STANDARD MEDICATION MANAGEMENT FOR BUP/NX TREATMENT OF OPIOID ANALGESIC DEPENDENCE FOR USE IN NIDA CTN-0030

Based on:

Manual for Standard Medical Management of Opioid Dependence with Buprenorphine
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Manual for Standard Medical Management of Opioid Dependence with Buprenorphine

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Overview of the CTN-0030 SMM manual

This manual describes the procedures involved in the optimal delivery of Standard Medical Management (SMM) of opioid analgesic dependence with buprenorphine. The manual is based upon the Manual for Standard Medical Management of Opioid Dependence with Buprenorphine By David A. Fiellin, M.D., Michael V. Pantalon, Ph.D., Richard S. Schottenfeld, M.D., Lynn Gordon, R.N., M.P.A., and Patrick G. O'Connor, M.D., M.P.H. at Yale University. Originally the manual was designed for routine use by a specially trained physician and Registered Nurses in a primary care setting. For CTN-0030, the manual was revised slightly in structure to conform to the study design of CTN-0030 including variations in visit schedule, length of treatment, two-phased study design, and the study population (opioid analgesic dependent in the absence of heroin dependence, with and without chronic nonmalignant pain).

This manual describes the general and specific aims of SMM and details a structured format for conducting the initial and subsequent SMM sessions. Each session will be conducted on an individual basis and last approximately 15 minutes and no longer than 20 minutes [except the first session of each phase (induction visit), which is 60 minutes].

Use of the SMM manual

This manual is designed to provide the reader with an overview and rationale for the skills needed to provide standard medical management of opioid analgesic dependent patients with buprenorphine. The material in this manual is designed to be augmented by didactic sessions, additional references, and practice cases to assist practitioners in providing the treatment in a competent manner. This manual should be used as a reference to be reviewed repeatedly during the treatment of opioid analgesic dependent patients.

This manual is one of several documents to be used by CTN-0030 SMM clinicians during the CTN-0030 study. CTN-0030 SMM clinicians must be certified as competent to deliver SMM. The details of training and certification are detailed in the CTN-0030 SMM training plan. Additionally, SMM clinicians must read and maintain a current copy of the CTN-0030 study protocol, CTN-0030 manual of operations, and CTN-0030 training binder.

I. Theory of Standard Medical Management (SMM)

SMM is a relatively brief (i.e., 15 minutes per visit) manual-guided, medically focused counseling approach to the treatment of opioid analgesic dependent individuals. SMM as described in this manual is provided in weekly individual sessions by a specially trained practitioner.

A. Theory of opioid dependence

Opioid dependence is a state characterized by behavioral and physiologic symptoms that result in continued use of opioid substances. The hallmarks of opioid dependence include physiologic

tolerance to opioid substances and prolonged self-administration of opioid substances despite significant adverse effects. The physiologic and behavioral manifestations result from changes in brain receptor function and neuro-chemical signaling induced by chronic exposure to opioid agonist substances such as opioid analgesics.

B. Theory of the treatment of opioid dependence

In order to significantly reduce illicit opioid use or to achieve complete abstinence from such drugs, both biological and psychological/social (i.e., psychosocial) aspects of opioid dependence must be actively addressed. Opioid dependent individuals attempting to achieve either of these two goals require interventions to help them successfully cope with both biological (physical withdrawal and cravings for opioid analgesics), as well as psychological and social triggers of drug use, such as family problems and friends who use drugs, respectively. In SMM, buprenorphine maintenance targets the former, while brief, weekly counseling sessions assist patients with the latter. Buprenorphine, a synthetic opioid, acts a safe replacement for opioid analgesics and reduces the physical withdrawal and craving frequently associated with opioid dependence. The brief counseling sessions involve repeated support for and monitoring of medication compliance, and the provision of advice regarding established methods for coping with psychological and social factors that lead to drug use. The practitioner advises patients to attend self-help groups, avoid situations known to trigger drug use, change their daily lifestyle so that drugs can be avoided and other problems related to drug use, such as those pertaining to family life, employment, or health issues, can be addressed.

SMM is designed to encourage adherence to the medications prescribed to treat opioid dependence (i.e., buprenorphine maintenance) and to encourage patients to make the behavioral and lifestyle changes necessary to facilitate long-term abstinence and recovery.

C. Treatment of Opioid Dependence

1. Opioid agonist maintenance treatment

Much of the research on opioid agonist maintenance therapy is drawn from heroin addiction treatment research. However, there is no evidence to suggest that the mechanics of opioid agonist therapy differ for those addicted to opioid analgesics. Opioid agonist substitution and maintenance treatment, using methadone, LAAM or buprenorphine, is the most effective treatment for opioid dependence. Maintenance treatment with these long-acting agonists at the mu opioid receptor targets the major medical or biologic factors perpetuating opioid addiction. Continuous, steady-state opioid maintenance prevents withdrawal, which is one of the major factors perpetuating addiction. At sufficiently high doses, opioid agonist maintenance treatment also relieves craving for opioids (Dole, 1988). Gradual increases in the dose of the opioid agonist during maintenance treatment leads to the development of tolerance to opioids so that at sufficiently high maintenance doses, the euphoric effects of illicit opioid doses are blocked or attenuated. Finally, for patients who are self-medicating psychological and emotional distress with opioid analgesics, continuous, steady-state opioid agonist maintenance will be even more effective than intermittent illicit use in reducing psychological and emotional distress. Thus,

opioid agonist maintenance treatment blocks or attenuates virtually all of the reinforcing pharmacologic effects of opioid use, which, from a learning theory perspective, will lead to extinguishing the behavior (opioid analgesic self-administration).

There are a number of important advantages of using buprenorphine or methadone compared to opioid analgesics, for opioid agonist maintenance treatment. First, these medications may be administered sublingually or orally, and thus substitute a less dangerous route of administration for the more dangerous practice of injection drug use. Sublingual or oral administration also leads to a more gradual rate of rise of plasma (and brain) opioid levels. Since the rate of rise is associated with the intensity of euphoria or rush associated with drug use, sublingual or oral ingestion of buprenorphine or methadone, respectively, produces substantially less of a rush than intravenous, smoked or intranasal opioid analgesics use. Because buprenorphine is a partial agonist at the mu receptor, it has even a lower abuse liability than methadone. Second, while opioid analgesics must be used at least two to three times each day to prevent withdrawal, buprenorphine has been shown to be effective when administered as little as three times per week (methadone must be given daily). However, in this protocol, buprenorphine is taken daily. Substituting a longer acting for a shorter acting opioid thus reduces the amount of time each day an addicted patient focuses on obtaining and using drugs, which is one of the hallmarks of addiction. Third, because of the long duration of activity of these medications, plasma levels fluctuate within a relatively small range throughout the day, and maintenance treatment causes very little or no fluctuations in mood, cognition, or alertness. In contrast,plasma levels with short-acting opioid analgesics (e.g., Percocet, Vicodin) fluctuate much more widely in relation to repeated use. With the use of these drugs, patients generally experience a repeated cycle of incipient withdrawal (anxiety, early withdrawal symptoms) followed by symptom relief.

The effectiveness of opioid agonist maintenance treatment has been extensively documented through randomized clinical trials, quasi-experimental studies, and program evaluations. Methadone was the first medication approved for maintenance treatment. However, most such trials have examined patients dependent on heroin, not those dependent exclusively on opioid analgesics. The original studies conducted by Dole and Nyswander showed astonishingly good results in comparison to historical controls (Dole, 1965). Typically, more than 90% of patients relapse to heroin use within one year following detoxification. Yet, after two years of methadone treatment, only 13 of the initial 128 patients enrolled had been discharged for drug abuse or antisocial behavior. Of the 107 patients remaining in treatment, 71% were steadily employed or in school, and none had relapsed to heroin use. More recently, one-year retention rates in methadone programs still average 50% or more, far exceeding retention rates for any other treatment approach. Large-scale follow-up studies (e.g., TOPS and DARP) demonstrate substantial reductions in illicit drug use and criminal activity following methadone maintenance treatment entry (Hubbard, 1989; Simpson and Sells, 1990). Natural social experiments provide additional evidence of the effectiveness of methadone maintenance treatment. Following closure of the only methadone program in one California city in 1976, 54% of patients terminated from the program became readdicted to heroin within two years. In comparison, 31% of similar patients from a methadone program in another county that remained in operation became readdicted to heroin during this period. Arrest rates and incarceration rates among patients affected by the program closure were double the rates in the comparison group (Anglin, 1989).

As suggested by the results of the Swedish methadone study, methadone maintenance is also associated with a substantial reduction (about 75%) in the excess annual mortality rate experienced by heroin addicts. In a study conducted in Philadelphia in 1989-1991, 3.5% of methadone maintained patients became infected with HIV during an 18-month period, while 22% of untreated heroin addicts became infected during the same 18-month period (Metzger, 1993).

Buprenorphine is a partial opioid agonist. The partial agonist properties give it a similar action to methadone, and results in buprenorphine's ability to prevent opioid withdrawal, though with lower potential for abuse (and thus,presumably, diversion) compared with methadone, . This, combined with a long duration of action and a low potential for overdose make buprenorphine a unique medication and convey distinct advantages over current opioid agonist therapies. For instance, in comparison to methadone, which requires daily dosing, buprenorphine can be taken on a three times per week schedule creating greater flexibility for patients (although it is taken daily in this protocol).

2. The Role of Counseling in Opioid Agonist Maintenance Treatment

Buprenorphine and methadone target the major medical or biologic factors perpetuating addiction, but the efficacy of opioid agonist maintenance treatment can be substantially improved by also addressing behavioral, social, and psychological factors that contribute to continued drug use, relapse and addiction. McLellan and his colleagues (1993) found that weekly drug counseling markedly improved treatment outcome compared to minimal counseling in patients maintained at a standardized methadone dose who were randomly assigned to counseling level. Patients who received enhanced services (on-site medical care and vocational assistance) in addition to weekly drug counseling had the best outcomes overall, but weekly drug counseling was most cost-effective (Kraft, 1998). Drug counseling is used to encourage patients to make lifestyle changes that reduce their contact with drugs and drug users and increase their involvement in drug-free social, recreational, vocational and family activities. Drug counseling is also used to address the many social, legal, work, health, psychological and family problems that may have resulted from years of addiction.

SMM is designed to provide patients the basic advice about the elements of opioid dependence treatment (opioid agonist maintenance pharmacotherapy and lifestyle and behavioral changes) and encouragement to adhere to treatment recommendations that is needed for treatment to be effective. The brief, weekly counseling sessions in SMM provide an opportunity for repeated support for and monitoring of medication compliance, evaluation of the adequacy of medication dose, withdrawal, and adverse effects, and for providing advice regarding effective methods for addressing behavioral, psychological and social factors that contribute to drug use. Thus, early in treatment, the practitioner may focus predominantly on helping the patient adjust to the medications (e.g., monitoring withdrawal or other adverse symptoms, encouraging the patient to tolerate any discomfort and curtail illicit drug use while the maintenance dose is being adjusted). As treatment progresses, the practitioner may focus more on educating the patient about the social and behavioral factors perpetuating addiction and encourage behavioral and lifestyle change. Specifically, the practitioner will encourage the patient to attend self-help or 12-step groups, avoid situations known to trigger drug use, and make other lifestyle changes so that drugs

and drug users can be avoided and drug-free activities and relationships are promoted. The practitioner may also help identify other problems related to drug use, such as those pertaining to family life, employment, or health issues, and refer patients to specialty services (e.g., vocational counseling) to address these problems.

SMM is thus similar to a model of treatment frequently used by primary care practitioners for a number of medical diseases, including diabetes, hypertension, and coronary artery disease. Like opioid dependence, these illnesses all have both prominent biological and psychosocial components that can be individually addressed in an effective manner. For example, insulin is very helpful in controlling blood sugar, but the patient also needs to learn how to monitor blood sugar and to follow diet, nutrition and exercise instructions. Similarly, in SMM, the counseling component is designed to provide patients with more information about their disease - drug addiction - and to inform them about ways to manage it most effectively. Specifically, in the same way that one might discuss situations that may trigger an exacerbation of a patient's asthma, clinicians caring for patients with opioid dependence can discuss the importance of avoiding significant triggers for drug use (e.g., people they frequently buy drugs from) to help patients achieve or maintain abstinence.

II. Overview of SMM

A. Goal of SMM

The goal of SMM is to assist patients in achieving abstinence from illicit opioids.

B. Treatment elements

The following is a list of the critical SMM elements:

1. Provision of buprenorphine
2. Monitoring of compliance with buprenorphine
3. Monitoring of patients' drug use, symptoms, and progress
4. Education regarding opioid dependence and buprenorphine treatment
5. Encouragement to achieve abstinence from opioids and to adhere to all treatment recommendations
6. Encouragement to attend self-help groups
7. Provision of brief advice modeled on the education provided in standard drug counseling, such as encouraging patients to make lifestyle changes that support recovery, and to avoid potential triggers of drug use
8. Identification and treatment of medical complications of opioid use
9. If appropriate, monitoring of chronic pain status and referrals to speciality services (e.g. pain clinic) if necessary

10. Referrals to specialty services in the community (e.g., vocational, legal, housing or social services) if necessary

C. Expected outcome of treatment

Abstinence from illicit opioid use is the primary desired outcome of SMM. Concomitant with this outcome, treatment is expected to decrease or eliminate many of the negative effects of opioid dependence including the medical, legal and social problems. Experience indicates that patients who are abstinent have improved social role functioning and decreased psychosocial problems with treatment. In addition, a reduction in illicit drug use results in a decreased risk of infectious complications, especially for injection drug users.

D. What should not be expected from SMM?

SMM is a focused, medically-based psychosocial intervention designed to foster abstinence from illicit opioids. As such, SMM does not provide extensive social or psychiatric services that some patients with opioid dependence may need. Therefore, SMM should not be expected, by itself, to provide adequate treatment for patients with significant comorbid psychiatric disorders (i.e., Major Depression or Schizophrenia). In addition, it is expected that social services such as social workers, domestic violence services and housing agencies will be available to provide many services that go beyond the scope of SMM.

E. How is SMM similar to or different from other treatments?

SMM is similar to other treatments that combine medication with brief counseling and education. For instance, SMM is not unlike the treatment that is offered to a patient newly diagnosed with diabetes in which oral hypoglycemic medication or insulin are combined with recommendations about lifestyle changes that will help the patient achieve their goal of good blood sugar control. SMM is also similar to brief intervention techniques by primary care physicians that have been effective in reducing alcohol consumption in problem drinkers (Fleming, 1997) and in alcohol dependent patients receiving naltrexone in a primary care setting (O'Connor, 1998).

The difference between SMM and formal drug counseling is primarily in duration and content. SMM provides brief focused advice on a limited range of topics whereas drug counseling is designed to spend an extended period of time on a broad range of topics.

III. Roles and responsibilities in SMM

A. Who is qualified to implement SMM

SMM should be administered by clinicians who have received training in the provision of buprenorphine for maintenance and the components of treatment as outlined in this manual.

B. Training

Training for SMM should include review of this manual, lectures on the epidemiology, physiology, and psychology of opioid dependence, case discussions and role plays.

IV. Sequence of events in SMM

A. Description of Phase 1 and Phase 2

1. PHASE 1

		SMM only	SMM + EMM	BUP/NX dose
Month 1	Week 1 **2 visits**	Induction: 1 hour SMM Follow-up: 15-20 minute SMM	Induction: 1 hour SMM 45 minute (approx.) EMM Follow-up: 15-20 minute SMM 45 minute (approx.) EMM	Flexible
	Week 2	15-20 minute SMM	15-20 minute SMM Two 45 minute (approx.) EMM	Flexible
	Week 3	15-20 minute SMM	15-20 minute SMM Two 45 minute (approx.) EMM	Taper
	Week 4	15-20 minute SMM	15-20 minute SMM Two 45 minute (approx.) EMM	Taper
Month 2	Week 5			
	Week 6	15-20 minute SMM	15-20 minute SMM Two 45 minute (approx.) EMM	None
	Week 7			
	Week 8	15-20 minute SMM	15-20 minute SMM Two 45 minute (approx.) EMM	None
Month 3	Week 9			
	Week 10	(follow-up visit only - no treatment)	(follow-up visit only - no treatment)	None
	Week 11			
	Week 12	(follow-up visit only - no treatment)	(follow-up visit only - no treatment)	None

2. PHASE 2

		SMM only	SMM + EMM	BUP/NX dose
Month 1	Week 1 **2 visits**	Induction: 1 hour SMM Follow-up: 15-20 minute SMM	Induction: 1-hour SMM and 45-minute EMM Follow-up: 15-20 minute SMM and 45-minute (approx.) EMM	Flexible
	Week 2	15-20 minute SMM	15-20 minute SMM two 45 minute (approx.) EMM	Flexible
	Week 3	15-20 minute SMM	15-20 minute SMM two 45 minute (approx.) EMM	Flexible
	Week 4	15-20 minute SMM	15-20 minute SMM two 45 minute (approx.) EMM	Flexible
Month 2	Week 5	15-20 minute SMM	15-20 minute SMM two 45 minute (approx.) EMM	Flexible
	Week 6	15-20 minute SMM	15-20 minute SMM two 45 minute (approx.) EMM	Flexible
	Week 7	15-20 minute SMM	15-20minute SMM 45-minute (approx.) EMM	Flexible
	Week 8	15-20 minute SMM	15-20minute SMM 45-minute (approx.) EMM	Flexible
Month 3	Week 9	15-20 minute SMM	15-20minute SMM 45-minute (approx.) EMM	Flexible
	Week 10	15-20 minute SMM	15-20minute SMM 45-minute (approx.) EMM	Flexible
	Week 11	15-20 minute SMM	15-20minute SMM 45-minute (approx.) EMM	Flexible
	Week 12	15-20 minute SMM	15-20minute SMM 45-minute (approx.) EMM	Flexible
Month 4	Week 13	15-20 minute SMM	15-20 minute SMM	Taper
	Week 14	15-20 minute SMM	15-20 minute SMM	Taper
	Week 15	15-20 minute SMM	15-20 minute SMM	Taper
	Week 16	15-20 minute SMM	15-20 minute SMM	Taper
Month 5	Week 17			
	Week 18	(follow-up visit only - no treatment)	(follow-up visit only - no treatment)	None
	Week 19			
	Week 20	(follow-up visit only - no treatment)	(follow-up visit only - no treatment)	None
Month 6	Week 21			
	Week 22	(follow-up visit only -no treatment)	(follow-up visit only - no treatment)	None
	Week 23			
	Week 24	(follow-up visit only - no treatment)	(follow-up visit only - no treatment)	None

B. Phase 1 SMM induction visit

The initial patient visit will provide an opportunity for the physician to meet the patient. Prior to the first session the clinician will review the patient's intake packet to become familiar with prior medical, psychiatric and substance abuse history. The first visit should last approximately an hour. The clinician will spend approximately 45 minutes with the patient and will be responsible for reviewing the patient's medical, psychiatric and substance abuse history in detail and reviewing the evidence in support of the diagnosis of opioid dependence. Following this the physician will briefly review a treatment plan that includes all of the critical elements of SMM. Finally, it will be an opportunity to and to establish rapport, and reinforce compliance with the program and treatment plan as outlined below.

V. Components of the first SMM session

a. Establish rapport with the patient
b. Review medical, psychiatric, and substance abuse problems
c. Review diagnosis with patient
d. Develop the treatment plan
e. Advise abstinence from all drugs
f. Refer to self-help group
g. Other referrals
h. Delineate and reinforce the program guidelines
i. Answer any questions the patient may have

A. Establish rapport with the patient

One of the critical aspects of the first SMM session is establishing rapport with the patient. Patients with opioid dependence may have had negative experiences (inadequate pain relief, prejudiced attitudes) in health care settings in the past and it is important to reinforce the concept that they have a medical condition that requires treatment. A number of approaches can help to establish rapport including the use of empathy and an assessment of the patient's motivation and goals.

B. Review medical, psychiatric and substance abuse problems

After reviewing the intake packet, which includes background information, previous treatment attempts, diagnostic formulation, etc. and the physician’s assessment, the clinician interviews the patient about his/her medical, psychiatric, and substance abuse history. The clinician should clarify significant findings (e.g., long history of methadone maintenance treatment).

In the process of assessing the patient's symptoms and experience of their substance abuse, the clinician should monitor for adverse events, concomitant medications, and other safety issues as described in the CTN-0030 Manual of Operations.

1. Review of Medical Problems

Primary Objectives: The primary objectives of this review are for the clinician (1) to be aware of the patient's past medical history and specific diagnoses that have resulted from the patient's prior substance abuse. (NOTE: The clinician may already have some awareness of these issues if they were the clinician who completed the baseline assessment medical history and physical exam, but a review of these issues is appropriate.) and (2) to be aware of any chronic pain problems that may exist. Such pain problems may influence the patient's recovery from substance abuse OR cessation of opioids may require referral to a pain specialist or primary care provider as a result of increase in physical pain.

In patients with any history of injection drug use (note: individuals with history of heroin injection will be excluded from this study) there should be a discussion of prior episodes of cellulitis, abscesses, endovascular infections, including endocarditis, septic arthritis and their complications. While these medical conditions may have resolved, it is useful to reiterate the adverse consequences of persistent substance use to reinforce motivation for abstinence.

Because of the increased risk of viral infections including HIV and hepatitis (B and C) there should be discussion of hepatitis screening and HIV testing and status with all patients. Prior test results should be verified and referral for HIV counseling and testing made for those who have an undetermined status. Finally, there should be discussion between the clinician and patient concerning the need for immunization against Hepatitis B, Tetanus, and Pneumococcus.

Patients who abuse illicit drugs are at increased risk for sexually transmitted diseases because of the lack of inhibition that occurs during use and because of the exchange of sex for money or drugs that can occur. A frank discussion of sexual practices (number of partners, specific activities, use of barrier methods) combined with acknowledgment and acceptance that the patient may have engaged in high risk behavior that they now regret, can help elicit the appropriate history. Additional routine screening for symptoms of sexually transmitted diseases is also recommended.

In addition to these complications of substance use, there should be an assessment of opioid withdrawal symptoms. Withdrawal symptoms include, but are not limited to, craving, restlessness, insomnia, irritability, yawning, muscle cramps, rhinorrhea (runny nose), lacrimation (tearing), piloerection (goose-flesh), nausea, emesis and diarrhea. Objectively withdrawal can be noted using the COWS (see CTN-0030 Manual of Operations) and by an increase in vital signs including fever, tachycardia and hypertension. By establishing symptoms directly related to substance use and opioid dependence the clinician can identify subjective targets that treatment will relieve with time (e.g., craving, withdrawal symptoms) and monitor buprenorphine's effect on these reactions. This will serve to set the stage for a discussion about how the medication works (see "Rationale for Buprenorphine" section).

2. Review of Medications

Any prescribed medications or the use of over the counter medications should be recorded. Patients should be told that if they require an analgesic while on study medication, their doctor should be advised that they are on buprenorphine. Patients will be provided with an emergency wallet card identifying the person as taking buprenorphine.

In general, it is important to coordinate prescription medication use and all other medication use with the clinical team. The use of non-prescription medication that the patient may take under ordinary circumstances such as aspirin or acetaminophen for headache or laxatives for constipation is acceptable, but the use of prescription opioid medication is not allowed without consultation with the clinician. For appropriate adjunctive medications, please refer to the CTN-0030 Operations Manual.

3. Review of Psychiatric Problems

Primary Objective: The primary objective of this review is for the clinician to be aware of the patient's past psychiatric history and current problems in order to be alert to any problems that might emerge during treatment.

There is an increased incidence of psychiatric disorders in patients with substance use disorders. While patients with acute psychosis or unstable severe psychiatric illness and comorbid opioid dependence are not appropriate for SMM (and will be excluded during the baseline assessment), some patients may have a history of psychiatric care that predates treatment. Recognizing that patients may self-treat with illicit substances for psychiatric symptoms can help providers explore prior symptoms and monitor for the emergence of symptoms with treatment.

4. Substance Use Problems

Primary Objective: The primary objective of this review is for the clinician to be aware of the patient's current pattern of drug use.

This assessment is done in an effort to ascertain the severity of the patient’s substance abuse problem, so that the practitioner may establish a “benchmark” against which to assess improvement during treatment, as well as to elicit “motivators” for the patient, and to determine whether there may be a need for referrals to other services.

This information should be detailed in the intake package and the physician's initial note.

This assessment includes how much, how often, when, with whom, and in response to what environmental cues, drugs are used. It also includes an assessment of negative social, family, legal, and vocational consequences related to the patient’s drug use. Substance abuse may have its most severe adverse effects on patients’ family social, and/or vocational functioning, and may be associated with criminal activities, arrest and incarceration. Problems in these areas may also

seriously interfere with the patient's ability to remain in treatment. It is thus important to review the patient's current social, vocational, and living situation, and prior history.

The clinician should summarize all of the above in an effort to motivate the patient for change. The areas that should be summarized include the patient's reasons for seeking treatment and wanting to quit illicit drug use, the problems that have occurred as a result of his/her drug use, and the things that have worked for the patient in the past.

When summarizing past treatment efforts, the clinician should highlight positive outcomes and the specific behaviors the patient engaged in to achieve these outcomes. Summarizing previous efforts to achieve abstinence will help to increase the patient's motivation for treatment. For example, if a patient was able to remain abstinent from heroin for a period of 2 months following three separate detoxification programs, the practitioner should praise the patient for this and ask how the patient was able to do this. The clinician should then summarize the behaviors the patient reports as instrumental in achieving abstinence and discuss the importance of engaging in these behaviors during the present treatment program. The practitioner should also ask about the things that prevented the patient from maintaining abstinence for longer periods, empathizing with the patient regarding the situations that acted as obstacles to continued abstinence (e.g., marital dispute). Then the clinician should ask how the patient will be able to prevent these obstacles from getting in the way of their progress again.

C. Review diagnosis with patient

As in the care of patients with other chronic medical conditions, the clinician should briefly summarize the evidence in support of the diagnosis of opioid dependence and conduct a discussion of its medical basis.

SAMPLE DIAGNOSTIC REVIEW

"Based on your intake and the information you've given me, you have used hydrocodone since age 18, and it appears that it has greatly affected your life. Your drug use made it difficult for you to finish school or become employed; you've made a number of unsuccessful attempts at quitting and the amount of your use has steadily increased; you experience symptoms of withdrawal when you stop using. Taken together, these problems would be classified as opioid dependence, which is a treatable problem given the right combination of medication and discussions about other ways to achieve abstinence from all drugs."

A discussion of opioid addiction as a chronic disease legitimizes seeking medical care for opioid use per se and not just for its medical consequences. The comparison of opioid addiction to other chronic diseases, such as diabetes or hypertension, whose treatment also requires behavioral changes, reinforces the fact that abstinence from opioids and taking agonist medications is therapy, not punishment, and not merely "a crutch." Understanding opioid use as a disease and not as an expression of personal inadequacy or lack of will power allows the patient to identify with the healthier aspects of his/her personality and to address the substance abuse with less guilt.

D. Develop the treatment plan

The treatment plan is designed to link the problems due to opioid dependence noted in the assessment to specific actions. For SMM patients, the primary problem is opioid dependence and the core of the SMM treatment plan is medication compliance and brief counseling. The counseling is designed to provide support for patient's efforts at making lifestyle changes, NA attendance, avoiding drug triggers and following up on referrals.

Once the diagnosis of opioid dependence has been established based on the assessment, the clinician gives the patient a rationale for treatment with buprenorphine and SMM. A clear and readily understandable explanatory model of how and why treatment works can help the patient successfully comply with and benefit from the program. Rationales should be presented in the patient's own language and discussion of the patient's concerns and questions should be actively facilitated.

It is useful to provide the patients with the rationale for each of these components when discussing the treatment plan.

Rationale for the Phase One Buprenorphine Taper

The goal of reviewing the rationale for the Phase One buprenorphine taper is to help patients see the study as proceeding in phases. Since patients who enter the study have expressed a desire to stop using opioids, the initial approach that is most commonly used by buprenorphine-certified physicians is to taper the patient from opioids, using buprenorphine. Indeed, detoxification is the prevailing practice among physicians using buprenorphine, according to a survey of 10% of all physicians who have been trained to use buprenorphine (CR Schuster, personal communication). The patient should be told that he/she will be stabilized on buprenorphine for two weeks, then gradually tapered off the medication over a two-week period.

There is some evidence that a substantial minority of opioid-dependent patients who undergo even a brief detoxification from buprenorphine show substantial improvement. For example, Gandhi et al. (2003) examined 123 heroin-dependent men and women aged 18-25 years, who entered an outpatient buprenorphine 3-day detoxification program. Termination of buprenorphine was associated with dropout from treatment of all patients by day 10. However, at one-month follow-up, 75 of 119 participants located reported either no use of heroin (n=44, 46%) or reduced use of heroin (n=31, 33%). This trend toward reduced opioid use was maintained at 3- and 6-month follow-ups, despite lack of participation in any formal treatment for substance abuse. These are significantly better outcomes when compared with outcomes from two other studies of brief buprenorphine detoxification in older heroin-dependent individuals (mean age = 35). Katz et al. (2004) showed an 88% relapse rate by one week following detoxification, and Kakko et al. (2003) found that all 20 participants in their trial who received a one-week buprenorphine detoxification with a psychosocial adjunct had relapsed and dropped out of treatment before 3

months. These studies suggest that a relatively brief buprenorphine detoxification can be associated with better outcomes in younger individuals.

Because Moore et al. (2004) found that participants in their study who were dependent on prescription opioids were significantly younger and had significantly fewer years of opiate use than heroin-dependent individuals, one might expect better outcomes following detoxification in this population than in traditional heroin-dependent populations. Moreover, Moore et al. (2004) also found substantially better outcomes for those dependent on prescription opioids than for participants dependent on heroin (63% vs. 31% of participants achieving 6 consecutive weeks of opiate-negative urines in a 24-week BUP/NX trial); this trend is an additional reason to posit that individuals dependent on prescription opioids would fare better with detoxification than more traditional heroin-dependent populations.

Rationale for Buprenorphine Maintenance in Phase Two

For patients who relapse to opioid use during or soon after receiving a buprenorphine taper, the next option is generally to try a longer course of buprenorphine. The goal of reviewing the rationale for buprenorphine maintenance is to provide a biologic explanation of the effectiveness of buprenorphine. The symptoms of opioid withdrawal are so uncomfortable for opioid dependent patients that concern over becoming "dope sick" can lead to continued drug use even before these symptoms develop. Therefore it is important to establish early on for the patient confidence that buprenorphine has potent and prolonged activity at opioid receptors and will prevent symptoms of opioid withdrawal. In addition it is useful to review how buprenorphine will block the "high" from continued heroin use and therefore help the patient remain abstinent by removing the incentive to continue to use drugs. Specific information can be discussed regarding the expected onset of action of buprenorphine (hours not minutes) and the potential for withdrawal symptoms with continued drug use. While these phenomena vary by patient, it can be useful and reassuring to the patient to anticipate questions on these topics. Finally, it is useful to discuss the differences between buprenorphine, methadone and naltrexone with the patient.

"Buprenorphine is a very promising new treatment of opioid dependence. It acts on the opioid receptor somewhat like methadone. However, it offers some advantages over methadone, including a longer duration of action that allows the possibility of providing doses three times a week. Because you are physically dependent, you experience withdrawal when you don't use heroin; that is, you get "dope sick." Buprenorphine works to prevent this "dope sickness." Additionally, buprenorphine will block your high-it will take away a good amount of the pleasurable effects you get from opioid analgesics so that you won't get as much out of the drug. This way, you will experience less of a need for opioid analgesics. So, to summarize, the buprenorphine will help you achieve abstinence from opioids in 2 ways. First, it will prevent withdrawal and therefore the need to use in response to being "dope sick." Second, it will make the use of opioid analgesics less appealing because it takes away the effect you look for."

Rationale for SMM visits

Clinicians should provide an explanation of the reason for medical management in the treatment of patients with opioid dependence. A direct analogy to medical treatment for other chronic diseases including diabetes, hypertension and coronary artery disease should be made. Included in this explanation should be a discussion of the need for a multifaceted approach to treatment including education and advice regarding issues of dependence and how to achieve abstinence, modification of lifestyle, habits, self monitoring of symptoms and compliance with all components of treatment including, but not limited to pharmacotherapy.

"Your meetings with me will combine medication with brief counseling to help you achieve abstinence from illicit opioids. We combine these two things because our basic philosophy of treatment includes both physical and psychological/social aspects of opioid dependence. For example, we will be giving you buprenorphine to manage withdrawal and physical craving for opioid analgesics as I just described, but we will also be meeting with you each week to talk about how to cope with social or psychological triggers of drug use, such as friends who use drugs or family problems and negative moods. We will discuss the importance of attending self-help groups, staying away from situations you know will tempt you to use drugs, and changing your daily lifestyle so that you are able to avoid drugs and take care of other problems, such as those related to family life, employment, or health issues. We will also be able to refer you to other services if you require further assistance with legal, employment, or family issues."

The SMM Treatment Plan specifies the problem areas that are of importance to the patient, the goals the patient wishes to achieve in each, and the specific methods by which the goals will be accomplished. The primary problem area for all patients should be opioid dependence, but problems in other areas that are related to drug use (e.g., violation of probation) may also be addressed in SMM. The clinician should develop the treatment plan collaboratively with the patient so as to increase the relevance and effectiveness of the plan, as well as the likelihood that the patient will adhere to it. The clinician should use the table below as a guideline for the selection of problems, goals, and treatment methods. The clinician should also explain the nature of each of the treatment components, and how each will assist the patient in achieving abstinence. Careful attention should be paid to linking each treatment component to specific problems identified in the assessment.

The following table outlines the components of a treatment plan.

Problem Area	Goals & Methods
Opioid dependence	Goals: 1) Pt will provide urine sample negative for illicit opioids within one week (short-term); 2) Complete cessation of illicit opioid use, based on pt report and 3 consecutive weeks of negative urine toxicology tests Methods: 1) Provision of rationales for buprenorphine & SMM sessions 2) Daily buprenorphine 3) Weekly SMM sessions 4) Urine testing for illicit drug use 5) Advise patient to be abstinent 6) Referral to self help group 7) Brief advice on avoiding drug triggers 8) Medical treatment or referral for any drug-related medical problems 9) Referrals for psychiatric symptoms that require specialized follow-up, or to community agencies for help with practical or legal needs (e.g., housing department, department of children and families)

E. Advise abstinence from all drugs

Patients are routinely advised that complete abstinence from all drugs is preferable to other goals because it helps prevent withdrawal and will allow the patient to reap all the benefits of treatment. Therefore, an explicit statement should always be made to the patient advising complete abstinence from all drugs and alcohol. However, this should be done in such a way that the patient understands that abstinence is something toward which he/she strives and that every small step in that direction is significant. This ensures that the patient does not give up the goal of complete abstinence, especially if he continues to use, and that he/she returns the next session and gives the clinician accurate information about drug use and efforts towards its reduction.

F. Refer to a Self-Help Group

In addition to "on site" treatment, patients should be strongly encouraged to attend self-help groups such as Narcotics Anonymous or Alcoholics Anonymous regularly. Many patients will be reluctant to attend a self-help group. Therefore, when referring a patient it is important to convey that one is familiar with these programs and has confidence in them. Immediate referral, taken while the patient is in the office, may consist of educating patients about the "self help group" process, providing patients with a meeting schedule, and letting the patient request a contact to take him/her to a convenient meeting.

When making a referral it is important to provide a clear rationale for attendance to the patient. It is also helpful to inform the patient that self-help groups can: 1) provide an opportunity to meet others with similar problems and experiences, who will be supportive and helpful; 2) provide a support system throughout the country and for as long as client decides to use it; 3) provide a sense of meaning, friendships, closeness; 4) encourage the patient to find meetings with members similar to the patient; and 5) address concerns about the spiritual aspects-recognizing and accepting that change is impossible in a personal vacuum that allows no one else to be involved. The clinician should also address the patient's possible concerns regarding success, and inform the patient that, although many are successful without self-help groups, research shows that those who remain involved on a long term basis have a good chance of being successful. It should also be noted that some 12-Step Self-Help groups may stigmatize people who take medications. This should not deter them from seeking a meeting that is accepting of the medication buprenorphine. Finally, give patients publications from self-help groups, which provide printed educational aids in the form of pamphlets. NA provides these materials at its local and central offices (NA World Services, Box 459, Grand Central Station, New York, NY 10017), or at meetings. The clinicians should also have a selection of pamphlets for the patient.

Finally, patients should be referred to meetings that are sensitive to issues pertaining to drug dependent individuals who are on agonist maintenance treatment. A list of such meetings is available to staff. SMART Recovery meetings are also encouraged if the patient is not interested in attending NA or AA.

G. "Other Referrals"

1. Employment, Social/Family & Legal Problems

If it appears that the patient's substance use has interfered with his/her ability to satisfy basic needs (e.g., housing, child care) or to address practical issues (e.g., assistance with legal matters), the clinician should state their concern (i.e. "It sounds like your drug use is preventing you from really taking care of this issue.") and make a referral to the social work staff. Follow up of identified issues with the patient (e.g., "Was the social worker able to help you?") will be helpful in the longitudinal care of the patient.

Feedback regarding employment, social/family, and legal issues should be given as well. For example, feedback to a patient with legal difficulties should include statements about the increased risk of legal problems with continued use, the connection between past use and patient's arrest record, and the importance of adhering to the current recommendations so as to have the best chance of achieving abstinence and thereby reducing the likelihood of future legal difficulties.

In general, patients should repeatedly be informed that the focus of this treatment is achieving and maintaining drug abstinence and that doing so is one of the best ways of increasing the likelihood of effectively addressing other life problems such as employment, legal problems, etc.

H. Delineate and reinforce program guidelines

The clinician should go over the program expectations to insure full comprehension and compliance. This will include a buprenorphine treatment agreement (see Appendix xxx). The following expectations should be reviewed at intake and as necessary. The patient is expected to: 1) attend all scheduled SMM sessions and (EMM sessions if appropriate) and call in advance if re-scheduling becomes necessary; 2) take the maintenance medication as prescribed; 3) provide urine samples for toxicology testing, and 4) cooperate with medical procedures, such as vital signs, weight, temperature measurements, and breathalyzer readings.

I. Answer any questions the patient may have

Another way of increasing the patient's investment in and adherence to SMM treatment recommendations is to address questions or concerns regarding any of the elements of the treatment (either buprenorphine or SMM).

VI. Conducting the Phase 2 Initial Visit

The Phase 2 initial visit should be conducted in a manner similar to the Phase 1 Initial Visit described above. This is a chance to orient the patient to maintenance therapy as compared to a buprenorphine taper as well as touch base on any significant changes in the patient's medical status since the last visit.

As described more fully in the CTN-0030 protocol and CTN-0030 Manual of Operations, all participants randomized into Phase 2 will have failed Phase 1 treatment either during treatment or subsequent to the end of treatment. As a result, participants will arrive for the Phase 2 Initial Visit with varying Phase 1 experiences. It is important for the clinician to consider this and address relevant Phase 1 events with the participant as part of the Phase 1 initial session. For example, some patients in Phase 2 will be randomized to SMM alone after having received SMM plus individual drug counseling in Phase 1, and vice versa. This raises the possibility that at least some patients may be disappointed in their Phase 2 treatment assignment. It is important for the clinician to address these concerns rather than overlook them.

The most likely concern anticipated is from individuals who received Drug counseling + SMM in Phase 1 and SMM alone in Phase 2. For these patients, the clinician should emphasize that buprenorphine maintenance is a different and more intensive intervention than the taper they received in Phase 1. In addition to the longer course of medication, it provides the patient with extended contact time with the clinician for monitoring and counseling.

VII. SMM Documentation

See appendix for SMM forms.

VIII. Subsequent SMM visits

The patient should be instructed that their second and all future visits will be brief (i.e., 15 minutes), and devoted to reviewing the patient's progress in a number of areas and providing brief education and advice on recovery from drug dependence. Specific information from SMM sessions should be documented in the brief, structured CRF entitled "SMM Visit form" (see Appendix). Clinicians should review these forms prior to each session.

The content of each subsequent SMM session should include:

a. Review of medication compliance and substance use since prior visit and beginning of treatment
b. Review response to medication
c. Review lifestyle changes and level of NA participation
d. Advise abstinence from all drugs
e. Offer support for patients' efforts to abstain from drug use
f. Provide brief education & advice on drug dependence & recovery
g. Address noncompliance (where necessary)
h. Make new referrals (if necessary) and follow-up on earlier referrals
i. Dispense medication (if applicable)

In the following section, each of the above procedures will be discussed in further detail.

A. Review of medication compliance and substance use since prior visit and beginning treatment including review of urine toxicology results.

"Tell me about your drug use since we last met"
"How much have you used and when?"

B. Review response to medication

The clinician should cover issues related to treatment response and potential adverse effects.

SAMPLE QUESTIONS

"How is the medication working for you?"

"Have you experienced any problems with the medication?"

C. Review lifestyle changes and level of NA participation

SAMPLE QUESTIONS

"Have you attended an NA meeting?"

"How did you like the meeting?"

"What were some of the obstacles that got in your way of attending a meeting?"

"Could you agree to try to attend another meeting? Let's look at the schedule and pick a meeting place and time."

D. Advise abstinence from all drugs

- Offer support and praise patients for self-reported efforts to abstain from drug use (e.g., spending more time with nondrug-using friend).

- Provide brief information & advice on drug dependence & recovery (as described below).

Brief education and advice is given to the patient regarding: 1) diagnostic issues (i.e., recognizing symptoms & course of the opioid dependence); 2) the importance of achieving improved functioning in social, family, legal, and vocational areas, as well as abstinence; 3) the avoidance of people, places and things that may trigger drug use; 4) active participation in self-help groups; 5) monitoring potential warning signs of relapse; and 6) encouraging patients to consistently adhere to their plan for maintaining abstinence, once achieved, and to anticipate the effects of major life changes on treatment and the patient's progress. The clinician will be provided with readings and training (adapted from Mercer et al.'s (1992) Group Drug Counseling Manual and Nowinski et al.'s (1992) Twelve-Step Facilitation Manual on how to give brief advice regarding each of these areas.

E. Address nonadherence (where necessary)

In general resistance (e.g., uncooperativeness, anger) and poor therapeutic response (e.g., consistently positive urine toxicology results, missed sessions) should be handled in a non-judgmental, empathic, and supportive way. Physicians and clinicians should acknowledge that it is often very hard for patients to make the changes they want. Change also often occurs slowly,

F. Dispense medication (if applicable)

G. Monitor and address pain symptoms (if applicable)

IX. Common Issues in Treatment

A. FIRST SESSION ISSUES

1. Patient fails to attend self-help group meetings

"I've tried NA and AA before, it doesn't work for me"

The clinician should first ask about what "didn't work" for the patient in order to ascertain the kind of difficulties the patient had with the group. For example, the patient may disagree with the philosophy of the 12-step approach and its emphasis on spirituality or, on the other hand, he/she may simply not have liked the particular group he/she attended. In determining the difficulty, the clinician can decide whether to suggest a different type of self-help group or a trial of several different self-help groups. Those who have gone exclusively to NA should try AA, or vice versa. If the issue pertains to the patient's discomfort with being in an NA group that discourages the use of agonist maintenance, the clinician should encourage the patient to attend meetings that are "medication-friendly" or to try non-12 step meetings, such as SMART Recovery. Clinicians should routinely empathize with patient's concerns or difficulties with meetings, but also highlight their advantages, such as social support and helpful advice, two critical aspects of successful recovery from opioid dependence.

If the patient doesn't like the spirituality aspects, one strategy is to emphasize that patients do not necessarily have to believe every aspect of the program to make use of those aspects that are beneficial. A lot of patients do not like the spirituality component but still derive enormous benefits from the opportunity to learn from other individuals who are successful in recovery or from the opportunity to develop contacts with people who are not using drugs. Alternatively, recommending a non-12-step self-help group such as SMART Recovery can be helpful, as these meetings do not include a spiritual component.

B. SECOND AND SUBSEQUENT SESSION ISSUES

1. Patient complains that the dose of buprenorphine is not sufficient

"I'm not sure if the medication is 'holding' me."

This may be an issue more in Phase Two, as patients will be tapered in Phase One. During induction patients may feel as if the dose of buprenorphine is inadequate to "hold" them to their next medication session. This should be noted with concern regarding the patient's symptoms and support for their continued adherence to their visits and medication. It is useful to inform the patient that their withdrawal symptoms get better with time and that the buprenorphine "holds you better" as they decrease and eventually stop their opioid use. After induction, patients may also express concern that they are unsure that the medication is adequate to prevent symptoms of opioid withdrawal. When this occurs, the clinician should review a few potential explanations and ask specific questions to help elicit the patient's symptoms. Potential explanations for this compliant are that the patient is 1) on an inadequate dose of medication, 2) anticipating

withdrawal but not experiencing any symptoms, 3) expects a high from an increased dose of medication or 4) not receiving the medication appropriately (incomplete dissolving of medication). The clinician should consider these and ask questions directed towards determining which scenario is likely. A trial of a dose escalation can help determine how the symptoms respond and may help to engender trust between the patient and provider.

2. Patient continues to use illicit drugs

"I don't want to totally quit; I just want to cut down."

It is not uncommon, at least during induction, for patients to continue to use illicit drug while receiving buprenorphine. Following induction, however, continued illicit drug use should prompt an evaluation of possible causes. There are a number of potential explanations for continued use including withdrawal symptoms, inappropriate dose of medication, lack of motivation towards abstinence. These explanations should be investigated with the patient in a non-judgmental manner.

3. Patient requests assistance with problems other than opioid dependence

"What I really need is help with my legal (family, child care, medical) problems?"

In this case, the clinician should reiterate the buprenorphine and SMM rationales, highlighting the point that one of the best ways of addressing various life problems is to first become abstinent from drugs. The clinician can explain that this will enable the patient to make the best use of resources and social support available to him/her. The clinician might also ask the patient to give personal examples of his/her prior success with dealing with such problems, and ask whether their drug use was a help or hindrance. More often than not, patients will admit that their drug use not only got in their way of solving important problems, but they were the major cause of the problems. Finally, the clinician should explain, as noted above, that referrals will be given to the patient to secure assistance in these areas.

4. Patient not attending (or failed to attend a) SMM session(s)

"All I need is my medication; I don't need to talk to anyone."

With this patient, the clinician should take care to assess first what the patient means by this statement by asking several open-ended questions, such as, "What leads you to say this?" "How have your previous experiences gone with counseling?" or "What are your goals for this program, and how would you like to achieve them?" Responses from these questions will give the practitioner a better idea of the patient's resistance to counseling and the methods by which he/she believes treatment goals can best be achieved. For example, this patient may be under the mistaken impression that SMM entails in depth psychotherapy, rather than a brief, medically focused counseling. By assessing the patient's thoughts about achieving treatment goals, the clinician can reiterate the SMM rationale so that it becomes individually tailored to the patient.

For example, this patient might state that he "just wants the buprenorphine to get clean," and that he does not need help with anything else. In response, the clinician could reiterate that the SMM visits are geared toward helping the patient make the best possible use of buprenorphine by assessing changes in use from week to week, monitoring withdrawal and the potential need for increases in dose, to monitor possible medical complications as a result of continued opioid analgesics use, and to encourage seeking out other support for abstinence, primarily in the form of NA meetings.

5. Discrepancies between self-reported use and urine toxicology results

Sometimes, there is a discrepancy between self-reported and objective measures of drug use. For example, the following situation could occur: A patient reports that he has not used opioid analgesics for the past 5 days, but his urine toxicology test is positive for opioids. It is crucial that such a discrepancy is addressed in the SMM session. However, it should be addressed in a neutral and non-judgmental way.

SAMPLE STATEMENT

"I think it's great that you're cutting down on your opioid use, and I'm sure that pretty soon you will be very close to your goal of abstinence. On the other hand, I notice that your urine is still showing a positive result for opioids, meaning that some amount of opioids is still in your system. The amount of time it takes for the drug to clear through your system can be different from person to person or from week to week. In that case, I think we should review your use day-by-day for the last week to see exactly how many hours it has been since you've had even a very small amount of drugs."

This allows the clinician an opportunity to reinforce whatever small steps the patient has taken to reduce drug use, to offer optimism regarding future change, and to educate the patient further about urine testing. What it also does is focus the "blame" elsewhere at first, which allows for a more detailed discussion of recent use, which could potentially reveal inconsistencies in the patient's report. These inconsistencies are then gently brought to the patient's attention and he/she is asked to clarify them.

There are a number of other ways a clinician could handle such a situation. For example, one could gently confront the patient by saying…

"It seems that what your saying about how much you used this past week doesn't coincide with your urine toxicology result. Sometimes when this happens, it suggests that a person has used more recently than he has reported. Could that be a possibility here?"

or…

"What you report and what the urine toxicology test shows is different. What do you think could account for that?"

If a patient becomes defensive and argumentative with these or other queries about the discrepancy, it is advisable to move on to the other business of the session and then re-visit this issue later on in the same session. Often, by avoiding the urge to argue this point with the patient and by addressing other issues brought up by the patient (e.g., the way the buprenorphine is working for him), the clinician may gain some insight into what may have contributed to the above discrepancy. For example, the patient may vehemently deny any use in the past days at the beginning of the session, but later reports that he is feeling some symptoms of withdrawal. The clinician's response to these symptoms could actually engender a more accurate patient report of recent drug use. For example, if the clinician offers support (e.g., "That must have been difficult for you"), educates the patient about potential solutions (e.g., increase in medication), and/or "normalizes" this experience (e.g., "Many people have had the same reaction and have ended up using simply because they felt more discomfort than they had expected"), the patient may clarify his initial report and indicate that he did, for example, use "some opioid analgesics two days ago to get over those withdrawal symptoms."

The clinician should also reassess the relationship between drug use (or abstinence) and medical and/or psychiatric problems identified in the first (or prior) session.

"How has your drug use or refraining from drug use affected the problems we talked about during our initial session (last meeting)?"

6. Patient comes to SMM session intoxicated

If a patient presents for medication while intoxicated or smelling of alcohol, a breath analysis for alcohol must be performed.

Patients with a positive breath alcohol result should be advised not to drive and offered a cab or directed to the nearest bus station.

Intoxicated patients should not receive a full dose of buprenorphine and the clinician should consult the physician for appropriate dosing. In some circumstances patients may be advised to leave and return for dosing at a later time.

Intoxication should be recognized as an indication that the patient may have more of an alcohol problem than was previously appreciated. While brief counseling strategies regarding the goal of abstinence from drugs and alcohol should occur, the clinician should consider an evaluation for alcohol abuse or dependence if a patients continues to present for medication intoxicated.

7. Patient complains of side effects

The possibility of the occurrence of adverse effects during treatment may need to be discussed. Side effects may include nausea, lightheadedness, fatigue, headaches, and/or weight loss. Mild side effects may often be adequately managed by explaining to patients that the severity of side effects usually decreases over time. This is most effectively accomplished through discussion carried out in the context of a concerned, reassuring and supportive attitude on the part of the

clinician. At intake, patients should be encouraged to report anything they think might be a side effect of the buprenorphine.

The patient should be instructed that these side effects are not dangerous if reported to the clinician and managed correctly. Further discussion of the possible effects of buprenorphine on liver functioning should be reviewed as outlined in the consent form. Appropriate medical evaluation will be made available for symptomatic patients.

The clinician should give the patient an emergency card, which states that the patient is in treatment in a research program and is receiving the medication buprenorphine. It also gives the telephone number of the clinic in case of an emergency. The clinician should explain to the patient what constitutes an emergency and instruct the patient to carry the emergency card in his/her wallet at all times, and alert medical personnel to the fact that he/she are on buprenorphine in case of an emergency.

The clinician will be also available to the patient for telephone calls regarding general concerns and questions about side effects, which may occur between appointments especially during the early weeks of treatment. The patient should also be instructed that in the event that his/her clinician is not available, there is an emergency number he/she can call to contact a member of the team 24 hours a day.

8. Patient becomes depressed or suicidal

Patients who develop potentially life-threatening medical or psychiatric problems will be evaluated by an independent psychiatrist to assess their treatment needs and whether they can continue safely in the study. Patients who cannot be maintained safely in the clinical trial will be referred by the Medical Director for appropriate treatment.

9. Patient complains of pain

When a patient complains of pain, the clinician needs to first determine whether this is most likely due to an ongoing problem (perhaps exacerbated by withdrawal) or whether a new disease process may be emerging. A different type of pain, a new pattern, or an increased level of intensity may trigger the physician to refer the patient to their outside treating physician for further evaluation. In general, patients should be warned, however, that they are likely to be uncomfortable (particularly during Phase One), and that accepting some level of discomfort (while not ignoring dangerous pain) may be critical to achieve recovery. All patients will be given a book on Pain Management, and should be encouraged to read this over to help with pain management issues.

X. Termination and transfer

Even though supportive medication management is less intensive than other forms of active psychotherapy, a significant provider-patient relationship will likely develop during the weeks of the study. In light of this, discussion of termination should occur and will likely be an important

element of the last several sessions. In fact, discussion should begin no later than 8 weeks prior to termination, and by 4 weeks prior, should be an element in every scheduled SMM visit. A sensitively directed inquiry and guided discussion that permits the patient to express his/her feelings and ideas about having participated in the study, attitude towards the clinician, future plans, and possible future therapy needs, is a necessary component of the general therapeutic process. Deficiencies in dealing with termination issues can lead to instances of "acting out", (e.g., patients abruptly not returning for tapering sessions). Further concerns about form, substance, or timing of such interventions can be usefully addressed and discussed in consultation. If for example, a clinician thinks that an additional session during the tapering phase is necessary to discuss previously unrecognized or currently unresolved termination issues, a consultation should be arranged with one of the physicians to discuss the problem.

If at any time during the course of treatment, the patient inquires about continuing treatment beyond the study period he/she should be reassured that an appropriate referral will be made at the end of the study period.

XI. General strategies for Working with the Substance-Abusing Patient

A. Be Empathic and Hopeful

Presenting education regarding addiction and recovery as an expression of concern for the patient's health or safety can further the clinician's alliance with the patient. For example, the clinician should inform the patient that opioid analgesics addiction is a treatable disease and that the treatment provided in this program is extremely effective (a large number of patients have been able to become abstinent as a result), and that with it, patients can make major changes, even those who have had difficulty doing so in the past. Further, it should be reiterated that this is possible only if patients follow the advice given herein and complies with the program procedures. The clinician needs to counter the substance user's low self-esteem and expectation of rejection by providing a clear message of hope and acceptance for improvement with treatment. Often substance users are keenly aware of the stigma with which society at large paints addiction, and have internalized this. This, in turn, is frequently compounded by internalized shame, sometimes dating from the patient's upbringing, and accentuated by the state in which the patient perceives him/herself at the time of treatment entry (e.g., having hit “rock bottom"), as well as the actions in which the patient has engaged to support their disease. For these reasons, substance users frequently become nihilistic, or risk-phobic, perceiving themselves as incapable of being or accomplishing anything more than being “just a junkie." Often a substance abuser's sense of hopelessness is so pervasive that it may envelop the clinician. Even when it may seem unwarranted by the history, a posture of therapeutic optimism may interrupt the cycle of drug use and despair.

B. Avoid Arguments

It is important to avoid arguments about the general or specific aspects of the diagnosis. Although recovery from opioid addiction is predicated and predicted by the acceptance of the diagnosis, a patient's refusal to call him/herself ‘addicted’ need not stand in the way of treatment

as long as the patient is able to connect his drug use in a general way with its negative consequences. Many patients need to deny aspects of the diagnosis even while exploring treatment options. Furthermore, the patient's definition of addiction may differ from the clinician's. It is always useful to elicit the patient's conception of the word "addiction," so that educational efforts can address the patient's specific concerns.

C. Working with Ambivalence about Change

In this program, patients are asked to make significant changes in their substance use and lifestyle that they might not be able to make right away, or that they are ambivalent about. These issues should be approached carefully. Ambivalence is an expected part of substance abuse treatment and in order for behavior change to occur, it is considered necessary to recognize and address the patient's ambivalence. Unless a patient fully understands and accepts that they may lose certain aspects of drug use, that he/she perceives as positive (e.g., getting high, friendships), by becoming abstinent, it will be very difficult for him/her to comply with treatment (i.e., failing to discuss ambivalence will result in resistance on the part of the patient).

It is important to realize that when a patient decides to stop using substances, they are, in part, experiencing a serious loss. The substance or substances of choice, after all, have provided comfort, escape, euphoria, and a kind of companionship and a lifestyle with which the patient is familiar. In seeking abstinence, the patient is departing from these known quantities, into an arena that they may perceive as being lonely, hostile, and definitely foreign to some extent. No one approaching such a situation-no matter how desirable-is completely free of doubts or fears, and these must be acknowledged as the patient begins treatment.

The clinician should make every attempt to convey acceptance of the patient and to place the patient at ease. It should be kept in mind that the patient's improvement is powerfully influenced by the therapeutic relationship. Remaining empathic even in the face of ambivalence, slow change, or no change can enhance the relationship. This is especially true during the earlier part of treatment, and perhaps even the success of the pharmacotherapy will rely heavily on the therapeutic relationship established. If this relationship is not adequate, the patient's compliance with medication is less likely to be maintained, especially in the context of the occurrence of any drug related side effects.

XII. Summary

This manual is intended for use by practitioners for the SMM of opioid analgesic dependence with buprenorphine. The manual describes the use of SMM and details specific procedures for the initial/intake and second sessions. Further, it illustrates a variety of SMM interventions that are to be used during the second and subsequent sessions, each of which last 15 minutes. The clinician selects whichever interventions are best suited for a particular individual, given their specific medical and/or substance abuse issues. However, the manual is only meant as a guide for trained clinicians. Training seminars and supplemental readings are crucial to the successful implementation of SMM.