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Report to the Chairman, Select Committee on Narcotics Abuse and Control, House of Representatives

March 1990

METHADONE MAINTENANCE

Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed

GAO/HRD-90-104

GAO

United States
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Human Resources Division

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The Honorable Charles B. Rangel
Chairman, Select Committee
on Narcotics Abuse and Control
House of Representatives

Dear Mr. Chairman:

In response to your request, we reviewed the activities of a number of methadone maintenance treatment programs. This report focuses on the (1) extent of drug use by patients in methadone maintenance treatment programs; (2) the goals, objectives, and approaches of the treatment programs; and (3) the types of services available to patients in treatment. It also presents information on federal oversight of the effectiveness of treatment programs and the status of proposed regulations to allow methadone to be dispensed without counseling or other supportive services that are required under current federal methadone maintenance treatment regulations.

Copies of this report are also being sent to the Secretary of Health and Human Services; Commissioner, Food and Drug Administration; Director, National Institute on Drug Abuse; Director, Office of Management and Budget; and other interested parties.

The major contributors to this report are listed in appendix II.

Sincerely yours,

Mark V. Nadel

Mark V. Nadel
Associate Director, National
and Public Health Issues

Results in Brief

Research indicates methadone maintenance can be an effective treatment for heroin addiction. In practice, however, the continued use of heroin that GAO found among patients in 24 methadone maintenance treatment programs indicates that many programs are not effectively treating heroin addiction. The use of heroin by patients in treatment for more than 6 months ranged from 1 percent at one program to 47 percent two others. (See pp. 17-20.)

GAO found that policies, goals, and practices varied greatly among the 24 methadone maintenance treatment programs. None of the 24 programs evaluated the effectiveness of their treatment. There are no federal treatment effectiveness standards for treatment programs. Instead, federal regulations are process oriented in that they establish administrative requirements for programs. Even with regard to these requirements, federal oversight of methadone maintenance treatment programs has been very limited since 1982. (See pp. 27-28.)

Recent federally sponsored research found that interim maintenance would not significantly reduce intravenous (IV) heroin use and the corresponding risk of acquired immunodeficiency syndrome (AIDS). GAO also did not find clear evidence of an overall serious shortage of methadone treatment slots that would justify interim maintenance.

Principal Findings

Program Treatment Goals, Policies, and Results Differed

Heroin use continued among a number of patients, with significant differences among the 24 methadone maintenance treatment programs we visited. At 10 of the 24 clinics more than 20 percent of the patients continued to use heroin after 6 months of treatment—a higher percentage than experts believe should occur among patients in treatment. At two programs, almost one-half the patients continued to use heroin. GAO found that many of the patients also used other drugs, primarily cocaine. (See pp. 17-20.)

GAO found that programs established their own goals, policies, and practices, which varied greatly. Program goals varied from treating only heroin addiction to treating abuses of all drugs with the goal of freeing the patient of all drug use, including methadone. A wide variance also existed among program policies with respect to urine testing, dismissing patients, counselor staffing levels, and methadone dosage levels. Urine

would not significantly reduce heroin use.[1] The VA researchers stated that:

"methadone by itself does not guarantee clinical improvements or reduced AIDS risk."

The report concluded that merely increasing the availability of methadone in the absence of administrative, counseling, and rehabilitative services may not adequately protect the majority of patients from continued drug use and the risk of AIDS. Given this research and the lack of evidence of an overall shortage of methadone treatment slots, GAO does not believe that interim maintenance will achieve its stated purpose. (See pp. 30-33.)

Recommendations to the Secretary of Health and Human Services

To better monitor and assess methadone maintenance treatment programs, GAO recommends that the Secretary of Health and Human Services direct FDA or NIDA, as appropriate, to (1) develop result-oriented performance standards for methadone maintenance treatment programs, (2) provide guidance to treatment programs regarding the type of data that must be collected to permit assessment of the programs' performance, and (3) increase program oversight oriented toward performance standards.

GAO also recommends that the Secretary withdraw the proposed interim maintenance regulations until such time as (1) documented evidence demonstrates that demand greatly exceeds treatment capacity for methadone maintenance treatment programs and (2) research demonstrates that interim maintenance is significantly better than no treatment at all in preventing IV drug use and the corresponding risk of AIDS. (See p. 34.)

Agency Comments

GAO did not obtain official agency comments on this report. However, GAO did obtain the views of FDA and NIDA officials and incorporated their views where appropriate.

[1]Childress, Anna Rose, A. Thomas McLellan, George E. Woody, and Charles P. O'Brien, "Are There Minimum Conditions Necessary for Methadone Maintenance to Reduce Intravenous Drug Use and AIDS-Risk Behaviors?"

Abbreviations

ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
AIDS	acquired immunodeficiency syndrome
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
GAO	General Accounting Office
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
IV	intravenous
LAAM	levo-alpha-acetylemthadol
mg	milligrams
NIAAA	National Institute on Alcoholism and Alcohol Abuse
NIDA	National Institute on Drug Abuse
VA	Department of Veterans Affairs

An ongoing philosophical debate has surrounded the use of methadone maintenance since its development as a treatment method. Some treatment practitioners believe drug-free treatment is the only valid treatment method. They discount the efficacy of methadone maintenance on the grounds that it merely substitutes one narcotic drug for another. In contrast, other treatment practitioners view methadone as a medication for treating heroin addiction, and some compare it to taking insulin for diabetes.

Research studies have demonstrated the effectiveness of methadone maintenance. NIDA and the National Institute on Alcoholism and Alcohol Abuse and Alcoholism (NIAAA), the federal government's two primary agencies for researching drug and alcohol abuse issues, respectively, have concluded that methadone is the most effective method available for treating heroin addiction.

Program Effectiveness Linked to Counseling and Rehabilitative Services

Methadone maintenance programs are more effective when linked with comprehensive treatment services, according to a major NIDA-sponsored study.[2] This in-depth 3-year study of six methadone maintenance treatment programs noted that effective programs reduced intravenous (IV) drug use and needle sharing among most heroin addicts; thus reducing the risk of contracting or spreading the human immunodeficiency virus (HIV) that causes acquired immunodeficiency syndrome (AIDS) through needle use. However, the study found marked differences in the effectiveness of various programs in reducing IV drug use.

Among the six programs, IV drug use varied from less than 10 percent to over 57 percent of patients that were in treatment longer than 1 year. The difference in the programs' effectiveness to reduce IV drug use was related both to the length of the patient's stay in treatment as well as the quality of the treatment provided. The more effective programs had high patient retention rates; adequate methadone doses; high rates of scheduled attendance; a close, consistent, and enduring relationship between staff and patients; and year-to-year stability of treatment staff. The research study concluded that:

"Although both the short-term pharmacological and the long-term rehabilitative aspects of methadone maintenance are significant in successful treatment, the latter seem more important with respect to reducing IV use."

[2]Ball, John C., W. Robert Lange, C. Patrick Myers, and Samuel R. Friedman, "Reducing the Risk of AIDS Through Methadone Maintenance Treatment." Journal of Health and Social Behavior 1988, Vol. 29 (Sept.), 1988, pp. 214-26.

Objectives, Scope, and Methodology

The Chairman of the House Select Committee on Narcotics Abuse and Control, requested that we assess the effectiveness of methadone maintenance treatment. In subsequent discussions with the committee staff, we agreed to visit a limited number of methadone maintenance treatment programs to determine (1) the extent of drug use by patients in such programs; (2) the goals, objectives, and approaches of the treatment programs; and (3) the types of services available to patients during and after methadone maintenance treatment. We also agreed to obtain information on current federal efforts with regard to (1) developing alternative nonaddictive drug therapies to methadone,[3] (2) oversight and monitoring of program effectiveness, and (3) the status of efforts to alter federal methadone regulations to allow the dispensing of methadone without rehabilitative services.

We used a case-study approach to gather information concerning 24 methadone maintenance treatment programs in eight states. We selected states that had large numbers of IV drug users, methadone maintenance treatment programs receiving public funds, and that provided geographic variability. Seven of the states are among the top 10 states in the country that have the largest IV drug-using populations and one state is ranked twelfth. The eight states we selected are California, Florida, Illinois, Maryland, New Jersey, New York, Texas, and Washington.

We selected the 24 programs using criteria based on program size (greater than 200 patients in treatment where possible) and years of operation (those operating for at least 5 years). We collected data on all active patients in methadone maintenance treatment at 21 of the 24 programs we visited. Because of large patient populations at three programs, we collected data on a random sample of active patients.[4] In total, we collected data on 5,600 active patients at the 24 programs. The patient data included the length of time in treatment, methadone dosage in milligrams, most recent urinalysis test results, age, race, sex, employment status, method of payment, and the number of days patients missed their appointments at the clinics to take their prescribed methadone within a 30-day period immediately preceding our visit at each program.

We interviewed treatment officials at the 24 programs. We obtained information from them regarding each program's operations, including

[3]This information is presented in appendix I.

[4]Active patients include those in treatment for more than 30 days. They do not include patients who were hospitalized, incarcerated, or in the process of being removed from treatment.

Methadone Maintenance Treatment Programs Vary in Approach and Effectiveness

Research indicates that a well-managed methadone maintenance program can be an effective treatment method for heroin addiction. But, judging from the continued use of heroin among patients, in practice, nearly one-half the programs we visited are not effective in treating heroin addiction.

There were significant differences in heroin use among the 24 methadone maintenance treatment programs we visited. At 10 of the 24 clinics, more than 20 percent of the patients continued to use heroin after 6 months of treatment—a higher percentage than experts believe should occur among patients in treatment. At two clinics almost one-half the patients continued to use heroin. We also found that many of the patients used other drugs, primarily cocaine.

The 24 methadone maintenance treatment programs we visited established their own treatment policies, goals, and practices, which varied greatly among the programs. A wide variance also existed among programs with respect to staffing levels, the extent of rehabilitative services provided to patients, and the availability of aftercare.

There are no federal performance standards for methadone maintenance treatment programs (see ch. 3). Further, none of the methadone maintenance treatment programs we visited evaluated the effectiveness of their treatment. Given the wide variation of approaches and results, there is a need for greater federal leadership in assessing methadone treatment and determining components of effective treatment.

Treatment Goals and Policies Differed Among Programs

Research indicates that treatment goals influence program objectives. The programs we visited developed their own treatment goals, which varied widely.

- Five programs sought to treat only heroin addiction, and did not treat patients for abuse of other drugs. Directors of some of these programs told us that methadone maintenance treatment is only intended to treat heroin addiction.
- Eleven programs sought to treat all drug abuse. Although methadone treatment is only effective for treating heroin and other opiates, these programs used other treatment approaches to address the abuse of other drugs. Some program directors told us that it was appropriate to provide methadone treatment indefinitely unless the patient requested treatment be terminated. One clinic director said that a totally drug free

Table 2.1: Methadone Dose Among Patients at the 24 Methadone Maintenance Treatment Programs

Figures are milligrams

Program	Mean	Median	Mode
California			
A	47	50	50
E	52	50	80
I	50	50	80
J	51	55	70
K	64	66	80
L	68	70	80
M	51	55	70
New York			
N	51	50	50
O	58	60	60
P	58	60	70
Q	56	55	50
Z	55	60	60
Florida			
D	49	50	60
H	33	30	25
Illinois			
R	21	20	30
S	27	30	30
Texas			
C	36	35	40
G	31	30	25
Maryland			
V	36	40	40
W	67	70	80
New Jersey			
T	50	50	50
U	56	55	50
Washington			
B	38	40	50
F	49	50	60

program rules vary, different programs have different take-home policies. Most of the programs we visited would reduce or revoke take-home privileges if a patient used heroin or other drugs. Two programs would discharge any patient that was given take-home methadone if urinalysis tests showed that the patient was not taking the methadone. One program that did not treat cocaine or other nonopiate drug use, did not reduce or eliminate take-home privileges for patients that tested positive for those drugs.

Cost and Payment

Funding for methadone programs varies by state and local government. Public and nonprofit programs may receive funds from Medicaid, block grants, and other assistance. The monthly income received from all sources by the programs we visited ranged from $145 to $533 per patient. The out-of-pocket costs to the patients for treatment ranged from no charge to $280 per month. In most cases, costs to patients depended in part on their ability to pay.

Substantial Variation Found in Program Results and Services

Just as program goals varied, we found great variation in patient results, the kinds and amounts of services provided, program staffing levels, and aftercare. None of the programs systematically evaluated their effectiveness in treating patients.

Many Patients Continue to Use Heroin and Other Drugs

We found that many patients in treatment for more than 6 months—ranging from 13 to 67 percent—continued to use heroin and other drugs. At 10 of the 24 programs we reviewed heroin use among these patients exceeded 20 percent, ranging from 21 to 47 percent. For the remaining 14 programs, heroin use among patients was less than 20 percent and ranged from 1 to 13 percent. Drug treatment experts consider a program to be ineffective if heroin is still being used by more than 20 percent of the patients in treatment longer than 6 months. The Deputy Director for Demand Reduction, Office of National Drug Control Policy, also believes that after patients have been in treatment 6 months, an effective program should not have more than 20 percent, and possibly as few as 10 percent, of patients who receive appropriate doses of methadone and rehabilitative services using heroin.

Table 2.2: Percentage of Heroin, Cocaine, and Overall Drug Use Among Patients in Methadone Maintenance Treatment for 6 Months or Longer

Program	Drug Use		
	Heroin	Cocaine	Overall[a]
California			
A	47	0	47
E	24	5	29
I	21	3	25
J	32	7	35
K	30	5	38
L	22	3	24
M	28	1	33
New York			
N	5	15	21
O	4	13	15
P	5	40	42
Q	2	8	20
Z	4	21	29
Florida			
D	6	6	22
H	12	27	45
Illinois			
R	47	30	67
S	4	30	65
Texas			
C	32	15	49
G	5	28	32
Maryland			
V	22	23	37
W	1	1	2
New Jersey			
T	9	23	27
U	5	15	26
Washington			
B	13	11	20
F	11	10	19

[a]Overall drug use includes heroin and other opiates, cocaine, benzodiazepines, amphetamines, and barbiturates.

Although none of the 24 programs performed urinalysis tests for alcohol use, some program directors stated that they administered a breathalyzer test to patients suspected of being intoxicated before they would administer a daily dose of methadone. Most program directors believed that alcohol abuse remains a serious problem for many patients

Table 2.3: Percentage of Patients That Missed a Daily Dose of Methadone in a 30-day Period

Program	Percent of patients that missed a dose
California	
A	27
E	16
I	16
J	29
K	19
L	16
M	23
New York	
N	51
O	11
P	25
Q	9
Z	23
Florida	
D	6
H	30
Illinois	
R	49
S	46
Texas	
C	24
G	33
Maryland	
V	43
W	4
New Jersey	
T	41
U	16
Washington	
B	14
F	8

Research studies indicate that patient improvement—as measured by decreased heroin and other drug use, decreased criminal activity, and increased social productivity—is directly correlated to the length of time in treatment. While a necessary duration of methadone treatment has not been established, one research study demonstrated that patients who were in treatment less than 3 months did not differ significantly in drug use from addicts who received no treatment.

Table 2.4: Retention of Patients at 21 Methadone Maintenance Treatment Programs

Program	Percentage of patients remaining in treatment after 3 months	after 6 months
California		
A	81	67
E	84	66
I	89	76
J	77	72
K	78	56
L	83	58
M	70	47
New York		
N	73	59
P	91	83
Q	90	80
Z	79	62
Florida		
D	69	53
H	54	43
Illinois		
R	78	62
S	90	66
Texas		
C	86	61
G	81	56
Maryland		
V	86	69
W	84	63
New Jersey		
T	45	42
Washington		
B	68	51

Programs Are Lax in Providing Vocational and Educational Services

Vocational and educational services, which are required by federal regulation, are intended to assist patients in treatment programs to develop skills needed to function as productive members of society. They also help to refocus a patient's attention away from drug use and more towards productive activities.

Only 6 of the 24 programs offered educational services on site and only 4 programs provided vocational services on site. For the programs that

treatment. Since March 1989, the formerly mandated counselor/patient ratio has been restated as a recommended practice.

All 24 programs provided counseling. However, at many of the programs the ratio of counselors to patients was higher than clinic counselors and directors believed it should be in order to provide effective counseling. For the 24 programs, the ratio of counselors to patients ranged from 1 counselor for every 15 patients to 1 for every 96 patients. At 17 of the 24 programs counselor caseloads exceeded 35, and at 7 programs counselor caseloads were 50 or more. In many programs, counselors spent no more than half an hour twice a month per patient. Table 2.5 identifies counselor/patient ratios and the average number of counseling sessions per month at the 24 programs.

meaningful counseling sessions, greater interaction between counselor and patient, and increased rates of patient retention.

Programs Did Not Provide Aftercare for Patients Detoxified From Methadone

An aftercare program should provide patients who detoxified from methadone with counseling, recovery training, self-help meetings, and recreational and social activities to assist in the recovery processes. Only 1 of the 24 programs we visited had a separate aftercare program. Of the remaining 23 programs, 9 would allow patients to continue to receive counseling even though they no longer were being maintained on methadone. However, only a few patients chose to use the counseling services from these programs. The remaining 14 programs did not allow patients who detoxified from methadone to receive further services from the program. Further, one official stated that they do not receive public funding for a patient that no longer takes the drug methadone but remains in treatment for counseling.

Treatment Programs Are Not Assessing Their Effectiveness

None of the 24 methadone maintenance treatment programs we visited systematically evaluated their effectiveness in treating patients. Data related to urinalysis tests, patient attendance, or patient retention were not maintained at the program level except for three treatment programs. These three programs did summarize patient data, but did not use the aggregate data to assess patient progress or program effectiveness.

FDA Inspections Have Been Infrequent and Do Not Assess Program Performance

FDA's policy is to routinely inspect each methadone program once every 2 years to determine whether programs are complying with federal methadone regulations. However, FDA's inspections of methadone treatment programs have been less frequent. At the time of our visits, the 24 programs we reviewed had not been inspected for over 5 years.

FDA officials told us that they had conducted biennial compliance inspections of methadone treatment programs before 1982. At that time, the field resources for inspecting methadone treatment programs were reduced because these inspections were considered a lower priority compared with other FDA responsibilities. With field resources reduced, the number of inspections declined. FDA inspected only 24 of the nation's 668 methadone maintenance treatment programs in fiscal year 1988.

FDA's Associate Commissioner for Health Affairs told us that in May 1989, FDA established a new policy calling for increased methadone treatment program compliance inspections. Inspections have become a priority for FDA because of concerns of the FDA Commissioner and other senior government officials involved in drug abuse issues that some programs may not be operating in accordance with federal regulations.

Additional resources under the Anti-Drug Abuse Act of 1988 provided funding that, according to FDA, was used to acquire 21 additional inspectors to assist in the inspection of methadone maintenance treatment programs. FDA again intends to inspect all such programs over the next 2 years.

However, the inspections carried out by FDA do not assess or evaluate the effectiveness of the methadone maintenance treatment programs, but, rather, are to insure that treatment programs are adhering to current regulatory requirements.

FDA Finds Programs in Violation of Federal Regulations

FDA officials told us that during the 5-month period, May to September 1989, FDA had planned to inspect 480 methadone treatment programs. However, the officials were unable to tell us how many inspections FDA completed in fiscal year 1989. While the total number of inspections is not known, FDA inspection records show that 62 programs failed to comply with methadone treatment regulations. Letters of adverse findings were sent to 57 of these programs. In addition, five programs received regulatory letters. According to FDA officials, an adverse finding letter is issued only when serious regulation violations exist, which, if not promptly corrected, will result in further regulatory action. This action

New York State records indicated that, as of June 1989, 900 persons were on waiting lists for methadone maintenance treatment, 885 of these were in New York City. The records further indicated that more than one-half of the persons awaiting treatment were on the waiting lists of one treatment provider. Two phone surveys conducted by a New York City methadone provider addressed the availability of methadone treatment in New York City. Of the programs that responded to the survey, performed in August 1989, over 600 methadone treatment slots were identified throughout New York City for addicts who sought treatment. The results of a November 1988 survey identified over 400 available methadone treatment slots.

While the phone surveys indicated that treatment was available, treatment slots may have been inaccessible to many addicts because of their location. However, without a mechanism for informing addicts seeking treatment of available slots in New York City as well as other locations, many addicts may continue to wait for treatment while slots remain unfilled.

Research and Treatment Officials Indicate That Interim Maintenance Is Not Effective

In March 1989, FDA and NIDA proposed revised methadone maintenance regulations to allow interim maintenance. The purpose is to get addicts who are waiting for comprehensive treatment into treatment more quickly, thereby decreasing the incidence of IV drug abuse and risk of AIDS.

The proposed regulation recognizes that comprehensive methadone maintenance treatment programs are more effective than interim maintenance treatment. Therefore, at a minimum, interim maintenance is only justified if it is significantly better than doing nothing to prevent IV heroin use. We doubt, however, that even this minimum condition would be met.

Recent research has shown that interim maintenance is, at best, only marginally better than doing nothing. A new study by the Department of Veterans Affairs (VA) and the University of Pennsylvania medical school shows that methadone, without comprehensive services (essentially similar to dispensing methadone under the proposed interim maintenance), is not effective in reducing IV drug use.[1] Moreover, NIDA's

[1]Childress, Anna Rose, Thomas A. McLellan, George E. Woody, and Charles P. O'Brien, "Are There Minimum Conditions Necessary for Methadone Maintenance to Reduce Intravenous Drug Use and AIDS-Risk Behaviors?"

Officials from substance abuse agencies in the eight states included in our review varied on whether to implement interim maintenance. Officials for only one state indicated that they would approve the use of interim maintenance as proposed. Officials in three states said that their states would not allow interim maintenance. Officials in the remaining four states indicated that they had not yet determined if they would allow interim maintenance to be provided in their states.

not require daily administration. Further, research indicates that withdrawal from buprenorphine is less difficult than from methadone. Early evidence indicates that buprenorphine may also work as an antagonist for cocaine. Although FDA has not yet approved buprenorphine for drug treatment, independent researchers have been granted permission to use it in clinical trials.

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Alternative Treatments Developed for Heroin Addiction

The National Institute on Drug Abuse (NIDA) recognizes that additional methods are needed for treating heroin addiction. Some alternative drug therapies for the treatment of heroin and other drug addictions have been approved or are under investigation. One such alternative drug therapy, naltrexone, has received Food and Drug Administration (FDA) approval for treating opiate addiction. However, its use has been limited because of the reluctance among heroin addicts to take the medication. Two other drugs are undergoing clinical trials to determine their safety and effectiveness. To date, methadone treatment remains the primary treatment method for heroin addicts.

Naltrexone, an opiate antagonist,[1] is the only FDA-approved drug alternative currently available. Yet, few heroin addicts seek this type of treatment. Naltrexone has been proven to effectively block the euphoric effects of heroin use. However, naltrexone has no agonist effect[2] and should be used only after a patient has abstained from heroin use for at least 1 week. Naltrexone is not addictive, but must be taken regularly. Patients feel no effect when they stop taking the drug, and must be highly dedicated to continue this treatment.

Levo-alpha-acetylemthadol (LAAM) treatment, a long-acting and a less addictive substitute for heroin, has received limited-use approval from FDA for drug treatment research. Unlike methadone, which must be taken daily, LAAM can be used less frequently, thus reducing the frequency of clinic visits. This quality makes LAAM an attractive alternative to methadone from a diversion-control standpoint. Intensive clinical trials to test the effectiveness of LAAM were conducted during the 1970s by NIDA, but FDA has not yet approved it for commercial use. LAAM has caused some controversy because some research indicates that LAAM may cause cancer in humans.

Buprenorphine, which FDA approved for use as a analgesic, has been found to have both opiate agonist and antagonist properties, and is being considered as another treatment for heroin abuse. Clinical trials are ongoing to determine its safety and effectiveness in treating heroin addicts. Recent studies have found that buprenorphine alleviated opiate cravings in heroin addicts (agonistic effect). Requiring lower dosages than methadone, buprenorphine remains in the system longer and does

[1]Blocks narcotic effects.

[2]Produces a narcotic effect.

Conclusions and Recommendations

Conclusions

Research indicates that a well-managed methadone maintenance program can provide effective treatment for heroin addiction. However for the programs we visited, the continued use of heroin among patients indicates that nearly one-half the programs we visited were not effective in achieving the benefits of methadone maintenance treatment.

More federal leadership is needed to better assure that methadone maintenance programs provide effective treatment. In this regard, we believe:

- Result-oriented performance standards should be developed to set expectations for treatment programs and provide a basis to assess their effectiveness as contemplated by the President's National Drug Control Strategy.
- Standards should be based on results obtainable from proven treatment approaches that combine appropriate doses of methadone and comprehensive rehabilitative services.
- Greater program oversight is needed and should be based on performance standards.

Recent federally sponsored research found that interim maintenance would not significantly reduce IV heroin use and the corresponding risk of AIDS. We did not find clear evidence of an overall serious shortage of methadone treatment slots that would justify interim maintenance. Therefore, the justification for interim maintenance is questionable.

Recommendations

To better monitor and assess methadone maintenance treatment programs we recommend that the Secretary of Health and Human Services direct the Food and Drug Administration or the National Institute on Drug Abuse, as appropriate, to: (1) develop result-oriented performance standards for methadone maintenance treatment programs, (2) provide guidance to treatment programs regarding the type of data that must be collected to permit assessment of programs' performance, and (3) assure increased program oversight oriented toward performance standards.

We also recommend that the Secretary withdraw the proposed interim maintenance regulations until such time as (1) documented evidence demonstrates that demand greatly exceeds treatment capacity for methadone maintenance treatment programs and (2) research demonstrates that interim maintenance is significantly better than no treatment at all in preventing IV drug use and the corresponding risk of AIDS.

research findings (discussed in ch. 1) demonstrate that for programs to be effective, comprehensive treatment services are needed. The NIDA study further indicated that long-term rehabilitative services were important for reducing IV drug use.

The report by researchers at VA and the University of Pennsylvania found that over 90 percent of patients that received treatment that was essentially the same as that proposed for interim maintenance, continued to use heroin. The report stated: "Clearly, administering methadone does not by itself guarantee clinical improvements or reduced AIDS risk." The report concludes that merely increasing the availability of methadone in the absence of administrative, counseling, and rehabilitative services may not adequately protect the majority of patients from continued drug use and the risk of AIDS.

The proposed interim maintenance regulations are based, in large part, on a pilot interim maintenance project known as the Innovative AIDS Risk Reduction Project. The project was carried out by Beth Israel Medical Center of New York City. Beth Israel concluded that an interim maintenance program that provides minimal services could have a significant impact on decreasing IV drug use and therefore reduce the risk for contracting or spreading AIDS.

While the report on the pilot interim maintenance project at Beth Israel provided a substantial basis for FDA's proposed regulations, the pilot study had a methodological problem in that it relied on patient self-reporting for evidence concerning reductions in heroin and cocaine use. Research indicates that patient self-reporting is a much less reliable method of determining reductions in heroin use than through the use of urinalysis testing. Therefore, we believe that the pilot study does not provide an adequate basis of support for the proposed interim maintenance regulations.

Many treatment program administrators also expressed their concern over the interim maintenance proposal. One official stated that new patients are the ones most in need of comprehensive care. He indicated that while it is important to provide heroin addicts seeking treatment with immediate access to methadone treatment, to do so without clinical and supported services will ultimately lead to the end of methadone treatment in the United States. An official of the New York State Division of Substance Abuse Services expressed concern that unless additional funds were forthcoming, funds intended for comprehensive treatment would be diverted to cover the cost of interim maintenance.

may include FDA's revocation of the program's approval to operate. A regulatory letter is sent for the most serious of violations and provides for the closing of a treatment program if full regulatory compliance is not achieved within specified time limits. Violations found among the 62 treatment programs included failure to (1) meet minimum urine testing requirements, standards for admissions, and medical evaluation requirements; (2) comply with frequency of attendance and take-home requirements; or (3) maintain an adequate patient record system.

Proposed Interim Maintenance Regulations Should Be Withdrawn

In March 1989, FDA and NIDA proposed revised methadone maintenance regulations to allow the use of interim maintenance. The proposed regulation is based on the assumption that (1) demand greatly exceeds treatment capacity at methadone maintenance treatment programs and (2) the immediate availability of methadone to addicts awaiting treatment would reduce IV heroin and other narcotic drug use and consequently the attendant risk of AIDS.

While we found that some programs had waiting lists, there is no clear evidence of a serious shortage of treatment slots. Moreover, research studies indicate that interim maintenance would not significantly reduce heroin use.

Availability of Treatment Varied by Program

A primary reason for the development of interim maintenance regulations was the perception that treatment slots were not available. We found that 14 of the 24 methadone treatment programs we reviewed did not have waiting lists and would accept addicts seeking treatment into their program. The remaining 10 programs indicated that their treatment capacity was full and they were placing people on waiting lists. Of the 10 programs, 4 were located in California, and 2 each in New York, Illinois, and New Jersey. One of the 10 programs (a California clinic) did not have any publicly funded treatment slots available, however, it would accept a person who had the ability to pay for treatment.

At the time of our review, the 10 programs had a waiting period ranging from 1 week to 3 months. About 1,000 addicts were awaiting treatment at these programs; however, most of these addicts were on the waiting list at 1 of the 10 programs. Moreover, because 4 of the 10 programs did not update their waiting lists to remove addicts that entered treatment elsewhere or who were no longer interested in treatment, the actual total number of patients awaiting treatment may be smaller.

Improvements in Federal Oversight of Methadone Maintenance Needed

Although the Food and Drug Administration and the National Institute for Drug Abuse have responsibility for regulating methadone maintenance treatment programs, these agencies have provided little oversight for the programs. Federal methadone maintenance regulations, developed jointly by FDA and NIDA, do not establish performance standards, such as the percent of patients no longer using heroin. Instead, the regulations are process oriented in that they establish certain conditions for providing methadone treatment, such as admissions requirements and the security of methadone supplies. Neither agency routinely evaluated the effectiveness of treatment programs. FDA's recent compliance inspections of these programs have found serious problems.

In March 1989, FDA and NIDA proposed revised methadone maintenance regulations to allow interim maintenance—the provision of methadone without any treatment-related counseling or rehabilitative services for addicts who are on waiting lists for comprehensive methadone maintenance treatment. The proposed regulations are based on the assumptions that many addicts are on waiting lists for treatment and that interim maintenance would result in reduced IV heroin use and the attendant risk of AIDS. However, we found no clear support for either assumption.

Federal Regulations Lack Standards for Treatment Effectiveness

Pursuant to the 1974 Narcotic Addiction Treatment Act, NIDA and FDA developed methadone maintenance regulations that specify the conditions of use for methadone in the treatment of narcotic addictions. However, the regulations do not establish treatment performance standards for use in determining whether programs are effectively treating their patients. Moreover, there are no requirements for federal agencies or treatment programs to evaluate the effectiveness of individual treatment programs. Without program evaluation, treatment programs and federal oversight agencies do not know how useful and effective the programs are in carrying out their treatment activities.

The President's National Drug Control Strategy recognizes the need to improve drug addiction treatment and calls for federal action to award federal treatment funds to states on the condition that they develop and implement treatment action plans. The President's strategy seeks to (1) ensure that treatment programs are accountable for their effectiveness and (2) obtain information concerning the performance of individual treatment programs to understand what treatment methods work for different types of addicts.

Table 2.5: Average Patient Caseloads and Number of Counseling Sessions for the 24 Methadone Maintenance Treatment Programs

Program	Average patients per counselor	Average monthly counseling sessions
California		
A	40	2
E	40	2
I	36	2
J	40	2
K	50	2
L	44	2
M	34	2
New York		
N	42	2
O	49	[a]
P	67	1
Q	55	1
Z	65	2
Florida		
D	25	2
H	35	2
Illinois		
R	15	4
S	21	4
Texas		
C	45	2
G	32	3
Maryland		
V	29	4
W	39	1
New Jersey		
T	51	2
U	96	2
Washington		
B	50	2
F	48	2

[a]The average monthly counseling sessions for this clinic varied.

For programs with high counselor/patient ratios, the potential benefits of counseling may not have been realized. Many counselors and program directors told us that it was difficult to provide more than minimal counseling to patients when a counselor's caseload exceeded 35 patients. They also stated that smaller counselor/patient ratios can lead to more

did not offer services on site, program officials stated that they referred patients to other agencies or private programs for these services. Most programs with on-site vocational or educational training were able to track patient progress. However, program officials at most of the programs that referred patients elsewhere for these services did not know whether the patients used the service or how they were progressing.

Only three programs had information regarding the number of patients utilizing the services they had been referred to. Little, if any, feedback occurred between the program and the referral agency. Without feedback, treatment programs cannot determine whether the services were utilized or beneficial to the patient.

Given the low employment rates at a number of the programs we visited, vocational and educational services would appear to be needed to assist patients in treatment. However, patients were not required to use these services. For example, at one program offering on-site vocational services, 5 percent of all patients utilized vocational training while 74 percent of the patients were not employed. In the best-case example among the four programs offering on-site vocational training, 19 percent of the patients utilized vocational training while 55 percent of the patients were not employed.

Limited Counselor Staff May Affect Quality of Treatment

The counselor's primary role is to assist patients in the recovery process. Counselors help patients address their addiction as well as determine what additional treatment may be required.

Research indicates that a good relationship between the counselor and the patient improves treatment results. These relationships could be expected to be developed over time. We found for the 19 programs that provided us data, the average length of employment for counselors ranged from 6 months to over 8 years. However, over one-half of the counselors had been employed for 1 year or less. Salaries and work loads could be factors for the low average employment tenure among counselors at the programs. Counselor salaries ranged from $12,500 to $30,200 annually. Over one-half the counselors made less than $20,000 annually. While some counselors had little or no college experience, most (70 percent) had 4-year college or graduate degrees.

Until recently, federal regulations required that no more than 50 patients be assigned to each counselor. Regulations do not address the amount of patient counseling or the length of a session for patients in

Treatment program officials told us that insufficient services, including counseling, can contribute to a patient leaving treatment and returning to drug use. We found the percentage of patients who remained in treatment for more than 6 months at 21 programs we visited ranged from 83 to 42 percent.[5] At 9 of the 21 programs, more than 40 percent of patients left treatment before 6 months. At two of the programs more than 40 percent of the patients left treatment before 3 months. Table 2.4 lists retention rates by program for both the 3- and 6-month periods.

[5]We calculated patient retention rates at 21 of the 24 programs (3 programs did not have the necessary information). At the 21 programs, we determined the number of patients who entered treatment during the period January 1 through August 31, 1988. Patients who were discharged from treatment only to reenter at another time within this time period were counted as separate admissions. We matched the admissions information with discharge data collected for the period January 2, 1988 through February 28, 1989.

in treatment. Program directors stated that many patients have alcohol problems at the time they are admitted into treatment. One official said while patients reduce opiate use, which includes heroin, during treatment, many increase their consumption of alcohol.

For the 24 programs we visited, the rate of patients who missed receiving their daily dose of methadone ranged from an average of 4 percent at one program to 51 percent at another. At nine programs, 25 percent or more of the patients missed their daily dose of methadone. Patients must take the appropriately prescribed levels of methadone daily because, as a long-acting opiate (usually 24 to 36 hours), it interrupts and prevents the craving for heroin. Table 2.3 provides the attendance data for the 24 programs.

Besides heroin, patients used other drugs—primarily cocaine,[2] but also amphetamines, benzodiazepines,[3] or alcohol. At eight of the 24 treatment programs, between 20 and 40 percent of patients used cocaine. Cocaine use at the remaining programs ranged from none at one program to 15 percent at three others. Table 2.2 shows the percentage of heroin, cocaine, and overall drug use by patients in treatment longer than 6 months.[4]

[2]Most treatment modalities (drug-free, therapeutic communities, etc.) have seen recent increases in the number of patients seeking or receiving treatment for cocaine use.

[3]A class of drugs used for treating anxiety and sleep disorders.

[4]Total drug use includes heroin and other opiates, cocaine, amphetamines, benzodiazepines, and barbiturates.

Wide Variation Found in Testing, Discharge, Take-Home Policies, and Costs

As with treatment goals, programs differed widely in their policies regarding urinalysis testing, patient discharge, and methadone take-home privileges. Urinalysis results are the primary tool used by programs to determine if patients are continuing to use heroin or other drugs. Federal regulations require that, during the first year of treatment, treatment programs test patients' urine at least eight times a year and thereafter at least quarterly. The number of times programs tested patients varied from once a week to eight times a year. Officials from the 15 programs that tested patients once a month or less, said that the costs for the tests prohibited their programs from testing more often. The costs of urinalysis tests ranged from $0.00 to $19.00 and averaged $6.51 for the 24 programs.[1]

A NIDA researcher told us that to ensure accurate urinalysis test results, programs must observe the collection of urine samples. Nine of the 24 programs we visited did not observe urine collection. Program officials said that urine collections were not observed because it would increase the work load for their staff.

A consequence of continued drug use could be discharging patients from methadone maintenance treatment for any drug use, including cocaine. Seventeen programs discharged patients for continued drug use while six programs would not, even if a patient's urinalysis tests were repeatedly positive for heroin or other drug use. The remaining program would discharge patients in publicly funded slots but not patients that paid for their own treatment. Programs in the state of Washington are required by state regulations to discharge patients from a program if they test positive for any illicit drug three times in a 6-month period. Officials from programs that allowed patients who continued to use drugs to stay in treatment said that the risk of contracting AIDS was the primary reason for retaining these patients in treatment. However, four programs that did not discharge patients from treatment for continued use of drugs would discharge patients if they were delinquent in paying their fees for treatment.

Federal regulations allow take-home methadone doses to be provided to patients on days that a program is closed or for patients who have demonstrated improvement and who can adhere to program rules. Take-home methadone doses permit patients to reduce the number of days they must come to the program to receive methadone. However, because

[1] In two cases, urinalysis testing was paid for by the state, and the programs were not charged for these costs.

state is preferable, but a patient should not be forced to stop taking methadone.

- Eight programs sought to stop all drug use, including methadone. Some program directors told us that patients should ultimately become completely free of all drugs. One program director told us that he only uses methadone maintenance if patients are unwilling to undergo or unable to successfully complete a 90- to 180-day detoxification period.

Methadone Dosages Varied

Programs had different philosophies and practices regarding the appropriate methadone dosage level. The National Institute on Drug Abuse believes that an adequate dose of methadone is necessary to stop heroin use. NIDA found that 60 milligrams (mg) to be the lowest effective dose and that low-dose maintenance (20 to 40 mg) is considered "inappropriate."

However, physicians at the various programs we visited differed concerning the amount of methadone they believe should be prescribed to patients. At 21 of the 24 programs the average milligram dosage of methadone prescribed was below 60 mg—the lowest effective dose. The average dose of methadone at the 24 programs ranged from 21 to 68 milligrams. One program physician told us that program rules prevented him from prescribing methadone in doses greater than 50 milligrams to any patient. This rule was based on internal administrative policy. The mean dose of methadone among programs and the median and mode for patient dosages are listed in table 2.1.

treatment goals and the types of rehabilitative services provided. To determine the federal role in regulating and overseeing methadone maintenance treatment programs, we reviewed current and proposed federal methadone maintenance regulations and interviewed officials from the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), FDA, NIDA, and DEA. We also reviewed records of the most recent FDA compliance inspections for each of the 24 programs we visited to determine when they took place and to review the findings of the inspections.

To examine the effectiveness of methadone maintenance and the status of alternative strategies, we reviewed the relevant literature and interviewed NIDA officials and other experts in the drug treatment field.

Our review was performed between March and October 1989 in accordance with generally accepted government auditing standards. We did not obtain official agency comments on this report; however, a copy of the draft report was provided to FDA and NIDA officials and we incorporated their views where appropriate.

Program Profiles

There is no typical methadone maintenance treatment program. Programs can be found in rural and suburban areas and inner cities. Programs may range in size from fewer than 100 to more than 700 patients. Many programs are established by private not-for-profit organizations and others are private for-profit and public programs. These programs can be linked with a hospital. Under federal regulations, admission to methadone treatment is limited to persons who have been addicted to heroin or other opiates for at least 1 year.

Funding for methadone maintenance treatment varies by state and sometimes by county. Many private for-profit programs do not receive public funding and charge their patients a fee for services. Depending on the state and/or local governments involved, programs may receive public funds in the form of Medicaid, block grant funds, or other state and local government assistance.

Heroin addicts come from every race and may be from rich, poor, or middle-class families. Many patients in treatment are employed, including some in professional careers. Costs to the patients also vary by location and often the patient's ability to pay.

A new problem faced by heroin addicts and methadone maintenance treatment programs is AIDS. Heroin is commonly administered intravenously, and IV drug users are the second largest population at risk of AIDS. Some experts have estimated that in New York City over 60 percent of IV drug users are HIV infected. Further, methadone maintenance treatment programs have become involved with a host of problems associated with heroin use, including homelessness and mental illness, tuberculosis, pneumonia, and numerous other debilitating diseases.

Federal Agency Responsibilities

At the federal level, the Food and Drug Administration (FDA), NIDA and the Drug Enforcement Administration (DEA) share responsibility for issuing methadone maintenance treatment regulations and for overseeing methadone maintenance programs. FDA is responsible for approving the operations of methadone maintenance treatment programs and has primary responsibility for ensuring that programs comply with the methadone maintenance regulations. NIDA works with FDA in developing methadone maintenance regulations and is responsible for federal research of drug treatment. DEA registers programs to procure and dispense methadone. It also is responsible for ensuring that supplies of methadone are safeguarded appropriately by methadone programs and methadone manufacturers and distributors.

Introduction

Heroin addiction is widespread in the United States. The National Institute on Drug Abuse (NIDA) estimates that there are approximately 500,000 heroin addicts in the United States. Treatment experts believe that heroin addiction is a chronic and relapsing disease that addicts will battle the rest of their lives. The most commonly used treatment for heroin addiction is methadone maintenance.

Methadone is an orally administered synthetic narcotic. Methadone "blocks" the effect of heroin and prevents withdrawal symptoms. It is not a "cure" for addiction. It is provided in clinics as a substitute for heroin and other narcotic drugs.[1] In 1988, approximately 100,000 heroin addicts received methadone maintenance treatment at over 650 programs nationwide. These treatment programs attempt to help addicts stop using street drugs and lead more stable and productive lives by combining the use of methadone with counseling and other services.

The Chairman of the Select Committee on Narcotics Abuse and Control, House of Representatives, requested that we review the treatment provided to patients in methadone maintenance treatment programs and examine the federal government's oversight of methadone maintenance programs. In requesting our review, the Chairman expressed concern about the kinds of treatment services made available to methadone patients, and whether methadone programs pursue a goal of restoring patients to a totally drug-free state where they no longer use methadone.

Concerns and Controversy Have Surrounded Methadone Treatment

The use of methadone as a method of drug treatment for heroin addiction started in the early 1960s. As methadone programs expanded in the early 1970s, concern emerged over the diversion of methadone to illicit use. In 1974, the Congress, recognizing both the potential benefits of methadone maintenance and the risk of diversion, passed the Narcotic Addict Treatment Act of 1974 (P.L. 93-281). Legally sanctioning narcotic maintenance treatment, the legislation required the then-Department of Health, Education and Welfare (now the Department of Health and Human Services) to establish regulations regarding who may enter methadone maintenance treatment programs and the conditions under which the drug could be administered.

[1] Narcotic drugs include heroin, morphine, and other morphine-like drugs, but do not include drugs such as cocaine, marijuana, and certain other drugs.

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testing ranged from once a week to 8 times a year, 15 programs dismissed patients for repeated drug use while 9 programs did not, counselor patient ratios ranged between 1 to 15 and 1 to 96, and average methadone dosage levels ranged from 21 to 67 milligrams. (See pp. 13-17 and 25.)

There are no federal treatment standards for methadone maintenance treatment programs. Further, none of the programs we visited evaluated the effectiveness of their treatment. (See chapter 3 and p. 27.)

Federal Oversight of Methadone Maintenance Limited

FDA and NIDA have responsibility for regulating methadone maintenance treatment programs. These agencies provided little oversight of the programs between 1982 and early 1989. Neither agency routinely evaluated the effectiveness of treatment programs. FDA's recent inspection of programs for compliance with the administrative requirements of federal methadone maintenance regulations have found serious problems. FDA inspections in fiscal year 1989 found 62 programs that failed to (1) meet minimum urine testing requirements, standards for admissions, and medical evaluation requirements; (2) comply with frequency of attendance and take-home requirements; or (3) maintain an adequate patient record system. (See pp. 28-30.)

Effectiveness of Interim Maintenance Questionable

In March 1989, FDA and NIDA proposed revised methadone maintenance regulations to allow interim maintenance—the provision of methadone without any counseling or rehabilitative services for addicts who are on waiting lists for comprehensive methadone maintenance treatment. The proposed regulation is based on the assumption that (1) demand greatly exceeds treatment capacity at methadone maintenance treatment programs and (2) the immediate availability of methadone to these addicts would reduce IV heroin use with its attendant risk of AIDS.

While we found that some programs had waiting lists, there is no clear evidence of a serious shortage of treatment slots. Moreover, recent research findings by the Department of Veterans Affairs (VA) and University of Pennsylvania researchers indicate that interim maintenance

Executive Summary

Purpose

Methadone maintenance is the most commonly used treatment for heroin addiction. The treatment combines the use of methadone, an orally administered synthetic narcotic, with counseling and other rehabilitative services. Methadone is not a "cure" for heroin addiction, rather, treatment programs attempt to help addicts stop using illegal drugs and lead more stable and productive lives. Treatment experts believe that heroin addiction is a chronic and relapsing disease that addicts will battle their entire life.

The Chairman of the House Select Committee on Narcotics Abuse and Control requested GAO to review the treatment provided to patients in methadone maintenance treatment programs and to examine the federal government's oversight role for such programs. The Chairman expressed concern about the extent of treatment services made available to methadone patients and whether treatment programs have been successful in reducing heroin and other drug use among their patients. He also expressed concern over a recently proposed regulation, referred to as interim maintenance, that would allow methadone to be dispensed without supportive services.

Background

The use of heroin remains a widespread problem in the United States. Government estimates place the number of heroin addicts nationwide at about 500,000. In 1988, approximately 100,000 heroin addicts received methadone maintenance treatment in over 650 programs. (See p. 8.)

There is no typical methadone maintenance treatment program. Programs can be found in rural and suburban areas and the inner cities. They may range in size from fewer than 100 to over 700 patients. Many programs are established by private not-for-profit organizations while others are private for-profit and public programs. (See p. 10.)

Federal Agency Responsibilities

The Food and Drug Administration (FDA), National Institute on Drug Abuse (NIDA), and Drug Enforcement Administration (DEA) share responsibility for regulating methadone maintenance treatment programs. FDA approves methadone maintenance treatment programs and has primary responsibility for ensuring programs comply with federal methadone maintenance regulations. NIDA is responsible for federal research of drug treatment. DEA registers programs and is responsible for ensuring that supplies of methadone are safeguarded against illegal diversion. (See p. 10.)