United States General Accounting Office

GAO

Testimony

For Release
on Delivery
Expected at
9:30 a.m. EST
Friday
March 23, 1990

METHADONE MAINTENANCE: Some Treatment Programs Are Not Effective; Greater Federal Oversight Needed

Statement of
Mark V. Nadel, Associate Director
for National and Public Health
Issues
Human Resources Division

Before the
Select Committee on Narcotics
Abuse and Control

GAO/T-HRD-90-19

048077/140943

GAO Form 160 (12/87)

SUMMARY

Heroin addiction is widespread in the United States. The National Institute on Drug Abuse (NIDA) estimates that there are 500,000 heroin addicts in this country.

Methadone maintenance is the most commonly used treatment for heroin addiction. In 1988, about 100,000 heroin addicts received methadone maintenance treatment at over 650 programs nationwide. These programs try to help addicts by combining methadone maintenance with counseling and other services.

Using the results of federally sponsored research and its own review of the activities of 24 methadone maintenance treatment programs, GAO found the following:

Program policies, goals, and practices differed. These program characteristics are set by the programs themselves and vary greatly.

Many programs are not effectively treating heroin addiction. A substantial percentage of patients continued to use heroin after 6 months of treatment.

None of the 24 programs evaluate their effectiveness. With one exception, the programs did not know the extent to which their treatment goals were met or the overall level of continued drug use in the programs.

Federal oversight of methadone maintenance treatment programs has been very limited since 1983. There are no federal treatment effectiveness standards for these programs. Instead, federal regulations have primarily established administrative requirements.

Interim maintenance, without other supportive services, is not effective. GAO concluded that interim maintenance--the provision of methadone without any counseling or rehabilitative services--would not significantly reduce heroin use.

\- - - -

GAO recommends that the Secretary of Health and Human Services (1) develop performance standards for programs, (2) give guidance to programs regarding data collection so that NIDA can assess program performance, and (3) increase program oversight. GAO also recommends that the proposed interim maintenance regulations be withdrawn.

Mr. Chairman and Members of the Committee:

Mr. Chairman, I am pleased to be here today to discuss our report on methadone maintenance programs. The report resulted from your request concerning 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. You also expressed concern over a recently proposed regulation that would allow methadone to be dispensed without the supportive services that are considered important components of effective treatment for heroin addiction. This proposed treatment is commonly referred to as "interim maintenance."

In response to your request, we reviewed the activities of 24 methadone maintenance treatment programs. These programs were located in eight states: California, Florida, Illinois, Maryland, New Jersey, New York, Texas, and Washington.

Using the results of federally sponsored research as well as our review of the 24 programs, we also assessed the potential effectiveness of the proposed interim maintenance program.

In summary, we found:

-- Many programs were not effectively treating heroin addiction. A substantial percentage of their patients

continued to use heroin after 6 months of treatment. Patients also used other drugs, primarily cocaine.

-- Treatment programs set their own goals, policies, and practices, which varied greatly. However, programs did not evaluate the effectiveness of their treatment and, therefore, did not know the extent to which their goals were met or the overall level of continued drug use in their programs.

-- Just as program goals varied, we found great variation in the programs for the services they provided, their staffing levels, and the aftercare they provided.

-- There are no federal performance standards, and federal oversight of methadone programs has been virtually nonexistent.

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

BACKGROUND

There is no typical methadone maintenance treatment program. Programs can be found in rural and suburban areas as well as the inner cities, and may range in size from less than 100 patients to over 700. While most programs are established by private not-for-profit organizations, there are also private-for-profit and public programs.

Many private-for-profit programs do not receive public funding and charge their patients a fee for services. Publicly operated and private not-for-profit programs may receive public funds. These funds may be in the form of Medicaid, block grants, or other state and local government assistance. In the programs we visited, monthly revenue from all sources ranged from $145 to $533 per patient. Out-of-pocket costs to patients, which partially depend on ability to pay, ranged from no charge to $280 per month.

The Food and Drug Administration (FDA), National Institute on Drug Abuse (NIDA), and the 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 drug treatment evaluation and research. DEA

authorizes programs and is responsible for ensuring that supplies of methadone are safeguarded against illegal diversion.

PROGRAM TREATMENT GOALS, POLICIES, AND RESULTS DIFFERED

Methadone maintenance treatment 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 eventual goal of getting the patient free of all drugs, including methadone. A wide variance also existed among program policies with respect to methadone dosage levels, urine testing, dismissing patients, and counselor staffing levels.

An adequate dose of methadone is necessary to stop heroin use. According to NIDA, 60 milligrams (mg) is generally the lowest effective dose, and low dose maintenance (20 to 40 mg) is considered "inappropriate." The average dose of methadone at 21 of the 24 programs we visited, however, was less than 60 mg.

Methadone maintenance can be an effective treatment for heroin addiction. But, judging from the continued use of heroin among patients, in practice, nearly half the programs we visited are not effective in treating heroin addiction. At 10 of the 24 programs, more than 20 percent of the patients continued to use heroin after

6 months of treatment. This is a higher percentage than experts believe should occur among patients in treatment.

At the 24 programs we visited, urine testing to determine the use of illicit drugs ranged from once a week to 8 times a year. At five New York programs, urine testing occurred once a week, but only one of the five programs observed the collection of urine in order to prevent a patient from tampering with the sample. A consequence of continued heroin or other drug use could be dismissal from a program. Fifteen of the programs dismissed patients for repeated drug use while nine did not.

Comprehensive services, including counseling and vocational training, have been found to be essential to program effectiveness and here, too, we found wide variation. Counseling is a key component of methadone maintenance treatment. 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. Patient ratios at our programs ranged between 1 to 15 and 1 to 96. Research indicates that a good relationship between the counselor and the patient, which is developed over time, improves treatment outcomes. The average length of employment for counselors at the 20 programs that provided us data ranged from 6 months to over 8 years, but less than one-half the counselors had been employed for more than 1 year.

Most of the programs were lax in providing vocational and educational services, which are required by federal regulation. Few programs had such services on their premises and those that referred patients to services off-site did not track patient use or progress.

None of the methadone maintenance programs we visited evaluated the effectiveness of their treatment.

FEDERAL OVERSIGHT OF METHADONE MAINTENANCE VERY LIMITED

Federal regulations require that in order to use methadone in treatment, programs meet certain conditions such as requiring urine testing for continued drug use. FDA and NIDA have primary responsibility for regulating programs, but these agencies provided virtually no oversight of the programs between 1982 and early 1989. When FDA did begin inspecting programs for compliance with the administrative requirements of federal methadone maintenance regulations it 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; (3) maintain an adequate patient record system; (4) or meet minimum program standards. Thirty of the 62 programs were in New York.

Current regulations are process rather than results oriented. There are no federal treatment performance standards for methadone maintenance treatment programs such as the overall level, if any, of continued drug use that is permissible. Thus, oversight has been oriented towards regulatory compliance rather than program effectiveness.

EFFECTIVENESS OF INTERIM MAINTENANCE IS 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. The purpose is to get addicts who are waiting for comprehensive treatment to reduce IV heroin use with its attendant risk of AIDS infection. The proposal is based on the assumption 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. Both assumptions, however, are questionable.

First, we found that while some programs had waiting lists, there is no clear evidence of a serious shortage of methadone treatment slots.

Second, a recent study by Department of Veterans Affairs (VA) and University of Pennsylvania researchers found that interim maintenance is not effective in reducing IV drug use. 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.

RECOMMENDATIONS

In our report, we have made a number of recommendations to the Secretary of Health and Human Services. These include the development of performance standards, guidance for data collection on program performance, and increased program oversight. Additionally, we recommend that the interim maintenance proposal be withdrawn until there is sufficient evidence to clearly demonstrate its effectiveness in actually reducing intravenous heroin use.

- - - -

This concludes our prepared statement, Mr. Chairman, we would be pleased to answer any questions you may have.