The Connecticut Methadone Medical Maintenance Pilot Project

Final Report to the Connecticut Department of Mental Health and Addiction Services

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I. Introduction/Overview

Methadone maintenance is currently the mainstay of treatment for opioid dependence, with an estimated 170,000 patients treated in this modality nationally. Methadone maintenance results in decreased drug use, decreased drug injection, "safer" drug use behaviors, decreased criminal behavior, and increased employability. However, a significant barrier to access to methadone maintenance is the lack of available treatment services in many areas of the country. For instance, it is estimated that there are between 600,000 and 800,000 untreated opioid dependent patients in the U.S. In addition, administrative and regulatory requirements necessitating frequent clinic attendance (daily to several times per week or, minimally, weekly) impose additional burdens on patients and may discourage continuing participation in treatment for those benefiting most from treatment. Finally, the requirement for continuing clinic attendance for patients who have been abstinent from illicit drug use while receiving methadone maintenance may be experienced as stigmatizing or lead to continued contact with active drug users entering treatment or patients at earlier stages of treatment who are continuing illicit drug use.

Consequently, consideration of these factors has led to the evaluation of new settings, including physician's offices, as an alternative to traditional maintenance clinics for methadone maintenance. Previously, physician-based methadone maintenance, referred to as "medical maintenance" (MM) has been effective for patients who have achieved long-term success in uncontrolled studies.

In 1997, the Connecticut legislature authorized a pilot program to assess the feasibility of methadone maintenance based in physician's offices in one geographical region of the state.

II. Background/project design

The purpose of the pilot project described in this report was to investigate the efficacy of physician-based methadone maintenance, medical maintenance, for the treatment of opioid dependence. Specifically, this research was designed to determine whether clinically stable opioid dependent patients receiving methadone would continue to remain stable and benefit from methadone maintenance following transfer from their usual care in a narcotic treatment program (NTP) to care coordinated through a physician's office. To evaluate these issues, a specific aim of the project was to compare the efficacy of medical maintenance with usual care in a NTP. Outcome measures of greatest importance included recidivism to illicit drug use, retention in treatment, patient and provider satisfaction, and cost.

The project was designed in accordance with a number of competing objectives. The first of these objectives was to develop a feasible model that could easily be expanded or implemented throughout Connecticut if the study results warranted expansion. Thus the project was designed to comply with federal regulations regarding the care of patients receiving methadone. These regulations, designed over the past 25 years, stipulate a number of key components involved in the care of patients receiving methadone. Included are regulations that pertain to special licensing of physicians who prescribe methadone for maintenance treatment, the doses of methadone that can be dispensed, the number of take home doses that a patient may receive, the frequency and duration of

counseling that must be provided along with methadone, storage and record-keeping requirements, and the frequency of urine toxicology testing. A second objective was to develop a model that could respond flexibly and appropriately to any potential clinical instability that patients might experience after being transferred to this new model of care. A third objective was to recruit office-based physicians without prior knowledge or experience in caring for patients with opioid dependence and train them in the appropriate practices and procedures involved in the care of patients receiving methadone maintenance. Since a major objective was to evaluate the impact of transferring patients from usual care to MM, patients assigned to remain at their methadone maintenance program experienced no change in their routine of counseling or medication dispensing. Finally, this program was designed as a six-month evaluation program. Therefore, following completion of the pilot program, patients were returned to their NTP.

The project enrolled opioid dependent patients who participated for 6 months. Eligible patients were randomly assigned to receive ongoing methadone maintenance services either in 1) a community-based physician's office (MM) or 2) their NTP.

Medical maintenance model

1. Patient care

Patients that were assigned to the medical maintenance arm had no need to visit the NTP during the six-month treatment period. In addition, an exemption was granted by the Food and Drug Administration (FDA) to allow patients who had been on methadone for fewer than 3 years to receive take home medication on a weekly basis. Thus patients visited a physician's office and were given a week's worth of methadone in bottles. They met monthly with their physician to address issues of relapse prevention, social stressors and general medical concerns. The content of these visits were recorded on a standardized form (see appendix I). Patients provided a monthly random urine sample for toxicology testing during one of the weekly visits to the physician's office.

2. Medication storage and dispensing

To ensure compliance with regulatory requirements, the FDA provided approval for the physicians to operate as methadone dispensing units. In addition, the Drug Enforcement Agency (DEA) provided special methadone registrations for the MM physicians following site visits to the physician's offices. Methadone was transferred on a weekly basis from the NTP to the physician's office. Methadone was stored, on-site, for no more than 24 hours in a locked storage cabinet. Patients presented to their physician's office on a weekly basis and were observed to take one dose of methadone. They received six bottles of methadone as "take homes" for self-administration. Patients were required to return all six empty bottles to their physician's office at their next weekly visit.

III. Physician recruitment and training

Recruitment

Physician selection for the Connecticut pilot program began in August of 1998. In order to recruit and train a cadre of physicians who were interested in medical maintenance and were providing longitudinal care for patients on methadone, patients were asked to provide the names of their current primary care providers. This strategy resulted in the identification of a cluster of physicians in the Greater Waterbury area. These physicians represented a spectrum of experience and practice settings. The practice settings included three community group practices, one suburban solo practice, one hospital-based primary care clinic and one urban federally qualified health center. We recruited 7 physicians, all general internists, and 4 with certification from the American Society of Addiction Medicine. Only 2 physicians reported prior experience caring for patients on methadone maintenance treatment. All physicians expressed a desire to become more involved in the care of patients with substance abuse issues. Ultimately, 6 of the 7 physicians participated in the project due to a medical condition in one of the trained physicians that precluded involvement.

Approvals

The selected physicians were enrolled for participation and their offices received special dispensation from the FDA to serve as medication dispensing units. Physicians also received special DEA registrations contingent upon offices site visits. The physicians were approved to serve as MM providers by the Connecticut Department of Mental Health and Addiction Services and the Connecticut State Methadone Advisory Committee. In addition, face-to-face interviews were conducted between the physicians and the narcotic treatment program, Connecticut Counseling Centers, Inc.

Training

Initial physician training consisted of two 1/2 day training sessions. The seven physicians were trained with draft materials that were created in conjunction with the Addiction Technology Transfer Center of New England and faculty at Yale University. These materials were refined during the remainder of the study based upon physicians experiences and have been compiled to create a guide, "Methadone Medical Maintenance: A training and resource guide for office-based physicians" (Fiellin, et.al, available at www.caas.brown.edu\ATTC). A procedure manual outlining the clinical aspects of the protocol was provided for each physician's office (Appendix II). Finally, in an effort to prepare the office staff, an in-service training was conducted with nurses and office personnel at each physician office regarding the nature of opioid dependence, treatment strategies, the rationale for opioid agonist maintenance and the importance of expanding care into office-based settings.

Monthly Reviews

On-site face-to-face monthly review of patients was performed by project physicians using structured tools (Appendix III). These included a review of patient's clinical charts, the on-site bottle logs, and the DEA 222 forms required for transfer of methadone from the hub program to the physician's office. Direct feedback was provided regarding the quality of the record-keeping, the appropriateness of the documentation and the need for remedial action. In addition, project physicians were also available to answer questions regarding the conduct of the project and clinical care issues.

IV. Relationship of MM patients to the "hub" NTP

Patients continued to remain registered in their NTP and the physicians who participated in the project were officially enrolled as medical staff in that program. All patients continued to pay their usual NTP treatment fees. Physicians were responsible for maintaining a separate clinical chart on each patient. Copies of monthly progress notes of patients assigned to physician's offices were transferred to the hub narcotic treatment program for review by the medical director and program director during and following the six-month treatment period.

V. Patient eligibility and recruitment

Charts were submitted by the senior counseling staff at the NTP based on an initial screening for one year of stability in the program and negative urine toxicologies. Each chart was reviewed by the Senior Clinical Policy Advisor, Office of the Commissioner, Connecticut Department of Mental Health and Addiction Services (DMHAS) for the following eligibility criteria:

1) Active in treatment at the NTP for greater than one year
2) Age 18-60
3) Demonstrated success in treatment and clinical stability as evidenced by the absence of positive urine drug screens for illicit opioids during the prior 12 month period
4) No history of significant psychiatric or medical conditions which would be compromised by leaving the NTP
5) No current dependence on cocaine, alcohol or drugs other than nicotine
6) Ability to arrange transportation to and from the NTP or physician's office
7) Evidence of a source of stable income
8) Evidence of a stable living situation

Chart audits included a review of admission date, date of birth, initial intake form, history and physical exam records, treatment plans, progress notes, urine toxicology results, program physician and psychiatrist clinical notes, and correspondence from medical providers. In addition, charts were reviewed for evidence of written warnings from the financial or administrative office for non-payment of fees. In cases in which chart audit data was ambiguous or contradictory, consultation was made with clinical or supervisory staff. Finally, clarification from the program physician or psychiatrist was sought if clinical stability was unclear based upon chart review. During two rounds of audits, December 1998 and August 1999, 115 charts were reviewed. Of these 115 patients, 87 (76%) met the eligibility criteria (Table 1). Of the 87 eligible patients, 46 (53%) were enrolled into the study protocol and underwent randomization. As displayed in Table 1, a number of patients who would have otherwise met eligibility declined to participate due to a conflict with their work schedule. Because the pilot project used a model of medication dispensing directly from the physician's office, patients had to be available during daytime hours (e.g. 8:00 to 5:00) to receive medication. For many stabilized patients, who are employed and used to picking up their medication during off hours (e.g.

6:00 AM or 7:00 PM), the restrictions of the physician's office hours appeared to be a deterrent to program participation.

V. Results/Outcomes:

A. Baseline characteristics

Of the 46 enrolled patients, 24 were randomized to remain in the NTP and 22 were randomized to the MM treatment arm. The baseline demographics and clinical characteristics of the subjects are presented in Table 2. The mean age was 41 years in the NTP vs. 42 years in MM. Sixty-seven percent were male in the NTP arm vs. 64% in MM. There were significant differences in the proportion of patients in the NTP group compared with the office-based group who were white, 23/24 (96%), vs. 13/22 (59%); p=.01, who had a history of intravenous drug use, 21/24 (88%) vs. 12/22 (55%); p=.03, and who had previously participated in a opioid detoxification program, 24/24 (100%) vs. 18/22 (88%); p=.05. The majority of the patients in both arms had full-time employment and a high school education. Self-reported lifetime duration of methadone maintenance was 5.8 years in the NTP arm compared with 9.4 in the MM arm. The mean dose of methadone was 70 in the NTP arm and 69 in the MM arm.

B. Treatment retention and Illicit drug use

Treatment retention

In order to ensure patient safety and prevent continued use of illicit substances, criteria were established a priori as evidence of clinical instability and protocol violation. A patient was considered a protocol violator, and returned to the NTP if randomized to the MM arm, if both of the following criteria were met:

1) A random clinical urine sample had evidence of opiates or cocaine or lacked evidence of methadone
2) A repeat urine sample, conducted within one week of the original sample had evidence of opiates or cocaine or lacked evidence of methadone

The proportions of protocol violators by treatment group are presented in Figure 1. Criteria for protocol violation were met in 4/22 (18%) of MM patients compared with 5/24 (21%) of NTP patients (p=NS).

The rates of illicit drug use at anytime during the 6-month treatment period was measured by urine, hair and patient self-report in the two treatment arms. The most conservative measure of abstinence would be a positive result in any of these three categories. Fifty-nine percent (13/22) of MM patients compared with 46% (11/24) of NTP patients had evidence of any illicit drug use during the six month treatment period (p>.05). Fifty-five percent (12/22) of MM patients compared with 42% (10/24) of NTP patients had evidence of any illicit opiate use (p>.05). Twenty-seven percent (6/22) of MM patients compared with 25% (6/24) of NTP patients had evidence of any cocaine use (p>.05). Protocol violation, as described above, occurred in 18% (4/22) of MM patients compared with 21% (5/24) of NTP patients (p>.05). Patients who reported medically prescribed opiate analgesics following medical procedures during the six month study period, and

urine and hair toxicology tests positive for opiates during this period were not considered indicative of illicit opiate use.

The frequency of drug use was investigated by determining the proportion of urine toxicologies that were tested that had evidence of illicit drug use. Overall, there were 673 clinical and research urine toxicologies that were performed during the study. Of these, 63/673 (9%) were positive for opiates and 24/673 (4%) were positive for cocaine. The proportion of opiate positive urine toxicologies for those patients in office-based care was 22/252 (9%) and 41/370 (11%) for those treated in the NTP (p=NS). The proportion of cocaine positive urine toxicologies for those patients in office-based care was 9/251 (4%) and 15/369 (4%) for those treated in the NTP (p=NS).

Hair toxicology results and illicit drug use (Figure 2).
Hair samples obtained at baseline or entry into the study were retrospectively analyzed for evidence of illicit drug use. Despite the fact that all patients met the eligibility criteria of one year of urine toxicology testing that was negative for illicit substances, forty-four percent (20/46) of the subjects overall had baseline hair toxicology positive for opiates or cocaine. Thirty-three percent (15/46) of the baseline samples were positive for opiates and 22% (10/46) were positive for cocaine. When the association between baseline hair toxicology results and subsequent illicit drug use was evaluated (Figure 3) we found that 90% (18/20) of patients with baseline positive hair toxicology tests had evidence of any illicit drug use during treatment, compared with 20% (5/26) of those with baseline hair toxicologies that were negative ($p>.05$). This was true for any opiate use, 85% (13/15) vs. 16% (5/31), and any cocaine use, 60% (6/10) vs. 4% (2/36) ($p>.05$).

Among the 25 patients with baseline negative hair toxicology (Figure 4), 30% (3/10) of the MM patients versus 13% (2/15) of the NTP patients had any evidence of illicit drug use ($p>.05$). Twenty percent (2/10) of the MM patients with baseline negative hair toxicology vs. 13% (2/15) of hair negative NTP patients had any evidence of illicit opiate use during treatment ($p>.05$). Ten percent (1/10) of the MM patients with baseline hair toxicology negative versus 0% of hair negative NTP patients had any evidence of illicit cocaine use during treatment($p>.05$).

C. Patient Satisfaction
The results of patient satisfaction surveys are presented in Figure 5. During the treatment period, 20/22 (91%) of the office-based patients vs. 20/24 (83%) of the NTP patients reported that they were satisfied with the treatment that they received (p=NS). Seventy-three percent (16/22) of the MM patients compared with 13% (3/24) of the NTP patients felt the quality of the care that they received was excellent ($p<.05$). Ninety-one percent of the MM (20/22) patients compared with 58% (14/24) of the NTP patients indicated that in the future they would like to receive their medication in a physician's office. In addition, responses to questions on satisfaction questionnaires revealed that the majority of MM patients felt that the physician's offices were in convenient locations, that they received their medication on time, had convenient appointments, were seen on time, were treated in a manner similar to other patients, rarely felt out of place, and felt that the staff and physicians were courteous and responsive to their concerns.

D. Provider Satisfaction

The results of provider satisfaction surveys are presented in Figure 6.

With respect to provider satisfaction, MM physicians were satisfied with treating 90% (18/20) of patients compared with NTP providers who were satisfied with treating 74% (17/23) of patients ($p>.05$). MM physicians felt that they had a good to excellent rapport with 95% (19/20) of patients compared with 83% (19/23) of NTP providers ($p>.05$). In addition, responses to questions on satisfaction questionnaires revealed that MM physicians felt that their patients were on time, followed clinical advice, were compliant with medications, bottles, and payments, were honest about their drug and alcohol use, and had an excellent attitude toward office staff and other patients. MM physicians did report, however that the MM patients had higher needs for emotional support and more psychosocial stressors compared to their other patients.

E. Functional status

Functional status was measured using the Medical Outcomes Study Short Form-36. This 36 item structured questionnaire measures function in the following realms; physical function, general health, vitality, social, emotional and mental health function. Using this measure, there were no significant differences over time within or between treatment groups in functional status.

F. Use of Health, legal and social services

The use of health, legal and social services was measured by the Addiction Severity Index (ASI) and a detailed Treatment Services Review (TSR). These measures evaluated changes in and use of medical, psychiatric, legal, employment, family/social, drug-related, and alcohol-related services. The use of these services was similar between the two treatment groups and there were no significant changes over time.

G. Effectiveness of physician training

The effectiveness of the training was assessed in several ways. As part of the oversight of this pilot project, monthly on-site reviews were conducted and feedback was provided to physicians and office staff regarding effective and problematic situations and responses using a structured form (appendix III). Some of the issues noted in these monthly sessions are outlined below. In addition to these monthly meetings, the research team met periodically, approximately every 4-5 months during the conduct of the study with the MM physicians to review progress and held a focus group discussion at the completion of the study to gauge, among other things, the perceived effectiveness of the training. Recurrent themes generated in this focus group discussion centered around preparation for requests from detoxification from methadone, the importance of appropriate staff training in the procedures, the possibility of polysubstance abuse including cocaine, the importance of the monthly review regarding clinical and paperwork issues, the appropriate coverage of comorbid psychiatric and psychosocial issues, and the importance of the opportunity to observe an interview with a potential patient prior to beginning to provide MM.

H. Record keeping issues

Office-based medical maintenance with methadone required a series of new record keeping skills by physicians and their offices. Documentation in the physicians' offices was challenging. In particular, record keeping problems were noted in two specific areas; methadone receipt and transfer logs, and DEA methadone order forms.

Each physician's office was required to maintain records relating to the receipt and transfer of the weekly methadone bottles for each patient. This was accomplished through an "On-site bottle log" (see Appendix IV) in which all bottles of methadone were logged in (from treatment program), logged out (to patient), logged back in (empty, from patient), and logged back out (empty, to treatment program). In addition, physicians were required to complete a Drug Enforcement Agency (DEA) order form (DEA Form #222, see Appendix V for instructions) to document the ordering of all bottles of methadone for each patient receiving medical maintenance from their office. Discussion with the New England Region Diversion Program Manager of the DEA resulted in this form being filled out on a monthly basis by the medical maintenance physicians. Compliance with and maintenance of the "On-site bottle log" and the completion of the DEA Form 222 proved challenging. Review of these logs at the clinical sites revealed incorrect documentation of receipt and return of methadone bottles. This problem was solved through reformatting the bottle logs. New forms were created that allowed for documentation of bottle transfer for an individual patient on a monthly basis. Additional education was provided to physicians, office staff, and the hub program nursing staff regarding the appropriate use of the revised forms. Physicians and nurses ultimately responded to educational efforts and reminders regarding correct procedures and the need to turn in this paperwork in a timely manner. Future projects would benefit from providing training on the use of this form and a program of incentives to maintain up to date records.

I. Adverse events

There were no major or unexpected adverse medical events. There were some instances of protocol deviation regarding urine toxicology testing, difficulties with methadone delivery, and theft of blank research forms.

Urine toxicology results. Random urine samples were scheduled to be collected by both nursing and physician staff in the offices and by counselors in the NTP. Protocols were established at each site to ensure that urines were collected and that toxicology results, sent via fax to each office, were reviewed by staff on a timely basis. Despite these efforts there were instances in which urine toxicologies were not collected by program staff and abnormal urine results escaped the notice of clinicians. The majority of these breaches of protocol were noted by the research staff. However, several instances occurred in both treatment conditions in which abnormal clinical urines (e.g. toxicology with evidence of illicit substances, toxicology without evidence of methadone) were not handled according to protocol and were not followed up with increased surveillance via urine toxicology testing.

Methadone delivery. Episodic reports of problems with the timing of methadone delivery were noted by NTP and MM office staff. Constraints on medication storage in the MM offices and the desire to provide patients with their desired dates of medication pick-up required frequent deliveries of methadone from the NTP to the MM offices. Occasionally a patient would present to their MM office at the appropriate time but would have to be told to return later that day because the medication had not been delivered. In addition, some offices found it difficult to anticipate the timing of the methadone deliveries and would have to delay other patient care activities in order to accept the delivered medication.

Theft of research materials. On November 12, 1999 a briefcase belonging to a research assistant on this study was noted to be missing from a project research office. Subject interview packets containing names, study identification numbers, subject payments and telephone numbers for 14 participants were inside of this briefcase. In addition a checklist of interview forms, were among the materials in the missing briefcase. None of the forms had been completed. Neither the materials nor the briefcase were recovered. This incident was presumed to represent a robbery and was reported to all participating parties including the Yale Human Investigations Committee, the participating narcotic treatment program, the Connecticut Department of Mental Health and Addiction Services the Center for Substance Abuse Treatment and all 14 subjects. No adverse repercussions were reported as a result of this theft.

J. Costs

Cost data on the Connecticut Methadone Medical Maintenance Pilot Project will be submitted as an addendum to this report.

VI. Conclusions/Policy Implications/Recommendations

The results of this study demonstrate that provision of methadone maintenance treatment through physician offices for stable, long-term methadone maintained patients (Medical Maintenance) is feasible, comparable in efficacy to continued treatment in a narcotic treatment program with regard to treatment retention, protocol deviation and illicit drug use, and preferred by the majority of patients enrolled in the study. There was interest and willingness to participate in the program among both physicians in the region and patients in the methadone treatment program. After gaining the necessary regulatory approval for the program, there were very few difficulties registering physicians to participate in the program.

Despite the relatively limited experience with methadone maintenance treatment prior to receiving training for most of the physicians who participated, the initial training and subsequent continuing consultation were sufficient to lead to generally quite good adherence to the study protocol and regulatory requirements. The initial training sessions alone, however, were not sufficient to address or anticipate all of the clinical and administrative issues that arose during Medical Maintenance treatment or to lead to complete adherence to all of the regulatory requirements. Physicians and their office staff reported high levels of satisfaction providing Medical Maintenance, and these

provider ratings were consistent with corresponding patient reports of satisfaction with treatment and ratings of the quality of care received in physician offices.

Although the occurrence of episodes of illicit drug use was comparable for patients assigned to Medical Maintenance and standard treatment, overall there was evidence of at least one episode of illicit drug use in many patients enrolled in the study. These results are particularly notable given the stringent study eligibility criteria, which excluded from participation patients with any evidence of illicit drug use while in methadone treatment during the past year. Very few patients became clinically unstable and triggered the criteria for protocol violation and return to standard care, however, and the proportion of patients evidencing significant clinical instability was comparable for both the Medical Maintenance and standard care groups. Results of hair toxicology testing at baseline, which were available only for research purposes and were not used to evaluate eligibility for the study, documented recent illicit opiate or cocaine use in 44% (20/46) of the patients enrolled in the study. Patients with baseline hair toxicology testing were overwhelmingly more likely to show evidence of subsequent illicit drug use during the six-month study than were patients with baseline negative hair tests.

Despite relatively high levels of interest among patients, only a minority of eligible patients enrolled in the program. One of the main barriers to enrollment was the relatively constrained office hours for weekly methadone pick-up available in physician offices compared to the expanded range in the narcotic treatment program. Although not evaluated in this study, dispensing methadone weekly to patients through community pharmacies, which often have considerably longer and more convenient hours (including Saturday and Sunday hours) could provide a relatively simple mechanism for improving the ease of methadone delivery for patients. This approach would still limit the number of take-home methadone doses received by patients to six. It would also continue to require patients to attend a monthly visit with the physician, but a monthly visit would not be as great a deterrent as the requirement for weekly attendance. Pharmacy dispensing would also reduce some of the record-keeping and regulatory requirements for physicians and reduce the costs of delivering methadone bottles from the narcotic treatment program and storing them in physician offices.

The results of the study lead to the following conclusions and policy recommendations:

1. Medical maintenance, using the model developed for this program, is feasible to implement, appealing to both patients and physicians, and comparable in efficacy to continued treatment in narcotic treatment programs for clinically stable patients who have been maintained on methadone maintenance treatment for more than one year. The model developed facilitates ongoing oversight of patients receiving Medical Maintenance, easy consultation about clinical issues, and simplified transfer back to the narcotic treatment program of patients experiencing clinical deterioration or otherwise requiring this level of care.

2. Hair toxicology testing prior to entry into Medical Maintenance identifies most otherwise eligible patients who later show evidence of illicit drug use during the six

months following treatment entry. Baseline hair toxicology test negative for illicit drug use should be added to the clinical eligibility criteria for Medical Maintenance if the program is expanded.

3. In addition to training prior to certification for providing Medical Maintenance, continuing consultation and supervisory oversight is also needed for physicians providing Medical Maintenance.

4. Dispensing methadone through community pharmacies could reduce burdens on patients, physicians and the narcotic treatment programs.

5. The current research investigated a model of Medical Maintenance that used the narcotic treatment program as the treatment "Hub". While there have been proposed alternate models that use another entity, such as the State Methadone Authority, as the hub, the current pilot project did not investigate these possibilities and therefore cannot completely inform a discussion regarding the merits of one system over another.

Appendix 1

Medical Maintenance Project
MD Progress Note

Client Name _____ ID# _____

Date ___/___/___ Week# ___ ☐ No show

Scheduled Visit Time _____ Actual Visit Time _____

Medical Management

Heroin/Cocaine or other illicit drug use since last visit?

_____
_____
_____

Symptoms or signs that might imply relapse? (Changes in mood, physical appearance)

_____
_____
_____

Since the last visit, are there any problems with the following:

		If yes, explain
Drug Use	☐ Yes ☐ No	_____
Alcohol Use	☐ Yes ☐ No	_____
Psychiatric	☐ Yes ☐ No	_____
Medical	☐ Yes ☐ No	_____
Employment	☐ Yes ☐ No	_____
Social/Family	☐ Yes ☐ No	_____
Legal	☐ Yes ☐ No	_____

Any new problem to add to Treatment Plan Review ☐ Yes ☐ No _____

_____

Plan to address any new problem _____

_____
_____

Participation in Narcotics Anonymous or
Alcoholics Anonymous since last visit? ☐ Yes ☐ No

Length of session _____

_____
Physician Signature

Appendix III

Medical Maintenance Project
MD monthly visit

Date _____
M.D. _____
# of patients _____

Specific concerns or areas to address:

_____
_____
_____
_____
_____

Specific highlights in past month:

_____
_____
_____
_____

Topics discussed in counseling sessions:

_____
_____
_____
_____

Chart review:
Notes available. ☐ Yes ☐ No _____
Notes filled out completely. ☐ Yes ☐ No _____
Notes filled out correctly. ☐ Yes ☐ No _____
New problems included in Treatment Plan Review
☐ Yes ☐ No _____

Bottle-log review:
Log available. ☐ Yes ☐ No _____
Log filled out completely. ☐ Yes ☐ No _____
Log filled out correctly. ☐ Yes ☐ No _____

DEA Form 222 review:
Form 222 available. ☐ Yes ☐ No _____

Form 222 out completely. ☐ Yes ☐ No _____
Form 222 out correctly. ☐ Yes ☐ No _____

Notification of patient assignment	☐ No problem ☐ Problem_____
Scheduling	☐ No problem ☐ Problem_____
Patient on time	☐ No problem ☐ Problem_____
Interaction with staff	☐ No problem ☐ Problem_____
Interaction with patients	☐ No problem ☐ Problem_____
Manual	☐ No problem ☐ Problem_____
Patient binder	☐ No problem ☐ Problem_____
CCCI chart	☐ No problem ☐ Problem_____
Methadone transfer	☐ No problem ☐ Problem_____
Bottle transfer	☐ No problem ☐ Problem_____
Methadone storage	☐ No problem ☐ Problem_____
Bottle log	☐ No problem ☐ Problem_____
Patient visit	☐ No problem ☐ Problem_____
Counseling	☐ No problem ☐ Problem_____
Patient clinical status	☐ No problem ☐ Problem_____
Phone calls	☐ No problem ☐ Problem_____
Patient satisfaction	☐ No problem ☐ Problem_____
Methadone dispensing	☐ No problem ☐ Problem_____
Urine collection	☐ No problem ☐ Problem_____
Paperwork, documentation	☐ No problem ☐ Problem_____
Research assessments	☐ No problem ☐ Problem_____
Interaction with CCCI	☐ No problem ☐ Problem_____

Appendix IV

Patient Name_____ Month_____ Year_____

Date Bottles received from CCCI	**# bottles received from CCCI**	**Dose**	**Signature (MM Nurse)**	**Date Bottles returned to CCCI**	**# bottles returned to CCCI**	**Condition Good Damaged**	**Signature (CCCI Nurse)**
/ /		mg.		/ /			
/ /		mg.		/ /			
/ /		mg.		/ /			
/ /		mg.		/ /			
/ /		mg.		/ /			
/ /		mg.		/ /			

Monthly Total: ___ bottles at ___ mg.
Monthly Total: ___ bottles at ___ mg.

Note: 1) Please fill out one form per patient per month.
2) Each row should document the receipt and return of one shipment of medication.
3) Receipt and return dates are scheduled to occur at one week intervals.
4) Shipments that span two calendar months should be recorded on the first months form.

Appendix V

Medical Maintenance Project

Form 222 Instructions

1. Each physician must fill out a DEA-222 on a monthly (calendar) basis. That is, there should be a separate form for the months of May, June, July, etc. This form should represent bottles ordered for all patients cared for by a physician during that calendar month.

2. Fill out the forms completely.
   To: (*Name of Supplier)* **Connecticut Counseling Centers, Inc.**
   Street Address: **4 Midland Road**
   City and State: **Waterbury, Ct. 06705**
   Date: **Enter current date**

3. Fill out each line noting number of packages (bottles) ordered for each size of package (dosage).

4. Name of item: **Methadone**

5. Enter the number of the last line completed. **(1-10)**

6. Sign the form.

7. Keep the Purchaser's copy (Copy 3, blue).

8. Attach the monthly bottle log for each patient to this copy and store on-site to be available for DEA inspection. These records need to remain on-site for three years.

9. Forward the Suppliers copy (Copy 1, brown) and the DEA copy (Copy 2, green) to Connecticut Counseling Centers, Inc.

Table 1. Assembly of study participants

			n
Referred subjects			115
Exclusions			
Medical or psychiatric comorbidity		18	
Positive urine toxicology		9	
Financial instability		1	
Eligible subjects			87
Declined Participation		41	
Conflict with work schedule	19		
Perceived inconvenience	4		
Not interested	2		
Not randomized to MM	1		
Unknown	15		
Enrolled subjects			46

Table 2. Baseline demographic and clinical characteristics of patients receiving methadone in a narcotic treatment program (NTP) and physician's offices (MM)

Characteristic	NTP n = 24	MM n = 22	P
Age, years, mean	41	42	.38
% Male, (n)	67% (16)	64% (14)	.92
% White, (n)	96% (23)	59% (13)	.01
% Full-time employment, (n)	75% (18)	59% (13)	.40
Monthly income, $, mean (range)	1751(1337)	1311(849)	.21
% Never married, (n)	38% (9)	36% (8)	.82
% High School Education or greater, (n)	88% (21)	86% (19)	.91
% Prior attempted detoxification, (n)	100% (24)	82% (18)	.05
% History intravenous drug use, (n)	88% (21)	55% (12)	.03
Lifetime methadone maintenance, years, mean	5.8	9.4	.07
Current methadone maintenance, years, mean (range)	4.6(1-14)	3.4(1-9)	.24
Methadone dose, milligrams/day, mean (range)	70 (25-100)	69(20-100)	.91
% Known HIV positive, (n)	8% (2)	27% (6)	.09
SF-36 score, mean (SD)	113(21)	115(19)	.75
Center for Epidemiological Studies Depression Scale (CES-D) score, mean (SD)	11 (9)	10 (8)	.43