs might be seen as a threat to the existence of programs using other techniques. This is wrong. We must find ways to work together in the public interest. Those of us who have been directly involved in methadone programs are well aware of the need for other programs, especially those that can prove effective in preventing heroin addiction.

We do not forget that 18 percent of the patients admitted to methadone programs in New York City during the past 6 years have been discharged as failures. Although this is a relatively low failure rate as compared to what appears to be the dropout from other programs, the problem becomes a major one for society as the methadone program grows. What is to be done to control the antisocial behavior of 5,000 addicts discharged as failures from a group of 25,000 admitted to methadone treatment?

Analysis of the case histories of patients discharged from methadone programs in New York City shows that few of them, if any, were pharmacological failures. These patients were discharged for persistent and disruptive antisocial behavior, or for persistent abuse of nonnarcotic drugs (alcohol, barbiturates, amphetamines) for which methadone has no blockade effect—but even in the

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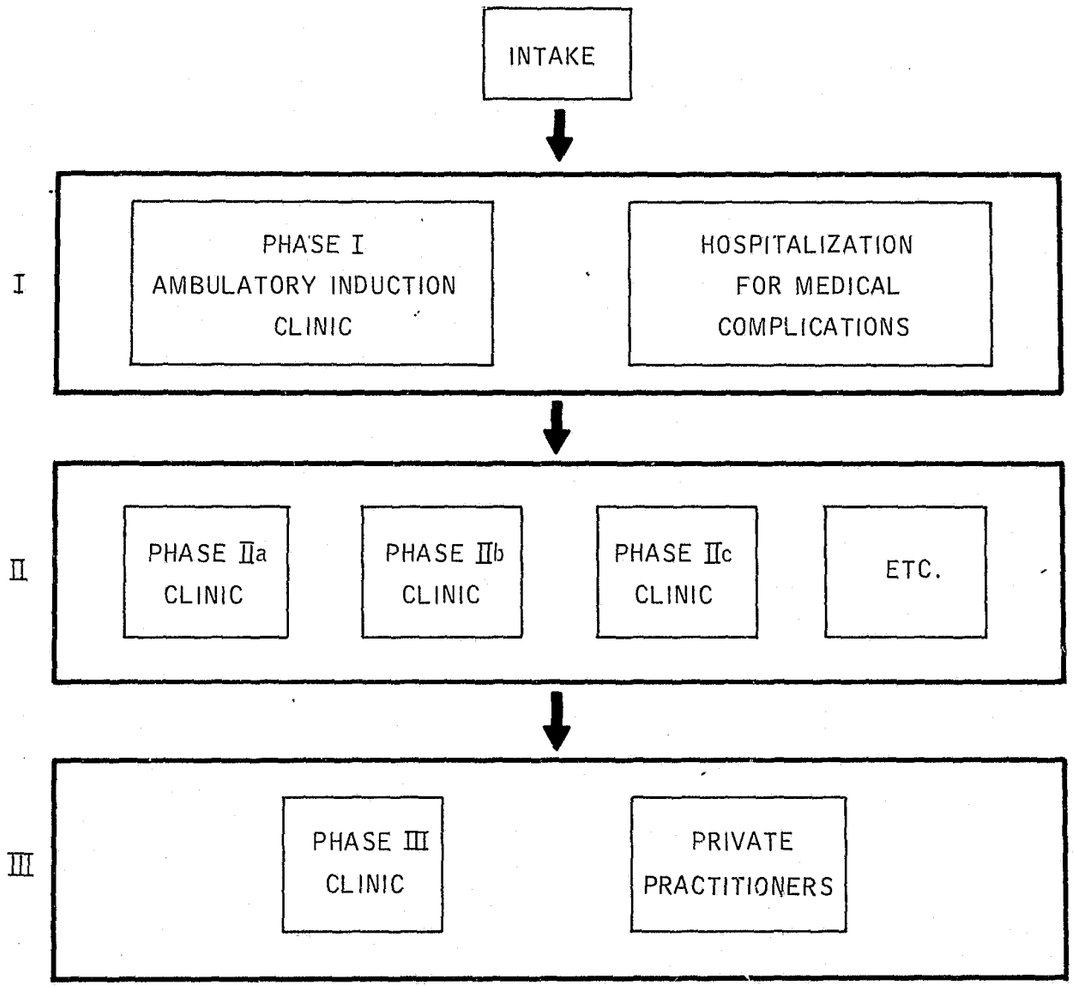
Figure 2



worst cases the regular use of heroin was stopped while the patients were taking their daily dose of methadone. This means that additional techniques for control of psychopathic behavior and for treatment of nonnarcotic abuses must be developed if the overall program is to be made more effective. Combinations of methadone blockade with residential support and various psychotherapeutic techniques are now being studied by research groups in New York and other cities. We need this research, and a climate of scientific objectivity. We need reliable data on the effectiveness and the cost of nonmethadone techniques alone and in combination with blockade treatment.

All of these problems have been with us in some degree since the beginning of the methadone research. Our relation to other social agencies, the maintenance of quality standards and reliable statistics, the effort to separate medicine from politics, the rivalries and jealousies among professionals, have always complicated the basic problem of treating addicts. With growth in size of methadone programs, these divisive problems will be intensified, but can be met with good will and good medical leadership.

There is, however, a serious danger that treatment programs will become subordinated to power struggles. So far, the programs have been effective because their direction has been medical. The procedure has been developed by physicians with personal experience in treatment of addicts, not by governmental agencies or the medical administrators chosen by them. The success of this treatment in rehabilitation of addicts will decline significantly if methadone programs cease to be medical institutions, and, instead, become the instruments of another bureaucracy.

I call upon the leaders of our major medical institutions—the deans and professors of medical schools, the administrators of teaching hospitals, the officials of medical societies—to take an active interest in the treatment of heroin addicts. The medical profession cannot ignore the leading cause of death in urban adolescents and young adults. Enough research has been done to show how heroin addicts can be treated successfully in a medical setting. If we apply what we know now, effectively and on a large scale, we can begin to control heroin addiction and related crime in our large cities.

URBAN CRIME AND THE RAPID DEVELOPMENT OF A LARGE HEROIN ADDICTION TREATMENT PROGRAM

Robert L. DuPont, M.D.

When the First National Conference on Methadone Treatment was held in 1968, the "crime capital of the Nation," Washington, D.C., had only a handful of heroin addicts participating in one treatment program. This program, called DATRC, was an outpatient abstinence program funded by the Office of Economic Opportunity and operated by the Department of Public Health.

A few months later, the Senate District of Columbia Committee dramatized the growing problems of crime and heroin addiction in the Nation's Capital. The committee concluded that both law enforcement and treatment efforts were failing (*1*). During the hearing, a study from the D.C. Department of Corrections was reviewed which demonstrated that the rate of commitment of known heroin addicts to jail had risen gradually from about 50 to 150 cases a year from 1958 through 1966. Beginning in 1967, however, there was an exponential rise to 450 cases in 1968 and to an annual rate of 1,400 by February 1969. This same study showed that before 1966, known heroin addicts constituted less than 3 percent of admissions to jail. In February 1969, the rate had increased to over 15 percent (*2*).

In August of 1969, a new study showed that the actual rate of commitment of addicts to jail was even higher. Using urine testing and interviews, it was shown that 45 percent of the men admitted to the D.C. jail were heroin addicts (*3*). This study also showed that the pattern of crimes committed by the addicts and the nonaddicts coming into the jail was similar. In both groups, property crimes exceeded crimes against people but the addicts committed many of the violent crimes, including criminal homicide, armed robbery, and assault.

Of the addicts identified in this study, only 27 percent were on the Bureau of Narcotics and Dangerous Drugs list of 1,200 male addicts in Washington. As a result, the estimate of the heroin addicts in the city was revised to at least 5,000. A later study of heroin overdose deaths in Washington showed that 52 people died of heroin intoxication during 1969. Using the ratio developed by Dr. Michael Baden that one in 200 heroin addicts died of overdoses each year, the figures were revised again to an estimate of 10,400 heroin addicts in the District of Columbia during 1969.

Six days after the release of the jail study, the D.C. Department of Corrections began a new heroin addiction treatment program. Methadone was a major treatment modality.

Prior to 1966, the rate of serious crimes reported in Washington had gradually increased for nearly a decade. But in 1966 there was a sudden, sharp increase from about 13,000 reported Index offenses in the first 6 months of 1966 to about 36,000 in the last 6 months of 1969.

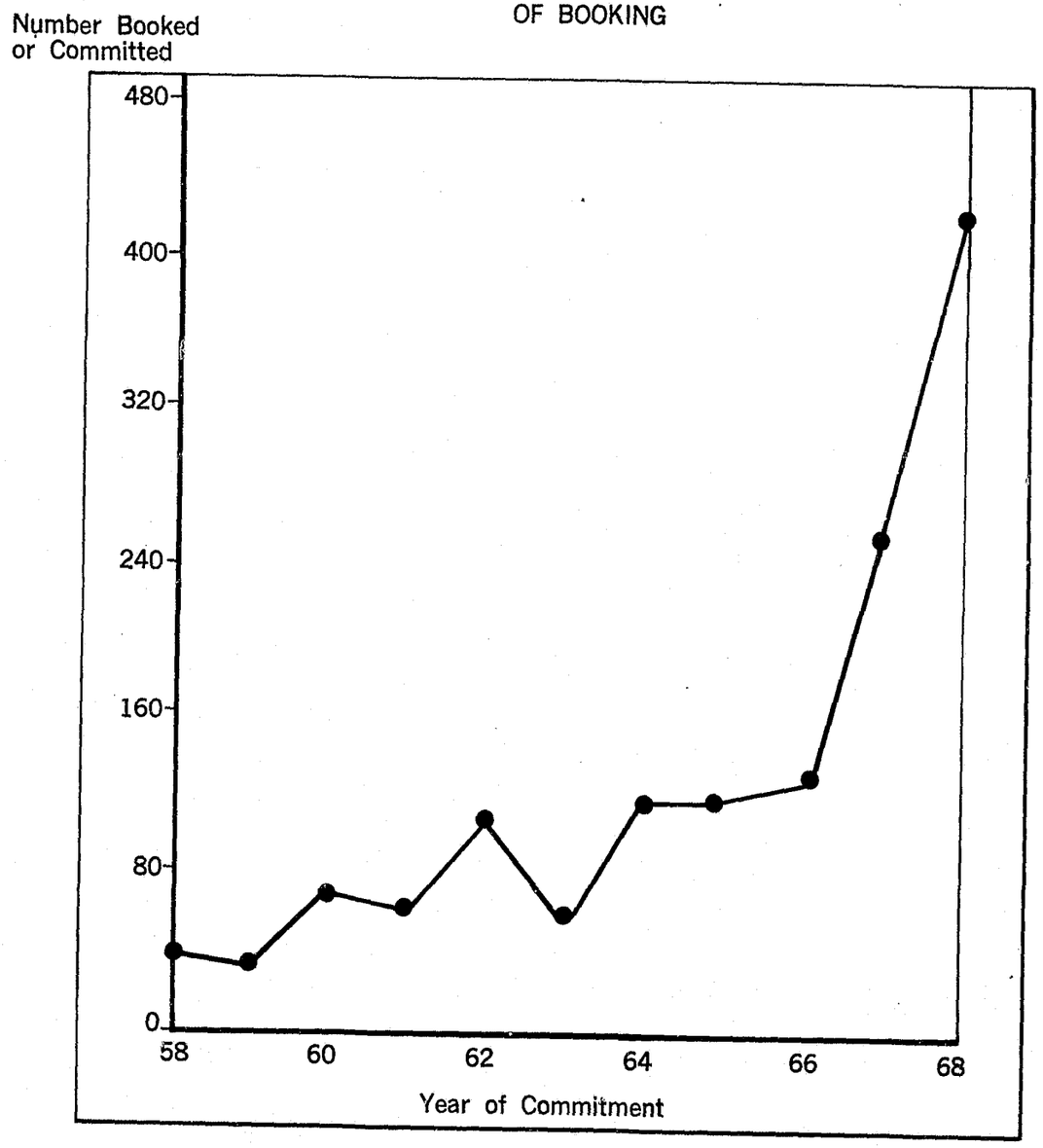
No one knows why this dramatic increase in crime began in 1966. It probably had several causes. However, the most persuasive hypothesis is that there was a sudden epidemic of heroin addiction in Washington which led to both the increased commitment rates of narcotics offenders at the jail and the parallel increase in reported Index crimes.

One year ago, at the time of the Second National Conference on Methadone Treatment, there were 10 patients in Washington's new treatment program, though only one was taking methadone.

As we meet today at the Third National Conference, there are over 2,300 heroin addicts in the city's program. More than 70 percent of them re-

Figure 1

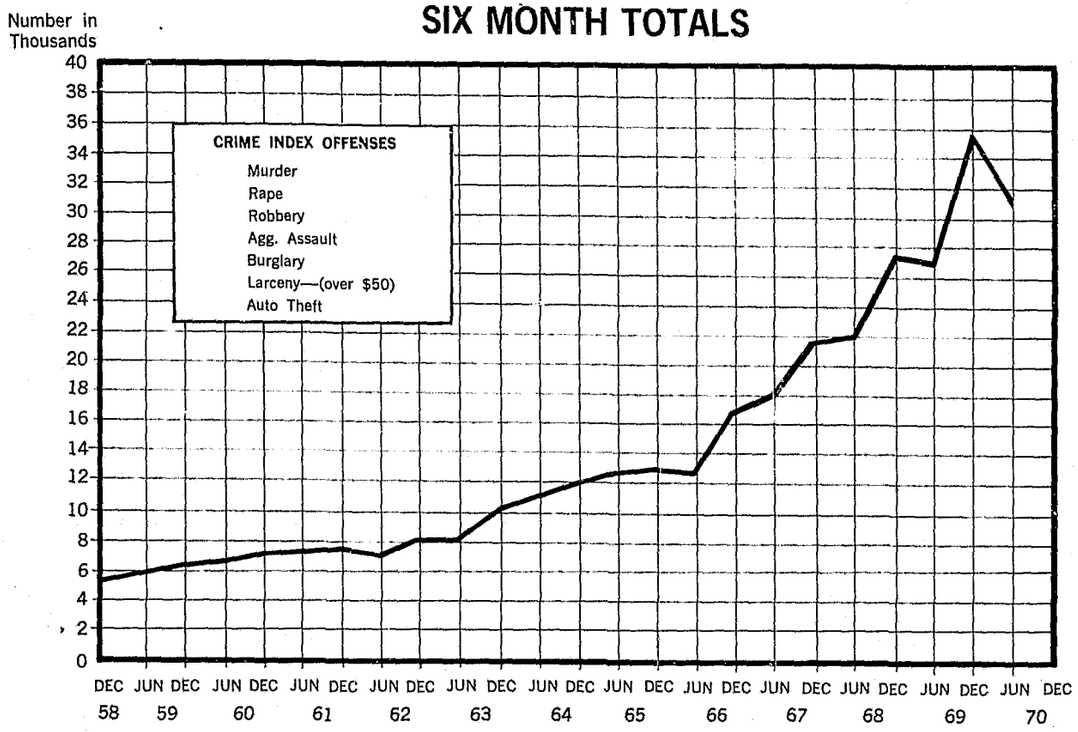
NARCOTIC OFFENDERS BOOKED INTO THE D.C. JAIL BY YEAR OF BOOKING



ceive methadone treatment. About half of the remainder are under 18 years of age. This new program in Washington has 65 hospital beds, 110 halfway house beds, and 10 treatment centers throughout the city. Four of the centers are operated by community-based programs on contract to the city. Four of the six centers operated by the city are now treating about 2,000 outpatients. The total city program is spending at an annual rate of about $3 million.

Figure 2

CRIME INDEX OFFENSES 1959 THRU 1970 SIX MONTH TOTALS



PROGRAM DESCRIPTION

The Narcotics Addiction Rehabilitation Center (NARC) opened by the Department of Corrections on September 15, 1969, treated chronic heroin addicts coming out of the D.C. prisons. This program formed the model for subsequent D.C. programs. It focused on three objectives for the patient: To stop illegal drug use, to stop crime, and to promote full-time employment or training. The primary counselors were former heroin addicts who were specially trained and supervised. Methadone maintenance treatment, as developed by Drs. Dole and Nyswander, was strongly encouraged (*5, 6*).

On February 18, 1970, as a result of the initial success of the NARC program, a new agency of the D.C. Government was created, the Narcotics Treatment Administration (NTA). Immediately, NTA launched a drive to retain in continuing treatment within 3 years all the estimated 10,000 heroin addicts in the city.

The NTA program design was both complex and flexible. However, the major elements were the following: (1) Extensive use of methadone treatment; (2) extensive use of ex-addict counselors in all programs including methadone treatment; (3) use of hospital beds, halfway, houses, and outpatient facilities with primary emphasis on outpatient services; (4) clear and limited program goals to stop illegal drug use, to stop crime, to promote full-time employment or training; (5) vigorous attempts to prevent program dropouts; (6) programing that included voluntary self-referrals; referrals from the criminal justice system through work-release, probation, and parole, and civil commitment; (7) active efforts to establish a cooperative network of drug treatment programs throughout the city by means of purchase of services contracts (especially utilizing community-

supported self-help organizations); and (8) evaluation of all the treatment programs throughout the city using a computer-based information system.

PROGRAM EFFECTIVENESS

The Narcotics Addiction Rehabilitation Center (NARC), the first of the NTA programs and the prototype for other city programs, was studied for effectiveness in achieving the primary program goal, reduced crime. The critical variable was the rate of arrest and detention at the D.C. jail over a 4-month period.

A July profile of the NARC population showed that 14 percent were voluntary self-referred patients. Forty-one percent came directly from prison, and the remaining 45 percent came from other agencies in the criminal justice system such as the Bail Agency, the Parole Division and the Probation Departments of the Court of General Sessions and the U.S. District Court. Ninety-four percent of the population were males. The NARC patients ranged in age from under 18 to over 40, with 45 percent being under 25. All had used heroin regularly, 65 percent also used cocaine and 43 percent used marihuana. Sixteen percent used amphetamines and 16 percent used barbiturates. All had arrest records, usually with many convictions and incarcerations. There was no screening procedure for suitability or for motivation and there was no waiting list for admission to the program.

There were 150 patients in the NARC program on May 1, 1970. Ninety-nine of these were on methadone maintenance (MM) and 51 were abstinent.

Followup of the 99 MM patients showed:

—Two patients were arrested while in treatment;

—Two MM patients who were halfway house residents were returned to Lorton prisons for house rule violations (such as curfew violations);

—Three patients were detoxified from methadone and had subsequently left the program. One of these was arrested after leaving the program;

—Four patients transferred to other NTA programs;

—Fourteen patients dropped out of MM during the 4-month period and left the program. Seven of these patients were arrested subsequently. None of the arrests was made within the first 3 days of dropping out; therefore, none of the dropouts was caused by arrests while in MM treatment;

—Seventy-four patients remained in MM treatment at the NARC Center and were arrest free.

Followup on the 51 abstinent patients showed:

—Eleven switched to MM and of these, two were subsequently arrested. The other nine were continuing in MM;

—Thirty-eight dropped out of the program after May 1 and of these, 10 were arrested by September 1;

—Two remained in the NARC program and have not been arrested.

A recent study by the D.C. Department of Corrections (7) found that the rearrest rate at 4 months with a similar population was as follows:

—22.8 percent for narcotic involved parolees not in special narcotics treatment programs;

—27.8 percent of parolees in DARTC (an outpatient abstinence program operated by the Health Department until February 1970);

—32.6 percent for narcotic involved offenders released from Lorton prisons who were neither supervised by parole nor in special narcotics treatment programs (expirees).

Comparing the NARC sample to patients previously referred to DATRC from parole, the most similar group, there was a substantial reduction in arrests. Of the total NARC sample of 150, 22 people or 14.7 percent were arrested. The 89 patients who stayed in the program had an arrest rate of 4.5 percent. Eighty-seven of these patients were receiving methadone maintenance treatment. The 55 patients who dropped out had an arrest rate of 33 percent. These figures were compared to the 27.8 percent arrest rate for DATRC referrals over a similar period of time and showed that there was an 83 percent reduction in arrest for those heroin addicts who stayed with the NARC program.

Similar followup studies are now in progress for all of the programs of the Narcotics Treatment Administration. The data appears to confirm these first results from the NARC component.

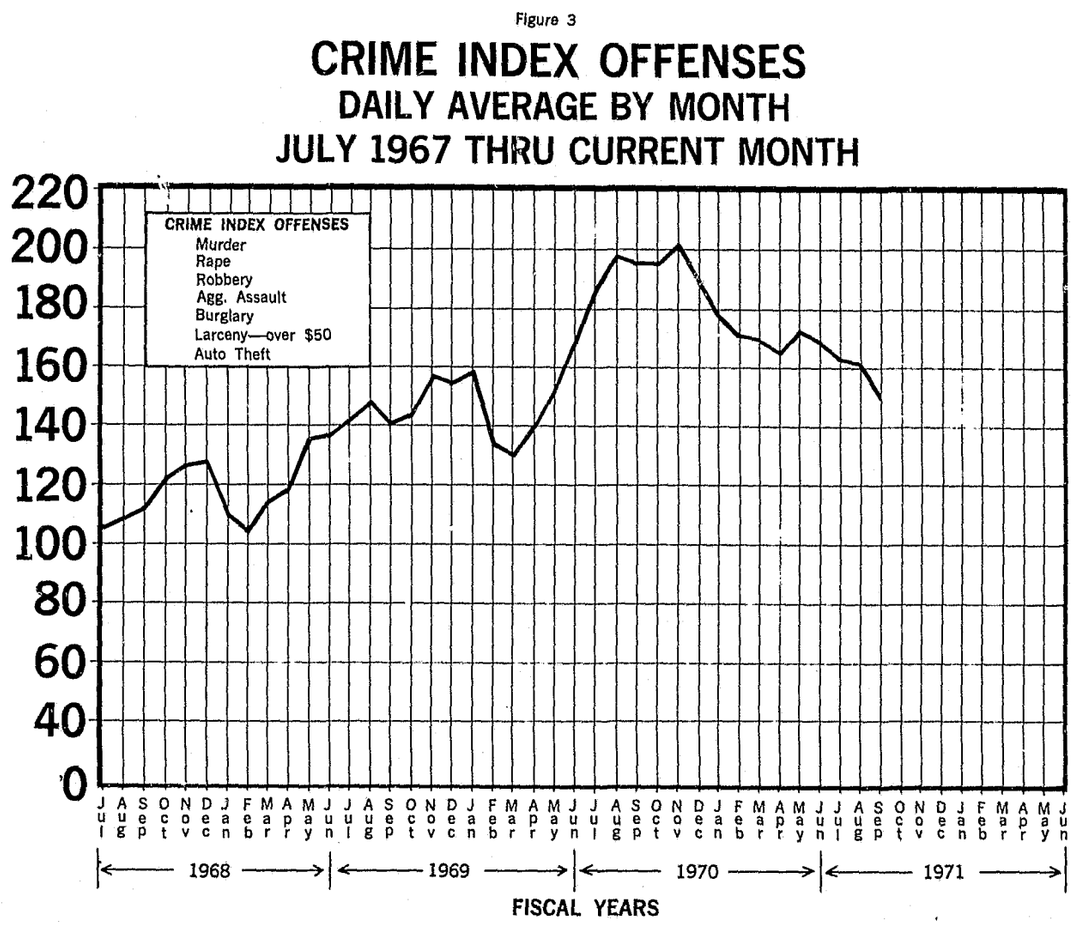
IMPLICATIONS

NTA programs have benefited the heroin addict patient and their families in many ways as shown by increased employment, decreased arrests, and decreased use of illicit drugs.

The Washington community has also benefited. Most obvious has been the impressive and sustained reduction in reported Index crime in Washington.

The crime rate, which had increased abruptly during the previous 3 years began to fall in December 1969. It has been falling every month since,

Figure 3



except for a small increase in May 1970. The number of reported Index crimes during the 3-month period ending September 30, 1970, was 19 percent below the same 3 months of 1969. This was the first time in many years that there was a reduction for a 3-month period compared to the preceding year. If this trend continues throughout 1970, this will be the first year since 1958 during which the total number of reported Index crimes has been less than the previous year.

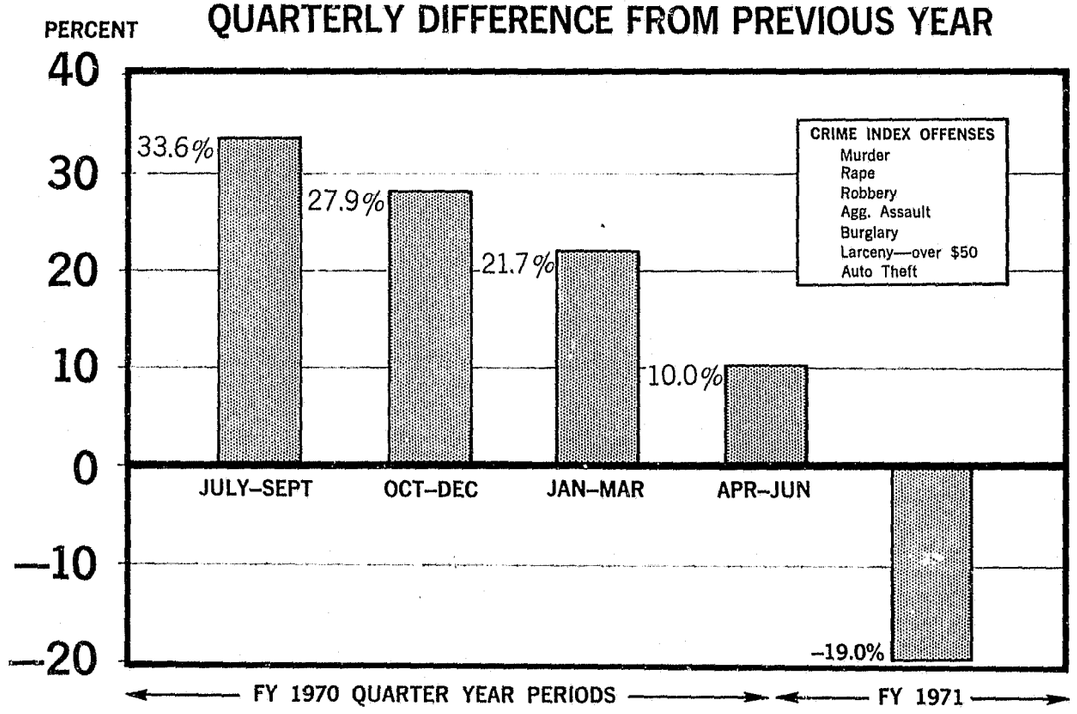
We don't know with certainty why the Washington crime rate rose rapidly during the years 1966 through 1969. Similarly, we don't know why it has fallen sharply during the last year.

However, we do know that there have been major improvements in the criminal justice system in Washington with the selection and support of energetic leadership in the Police Department, the U.S. Attorney's Office, the courts, and the Department of Corrections. These changes, and most particularly the increase in the police force and the leadership of the Chief of Police, have made a significant contribution to the reduction of crime in Washington.

The program of the Narcotics Treatment Administration is another major contributor to the dramatically reduced crime rate. Assuming that an epidemic of heroin addiction in Washington was the major cause of the sharp crime rise from 1966 through 1969, then it is obvious that large-scale heroin addiction treatment was necessary for the drop in crime in the last year.

In addition to the direct benefits associated with the continuing treatment of over 2,000 heroin addicts (or more than 20 percent of the estimated total in the city) the NTA played an indirect role as well. During the past year, there has been an awakening of the Washington community to the problems of heroin addiction. NTA has acted in a catalytic role in these community-based efforts.

Figure 4



THE FUTURE

If NTA continues its current course, we will have over 5,000 patients in treatment by next fall at the time of the Fourth National Conference on Methadone Treatment. We will have better data systems. We will reduce our dropout rate. We will have more money—perhaps spending at the rate of $10 million a year. And, as important as any of these plans, we hope to have the first report on our program performance from Dr. Francis Gearing of the Columbia School of Public Health. Outside evaluation of our program is vital to our continued growth.

The Narcotics Treatment Administration in Washington, D.C., demonstrates that a city can deal rationally with its need for heroin addiction treatment on a scale roughly appropriate to the dimensions and the gravity of the problem. It also demonstrates that there are impressive benefits to be gained from aggressive program growth.

We plan to continue developing our program until all the heroin addicts in Washington are receiving effective treatment.

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METHADONE MAINTENANCE TREATMENT: SPECIAL PROBLEMS OF GOVERNMENT-CONTROLLED PROGRAMS

Robert G. Newman, M.D.

"Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent. . . . The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding." (1)

Louis Brandeis, 1928, after completing 12 of his 23 years as Supreme Court Justice

INTRODUCTION

There is increasing debate in the United States regarding the extent of government involvement which is desirable in the delivery of health care services. In this presentation, focus will be placed on the particular problems which must be anticipated (and, hopefully, overcome) when such involvement relates to the treatment of narcotic addicts. In the case of methadone maintenance treatment, the difficulties affect all programs; since a great many people fail to distinguish among the different types of methadone clinics, problems of some invariably have serious implications for all the others.

Certain difficulties will be faced by any government health program. For instance, the reputation of free government facilities, whether warranted or not, is generally quite poor, and will certainly prejudice many people from the outset. There is also the relative inflexibility of civil service criteria for hiring and firing, wage scales that often are noncompetitive and difficult to adjust, intermittent job freezes, and frequent delays in purchasing and receiving supplies. Although these hurdles can be enormously frustrating, and their effect should not be minimized, this paper will deal primarily with more basic, conceptual features of government addiction programs, especially those which lend themselves to misuse and abuse.

THE PATIENT: THE INDIVIDUAL OR THE COMMUNITY

Obviously, there is no rigid distinction between the ills of individuals and those of the community, and treatment programs concerned mainly with one or the other will consequently overlap considerably. Nevertheless, methadone maintenance represents a departure from the usual role of public health services; unless this departure is stressed, erroneous assumptions regarding the goals of the program will be made, leading to unwarranted conclusions concerning the effectiveness of the treatment modality.

Evaluation reports to date have emphasized the success of methadone maintenance in terms of the individual, to whom it offers a unique opportunity to regain control, within the limits imposed by society, over his own destiny. The dramatic decrease in arrest rates, the markedly lowered need for welfare support, and the high percentage of patients employed or in school full time reflect the fact that the community also benefits from this treatment program. On the other hand, well-meaning advocates who state, or imply, that methadone will resolve the problem of addiction in the community will promptly be confronted with irrefutable arguments. For example, methadone is in no way preventive; educational components are not included in most programs; nothing is done about alleged corruption among law enforcement personnel; and no impact is made on the importation of drugs into the country or on their manufacture in America or abroad. Furthermore, methadone offers nothing to the nonnarcotic abuser, present Federal restrictions prevent its application to the growing number of youthful addicts, and many feel that this therapy should not and could not be forced on addicts who do not wish it.

These limitations can be summed up by defining the patient as the individual in treatment, and not the community. This fact must be recognized by government itself before launching a methadone maintenance program. Optimism regarding the broader scale, based on a lack of understanding, will only result in internal frustration and external criticism—to the detriment of all methadone maintenance programs.

THE CLIENT: THE INDIVIDUAL OR THE COMMUNITY

We have just considered the importance of recognizing who the patient is. Now we will turn to the client. There is a marked, though perhaps subtle, distinction between client and patient. The latter is the individual or group of individuals whose disease we are trying to treat; the former

relates to those in whose interests we are treating the patient. Once again, there is overlapping between the two categories.

A private physician who treats a person's gonorrhea acts primarily in behalf of his patient, though by removing one source of spread of the disease, he also provides some degree of benefit to the community. Health departments also treat individual patients, and benefit them by this treatment. Here, however, the main objective is to protect society at large from the disease, and providing medication is but one component, along with prevention, education, case-finding and followup of contacts. This broader definition of the client generally applies to government programs—and this is perfectly reasonable and appropriate. Unfortunately, however, some of these programs may benefit the client—i.e. society—at the expense of the individual being treated. Such is generally not the case with venereal disease control (except that confidentiality may be compromised). It is the case, usually, with imprisonment and commitment to mental institutions (Dr. Thomas Szasz provides cogent arguments for considering the two forms of incarceration to be identical). (2) It is also the case where medical care is forced on those who do not wish it, or withheld from those who do wish it, and for whom it is medically indicated, but whom the government feels it should not serve. These last two examples present the greatest potential dangers to methadone maintenance programs, especially those operated under the auspices, direction and control of government agencies.

1. *Compulsory methadone maintenance treatment:* To begin with, I would like to preclude semantic differences regarding the word compulsory. When a policeman, a judge, a parole board, or a probation officer present an individual with the choice of methadone maintenance or prison, this is encompassed by my definition of unequivocal compulsion.

I have previously referred to Szasz and his assertion that there is little difference between psychiatric commitment and imprisonment. It is pertinent to note that Szasz's condemnation of involuntary treatment extends to those forms of therapy which professionally are considered to be indicated and effective. He states that ". . . treating patients against their wishes, even though the treatment may be medically correct, should be considered an offense punishable by law." This is especially important to recognize by people who believe, as I do, that methadone maintenance has a unique capacity for restoring to a volunteer addict the freedom to determine how he wishes to lead his life.

Two key points must be emphasized. First, we cannot be sure how effective methadone maintenance is when provided under legal coercion. Secondly, treating a patient against his will, regardless of the outcome, raises very serious ethical questions which must be resolved. These questions apply to physicians employed in government health programs as well as to those working in the private sector. In the former setting, the doctor obviously has much less flexibility in determining his course of action. The ethical conflict is summed up by Szasz: "It is desirable not only for medical patients but also for so-called mental patients to assume maximal responsibility for their health care. Physicians who interfere with the medical patients' autonomy by treating them involuntarily are guilty of an offense, punishable by both civil and criminal statutes. Why should this not apply to similar offenses against mental patients?" (4) If one substitutes "addict patient" for "mental patient" the question becomes a critical one for all those involved in methadone programs who may come under pressure to accept into treatment individuals who have no power to refuse what is offered.

It would be unfair to discuss the dilemma only from the viewpoint of the patient-oriented physician. Courts, police, correctional departments, and parole and probation officials are delegated the responsibility of protecting society. Compared with the immediate aim of most health professionals, this is a different goal; it is not a better one, nor worse one, nor more important, nor less important. In fulfilling its obligation to safeguard the community, government must retain its power to punish those convicted of illegal actions. Incarceration has been the traditional means employed; although stated goal has been to rehabilitate as well as confine the convicted individual, most people would agree that "correction" has generally not been achieved by our so-called correctional institutions. Consequently, it is perfectly reasonable for law enforcement agencies to explore alternatives to imprisonment. Medical treatment, such as methadone maintenance, might have great potential in producing the results which our jails have proven incapable of.

Once again, goals frequently overlap, and often the criminal will receive more humane and beneficial treatment at the same time that the societal aims of government are more effectively being pursued. On the other hand, it is of utmost importance to appreciate that this is not always the case, and when conflict arises, it will be resolved in favor of the broader perspective of the community's well-being. This is not intended to be critical; it is the legal obligation of government to adhere to these priorities. Furthermore, it is by no means uncommon for the interests of patients to be the secondary consideration of medical staff. Generally, physicians employed by industry and insurance companies are in this situation; the Medical Corps of our military services likewise is mandated to place the mission above the individual. To avoid ambiguity and resultant ethical conflict, however, a medical program operating primarily for the department of corrections, for instance, should be part of the department. Also, probation and parole could have their own medical staff employing methadone maintenance as well as other modalities in treating heroin addicts placed in their charge after due process of law. Other clinics, governmental or private, should not accept referrals of individuals who are powerless to refuse, since ostensibly these clinics are oriented to the medical care of patients; they are not considered—and should not be used—as control agents for society.

2. *Withholding* methadone maintenance treatment: many proponents of methadone treatment dismiss as ridiculous the assertion by some militant groups that the program is a means by which the establishment can control (their word is enslave) certain communities. While I do not believe that this danger is an imminent one, I do agree that it is a very real potential threat. It is entirely conceivable to me that applicants might some day be rejected, or patients discharged, on the basis of political and/or antisocial behavior ("antisocial", of course, to be defined by those in power). The likelihood of such medical blackmail is increased by the intermingling of medical and social goals which certain programs set for themselves. We emphasize that, along with the medication which we dispense, we encourage the use of the supportive services which are offered to help the patient in his efforts to become "rehabilitated," to lead a socially acceptable and productive life. Providing such assistance to those who want it is a responsibility we should accept in treating "the whole patient." On the other hand, what if the patient does not want to be rehabilitated, and does not seek to adopt what we feel is a desirable pattern of behavior? Perhaps a patient wishes to spend the rest of his life collecting welfare payments instead of working; perhaps he is a highly successful and well-adjusted numbers-runner; perhaps he is a member of an extremist group (right or left makes no difference) who feels his calling in life is to make bombs in cellars, or attack policemen, or burn synagogues. How will the professional staff relate to such a patient who, despite his antisocial lifestyle, abstains from all drug use, reports punctually and regularly to the clinic for his medication, and whose activities in no way pose a threat to the treatment unit itself? Even more pertinent to the topic of this paper, how much latitude will the staff be permitted in resolving the conflict when the employer is the government?

My questions are obviously rhetorical. I believe that medical care should not be withheld except for strictly medical reasons, or when the care of other patients is compromised. An orthopedist would not refuse to set a broken ankle even if he knew the injury was incurred in the course of a burglary, and even though he were thoroughly convinced that, once healed, the patient would promptly return to his work. An epileptic is not refused his dilantin because the physician disagrees with his political activities. Similarly, though we offer a comprehensive program for our methadone patients, and encourage them to utilize what is available, we should not present our services on an all-or-none basis. To do so would be analogous to a doctor withholding insulin from a diabetic because the patient refuses simultaneous help in controlling his obesity.

Hopefully, most health workers share this view, and will defend it against all pressures which might arise to compromise what they should accept as the primary role: serving their patients.

THE NEW YORK CITY HEALTH DEPARTMENT METHADONE MAINTENANCE TREATMENT PROGRAM

Having discussed some of the key problems—real and potential—which are associated with a government-operated methadone treatment program, I shall briefly describe how our own staff has tried to meet the challenges. The New York City methadone maintenance treatment program is funded entirely by the State and is being implemented by a special bureau of the city health department created specifically for this purpose. It is thus difficult to envisage a more thoroughly government operation.

To begin with, we have stressed to government officials, to hospitals with which we are affiliated and to community groups that this is primarily a patient-oriented program; we emphasize that we are employing one specific modality which has been shown to be extremely effective in treating voluntary patients who meet the requirements, and that we are neither forcing treatment on potential applicants, nor disparaging other approaches. Furthermore, we selected the very restrictive title "bureau of methadone maintenance" in order to underscore the fact that our goals focus specifically on the provision of this form of treat-

ment to all those who want it and could benefit from it.

We have been supported by the pertinent city and State agencies in maintaining voluntarism as an absolute criterion for admission. Conditions for discharge unequivocally preclude the use of this medical treatment as a means of coercing social conformity among our patients. Finally, we are already exploring ways by which private practitioners can be involved in the management of methadone patients enrolled in the city program. In so doing, we are trying to anticipate the day when this form of therapy can be safely and effectively transferred from government to the private sector. As the acceptability and availability of methadone maintenance becomes more widespread, its potential use in exerting social control will lessen.

CONCLUSION

Having begun this presentation with a warning by Justice Brandeis, I shall conclude with one by Dr. Szasz: "Let us not forget that every form of social oppression has, at some time during its history, been justified on the ground of helpfulness toward the oppressed." (5) It is my conviction that the abuse and misuse of addiction treatment programs poses at least as great a threat to our patients as does the abuse of illicit drugs. On the other hand, I also recognize the desperate demand for methadone maintenance therapy by many thousands of addicts. Unquestionably, we should provide this service to every single applicant who wants and can benefit from it. In so doing, however, we must accept the added responsibility to maintain a continuing vigilance against the use of this medical program as a means of achieving social control.

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TWO STANDARD DATA PROCESSING PACKAGES FOR METHADONE MAINTENANCE FACILITIES IN NEW YORK: INTAKE AND TREATMENT

Alan Warner, Ph.D.

The methadone data system provides computer support services for intake centers and treatment units in New York City, Westchester, and Long Island. Data system officers are at Rockefeller University and the Bernstein Institute of Beth Israel Medical Center in New York City. Operations are financed by the New York State Narcotic Addiction Control Commission.

THE INTAKE PACKAGE

Most of the patients in the methadone data system enter treatment through one of seven intake centers which have agreed to send to the data office a "Report of Initial Contact" when an individual applies for treatment. This report contains the applicant's name, birthdate, mother's first name, and social security number, as well as date of contact. Data office staff check this information against a file currently containing 9,000 records of applicants, patients, and expatients in order to determine whether the applicant is known to one or more facilities in the data system. The response is mailed back to the intake center one business day after it is received or is given by phone if the applicant is being considered for urgent admission. No clinical information is given in the response. Typically, the data office indicates either that the information received from the intake center is not in the file and will be entered or that there is a record in the file of an individual with the same identifying information as on the report and that he was admitted and discharged at a given unit in the system on the date indicated.

The intake center which sent the report may then initiate its own clinical contact with the unit named by the data office.

THE TREATMENT PACKAGE

This group of services is currently provided to 65 clinical units in the data system which now treat 4,000 patients. Admissions to treatment are recorded by the data office in a telephone census of clinical units and on backup forms. Within 1 week after the new patient is reported to the data system his name is in the computer file and will be routinely processed thereafter in the following services:

1. *Monthly clinical summary reports.*—An analysis of status data on work, school, crime, staff reported drug abuse etc., as collected for each patient on the monthly unit director report. These data are made available to the administrator of each clinic for patients in his clinic and all clinics combined.

2. *Medication labels.*—A weekly supply of labels on which patient's name, ID number, and doctor's name are printed by computer.

3. *Preprinted urinalysis and pharmacy forms for each clinic.*—Lists patients alphabetically, with ID numbers and appropriate spaces for entry of drug-test and prescription data.

4. *Weekly unit director report lists.*—Alphabetical lists of all patients in the clinic last week, calling for a very brief checkoff report of attendance, location, and movement this week and for names of new patients. These reports confirm and add to data from the telephone census and are microfilmed by the data office for a permanent record on the patients.

5. *Weekly census.*—Tallies of admissions, transfers, discharges, and total patients in treatment are made weekly for each unit and for groups of units under a given administration. These census reports are available to administrators on a weekly or monthly basis.

6. *Data for Columbia University Evaluation Committee.*—The data office sends information to the committee as requested for all units in the system which are making their data available to the evaluation group.

7. *Maintenance of records.*—All machine retrievable data sent by units to the data office are maintained in a variety of files, accessible for retrieval for special research studies carried out by contributing units or by cooperating researchers.

COSTS

Costs for data operations have been found to depend on several major variables and a number of minor ones. Apart from overhead, the major ones, in order of magnitude, are data office staff, computer time, equipment rental, and card punching. These and the lesser ones vary in magnitude with such considerations as free institutional computer time, amount of systems development proceeding while the standard data packages are being maintained, and number of patients being processed routinely. Thus, for a system maintaining 1,000 patients, having 6 hours a week on a small institutional computer, in addition to commercial time, and doing some developmental and one-time research processing, our costs were $100 per patient year. With double the patient load we have estimated costs at $65 per patient year, thus showing the power of patient volume on reducing unit costs. Our most recent estimate, for a patient load of 3,000 without systems development, is $40 per patient year. We are now trying to isolate routine from special expenses, like system development, in order to advance our planning for maximum economy.

As we move ahead from a present patient load of 4,000 to a foreseeable 25,000 within 3 years we feel that the standard data packages can be maintained, with reasonable cost control, if we are conservative in the pace of new systems development, since increased numbers of units and patients in themselves oblige us to devote staff and funds to modify programs and advance our technology. Thus we must forego special requests from units for variations in the basic package. At the same time we are in the midst of evolving the standard packages in ways that meet more universal needs.

NEW OPERATIONS

Methadone dose record.—Entry of methadone dosages into computer files, so that relationships between dosage and patient response variables may be efficiently studied.

Computer support for intake.—Automated production of waiting lists and capabilities for retrieval of applicants by catchment areas.

Drug test system.—Use of optical scanner to read urine test data for entry into computer files and preparation of varied automated reports.

Cost control system.—A computerized accounting system for data processing expenditures, breaking out costs for sections of the standard data packages for groups of units under different administrations, and isolating developmental from routine system maintenance costs.

Private physicians in the system.—Private clinics with 25 or more patients will be offered the treatment package, providing the physician meets the commitment to reliably fulfill data requirements. The intake package, however, will be available to the private physician only if he affiliates with a treatment program or facility which has an intake office affiliated with the methadone data system; one which uses a well-defined screening procedure and is staffed to handle the multiple aspects of the intake process.

METHADONE DATA POOL

REPORT OF INITIAL CONTACT WITH APPLICANT

The following person has applied to _____ (Program or hospital) on _____ (Date) for methadone treatment.

NAME: _____ (Last) _____ (First) _____ (Middle)

ADDRESS: _____

ZIP CODE: _____

BIRTHDATE: _____ SEX: _____ (Male) _____ (Female)

MOTHER'S FIRST NAME: _____

SOCIAL SECURITY NUMBER: _____

Please advise _____ (Screening staff member) on result of checking applicant against computer list.

MAIL FORM TO: DR. ALAN WARNER
ROCKEFELLER UNIVERSITY
NEW YORK, N.Y. 10021

RESPONSE FROM METHADONE DATA OFFICE TO SCREENING STAFF:

Dr. A. Warner

(Date)

FC013/03
2/13/70

METHADONE PROGRAM
WEEKLY UNIT DIRECTOR'S REPORT: Part 2
Patients entering census group during this report period

CENSUS GROUP: _____

FROM: _____ to _____
Report Period

PATIENT'S NAME (-+, first, middle)	PRGM. NO. HOSP. NO.	IF NEW ON PRGM. GIVE ADMISSION DATE	IF TRANSFER FROM ANOTHER CENSUS GROUP	
			ARRIVAL DATE	OLD CENSUS GROUP
	PN HN			
	PN HN			
	PN HN			
	PN HN			
	PN HN			
	PN HN			
	PN HN			
	PN HN			

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UNIT DIRECTOR'S REPORT

F 4 69

ATTENDANCE / LOCATION / MOVEMENT — 42 ____

1) Regular
2) Missed Appointments — 43 ____
3) Discharged from Program (Give reason(s) in Comments section below.)
5) In Jail
6) In Hospital (Methadone Ward)
7) In Hospital (Not Methadone Ward)
8) Transferred to Cns. Grp. _____ NO.

Date of movement: _____

METHADONE REACTION

1) No. 2) Yes: _____ Specify

WEEKLY REPORT [ ] — 44 ____

MEDICAL PROBLEM

1) No, 2) Yes: _____ Specify

MONTHLY REPORT [ ] — 45 ____

BEHAVIOR PROBLEM

0) None, 1) Disruptive, 2) Assaultive, 3) Other: _____ Specify — 46 ____ 47 ____

SELF-ADMINISTERED DRUGS (Clinician's Impression or Patient's Self-Report) — 48 ____

1) None, 2) Heroin, 3) Amphetamine, 4) Barbiturate, 5) Other: _____ Specify — 49 ____ 50 ____ 51 ____

ALCOHOL PROBLEM

1) None, 2) Acute Episode, 3) Chronic, 6) Potential Prblm, 7) Improved — 52 ____ 53 ____

LEGAL STATUS

1) No Problem, 2) Arrested, 3) Convicted, 4) On Probation, 5) On Parole
8) Case Pending — 54 ____ 55 ____

HOUSING

1) Lives Alone, 2) With Friends, 3) Parents, 4) Family, 5) No Information 6) In Hospital — 56 ____

JOB

1) None, 2) On Same Job, 3) New Job, 4) Homemaker (women) — 57 ____ 58 ____

MEANS OF SUPPORT

1) Job, 2) Welfare, 3) Parents, 4) Spouse, 5) Friends, 6) Other: _____ Specify — 59 ____ 60 ____ 61 ____
8) None, Other than program services

SCHOOL

1) No, 2) Part Time, 3) Full Time — 62 ____

COMMENTS: CLINICIAN'S INITIALS: _____ — 63 ____ 64 ____ 65 ____

80 ____

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CENSUS GROUP: 105

URINALYSIS RECORD
METHADONE PROGRAM

PAGE 1

PATIENT LIST UPDATED 9/17/70

LAB. _____ LOCATION _____

TECHNICIAN(S) _____ SEND REPORT TO _____

PATIENTS (HOSP. NO.)	PRGM. NO.	PLT. NO.	DATE(S)	METH	QUIN	MRPH	BARB	AMPH	

424-195 O—71——10

PHARMACY LIST

CENSUS GROUP: 105

PAGE 1

PATIENT LIST UPDATED 9/17/70

WEEK OF_____

OPD NAME_____ RN'S SIGNATURE_____

PATIENTS (HOSP. NO.)	PRGM. NO.	DOSE	REMARKS	MON	TUES	WED	THURS	FRI	EMERG.

CENSUS GROUP: 105

PAGE 1

METHADONE PROGRAM
WEEKLY UNIT DIRECTOR'S REPORT: PART 1

Attendance/Location/Movement

REPORT PERIOD: 9/25/70—10/1/70

PATIENT LIST UPDATED 9/17/70

PATIENTS (HOSP. NO.)	PRGM. NO.	REGULAR ATTEND-ANCE	MISSED APPOINT-MENTS	IN HOSPITAL		IN JAIL	TRANS-FERRED TO CENSUS GROUP	DIS-CHARGED	DATE OF MOVEMENT
				METH. WARD	NOT METH. WARD				

VII. INSIGHTS FROM OTHER LANDS

METHADONE MAINTENANCE TREATMENT OF OPIATE ADDICTS IN SWEDEN

Jan H. Erikson, M.D.

BACKGROUND

The MMT ad modium Dole-Nyswander was introduced in Sweden by Gunne 1966. At that time the number of patients addicted to different types of narcotic analgetics was estimated to be about 300 located to a few cities, foremost Stockholm and Gothenburg. In Stockholm an experiment with prescription of opiates was going on and a lot of addicts were being maintained on methadone and other drugs for parenteral self-administration. Heroin was practically unavailable on the black market. The main narcotic drugs abused were morphine, meperedine, ketobemedone, methadone, dextromoramide, and raw opium. There was a widespread mixed addiction in this group. Amphetamine and phenmetraline i.v. in high doses where often abused together with the mentioned opiates.

SELECTION OF PATIENTS

Since January 1967 to October 1970, 83 addicts from the whole country have been admitted to our clinic for detoxification from opiates. Thirty-eight or 46 percent have entered the MMP. The major reasons for rejection are first too short history of opiate addiction, second, too heavy abuse of other drugs or alcohol and third, unwillingness to participate in the program by returning to an outpatient clinic every day for medication.

The criteria for selection were as follows:

1. At least 21 years of age
2. A primary addiction to opiates for at least 5 years
3. A history of repeated detoxifications and relapses
4. No evidence of endogenous psychosis or other overt psychiatric problems
5. Mixed addiction should be unimportant at the time of admission.

DESCRIPTION OF PROGRAM

All patients accepted for treatment have been inducted to tolerance in the same way as recommended by Dole and Nyswander. Methadone has been given in increasing doses during an in-hospital phase and the final stabilizing dose lies between 60 and 140 mg. daily. During the hospital stay the patients were given necessary social support and medical care.

After release from the hospital the patients have appeared daily for medication in a pharmacy in their home town. Two times a week they give urine samples to be sent to our clinic for TLC and GLC to detect use of other opiates, central stimulants and hypnotics.

Twenty-five pharmacies all over Sweden have participated in the outpatient program. Cooperation between the pharmacists and our clinic has been very good.

No ambulatory induction has been practiced.

DESCRIPTION OF PATIENTS

The patients in our methadone maintenance program have ben well established opiate addicts for an average of 10 years prior to admission. The age distribution has its median value at 30. Six have been women and 32 men.

A certain degree of mixed addiction has been tolerated and the extent of abuse of other drugs is given in Figure 1.

FIGURE 1

Alcohol	21 (55%)
Hypnotics	9 (24%)
Central stimulants	24 (63%)
None	9 (24%)

Abuse of central stimulants was as frequent as 63 percent. Only nine patients had no history of previous or present abuse beside opiates.

Figure 2 describes the pattern of drug abuse in the treatment group. The column I gives the distribution of the debute drugs. Cannabis smoking is not given in the table. The impression is that cannabis has played a minor part in the habits of these patients.

FIGURE 2

	I	II	III	IV	Total
Alcohol	19	1	1	0	21
Hypnotics	0	4	3	2	9
Central stimulants	7	11	5	1	24
Opiates	12	17	9	0	38
Total	38	33	18	3	

Nineteen of the patients had a history of alcohol abuse before they started on opiates. Twelve had opiates as their first drug of abuse, but had later on mixed with other drugs, preferably central stimulants. All patients subjected to methadone maintenance were, however, mainline opiate addicts at the time of admission.

RESULTS

As of October 31, 1970, among the 38 patients, 16 or 45 percent have been dispelled from the treatment program. The main reason for discharge from program has been drug abuse, preferably central stimulants and alcohol, which has necessitated the detoxification of 13 patients. In addition, three patients have asked to leave the program as they have found the daily dose administration inconvenient and difficult to combine with their occupational activities.

Urine test to detect the use of drugs beside the treatment program has revealed morphine, codeine, fenmetraline, and barbiturates in 0.2 percent of all tests. The 13 patients dispelled from the program because of frequent intoxications have not contributed to this figure. The reason is that these patients with multiple abuse of drugs have refused to give urine specimens at the pharmacy. They were later admitted to our clinic in an intoxicated state and detoxificated.

Measures of rehabilitation have been decreased in criminality and medical complications and increased in employment or training in schools. Since 21 of the 22 patients in the program had undergone earlier treatment with legal prescription of opiates for self-administration a comparison could be made between these two treatment systems. Prescription of morphine, methadone or pethidine for self-administration compared with MMT in equal time periods is illustrated in figure 3. When for instance a patient had been 10 months on MMT his rehabilitation figures for the last 10 months on self-administered opiates were used for comparison.

FIGURE 3

	Self-administration	MMT
Criminality	19 (86%)	6 (27%)
Employment or schools	5 (24%)	16 (76%)
Hepatitis	8 (36%)	0

The increase in employment from 24 to 76 percent is a result achieved to a large extent through cooperation with the local social agencies which have supported our patients in training and seeking jobs. The remaining 24 percent are on welfare or sporadically employed. In this study, medical complications during the period of self-administration were exclusively due to inoculation-hepatitis, which has been a frequent complication in other experiments with self-administration of drugs of addiction (Bewley, et al. 1968 and Louria, et al. 1967). The only medical complication observed during MMT was transient oedemas of the ankles seen in two patients.

In four cases it has been judged necessary to increase the dose after the first out-patient period. In all these cases the patients had previously been addicted to methadone.

Three patients, now functioning and self-supporting, have recently asked for withdrawal of methadone. They have all been in the program for more than 3 years.

DISCUSSION

The result of the present study seems to be comparable to those reported by the MMTP evaluation committee in March 1970. An acceptable degree of social rehabilitation was achieved in 76 percent in our material as compared with 82 percent in the New York City study. The majority of failures in our patients was accounted for by a heavy abuse of drugs outside the opiates.

A special problem was encountered in patients with a history of previous addiction to methadone. Six patients had prior to admission used 400 to 500 mg. methadone daily for parenteral administration. It has been very difficult to maintain these patients on the doses mentioned in our program. And the effect of methadone has in these cases been considerably shorter than in the other patients in the treatment group. These six patients have experienced withdrawal symptoms as early as 6 hours after an oral dose of 140 mg. of methadone. A dose increase up to 240 mg., on the other hand, made the patients drowsy and difficult to handle. These cases have later been stabilized on acetylmethadol (Gunne & Erikson, 1969). The results support the view expressed by Dole and coworkers that a methadone maintenance program should screen out those who have a mixed drug addiction or who are heavy users of alcohol. The local pharmacies have proved to be a useful substitute for outpatient clinics and the Swedish MMTP may serve as an example of how a small country can handle an opiate addiction problem of a moderate size.

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THE EVALUATION OF THE EFFECTIVENESS OF NARCOTIC MAINTENANCE CLINICS IN ENGLAND

Richard Phillipson, M.D.

Mr. Chairman, ladies and gentlemen, you must forgive me if this presentation is very brief and unprepared as I was asked to take the place of Dr. Thomas Bewley some 15 minutes ago and have spent the intervening time getting out some papers I have published in the past on the British drug system.

I propose to quote from one or two of these and also to refer to one table supplied to me by Dr. Bewley which gives details of total numbers of narcotic addicts known to the Home Office, London through the years 1958–69 inclusive.

HISTORICAL BACKGROUND

The Rolleston Committee

In Britain it has always been the custom to treat all forms of drug addiction as primarily a medical problem.

In 1924 the Minister of Health appointed a departmental committee under the chairmanship of Sir Humphrey Rolleston (an eminent physician). The task of the Rolleston committee was to advise on a number of problems which had arisen in operating the Dangerous Drugs Act, 1920. The terms of reference of the Rolleston committee were "to consider and advise as to the circumstances, if any, in which the supply of morphine and heroin to persons suffering from addiction to those drugs may be regarded as medically advisable and as to precautions which it is desirable that medical practitioners administering or prescribing morphine or heroin should adopt for the avoidance of abuse, and to suggest any administrative measures that seem expedient for securing observance of such precautions."

The Rolleston committee reported in 1926, (1) and on the question of the supply of drugs to addicts, expressed the view that "morphine or heroin may properly be administered to addicts in the following circumstances, namely: (a) where patients are under treatment by the gradual withdrawal method with a view to cure; (b) where it has been demonstrated after a prolonged attempt at cure, that the drug cannot be safely discontinued entirely, on account of the severity of the withdrawal symptoms produced; (c) where it has been similarly demonstrated that the patient, while capable of leading a useful and relatively normal life when a certain minimum dose is regularly administered, becomes incapable of this when the drug is entirely discontinued." The committee considered, but rejected, (1) the desirability of requiring medical practitioners to notify cases of addiction to the Home Office, and (2) the question of providing "by regulations that a practitioner should obtain a second medical opinion before consenting to administer morphine or heroin for an indefinite time to a person who does not need them otherwise than for the relief of the symptoms of addiction."

The Rolleston committee did, however, recommend that, in addition to the power which the Home Secretary already had of withdrawing from a medical practitioner (who had been convicted of an offense against the Dangerous Drug Act) the authority to possess and supply drugs to which the act applied, provision should be made for withdrawal of that authority by the Home Secretary on the advice of a medical tribunal, without the need to obtain a conviction in the courts.

The recommendations of the Rolleston committee were accepted by the Government, and amending regulations were introduced in 1926, giving the Home Secretary the power to withdraw a doctor's authority on the advice of a tribunal consisting of three medical members and a legal assessor.

Although this method of dealing with doctors who abused their authority was regularly used thereafter in Northern Ireland, where similar regulations were introduced, the tribunal procedure was never invoked in Britain, for reasons which have never been clearly established. Cases continued to occur, from time to time, after 1926, of so-called "script doctors" who were prepared, at a price, to ignore the Rolleston committee's warnings against too ready an acceptance of the need for continuing supplies but, in general, the freedom of the addict to obtain supplies legitimately caused no major problem for many years.

In retrospect, however, it is apparent that the so-called "British system" was workable only so long as there was no widespread tendency towards any abuse in Britain and the first signs of a change in this respect began to appear soon after the Second World War. In 1951 a large quantity of morphine, heroin, and cocaine was stolen from the dispensary of a hospital in Kent in the South of England and it was subsequently learned that the young man responsible for the theft began to peddle those drugs around the London jazz clubs and the coffee bars frequented by jazz musicians. He was finally arrested by the metropolitan police, some 3 months after the theft, when it was found that, while the morphine he had stolen was still virtually intact, the heroin and cocaine had been largely disposed of, and documentary evidence found on him indicated that he had some 15 regular customers for these two drugs. All these 15 "nontherapeutic addicts" were not only associated with jazz music, they were also under 35 years of age, and most sinister of all when they approached the script doctors for supplies some of them began to ask for larger quantities than they themselves needed in order to supply the supplies to others in their group who, when they became addicted, approached doctors in their turn.

The First Brain Committee

By 1958 the number of known addicts (to all narcotic drugs) had almost doubled that known in 1947. As a result of this, the first interdepartmental committee on drug addiction was appointed on June 3, 1958, under the chairmanship of the then Sir Russell Brain, what came to be known as the first Brain committee composed of seven members.

The terms of reference of the committee were "to review, in the light of more recent developments, the advice given by the departmental committee on morphine and heroin addiction in 1926 (the Rolleston committee); to consider whether any revised advice should also cover other drugs liable to produce addiction or to be habit-forming; to consider whether there is a medical need to provide special, including institutional, treatment outside the resources already available, for persons addicted to drugs; and to make recommendations, including proposals for any administrative measures that seem expedient, to the Minister of Health and the Secretary of State for Scotland."

The first Brain committee reported in November 1960 (2) and included among 20 separate conclusions and recommendations were (1) the committee was satisfied that the incidence of addiction to dangerous drugs was still very small; (2) that departmental arrangements insured that nearly all addicts to dangerous drugs were known; (3) the Home Secretary should not establish medical tribunals to investigate the grounds for recommending him to withdraw a doctor's authority to possess and supply dangerous drugs; (4) apart from item (3), the committee underlined and supported the main conclusion of the Rolleston committee, which were included in a memorandum on the dangerous drugs act and regulations, which was prepared by the Home Office for the information of doctors and dentists.

The Second Brain Committee

In the 3 years following the publication of the first Brain report (1961), there was a further steep rise in the incidence of addiction to dangerous drugs. The number of known addicts to heroin increased fourfold and most of these were also addicted to morphine. The Brain committee was therefore reconvened in July 1964 as it was by then evident that the sudden increase was due, at least in some measure, to the prescribing methods of a certain small number of doctors.

The terms of reference of the second Brain committee were "to consider whether in the light of recent experience the advice the interdepartmental committee gave in 1961 in relation to the prescribing of addictive drugs by doctors needs revising and, if so, to make recommendations."

The second Brain committee reported in July 1965 (3) and a summary of the 12 main conclusions and recommendations made by them included the following:

1. There has been a disturbing rise in the incidence of addiction to heroin and cocaine, especially among young people. (Through the years 1959–64 the total number of addicts to dangerous drugs rose from 454 to 753 and this included a rise in addicts to heroin from 68 to 342; of the 342 known addicts, 328 were of nontherapeutic origin.).

2. The main source of supply is the overprescribing of these drugs by a small number of doctors. (The second Brain committee was informed that in 1962 one doctor alone prescribed 600,000 tablets of heroin (i.e., 6 kilograms) for addicts, the same doctor on one single occasion prescribed 900 tablets of heroin (9 grams) to one addict and 3 days later prescribed for the same patient another 600 tablets (6 grams) "to replace pills lost in an accident.") The second Brain committee also noted "the evidence further shows that not more than six doctors have prescribed these very large amounts of dangerous drugs for individual patients and these doctors have acted within the law and according to their professional judgment."

3. There is now a need for further measures to restrict the prescription of heroin and cocaine. "We remain convinced that the doctor's right to prescribe dangerous drugs without restriction, for the ordinary patient's needs, should be maintained. We have also borne in mind the dilemma which faces the authorities responsible for the control of dangerous drugs in this country.

To prevent this abuse without sacrificing the basic advantages of the present arrangements we suggest:

(a) A system of notification of addicts.
(b) The provision of advice where addiction is in doubt.
(c) The provision of treatment centers.
(d) The restriction of supplies to addicts.

4. The committee defined an addict, for the purposes of their report, as follows: " A person who, as a result of repeated administration, has become dependent upon a drug controlled under the Dangerous Drug Act and has an overpowering desire for its continuance, but who does not require it for the relief of organic disease."

5. There should be a power for compulsory detention of addicts at treatment centers.

6. The prescribing of heroin and cocaine to addicts should be limited to doctors on the staff of treatment centers.

7. It should be a statutory offense for other doctors to prescribe heroin and cocaine to addicts.

8. Disciplinary procedures against doctors alleged to have prescribed heroin and cocaine, irregularly, to addicts should be the responsibility of the general medical council.

9. An advisory committee should be set up to keep under review the whole problem of drug addiction.

THE IMPLEMENTATION OF THE SECOND BRAIN REPORT

Following the publication of the second Brain report in July 1965, the following events are worthy of note:

1. On April 28, 1966, the Minister of Health, replying to a question in the House of Commons, "To ask the Minister of Health what action he had taken to implement the recommendations of the Brain committee on drugs" said, "The treatment facilities are under review and the Government has decided to accept the recommendation to set up an advisory committee on the whole problem of drug addiction. Consideration is still being given to the committee's other main recommendations which require legislation."

On August 2, 1966, in a written answer the Minister of Health, replying to a question in the House of Commons "To ask the Minister of Health whether following his announcement about the standing advisory committee he would now make a statement about the other recommendations in the Brain committee report," stated "There are already centers for the treatment of addicts and more beds could be made available if the demand increases. A conference of doctors experienced in the treatment of drug addicts is being convened in order to have the medical knowledge of the subject. Steps are being taken to set up a unit in which research into the problem of drug dependency can be undertaken. The Government is preparing legislation to implement the committee's recommendation for the compulsory notification of addicts by doctors and for limiting the authority of doctors (other than those at treatment centers) to prescribe or supply heroin and cocaine to addicts, except where it is required for the relief of pain due to organic disease or following injury or operation. The details will be discussed with the medical profession. The Government has, however, decided not to provide initially for the detention of addicts at treatment centers, but would reconsider the position if experience showed that such powers were essential."

MEMORANDUM ON TREATMENT

On March 7, 1967 (4) the Minister of Health issued a hospital memorandum on "The treatment and supervision of heroin addiction." Paragraph 3 of memorandum, on the question of power to detain at treatment centers patients who wish to terminate a course of treatment they entered into voluntarily, stated: "The question of compulsory treatment raises wide and difficult issues and the Minister is not satisfied that the case for this recommendation has been fully established."

Paragraph 8 of the memorandum, under the heading "outpatient services" stated: "Some addicts will not accept withdrawal treatment, at any rate to start with, and complete refusal of supplies will not cure their addiction—it will merely throw them on the black market and encourage the development of an organized illict traffic on a scale hitherto unknown in this country. The aim is to contain the spread of heroin addiction by continuing to supply this drug in minimum quantities where this is necessary in the opinion of the doctor, and where feasible to persuade addicts to accept withdrawal treatment. Paragraph 10 of the memorandum, on the question of the supply of drugs, stated: "The decision to supply an addict with drugs and whether to seek to substitute other drugs, the asessment of dosage, and the method of suppy rest with the clinician."

In Britain, in March 1970 (*5*), Mr. James Callaghan, the Secretary of State for the Home Department, moving the second reading of the misuse of drugs bill, in the House of Commons, said:

"Drug-taking is a scourge. We know far too little of its causes or consequences. The law has a part to play—hence the bill—but it is by no means the only agency, because law enforcement which attempts to control personal consumption, is difficult. I emphasize at the outset that there is a need for a concerted effort in the legal, social, and medical fields. The bill on its own, although it would serve a useful purpose, would by no means deal with the problem, which is growing so fast today.

"Compared with even 3 years ago, the pattern of misuse of drugs is much more complicated and more serious. Then, the main problem was a sharply increasing growth of heroin addiction coupled with a widened use of pep pills, cannabis and LSD. Drug-users, even that short while ago, tended to go for a single drug of their choice. Today, the increase in heroin addiction has tapered off, almost certainly because control by the treatment centres of supplies to addicts has reduced the amount available to potential new addicts in the black market. But there is a more sinister side. Some would say that because of this very control many addicts have resorted to substitute drugs.

"Indeed, 2 years ago, in 1968, there was an epidemic of 'fixing' by amphetamines which was largely fed by the activities and over-prescribing of no more than 2 doctors in London. It could be stopped only by a voluntary scheme for restricting supplies to hospital pharmacies. Many of the needle-users—a term to which I shall return later, then turned to methadone, a narcotic used by some treatment centres to wean addicts off heroin and made available for general practitioners to prescribe. They are free to prescribe it.

"I want to give an indication of the measure of the problem, and the speed with which addiction can come upon us. There are now just over 2,000 registered addicts of heroin. Of these, 700 are under the age of 20. But as a result of the increase in the over-prescription of methadone in 1969 alone, 337 cases of addiction to methadone first came to the notice of the Home Office. Methadone ampoules now command much the same black market price as heroin did before the 1968 restrictions. More recently—within the past 12 months—some addicts have taken to the highly dangerous and destructive practice of injecting themselves with barbiturates.

"It therefore comes to this. We can draw comfort from the fact that heroin addiction appears to be less of a threat and that convictions for drug offenses in the first half of 1969 were no more than 10 percent higher than in the same period in 1968. Nevertheless, the possibilities of much more serious and new trouble are very real; first, because it is difficult to predict what the pattern of misuse will next be and those exposed to it have become much more vulnerable.

"Second, there are evil men who see a profit in exploiting misuse, and have greater resources and greater opportunities for doing so, whether by manufacturing new drugs for this market or by smuggling and traffiking. Third, is the speed of change in fashion for drugs, which is so depressing; and fashions can be spread by such a handful of irresponsible medical practitioners.

"This has meant that our defenses are far too inflexible against these evils. The legislative scene is static, but the drug scene is constantly changing. And the Home Secretary concluded, 'There is a need for different treatment of different groups. The addicts of the hard drugs—those who are on heroin, or have been weaned from it and are on methadone or are injecting barbiturates—are very sick people, unable to face the problems of life, unable to come to terms with life or with their fellows. These people need help and understanding and treatment. At the other end of the scale are the youngsters who experiment for kicks. Most of them escape the worst consequences, but some are caught in the web at regular intervals.'"

Before concluding this brief reference to the evaluation of the effectiveness of narcotic maintenance clinics in England, I would like to refer to a statement in the Annual Report of the Chief Medical Officer of the Department of Health and Social Security 1968 (*6*) where Sir George Godber said:

"There is now evidence to suggest that medical services are beginning to contain the problem of heroin addiction. For example, it is known that the total amounts of heroin prescribed to addicts throughout the country are being gradually reduced and the number of new outpatients reported by the clinics fell from 398 in April 1968 to 67 in December 1968.

Moreover, of these patients attending the special clinics, many are no longer receiving heroin. For example, a sample of 702 outpatients in 1968 showed the following figures:

Receiving heroin on a nonreducing basis	214
Receiving heroin on a reducing basis	217
Withdrawn from heroin	271

Of those withdrawn from heroin, 111, or 40 percent, had been withdrawn from all narcotics."

I do hope these 111 patients, Britain's first "cures" since the implementations of the recommendations of the second Brain committee are being followed up in a scientific way in the community.

Before I close, ladies and gentlemen, may I refer, albeit briefly, to figures supplied by the Home Office, London, of narcotic addicts in Britain and especially to the details of numbers known to be taking heroin on December 31, 1968—2,240 and December 31, 1969—793: also to those known to be taking methadone in the same period, 468 in 1968, 1,687 in 1969.

It will be readily seen that Britain would appear to have, at present, contained the problem of heroin addiction.

The full table of Home Office returns is shown at Table I.

HOME OFFICE RETURNS

	1958	1959	1960	1961	1962	1963	1964	1965	1966	1967	1968	1969
Total number	442	454	437	470	532	635	753	927	1,349	1,720	2,782	2,881
Drugs:*												
Number taking methadone	47	60	68	59	54	59	62	72	156	2[illegible]	486	1,687
Number taking morphine	205	204	177	168	157	172	162	160	178	1[illegible]	198	345
Number taking heroin	62	68	94	132	175	237	342	521	899	1,29[illegible]	2[illegible]	793
Number taking cocaine	25	30	52	84	112	171	211	311	443	462	[illegible]	330
Number taking Pethidine	117	116	98	105	112	107	128	102	131	112	12[illegible]	127
Origin:												
Number of therapeutic origin	349	344	309	293	312	355	368	344	351	313	30[illegible]	289
Number of nontherapeutic origin	68	98	122	159	212	270	372	580	982	1,385	2,420	2,367
Number of unknown origin	25	12	6	18	8	10	13	3	16	31	56	39
Sex:												
Number of male addicts	197	196	195	223	262	339	409	558	886	1,262	2,161	2,295
Number of female addicts	245	258	242	247	270	296	344	369	463	467	621	586
Professional classes (medical or allied)	74	68	63	61	57	56	58	45	54	56	43	42
Ages:												
Under 20			1	2	3	17	40	145	329	395	764	637
Under 20 taking heroin			1	2	3	17	40	134	317	381	709	160
Under 20 taking methadone												438
20 to 34	50	62	94	132	184	257	347	558	906	1,530		1,789
20 to 34 taking heroin	35	52	87	126	162	219	319	479	827	1,390		564
20 to 34 taking methadone												1,141
34 to 49	92	91	95	107	128	138	134	162	142	146		174
35 to 49 taking heroin	7	14	19	24	38	61	52	83	66	78		47
35 to 49 taking methadone												54
50 and over	278	267	272	274	298	311	291	286	279	260		241
50 and over taking heroin	26	27	24	22	20	22	16	20	24	20		14
50 and over taking methadone												32
Age unknown	34	16	7	16	8	7	10	14	7	82		40
Age unknown taking heroin									1	43		4
Age unknown taking methadone												22

*N.B. The figures refer to drugs used alone or in combination with other drugs. Thus an addict using both heroin and cocaine will be included under both drugs, and it must be pointed out that all but a handful of the cocaine addicts shown above are also using heroin.

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CHARACTERISTICS PREDICTING LONG-TERM RETENTION IN A METHADONE MAINTENANCE PROGRAM

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The retention power of the methadone maintenance modality is without equal in the addict rehabilitation field. It is almost as if this type of patient will continue in treatment regardless of what we do or do not do for them. Attrition does, however, occur and the purpose of this study was to isolate those attributes most associated with continuing in treatment. Our analysis included both single factor and multifactor techniques.

THE SAMPLE

Our study population was 679 patients admitted to the Dole-Nyswander program from its initiation in 1964 to March 1968. Our strategy was to compare those patients who remained in treatment for at least 2 years with those who did not. Within this study population, 541 or 80 percent continued in treatment a minimum of 2 years and 138 or 20 percent attrited prior to this minimum period. Even those who terminated earlier than the 2-year followup period, remained in treatment an average of 12.6 months (medium was 12.7 months).

THE REASONS FOR TERMINATION

An analysis of the primary reasons recorded for the 138 treatment terminations indicated 112 (81 percent) were involuntarily terminated; 22 (16 percent) voluntarily terminated themselves, and four (3 percent) were administrative terminations. A more complete distribution of the reasons for termination is as follows.

THE COMPARISONS

Utilizing a single factor or dependent-independent variable analysis where all attributes were collapsed to 2 by 2 contrasts produced some unexpected differences and failed to produce some differences one would anticipate.

Still utilizing a single factor or dependent-independent variable analysis but regrouping the data for another perspective reenforced the unanticipated results derived from our first analysis. For example:

1. Continuing in treatment was *not* related to the sex of the patient—80 percent of the male patients and 80 percent of the female patients remained in treatment for at least 2 years.

2. Continuing in treatment was *not* related to the marital status of the patient—86 percent of the patients with intact marriages and 79 percent of the patients who were not married remained in treatment for at least 2 years.

3. Continuing in treatment was *not* related to the multiple abuse of drugs—83 percent of the patients who had not been multiple drug abusers and 77 percent of those who had been multiple drug abusers remained in treatment for at least 2 years.

4. Continuing in treatment was *not* related to the abuse of alcohol—82 percent of those who had no history of alcohol abuse and 75 percent of those who had abused alcohol remained in treatment for at least 2 years.

5. Continuing in treatment was *not* related to the ethnicity of the patients—82 percent of the white, 77 percent of the black and 81 percent of the Puerto Rican patients remained in treatment for at least 2 years.

6. Continuing in treatment was *not* related to the education of the patients—79 percent of the high school graduates and 80 percent of those who were not high school graduates remained in treatment for at least 2 years.

7. Continuing in treatment was *not* related to the age at onset of heroin use—79 percent of those who began before age 21 and 80 percent of those who began at or after age 21 remained in treatment for at least 2 years.

8. Continuing in treatment was *not* related to the number of prior treatments experienced by the patients—81 percent of those with two or less treatments and 79 percent of those with three or more prior treatments remained in treatment for at least 2 years.

9. Continuing in treatment was *marginally* related to the conviction history of the patients—78 percent of those who had never been convicted and 80 percent of those with convictions remained in treatment for at least 2 years. However, the number of convictions was significantly related to continuing in treatment—85 percent of those with two or less convictions and only 72 percent of those with three or more convictions remained in treatment for at least 2 years (significant at 0.01).

10. Continuing in treatment *was* related to the length of abuse of narcotics—90 percent of those who had abused 5 or less years but only 77 percent of those who abused more than 5 years remained in treatment for at least 2 years (significant at 0.01).

11. Continuing in treatment *was* related to the employment status of the patient at time of admission—88 percent of those who were legally employed at admission but only 77 percent of those who were not employed remained in treatment for at least 2 years (significant at 0.01).

An expanded distribution of these attributes with a control for the sex of the patient permits a more focused associational analysis. For example:

1. In general and regardless of sex, the fewer the number of convictions, the greater the chance of remaining in treatment. This item had the greatest outcome differentiating power of all of the attributes when a statistical technique common in parole prediction was employed—the Mean Cost Rating technique. In brief, the MCR technique measures the extent an item has the ability to differentiate between categories with high and low outcome rates.

2. In general and regardless of sex, those patients who had concurrently abused amphetamines with the opiates were less likely to remain in treatment.

3. At least among the males, those most recently accepted into treatment were the ones most likely to terminate. The opposite is true for the female patients.

4. At least among the males, being employed at the time of admission into treatment has a positive association with remaining in treatment. Employment at admission is neither a positive nor negative association to outcome among the female patients.

5. In general and regardless of sex, having a problem with alcohol has a negative association with remaining in treatment. Having had such a problem, however, is no more negatively associated with outcome than never having had a problem.

6. Of all of the race-sex cohorts, Puerto Rican females most frequently remain in treatment and black females have the highest attrition rate.

7. Among males, the younger the age at admission, the greater the positive association with remaining in treatment. Among females, the most advantageous age is between 25 and 29, and the least is under age 25.

A complete expansion of the characteristics can be reviewed in table 3.

Our previous research and clinical experiences have led us to assume we can predict which types of patients might do better than others. We generally assume those patients with the least chance of remaining in treatment share combinations of the following characteristics:

a. Early onset age;
b. Long drug history;
c. Concurrent drug or alcohol abuse;
d. Multiple convictions.

In general, the combining of these characteristics suggests the following:

1. Being a multiple drug abuser or an alcohol abuser is probably more negatively associated with remaining in treatment than the length of time the patient has been abusing drugs.
2. Being a multiple drug abuser or an alcohol abuser is probably more negatively associated with remaining in treatment than the age at which the patient began abusing drugs.
3. Having been arrested and convicted a number of times is probably more negatively associated with remaining in treatment than being a multiple drug or alcohol abuser, the time when the patient began abusing drugs, and the length of time the patient had been abusing drugs.

Based upon the configural analysis, the potency of the number of convictions as our best predictor of remaining in treatment was reinforced.

Utilizing all three techniques, the patient with seven or more convictions and who had no employment skill to market was the least likely to remain in treatment (55.6 percent). One would assume ancillary services should be marshaled and focused toward the buffering against these attributes. Conversely, the patient with the fewest convictions and no multiple drug or alcohol problem was the mostly likely to remain in treatment (95.8 percent).

Table 1.—PRIMARY REASON FOR TREATMENT TERMINATIONS

I. Involuntary termination		81.2% (N=112)
1. Uncooperative behavior	17.4% (N=24)	
2. Antisocial behavior	7.2% (N=10)	
3. Unreachable psychopathology	7.2% (N=10)	
4. Drug abuse	8.7% (N=12)	
5. Alcohol	10.9% (N=15)	
6. Arrested	15.2% (N=21)	
7. Medical disability	2.2% (N= 3)	
8. Death	12.3% (N=17)	
II. Voluntary termination		15.9% (N= 22)
1. Voluntary discharge	14.5% (N=20)	
2. Loss to contact	1.4% (N= 2)	
III. Administrative terminations and unknowns.		2.9% (N= 4)
1. Administrative	.7% (N= 1)	
2. No information	2.2% (N= 3)	
Total		100.0% (N=138)

Table 2.—CHARACTERISTICS OF METHADONE MAINTENANCE PATIENTS BY LENGTH OF TIME THEY REMAIN IN TREATMENT

Attributes at time of admission into treatment (1964–68)	Less than 2 years (N=138)	2 years or more (N=541)	
I. Demographic characteristics			
1. Age: Range	22–52 years	19–60	years
Mean	33.2 years	32.6	years
2. Race: Whites	34%	39%	
3. Sex: Males	86%	85%	
4. Education: High school graduates	30%	29%	
5. Marital: Married at admission	15%	22%	
6. Occupation: Semiskilled or above	76%	81%	
7. Job status: Employed at admission	13%	25%	(P=<.01)
8. Work history: At least 36 months of continuous employment	49%	50%	
II. Arrest history characteristics			
1. Never convicted	9%	8%	
2. Three or more convictions	75%	66%	(P=<.05)
III. Drug abuse characteristics			
1. Onset age (heroin) age 18 or less	39%	43%	
2. Multiple/concurrent drug abuse	54%	45%	
3. History of drinking problem	29%	19%	
4. Five or more prior treatments	49%	51%	
5. Six or more months on waiting list	49%	47%	

Table 3.—EXPANDED CHARACTERISTICS OF METHADONE MAINTENANCE PATIENTS AND THEIR ASSOCIATION WITH REMAINING IN TREATMENT

Admission characteristics	Males		Females		MCR for males
	Number of patients	Percent in program 2 years later	Number of patients	Percent in program 2 years later	
Total	[1] 579	79.6	100	80.0	
Number of previous convictions:					
2 or less	178	84.8	38	81.6	0.181
3–6	260	81.5	32	87.5	
7 or more	140	69.3	30	70.0	
Job status at admission:					
Working	139	88.5	10	80.0	.135
Not working	428	76.6	86	80.2	
Year admitted:					
1964–65	64	84.4	5	40.0	.096
1966	181	82.9	30	80.0	
1967–68	332	77.1	65	83.0	
Other drugs—Addict or heavy use:					
No problem	291	82.8	37	81.1	.094
Barbiturates	31	77.4	7	85.7	
Amphetamines	11	72.7	2	50.0	
Other	199	76.9	38	79.0	
Alcohol:					
No problem	246	81.7	43	83.7	.093
Had problem	23	82.6	5	80.0	
Has problem	74	73.0	10	70.0	
Ethnicity:					
White	214	82.2	46	80.4	.081
Black	237	76.8	43	76.7	
Puerto Rican	109	80.7	8	87.5	
Other/no data	19	79.0	3	100.0	
Age at admission:					
24 years or younger	58	86.2	10	70.0	.071
25–29 years	149	81.9	19	89.5	
30–34 years	161	78.9	22	77.3	
35 years or older	203	76.4	47	80.8	
Marital status:					
Married	111	85.6	27	85.2	.069
All others	449	78.6	70	78.6	
Medical complications:					
None	307	80.8	41	85.4	.029
Some	251	78.9	55	80.0	
Longest job ever held:					
Less than 12 months	113	79.6	24	70.8	[2]
12–23 months	98	75.5	17	88.2	
24–35 months	77	84.4	13	84.6	
36 months or more	291	79.7	46	80.4	

Table 3.—EXPANDED CHARACTERISTICS OF METHADONE MAINTENANCE PATIENTS AND THEIR ASSOCIATION WITH REMAINING IN TREATMENT—Continued

Admission characteristics	Males		Females		MCR for males
	Number of patients	Percent in program 2 years later	Number of patients	Percent in program 2 years later	
Months waited before admission:					
0–2 months	105	79.0	25	80.0	[2]
3–5 months	151	81.5	24	79.2	
6 months or more	233	78.5	43	83.7	
Age when started using heroin daily:					
16 years or younger	135	83.0	16	81.2	[2]
17–18 years	121	79.3	16	81.2	
19–20 years	113	74.3	18	83.3	
21–22 years	77	83.1	11	90.9	
23–24 years	53	83.0	9	55.6	
25 years or older	80	76.2	30	80.0	
Number of previous hospitalizations:					
2 or less	173	80.9	32	84.4	[2]
3–4	103	73.8	25	76.0	
5 or more	301	80.7	42	78.6	
Last grade completed:					
Some college	61	86.9	5	60.0	[2]
Some high school	404	78.5	79	78.5	
Eighth grade or less	62	85.5	3	100.0	

[1] Not all items total 579 since unknown were not included.
[2] MCR not computed as not enough consistent relationship was observed by inspection to warrant its computation.

Table 4.—MULTIPLE FACTOR CLASSIFICATION FOR MALE PATIENTS BASED UPON CLINICAL ANTICIPATION

Years of abuse	Multiple use	Number of convictions	Age at onset	Number of patients	Percent in program 2 years later
5 years or less	No problem			24	95.8
	Multiple use			18	83.3
6–11 years	No problem		19 years or less	49	89.8
			20 years or more	40	80.0
	Multiple use		19 years or less	65	80.0
			20 years or more	47	74.5
12–15 years		6 or less		95	80.0
		7 or more		36	58.3
16 years or more		6 or less	20 years or more	49	91.8
			19 years or less	63	79.4
		7 or more	20 years or more	23	69.6
			19 years or less	35	67.5

Utilizing these data, a configural analysis was performed to verify the potency of the number of convictions as a predictor for remaining in treatment. The configural analysis is, of course, derived entirely from a statistical base.

The first step in carrying out a configural analysis is to take the item most related to outcome. In this case, it is number of previous convictions. This best item is then cross-classified with each of the next most related items and with outcome to determine which factors provide the most differentiation within each subgroup. For example, those with two or less previous convictions are the first subgroup in the configuration.

The factor that best differentiated as to outcome within this subgroup was concurrent use of other drugs and/or alcohol abuse. This type of operation was repeated within each subgroup, and as can be seen in table 5, different factors were used within each subgroup.

This statistically derived classification does differentiate between types as to outcome and the differences are in the direction expected.

Table 5.—CONFIGURAL CLASSIFICATION FOR MALE PATIENTS BASED UPON A COMBINATION OF SINGLE AND MULTIPLE FACTOR PREDICTORS

Admission characteristics		Number of patients	Percent in program 2 years later
2 or less previous convictions.	No problem with other drugs or alcohol.	76	88.2
	Concurrent use of other drugs and/or alcohol abuse.	102	82.4
3 to 6 previous convictions.	Employed at admission	49	93.9
	Not employed at admission	160	78.1
7 or more previous convictions.	Semiskilled or better	125	76.8
	Unskilled	45	55.6

DEVELOPMENT OF A NEWLY FORMULATED TABLET FOR METHADONE MAINTENANCE PROGRAMS

Ivan F. Bennett, M.D.
Eli Lilly and Company

I would like to express my appreciation to Dr. Dole and to the sponsors of this Conference for the opportunity to present a few brief remarks at your meeting here today. As I am sure you are aware, my company shares with you an interest in the current status of methadone maintenance treatment programs for heroin addicts.

Methadone was first synthesized in 1941 by German scientists who were searching for inexpensive morphine substitutes to meet their country's wartime needs. Shortly after the end of World War II, a team appointed by the Department of Commerce in Washington, D.C., visited Germany and, on their return to the United States, published the formula of a number of chemical compounds, including methadone, for the benefit of American science and industry. Several manufacturers became interested in the product, and in 1948 we marketed methadone as an analgesic and antitussive.

In the years following its introduction, methadone was sold on a modest scale. The market demand for the product was never very large; however, in our role as a broad line pharmaceutical manufacturer, we continued to manufacture it as an effective painkiller, with long-acting properties. Although seven companies originally manufactured methadone, the number has dwindled in recent years, leaving us as one of the remaining producers.

During the decade of the 1960's, the incidence of heroin addiction started to take on epidemic proportions, with resulting grave social consequences in this country. As you know, to help meet this problem, a considerable number of methadone maintenance clinics have been established in various cities during the last few years, supplementing programs that already existed for the rehabilitation of addicts.

Early this year, the Food and Drug Administration asked if we could develop an oral form of methadone that would be dispersible in water but that would not be suitable for injection. It was agreed that such tablets could be developed and that they would be manufactured for use only in approved clinics.

A group of our staff in Indianapolis immediately set to work on this task. At the same time, it quickly became apparent that we needed to gather some basic data on future production requirements. Up to this point, we had not been involved in working with methadone maintenance clinics and, therefore, had no market research findings on which to rely. In order to obtain an estimate of the amount of material that might be needed in future months, we contacted all clinics that were known to us. Based on the estimates provided by the clinics, we have come up with workable assumptions of manufacturing needs and are in close touch with the Bureau of Narcotics and Dangerous Drugs regarding the future supply of methadone.

As soon as our Indianapolis group of production and research personnel had completed their work, a letter was mailed to the clinics announcing that the company had developed a 40-mg. orange dispersible tablet, cross-scored so that it could be broken into quarters. These tablets are made in such a way that a large volume of water is required for solution of the material; it is, therefore, difficult to take by injection.

The letter announced that the tablets, methadone hydrochloride, should be treated as an Investigational New Drug (IND) and would be supplied only to qualified physicians who had obtained an IND number from the Food and Drug Administration for a methadone maintenance program. Supplies of the tablets would be shipped

directly from Indianapolis to physicians placing orders.

I think it is important to stress here that we are providing these tablets for clinical trial use only. The product is not available to physicians who do not hold IND numbers nor is it marketed through our usual trade distribution channels of wholesale distributors and retail pharmacies. The role that the company is filling, at the suggestion of the Food and Drug Administration, is that of supplying the drug as a clinical trial item.

Meanwhile, clinical trial data are being gathered from Dr. Dole's associates on patients at the Rockefeller University Hospital, the Morris J. Bernstein Institute of Beth Israel Hospital, and Harlem Hospital in New York City. This work is being accomplished in cooperation with the New York State Drug Abuse Program. Data are also being provided by Dr. Jerome Jaffe from patients at the University of Chicago Hospital, in this case in collaboration with the Illinois State Drug Abuse Program.

Over 6,000 hours have been spent so far in planning and in the actual processing of information that will be required in order to submit a New Drug Application (NDA) on the use of methadone in the maintenance treatment of heroin addiction. We have received and are analyzing 2,285 case reports.

During the early phases of this work it was necessary to develop an acceptable approach for showing the efficacy and safety of methadone for its new use. Such a proposal was presented to the FDA in June, and we obtained conditional approval of our plan. The proposed NDA will contain sections on general population information, patient profiles, effectiveness relative to dose, and to absence of abused drugs in the urine. Information on laboratory studies of safety and safety relative to adverse reactions will also be included. This proposal will summarize the clinical data using 225 tables and charts.

The preparation of an NDA for the review of the Food and Drug Administration is complex, time-consuming, and often involves a workload which is much heavier and more demanding than is generally realized. For this NDA alone, we are using seven code clerks, one medical information administrator, one data processing programer, and a secretary on a full-time basis. Three physicians, three secretaries, and five other staff members are spending part of their time on the preparation of these statistics.

As new methadone maintenance clinics are created and as interest grows in this type of therapy, we anticipate a need for a centralized pool of authoritative information. To meet this need, we have created a methadone bibliography of 440 articles, which have been carefully reviewed by our medical staff in Indianapolis. This bibliography is available to any interested person.

In conclusion, may I make one additional point. Although we have been a supplier of methadone for a number of years, the company does not have nor does it seek in any way an exclusive right to produce or market the product. Insofar as we are aware, there is no patent protection on methadone. Any manufacturer who is able to comply with Federal laws and regulations governing the manufacture and distribution of narcotic drugs is free to make and sell a product comparable to our tablet methadone hydrochloride.

We have undertaken the tasks that I have outlined because we feel a deep social concern about the problem of heroin addiction facing an estimated 50,000 to 200,000 individuals in our country. Our responsibility is to provide an adequate supply of clinical trial material. In addition, we intend to file a New Drug Application in 1971 so that methadone can be prescribed for the maintenance treatment of heroin addicts in accordance with appropriate procedures.

Thank you for this opportunity to be with you today.

SOME ENDOCRINOLOGICAL ASPECTS OF HEROIN ADDICTION AND METHADONE MAINTENANCE THERAPY

Paul Cushman, Jr., M.D.

The endocrinological implications of the widespread use of heroin and the increasing number of patients receiving methadone maintenance therapy warrant detailed study.

Human hypothalamic-pituitary-adrenal (HPA) function in addiction have not been adequately studied. There are abundant animal data implicating a significant effect of morphine to alter ACTH, adrenal and/or corticotropin releasing factor (CRF) secretion under various conditions (*1–3*). In man, there are also some data (*4,5*) suggesting that HPA function may not be normal during morphine administration to the herion addict. Although a different compound, methadone, in protracted high doses, has not been adequately evaluation for any potential disruptive effect on HPA function.

Furthermore, it is well known but poorly documented that heroin addicts complain of disturbed sexual function and appetite (*6*). It is not known whether their impotence, lack of libido, and delay in ejaculation times are due to heroin itself. Nor is it known whether their sexual problems are mediated through some endocrinological disturbance; or where, in the hypothalamic-pituitary-gonadal system, this defect might be.

The present study aims to provide some information regarding human HPA function in heroin addicts and methadone-maintained patients. Similarly, data on sex hormone and gonadotropins are being correlated with sexual functions.

METHODS AND MATERIALS

I. Inpatients

Male volunteer heroin addicted patients, in their fourth to fifth week of inpatient induction onto methadone, were studied under routine ward conditions in the Morris J. Bernstein Institute. While the usual routine of sleep, feeding, and wakefulness was followed, serial 24-hour urines were collected for 5 days. On Day 3, 750 mg. of oral metyrapone was administered for 6 q 4-hour doses. On the last day, 40 units of ACTH gel was administered q 12 hours. Cortisol levels (17–OH corticosteroid) were determined in plasma samples drawn at 8–9 a.m. and 4 p.m. on Day 2. The urinary concentrations of creatinine, 17 ketosteroids (KS) and ketogenic steroids (KGS) were quantified by standard techniques. All patients had normal physical examinations, were free of evident liver diseases by history and routine testing, including BSP.

II. Outpatients

Patient populations were: (1) normals, males 20–53, who were usually hospital employees and university graduate students; (2) former heroin addicts in good standing in a therapeutic community (Exodus House), male 21–44 years, believed to be free of heroin for at least 1 year by history, and serial urine determinations for the presence or absence or morphine; (3) heroin addicts, male, 20–53 years, who volunteered for a brief paid study; (4) methadone maintenance patients (20 males) 21–42 years of age, who were selected because they had been on maintenance for at least 12 months and agreed to undergo a short, paid study. All patients had normal physical examinations and liver function tests.

III. Patient tests

Insulin hypoglycemia was accomplished by the injection of 0.1–0.2 units of regular insulin intravenously into the fasting subjects. Plasmas before and 15, 30, 60, 120 minutes after insulin were examined for glucose and cortisol concentrations. Testosterone and luteinizing hormone level content in the fasting plasmas were measured by radioimmunoassay.

RESULTS

In table 1 are presented the clinical features and results in the hard-core, chronic heroin addicts maintained on methadone. Their urinary 17–KS and KGS excretions were normal. The rise in 17 KGS with metyrapone was normal in 14/15 subjects, using the criteria of an increase of at least 10 mg., or 40 percent, over the baseline. The capac-

Table 1.—PITUITARY-ADRENAL FUNCTION IN METHADONE-TREATED HEROIN ADDICTS

Name	Sex	Age	Years of addiction	Methadone		24-hour urine	24-hour urinary 17 KGS (mg.)			Plasma 17–OH CS g/100 ml.		
				Weeks	Dose (mg.)	17–KS (mg.)	Control	Metyrapone	ACTH	8 a.m.	4 p.m.	D.V.[1]
1. H.C.	M	23	0	4	50	12, 14	12, 14	43	60	11.6	11.9	No
2. J.M.	M	40	23	4	60	21, 16	17, 11	55	68	15.6	3.7	Yes
3. L.M.	M	24	9	4	80	5, 6	4, 5	24	17	20.6	17.8	No
4. R.S.	M	28	10	3	60	13, 13	10, 11	27	41	9.7	16.2	No
5. A.R.	M	40	8	4	80	20, 17	9, 11	45	42	15.9	8.5	Yes
6. F.H.	M	34	15	5	80	17, 18	9, 13	41	37	16.5	25.8	No
7. M.B.	M	39	19	5	80	12, 13	9. 2, 10	42	40	6.5	19.2	No
8. G.A.	M	27	10	4	60	8, 13	4. 7, 5	31	28	14.4	23.7	No
9. R.C.	M	28	7	5	110	15, 22	12, 14	39	62	26.4	13.5	Yes
10. G.R.	M	35	18	4	90	11, 10	6. 6, 4	28	17	9.2	3.4	Yes
11. R.K.	M	24	8	4	90	19	10	21	34	20.8	6.5	Yes
12. E.R.	M	34	7	4	50					18.4	15.8	No
13. A.W.	M	44	12	5	100	14, 16	11, 12	46	46	11.0	12.5	No
14. F.D.	M	23	8	4	60	14, 14	6, 9	28	27	5.0	9.7	No
15. N.B.	M	24	6	5	120	15, 10	9. 7, 6	23	15	16.0	7.7	Yes
16. L.J.	M	22	8	24	100	12, 10	12, 10	16	36	26.7	17.1	?
Normal						9–22	5–23		2–4x control	5–25		

[1] Diurnal variation.

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ity of the adrenal to respond to exogenous ACTH was established by the observed increases in 17 KGS in all subjects.

Plasma cortisol levels were normal in all patients at 8–9 a.m. However, at 4 p.m. only 6/16 showed a normal reduction in cortisol in relation to the 9 a.m. value. Another 6/16 had an actual reversal of the expected diurnal variation.

The clinical and narcotic history of the methadone maintenance patients undergoing I.V. insulin tolerance tests is listed in table 2. Their glucose and cortisol responses to insulin indicate that adequate hypoglycemia produced a normal rise in cortisol in 9/10. The heroin addicted patients, table 3, also had normal resting plasma cortisol concentrations, 7/9 responded to hypoglycemia with normal increases in cortisol. (Patients No. 4 and No. 7 did not appear to have been given an adequate hypoglycemia stimulus for rigorous evaluation of their HPA axis response.)

Table 2.—INSULIN HYPOGLCEMIA IN METHADONE-TREATED NARCOTIC ADDICTS (GROUP II)

Patient	Age	Addiction, years	Number of bags/day	Wt., lb.	Insulin, u/Kg.	Methadone, months	Glucose mg./100 ml FBS	30	FBS/30 (percent)	Plasma 17 OH CS µg/100 ml 0	60	120	Maximal increase
1. T.A.	30	6	10	150	0.10	9	94	27	29	10	12	31	21
2. P.B.	24	3	6	140	.15	4	89	40	45	15	15	25	10
3. S.D.	47	12	8	199	.10	24	109	46	42	16	------	16	−1
4. E.J.	45	25	30	145	.15	1½	84	43	51	18	5	34	16
5. L.M.	35	17	8	140	.15	25	89	31	34	1.2	------	26	25
6. R.E.	38	7	8	161	.10	1	158	42	27	9	32	20	23
7. S.D.	36	7	8	160	.10	10	76	31	41	9	16	30	21
8. L.J.	23	8	5	142	.10	12	104	24	23	4	15	18	14
9. A.D.	28	13	5	200	.10	14	105	46	44	------	26	19	------
10. F.D.	23	8	5	120	.10	14	105	45	43	25	31	23	6
	N=7				.10	Mean	37.3		35	11.9	20	25.5	15.9
						Standard deviation	9.6		------	6.8	10	7.3	7.9
	N=4				.15	Mean	20.1		37	------	------	------	------
						Standard deviation	18		------	------	------	------	------
NORMALS (8 males, 21–58 years)					.1	Mean	91	39.2	42.6	14.3	23	24	14.4
						Standard deviation.	6.2	2.9	6.3	4.8	7.2	6.2	------
						Range			34–49	------	------	------	8.9–27.6

Table 3.—INSULIN HYPOGLYCEMIA IN HEROIN ADDICTS

Patient	Age	Addiction, years	Number of bags/day	Insulin, u/Kg.	Glucose mg./100/ml FBS	30	60	30/FBS (percent)	Plasma 17 OHCS 0′	60	120	Maximal increase
1. T.A.K.	53	35	6	0.10	110	42	89	38	20.2	18	29.1	8.9
2. E.M.	35	15	8	.15	84	27	59	32	2.7	22.5	11	19.8
3. A.Q.	50	2	6	.15	114	45	64	39	30.2	45	19	15.0
4. A.V.	23	10	12	.15	115	58	73	50	22	26.7	10	4.7
5. R.Q.	52	33	11	.15	100	47	75	47	8.6	33.4	25	24.8
6. C.I.	31	14	20	.15	95	33	33	34	14	26	34.2	20.1
7. R.G.	32	15	6	.15	89	50	75	56	11	7.3	15.4	4.4
8. A.C.	51	22	5	.15	98	29	29	30	18.6	26	20	7.0
9. W.C.	41	22	3	.15	98	29	45	29	11	20	24.2	13.2
Mean						43.7		42.6	14.5	23.1	20.0	13.1
Standard deviation						10.5		8.9	------	------	------	8.0
Range								30–56	------	------	------	4.4–24.8

The sexual appetites, potency, and approximate time to accomplish ejaculation for the group of normal males are listed in table 4. Only one subject stated that he had difficulty in sexual activities. Their plasma LH levels ranged from 7–17, with a mean of 11.5 mIu/ml. The 13 patients with heroin addiction were somewhat older and from the chronic hard-core criminal, addict population.

They described more problems with libido, potency and, most frequently, a prolongation of time to accomplish an ejaculation. It is uncertain what reliance to place on the self-confessed histories of sexual difficulties in these patients in view of the well-known unreliability of heroin-addicted patients. It does seem reasonable to conclude that sexual disturbances are common in chronic heroin addiction; however, their plasma LH levels ranged from 8–19 mIu/ml with a mean that was similar to the normals.

The patients in the abstinent program also described notable difficulties in sexual performance and appetite during the time of heroin abuse. Only

Table 4.—SEXUAL APPETITE AND FUNCTION IN NORMAL MALES, HEROIN ADDICTS, AND EX-ADDICTS ON ABSTINENCE PROGRAM

	Age	Addiction, years	Plasma LH (mIu/ml)		Sexual function: Libido	Potency	Ejaculation time (minutes)
I. Normals:							
N=10	20–52	------	7–17	N	10	9	4–25
Mean	26	------	11.5	↓	0	1	
Standard deviation	±3	------	±3.5	0	0	0	
II. Heroin addicts:							
N=13	19–53	3–35	8–19	N	5	8	3
Mean	29	10.1	12.4	↓	8	5	7
Standard deviation	±14	±6.3	±3.3	0	0	0	0
III. Abstinence group:							
N=13	20–47	1–10					
Mean	31	3.5					
Standard deviation	±8	±2.6					
A. At present (>1 year drug free)			7–22	N	13	13	4–25
			11.9	↓	0	0	
			±1.3	0	0	0	
B. During heroin use				N	3	6	3
				↓	8	4	6
				0	2	3	2
C. When "high" on heroin				N	1	6	3
				↓	5	4	7
				0	7	3	3
D. After 3 weeks of detoxification				N	13	13	13
				↓	0	0	0
				0	0	0	0

N=Normal. ↓=Reduced. 0=Absent.

7.7 percent claimed normal libido when high, and only 23.1 percent claimed normal libido during the rest of the time. All 13 patients claimed their sexual problems disappeared during detoxification, whether in hospitals, detention, jails, etc. These retrospective histories have the disadvantage of reliance on recall some months after the time in question. However, they have the advantages of being requested several months after return to a new baseline of normal libido. Secondly, the abstinent program includes many group therapeutic sessions in which the patients' sexual adjustments are extensively discussed and, therefore, may make it easier for the patient to recognize his present and/or past sexual problems. All patients had measureable LH in the normal range.

Table 5.—SEXUAL FUNCTION AND PLASMA LH LEVELS IN METHADONE MAINTAINED MALE ADDICTS

Patient	Age	Methadone: Months	Dosage, mg./day	Potency	Libido	Ejaculation time	LH	Testosterone	During heroin use: Years	Cost/day	Libido	Potency	Ejaculation time	Detoxified
1	32	62	80	N	N	7–12	14	400	8	$35	↓	↓	>30	Yes
2	34	10	100	N	N	7–20	20	431	8	25	↓	↓	>30	Yes
		12	100	↓	N	∞	17	593						
		13	100	N	N	15	20	550						
3	30	24	100	N	N	7–10	18	570	6	25	↓	↓	N	Yes
4	41	36	50	N	N	7–12	15	------	7	35	↓	↓	>30	Yes
5	34	12	100	N	N	7–12	17	675	24	30	↓N	↓N	>30	Yes
6	24	36	110	N	N	7–15	16	495	3	30	↓N	↓N	>15	?
7	32	36	110	N	N	5–10	8	------	7	25	↓	↓	>30	?
8	28	24	80	N	N	7–10	15	905	10	20	↓	↓	>45	Yes
9	39	48	100	N	N	7–12	7	------	20	25	↓	↓	?	Yes
10	32	48	120	N	N	>30	12	------	7	35	N	N↓	>30	Yes
11	28	15	100	↓	↓	∞	16	------	14	40	↓	↓	∞	No
12	27	24	100	↓	N	>30	8	------	13	20	↓	↓N	20	------
13	34	15	100	N	↓	?	14	------	15	20	N	N	N	------
14	42	15	120	N	N	N	14	1,000	20	0	N	N	N	------
15	37	48	100	N	N	N	14	------	4	30	N↓	N	N	Yes
16	30	20	100	N	N	11	10	------	12	40	↓	↓	65	Yes
17	44	48	100	N	N	N	23	------	20	60	N	N	45	Yes
18	52	48	110	N	↓	30	17	274	17	0	N	N	N	------
19	25	36	100	↓	N	15	28	------	5	50	N	N	N	------
20	34	15	100	N	N	N	12	------	30	40	N	N	N	------

N=Normal. ↓=Reduced.

The methadone-maintained patients (table 5) were also from the hard core criminal-addicted population. At the time of study, they had been in treatment with methadone of 50–120 mg./day for 30.1 months with a range of 12–48. Many described their sexual activities during their heroin years to have been abnormal; i.e., decreased libido, prolonged time to ejaculate, and impotence. In confirmation of the data in the abstinent group, 11/12 replied that their sexual problems disap-

peared during detoxification, as listed in the last column of table 5. Their LH levels in all instances were measurable and within the range of normal. The presence or absence of present or past sexual problems was not accompanied by any detectable difference in LH levels. Furthermore, plasma testosterone measurements in 10 patients were within the range of normal in nine. One patient had serial LH and testosterone determinations before, during, and after a transient bout of impotence, coming on after a sickle cell crisis. There were no differences observed in either hormone level.

DISCUSSION

The data confirm the clinical impression of normal adrenal cortical function in the methadone-treated heroin addict, since their resting plasma and urinary steroids which usually reflect adrenal glucocorticoid status were normal.

In the methadone-treated addict, examination of the feedback mechanisms regulating HPA activity by means of metyrapone showed no impairment. The stress mechanisms governing HPA axis were normal in 8/9 subjects since appreciable increases in plasma 17-OH-corticosteroids followed insulin hypoglycemia. Since there is evidence that patients with occult HPA deficiency who are difficult to detect by routine plasma or urinary studies can be identified by testing their steroid responses to insulin hypoglycemia, these findings suggest that methadone-treated heroin addicts may not be potential hypopituitary subjects.

The data obtained in the heroin addicts support the conclusion that the stress mechanisms regulated in HPA activity are operative. Therefore, these studies do not demonstrate in man a significant heroin or methadone propensity to block hypothalamic function or either the feedback or stress mechanisms regulating HPA activity. In confirmation of the clinical impression, these patients would not appear to be particularly susceptible to overt or occult pituitary-adrenal insufficiency.

On the other hand, the studies of the diurnal variation of plasma corticosteroids in the methadone-treated addicts yielded different results. A normal or near-normal value (i.e., reduction of the 4 p.m. value to 50 percent or less of the corresponding 8–9 a.m. value) was demonstrable in only 6/16. It is recognized that these data consist of only two single points on a curve spaced some 7 to 8 hours apart rather than the full series of 4-hourly determinations, and therefore they may not be an accurate, full description of the diurnal variation of HPA activity. Nevertheless, the finding of six subjects with an actual reversal of the normal pattern, with higher values at 4 p.m. than at 8–9 a.m., suggests that a change in the circadian periodicity was present in some of these subjects.

The mechanism of this change was not established. It is possible that methadone or heroin may interfere with the normal nycthemeral periodicity, leading to a flattening or reversal of the usual pattern, without modifying the feedback or stress mechanisms.

Sexual problems were commonly encountered in heroin-addicted patients which usually took the form of impotence, loss of libido, and increased time for ejaculation. It appeared that these sexual problems were greatest when the addict was high and they tended to disappear during detoxification.

The patients in good standing in an abstinent program appeared to have regained full sexual function. In contrast, some patients on methadone had some sexual difficulties remaining. Most patients experienced a return to normal after induction onto methadone; 50 percent reverted within the first month and an additional 25 percent within the first year; another 10 percent within 18 months. Nevertheless, there are 10 percent with continuing sexual problems, apparently not present during heroin use. In addition, there were another 10 percent who experienced transient disturbance in sexual function during initiation of methadone treatment not present during heroin addiction.

The mechanism of these sexual difficulties is not clear. The present data exclude the possibility of failure of the pituitary gonadotropins. The hypothalamic-pituitary system regulating resting LH levels in plasma appeared normally operative whether or not the patients had past or present sexual problems. Since their physical examinations were normal, and their testosterone levels were generally normal, it is unlikely that androgen secretion had been significantly altered by heroin addiction and/or methadone substitution.

A possible contributing mechanism of the depressed sexual appetites and expression in some patients with heroin addiction may relate to the sedative action of heroin. Many patients described loss of sexual functions when high, only to improve on regaining baseline mental status. Furthermore, it is possible that the return towards normal of methadone-treated patients may be attributable to the gradual development of tolerance to the sedative effects of the methadone. During the periods of withdrawal from heroin, many patients described full sexual appetites but sexual activities were deferred until heroin was obtain and administered. The heroin hunger seemed to take precedence over the sexual appetite.

However, it is recognized that human sexual experience is multifactorial and much more extensive understanding of the kaliedoscope of human sexuality will be required before the sexual problems in heroin addiction can be unraveled.

CONCLUSIONS

1. Adrenal cortical function appears normal in heroin-addicted and methadone-treated patients.
2. Hypothalamic-pituitary function regulating ACTH-adrenal activity was normal in methadone-treated patients, except for a possible impairment of circadian periodicity.
3. Sexual disturbances are common in heroin-addicted patients. They are greatly reduced in methadone-maintenance treatment and appear to be lost at various rates. Abstinence programs and detoxification appear to be associated with a very rapid rate of return of full sexual function.
4. Measurement of LH levels in plasma of heroin addicts, methadone-maintained patients, and patients in abstinence were within the normal range. A few measurements of plasma testosterone in methadone-maintained patients were within the range of normal. It is unlikely that heroin or methadone significantly affect LH or testosterone. The mechanism by which these sexual disturbances appear is not understood.

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