

Report 2 of the Council on Scientific Affairs (I-94)

American Medical Association (1994)

Methadone maintenance in private practice

Note: This report represents the medical/scientific literature and AMA policy on this subject as of December 1994.

Resolution 428, introduced at the 1994 Annual Meeting by the Connecticut Delegation, and referred to the Council on Scientific Affairs through the Board of Trustees, asked that the American Medical Association (AMA) support the concept of "medical" methadone maintenance by qualified private practicing physicians as a rational public health measure in AIDS prevention.

Present AMA Policy

In previous policy statements, the AMA has encouraged (federal, state, and local governments to increase) the availability of methadone maintenance for persons addicted to opioids (Policy 20.966, *AMA Policy Compendium*), called for the removal of any federal and state regulations which are based on incomplete or inaccurate scientific and medical data that restrict or inhibit methadone maintenance treatment (Policy 20.966) and supported the development of new methadone treatment guidelines and regulations with a shift of emphasis from administrative process to performance-based standards of care with greater reliance on the physicians clinical judgment and scientific data in determination of treatment (Policy 95.964).

In 1972, the AMA Council on Mental Health published an explication of a previous (March 1971) combined guideline report with the National Research Council (NRC), Committee on Problems in Drug Dependence (CPDD), entitled *Oral Methadone Maintenance Techniques in the Management of Morphine-Type Dependence*.¹ The report stated: "The (methadone maintenance) program may establish satellite operations utilizing properly trained physicians in private practice....in the management of those patients whose needs for allied supportive services are minimal. Patients should be referred to satellite units for continuing treatment after their conditions have been stabilized at optimal maintenance methadone dosage level. These patients should remain in contact with the parent program for periodic review and evaluation, including urine testing."

Methadone maintenance

Although still controversial, methadone maintenance is a widely used method of treating chronic relapsing addiction to heroin or other opioids. There is no comparable alternative method of treatment for opioid dependence.

The concept of methadone maintenance was introduced by Dole and Nyswander in 1965.² Its rational basis, according to Dole,³ is the indication that there is a specific neurological abnormality underlying the compulsive use of heroin. Endogenous ligand-opioid receptor function in the addict has been altered by repeated use of the opioid drugs. Methadone treatment normalizes these neurological and endocrinological processes. Methadone, in the proper dose, suppresses opioid "craving" and produces a blockade of the euphoria induced by heroin. When neurophysiological stability has been restored, the addict, supported by counseling and social programs, is able to begin the process of social rehabilitation. An important element of the maintenance concept is that daily methadone administration continues indefinitely. Personal and social stability comes from maintenance of steady employment, avoidance of criminal activity (primarily related to the acquisition of drugs), cessation of alcohol or other drug abuse, and development of new social ties (away from drug users, drug dealers, and other elements of the drug "culture").

Standard methadone maintenance treatment is a rigidly prescribed program, defined in federal, state, and local regulations. Patients are required to make regular daily visits to the clinic (eligible for extension to three per week and then weekly visits only after 3 years in the program), undergo counseling on specified personal/social issues and have access to a variety of medical and rehabilitative services.

The regulations further state that a general physician may not treat a patient with methadone (or any other opioid) dependence. The only exception is the situation in which a hospitalized patient is given the opioid for stabilization (suppression of withdrawal syndrome) during treatment for another medical condition. Methadone program physicians may treat opioid dependent patients on an

outpatient basis up to 180 days for the purpose of detoxification. However, with individual exceptions, methadone treatment beyond 180 days is defined in federal regulations as methadone maintenance and may be conducted only in a federally approved clinic.

Methadone maintenance is considered an effective therapy for opioid dependence. A 1990 Institute of Medicine report⁴ concluded that there is strong evidence from clinical trials and other studies that heroin-dependent individuals have better outcomes on average when they are maintained on methadone than when they are not treated at all, acutely detoxified and released, expelled from treatment, or when the treatment program is closed. Methadone programs have higher rates of retention in treatment for opioid-dependent patients than do other treatment modalities applied to similar patient populations.

With impetus from the Nixon Administration and Presidential Drug Advisor Jerome Jaffe, MD, maintenance programs saw rapid expansion in the early 1970s. Involvement of the regulatory agencies and restriction of public funds followed closely thereafter and slowed the rate of expansion. At the present time, there are about 725 programs treating approximately 115,000 patients in 40 states (Center for Substance Abuse Treatment, Public Affairs Office, oral communication, 1994).

Medical methadone maintenance

At the time of admission to the program, most methadone maintenance patients are consuming large amounts of drugs and are involved in illegal activities, including the selling of drugs, on a daily basis. However, once a patient has progressed to a stable lifestyle, has completed the intensive counseling sessions and obtained a steady job, there is little need for the crisis-orientation and ancillary services of the standard clinic (although the need for daily methadone continues). At that point, regular clinic attendance requirements may actually inhibit further personal and career development. Beyond the inconvenience, clinic visits consume time and prevent travel for business (or vacation). These time and mobility restrictions of the standard program can affect job performance and patient morale. Clinic visits also bring the patient in continued contact with active or recently active drug-users. Former drug-using companions, recalling memories of the sights and sounds of the street, can be potent inducers of the sensation called drug "craving."

"Medical" methadone maintenance is defined by Novick as the treatment by primary care physicians of rehabilitated methadone maintenance patients who are stable, employed, not abusing drugs, and not in need of supporting clinic services⁵ or, the treatment of socially rehabilitated methadone maintenance patients in physicians offices rather than in licensed clinics.⁶

Twenty-three years ago, in the combined report with the NRC/CPDD noted above,⁷ the AMA suggested that research be conducted on the "use of properly trained practicing physicians as an extension of organized methadone maintenance programs in the management of those patients whose needs for allied services are minimal," (what is now called "medical" maintenance). Evaluation of the medical maintenance approach has at this point involved only two pilot studies.^{6,8} Study initiation is complicated by the need to get a waiver of regulatory requirements from the Drug Enforcement Administration (DEA) to prescribe methadone in a manner that would otherwise be illegal, and to acquire from the Food and Drug Administration (FDA) an investigational New Drug (IND) application covering the research protocol.

In these studies patients were seen at monthly or twice monthly intervals, given take home methadone medication to cover that period, and were subject to minimal counseling.

Novick et al⁶ reported on 100 patients followed over 42 to 111 months or until discharge. Patient admission criteria included five or more years in standard methadone maintenance with at least three years of stability (defined as stable employment, financial support, no criminal involvement, no use of illegal drugs, or excessive use of alcohol). Patients were dismissed from the study group for illegal drug use (determined by drug screening on urine submitted at each visit), excessive alcohol use, diversion or misuse of methadone, or failure to comply with all rules of the program. Outcome of the study was evaluated by measuring retention in the study group, reasons for discharge from the study, episodes of substance use, and episodes of "lost" methadone medication (presumed diversion). Fifteen patients were discharged unfavorably over the follow-up period, primarily for other drug use (cocaine) or presumptive diversion of methadone.

Senay et al⁸ reported on 130 patients followed for one year or discharge. Patient admission criteria were one year in standard methadone treatment with the most recent six months in a condition of stability (defined as stable employment, no legal incidents, no evidence of illegal drug use and compliance with all aspects of the treatment program). The investigator introduced a control condition by assigning one third of the study group to continue in the standard methadone treatment for the first six months of the study period. Outcome was evaluated by retention in the study, episodes of "lost" or "stolen" medication, reason for discharge and global evaluation by the Addiction Severity Index (ADI) score. Retention in the "medical" maintenance group was no different than the control group at six months (89 percent versus 85 percent respectively) and three out of four patients (73 percent) completed the year in good standing (identical to the control group). Most dismissals were for illegal drug use, primarily cocaine.

Senay also introduced a special methadone diversion control program as part of the study. The patient was required to respond to a random call from the clinic within 24-hours, bringing in all bottles of medication. The medication bottles were inspected for tampering and selected tablets were

chemically tested to confirm the presence of methadone. The patient was also required to submit a (random or unscheduled) urine sample at the same time. This unannounced urine test provided an additional objective means of evaluating prohibited drug use.

These two studies suggest that treatment retention in "medical" maintenance is at least as good as that obtained in the standard program.

Movement of stabilized patients to less intensive study programs might free up resources in standard programs that could be devoted to opioid-dependent subjects on the admission waiting list. Although not directly assessed in these studies, this suggests that there would be some cost savings. Senay estimates that the subset of the patient population that would qualify for the "medical" maintenance model would be approximately 10 percent to 20 percent (11,500 to 23,000 patients) depending on the duration of stability criterion that is applied for admission.

Patient questionnaires indicated that the programs were uniformly popular with the patients. The Institutional Review Board (IRB) at the University of Chicago⁸ concurred that return to the standard clinic schedule would constitute a hardship and approved continuation of the remaining subjects in the experimental condition. Patients said the program improved self-esteem by rewarding years of good treatment performance, provided status as legitimate medical patients and lessened the time constraints on their life and work activities.

HIV infection and methadone maintenance

Injection drug use is the second most important risk factor in the transmission of HIV in this country and the primary source of heterosexual and perinatal transmission. There is evidence that methadone treatment is effective in reducing exposure to HIV infection by reducing intravenous drug use and by decreasing needle sharing.⁹ Several studies indicate that it is effective in reducing the incidence of HIV infection among injecting opioid users.¹⁰

Both studies of the "medical" maintenance model evaluated evidence of HIV infection but the numbers involved are quite small. Novick found that none of 58 long-term, socially rehabilitated methadone patients had HIV antibody.¹¹ These former heroin users had entered treatment before or at the start of the HIV epidemic and due to successful treatment (cessation or greatly reduced injecting drug use) had avoided HIV infection. These patients were a source of subjects for their "medical" methadone study. Senay et al¹² also found no HIV positives among 31 of the first 95 subjects admitted to their study in the fall of 1988. Coincident rates of HIV positivity in the injecting drug user population of origin were 12 percent for those entering treatment and 20 percent for those not in treatment.¹³

Physician qualification

The issue of physician qualification to administer a methadone program is a longstanding controversy. In 1972, the *Medical Letter*¹⁴ reported on the AMA guidelines for methadone maintenance⁷ and "cautioned that these programs pose too many problems for private physicians to handle alone" yet some of the *Medical Letter* consultants believed that private physicians could treat heroin addicts. Novick et al⁶ recruited hospital-based physicians with little or no experience in addiction medicine to treat their subjects and feel that a short initial training program is sufficient to prepare the generalist to take on this responsibility. Senay on the other hand stresses the need for a physician with active links to the standard methadone treatment system so that the relapsing patient can be dealt with efficiently and effectively (Senay EC, oral communication, August 10, 1994). In 1971 and 1972, the issue of whether methadone maintenance is "feasible in the office practice of private physicians" was debated in the AMA House of Delegates without resolution.

Conclusions

The "medical" methadone maintenance model may be an appropriate approach for the subset of opioid dependent patients who have attained a degree of behavioral and social stability under standard treatment. Treatment that reduces street drug injection and needle-sharing will reduce the spread of HIV infection. Medical maintenance may be an efficient and cost effective approach to the related major problems of opioid dependence and an evolving HIV epidemic. Further investigation is needed to define the critical details of such programs.

Recommendations

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1994 AMA Interim Meeting.
The AMA:

1. Reaffirms its position stated in the 1971 guideline on *Oral Methadone Maintenance Techniques in the Management of Morphine-Type Dependence* that, "the use of properly trained practicing physicians as an extension of organized methadone maintenance programs in the management of those patients whose needs for allied services are minimal" (called "medical" maintenance) should be evaluated further.

2. Supports the position that "medical" methadone maintenance may be an effective treatment for the subset of opioid dependent patients who have attained a degree of behavioral and social stability under standard treatment and thereby an effective measure in controlling the spread of infection with HIV and other blood-borne pathogens, but further research is needed.
3. Encourages additional research that includes consideration of the cost of "medical" methadone maintenance relative to the standard maintenance program (for example, the cost of additional office security and other requirements for the private office-based management of methadone patients) and relative to other methods to prevent the spread of blood-borne pathogens among intravenous drug users.

References

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