

MMT & Beyond - Office-Based Methadone Prescribing

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In 1997, NIDA funded a 3-year research project on "Office-Based Methadone Prescribing" at Montefiore and Beth Israel Medical Centers, and the Albert Einstein College of Medicine. Following is a report from project director Ellen L. Tuchman, CSW, PhD (cand) and principal investigator Ernest Drucker, PhD.

More than 30 years since its inception, most methadone maintenance treatment (MMT) in the U.S. continues to be delivered only through clinics that are heavily regulated. After years of MMT, patients may still be attending the clinic 4 to 5 times per week, even though they are making every effort to avoid being in places that have any association with drugs or their previous lifestyle.

Methadone for addiction treatment remains a medication that cannot be prescribed by physicians outside of MMT programs. Furthermore, many MMT patients do not receive primary medical care and, if they do, that care is often divorced from their treatment for addiction.

The goal of our study was to explore the possibility of extending options available for methadone treatment by determining the safety, practicality, and efficacy of a primary care model for prescribing methadone.

Study Design

We enrolled 151 women in a randomized trial comparing "Office-Based Prescribing" (OBP) with usual care in MMT clinics. Fifty-three (53) patients were assigned to OBP (the experimental group) and 100 were followed as controls at their MMT clinics. Only women were included in this preliminary study to simplify the research design and reduce costs. In a subsequent stage men will be included.

To be eligible for the study, patients had to be on a stable dose of methadone for at least 6 months and at a reduced pickup schedule of 5 times or less per week. Patients with an existing primary care physician were excluded, so as not to interrupt already established medical care relationships.

The experimental and control groups were demographically equivalent. Average age and time in MMT for all subjects was roughly 41 years and 13 years, respectively. On average, the women were attending their clinics 3 to 4 days per week for methadone dosing at the start of the study. Methadone dispensing for both groups of patients continued to take place at participating MMT program clinics.

The objective of this study was to demonstrate equivalence: i.e., that the OBP patients would do as well as the MMT clinic controls. Two treatment outcomes were examined: retention and illicit drug use.

Results Twelve medical practitioners were recruited from primary care community practices and health clinics at Montefiore and Beth Israel Medical Centers. Physicians were trained in all aspects of methadone treatment.

Prescribing authority over methadone dosage and pickup schedules for the 53 OBP patients was then transferred to participating practitioners. OBP patients made monthly visits to these primary care providers, who could alter dosages and pickup schedules within the practice guidelines and regulations operative in the MMT programs. All OBP patients continued to attend their MMT clinics for regular methadone dispensing, urine tests, and ancillary clinic services.

For *treatment retention*, with 12-months follow-up, 5.7% of OBP patients left treatment compared with 6.1% of MMT patients.

For *use of illicit drugs*, with 12-months follow-up, 82.3% of the women in OBP vs 71.1% of the women in MMTP had not used heroin or cocaine. We defined "illicit use" as two or more positive urine screens.

Differences between groups for retention and illicit drug use were not statistically significant, demonstrating that office-based physicians apparently can safely manage methadone prescribing for stable patients. However, to be of practical significance and to help increase total MMT capacity, office-based prescribing must be coupled with community pharmacy dispensing of methadone.

Integrating Community Pharmacy Dispensing

During the next 4 years our research will be expanded under a new NIDA grant, "Office Based Prescribing and Community Pharmacy Dispensing of Methadone."

We have worked with the Pharmacists Society of the State of New York to identify and recruit 4 well-regarded community pharmacies that have agreed to participate in the study. All are already serving many methadone patients' general pharmacy needs and have submitted required applications for appropriate licensing to administer methadone.

Participating pharmacies are open at least 6 days and for an average of 70 hours per week. The pharmacist will obtain methadone on a weekly basis and be responsible for preparing observed and take-home doses.

Twenty-five (25) current study patients, who completed at least one year with an office-based prescribing physician, will be eligible for the new pharmacy program. Patients will select one of the participating pharmacies, which will serve as a "medication unit."

Each patient will have a case manager – a social worker who coordinates care and provides all required psychosocial services, and all documentation required by state and federal rules. The women will see this case manager at least once each month and as needed.

Patients will begin receiving medication at the pharmacy at their current dosage and pickup schedule. As is the case in MMT clinics, doses administered at the pharmacy will be observed. Participating pharmacies will have a private consultation area where these doses will be administered.

Expanded Spectrum of Care

MMT clinics are invaluable for those who first enter treatment, for those who continue abusing heroin and other drugs, and for those who need more intensive psychosocial services and other care.

At the other end of the spectrum, for the most stable patients, we already have medical methadone maintenance. These patients are seen by their physicians monthly and given up to 30 days of take-home methadone at the office visit. This is appropriate for only a small percentage of patients.

OBP and pharmacy methadone dispensing could serve a larger percentage of MMT patients, and would open significant space in existing clinics for new patients. Plus, there are many cities in the US (and 8 states) where there is no methadone treatment or not enough slots in existing methadone clinics for those who want treatment.

Other patients also could benefit. Travel, illness, and disabilities prevent many from remaining in MMT clinics. Working patients sometimes fear their jobs are in jeopardy because MMT clinic hours conflict with work schedules. Women with young children may lack the finances or social support for childcare so that they can attend the clinic. And some stable patients simply no longer need all the structure and support services of a clinic setting.

In one model proposed by the American Methadone Treatment Association, the MMT clinic is seen as the hub of all treatment. Patients in hub clinics would be able to move fluidly from the clinic to an office-based provider with community pharmacy dispensing, and perhaps then to medical maintenance. However, there would always be an option to return to the MMT clinic during a period of instability or relapse.

If this model is to be effective in expanding access to care and maintaining quality, it is imperative that MMT program staff develop the ability to work well with outside physicians and pharmacists. In the next phase of our project we hope to demonstrate the feasibility of this transition, and document the effects on patients and the responses of providers to this new model of care.

This report is based on a poster presentation at the College on Problems of Drug Dependency, (CPDD), in San Juan, Puerto Rico, June 2000. Office Based Methadone Prescribing in Primary

Care Practice: Results of a Randomized Trial of Feasibility and Efficacy. E. Drucker, D. Hartel, E. Tuchman, K. Bonuck, P. Vavaglaklis, J. Garfield, and W. McCarthy.