

Treating Opiate Dependence in Rural Communities

A Guide for Developing Community Resources

A Report Summarizing the
Opiate Medication Initiative for
Rural Oregon Residents
(OMIROR)

November 2003



The Addiction Technology Transfer Center Network

Funded by Substance Abuse and Mental Health Services Administration

Treating Opiate Dependence in Rural Communities

A Guide for Developing Community Resources

Prepared by

Linda F. Clary
Project Manager
ADAPT

Steve Gallon, Ph.D.

Northwest Frontier Addiction Technology Transfer Center
Department of Public Health and Preventive Medicine
Oregon Health & Science University
3414 Cherry Avenue NE, Suite 150
Salem, OR 97303

Prepared for

Center for Substance Abuse Treatment
Grant No. 1 KD1 TI13568-01
Substance Abuse and Mental Health Services Administration
November 2003

Published in 2003 by the Northwest Frontier Addiction Technology Transfer Center (NFATTC)
Department of Public Health and Preventive Medicine
Oregon Health & Science University
3414 Cherry Avenue NE, Suite 150
Salem, OR 97303

This publication was prepared by the Northwest Frontier Addiction Technology Transfer Center (NFATTC) under grant No. 1 KD1 TI13568-01 from the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT). All material appearing in this publication except that taken directly from copyrighted sources is in the public domain and may be reproduced or copied without permission from SAMHSA/CSAT or the authors. Citation of the source is appreciated. Do not reproduce or distribute this publication for a fee without specific, written authorization from the NFATTC. For more information on obtaining copies of the publication, call (503) 373-1322.

At the time of this printing, Charles G. Curie, MA, ACSW, served as the SAMHSA Administrator. H. Westley Clark, MD, JD, MPH, served as the Director of CSAT, and Karl D. White, EdD, served as the CSAT Project Officer.

The opinions expressed herein are the views of the NFATTC Network and do not reflect the official position of the Department of Health and Human Services (DHHS), SAMHSA or CSAT. No official support or endorsement of DHHS, SAMHSA, or CSAT for the opinions described in this document is intended or should be inferred.



The Addiction Technology Transfer Center Network

Funded by Substance Abuse and Mental Health Services Administration

Contents

Forward.....	1
Section 1—Building Regional Treatment Resources	3
Section 2—Developing Local Teams	11
Section 3—A Synthesis of Local Practice Guidelines.....	13
Section 4—Lessons Learned.....	19
Section 5—Evaluation Report for the Opiate Medication Initiative for Rural Oregon Residents (OMIROR).....	21
Section 6—References for Continued Learning	33
Appendix 1—Project Plan	35
Appendix 2—Information/Invitation Letter	39
Appendix 3—Pre-Conference Reader	41
Appendix 4—Conference Agenda.....	43
Appendix 5—First Local Team Meeting Outline	45
Appendix 6—Conference Process Guide for Team Members	49
Appendix 7—Buprenorphine Office Tools	55
Appendix 8—CSAT Notification Form.....	91

Forward

The multifaceted Opiate Medication Initiative for Rural Oregon Residents (OMIROR), conducted in 2002-2003, was a project designed to systematically develop new resources for the treatment of opiate dependence in rural areas. Specifically, the project introduced buprenorphine hydrochloride, in the form of Subutex and Suboxone, as a new tool available to primary care physicians. When teamed with local drug abuse treatment providers and pharmacists, physicians using buprenorphine represent an opportunity to enhance access to science-based treatment in areas where medication-assisted treatment has not been previously available.

Based on the principles and strategies for systems change outlined in *The Change Book: A Blueprint for Technology Transfer* (Addiction Technology Transfer Centers, 2000), the project was supported by a grant from the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Treatment (CSAT) and implemented by the Northwest Frontier Addiction Technology Transfer Center, a project of the Department of Public Health and Preventive Medicine at Oregon Health & Science University. The objectives for the project were to:

- I. Provide physicians and drug abuse treatment counselors with CSAT-approved training in the use of buprenorphine for the treatment of opiate dependence.
- II. Link community drug abuse treatment programs with trained physicians so that patients who receive agonist therapies will also have access to drug abuse counseling services.
- III. Develop a service model that encourages patients to participate fully in drug abuse treatment and recovery.

This report documents the successful implementation of the project and the lessons learned during its evolution. It is intended to provide guidance for rural communities wishing to further develop local treatment and recovery services for opiate dependent people. The design for the project proved successful and it is hoped that other communities will consider using the model described here to enhance their local drug abuse treatment system.

If you would like more information about buprenorphine or the treatment of opiate dependence we suggest you access the SAMHSA web site (www.buprenorphine.samhsa.gov) or the NFATTC web site (www.nfattc.org). If you have an inquiry please feel free to send us an e-mail to nfattc@ohsu.edu and we will help you find the information you need.

Northwest Frontier
Addiction Technology Transfer Center

Section 1—Building Regional Treatment Resources

Central and Southern Oregon comprise a mostly rural region extending from Bend and Eugene in the north, south to Klamath Falls and Medford near the California border and west to the Pacific Ocean. The area includes seven counties that participated in the OMIROR project. OHSU and NFATTC contracted with a community treatment provider located in Roseburg, near the center of this large area, to coordinate the project, thus providing local “intelligence” regarding treatment and the opiate dependent population. The project coordinator helped recruit physicians, drug treatment providers, pharmacists and other health professionals for county teams; served as the planner for the buprenorphine training event; and guided the county teams in the development of local practice guidelines for the treatment of opiate dependent individuals.

The first challenge was to identify and recruit a diverse group of qualified, interested and passionate health professionals from each county who would commit to learning about a new treatment approach to opiate dependency treatment, an approach that required the development of new professional relationships in their home communities.

This section describes the step-by-step approach taken by the OMIROR project. It is meant to help guide the planning and implementation of similar system change initiatives in other regions of the country. It describes how to organize a training conference, identify and recruit interested professionals, and develop multidisciplinary teams of professionals for the purpose of collaborating on local treatment guidelines.

Step One – Overall Project Planning

- I. Meet with project planners to develop objectives, timelines, deliverables, assignments, budget, recruiting plans, communication protocol, documentation and reporting needs, conference outcomes and evaluation processes.
- II. Develop a Project Plan (see Appendix 1).
 - A. The plan will serve as a guide, but will evolve and more details will develop as the project progresses. It is expected that each local area will customize a plan to address local needs and circumstances.
 - B. Identify immediate challenges:
 1. Locate resources for learning about opiate dependency treatment and the use of buprenorphine.
 2. Plan how to identify potential participants (doctors, treatment providers, pharmacists, and others) who are or could become leaders in their communities. Keep in mind that such individuals need to be opinion shapers, influencers, or early adopters of innovation.

- C. Anticipate resistance. (Resistance to acknowledging the problem; resistance to change; resistance to developing a network; resistance to developing a solution; resistance to implementing solutions and committing resources in local communities; resistance within the medical community; resistance to recognizing change as a community effort with no single owner.)

Step Two – Conference Planning

The centerpiece of the OMIROR project was an 11-hour training conference on the use of buprenorphine in the treatment of opiate dependence. The project coordinator did the following in organizing what turned out to be a well-received high impact event:

- I. Become familiar with science-based opiate dependence treatment, buprenorphine, accessible sources of knowledge for use during the course of the project, and potential partners in the planning and delivery of the training event.
 - A. Information sources include:
 - 1. American Society of Addiction Medicine (ASAM). Telephone number: (301) 656-3920 or www.asam.org
 - 2. Online Buprenorphine education course: www.danya.com/aaap
 - 3. Buprenorphine information: www.buprenorphine.samhsa.gov
 - 4. Center for Substance Abuse Treatment, Office of Pharmacologic Therapies.
 - B. Potential partners and co-sponsors of the training event include:
 - 1. ASAM and the local Chapter of ASAM.
 - 2. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Office of Pharmacologic Therapies.
 - 3. State Office of Mental Health and Addiction Services.
 - 4. County Drug Treatment Agencies.
 - 5. County Health Officers and Community Health Centers.
- II. Create a conference plan utilizing the principles, strategies and methods outlined in *The Change Book* (ATTC, 2000). *The Change Book* was developed by the Addiction Technology Transfer Centers (ATTC) to enhance understanding about how to implement successful system change initiatives in community agencies.
- III. Contact ASAM as a potential partner in planning the conference. Obtain application and information on how to work with ASAM to meet project objectives. Follow directions on the application form to develop curriculum and locate potential trainers. ASAM approval takes a couple of weeks from the submission date. (See references in Section 4 of this document for ASAM contact information.)

- IV. Recruit trainers, confirm their availability and hold a conference call to develop and discuss curriculum for the Conference.
 - A. Develop contract with each trainer.
 - B. Coordinate travel and lodging for trainers.
 - C. Discuss need to obtain teaching materials for reproduction.
 - D. Determine needs for A-V and other equipment.
 - E. Arrange for a pre-training coordination meeting the evening before the event. Include trainers, project coordinator, group facilitators, and sponsors.
- V. Contact other organizations that are doing similar trainings. Ask about what have they encountered and how they would describe their victories and failures? How would they improve on their event? What to leave out of training? ASAM can provide information about other organizations that have conducted buprenorphine training.
- VI. Locate a facility with the ability to support educational conferences.
 - A. The Conference Room should be large enough to accommodate participants at large round tables with sufficient space between to allow for break-out discussion sessions during the conference. Seat participants by teams, with a maximum of eight people per table. Crescent seating is strongly recommended to allow participants access to their printed materials during presentations. Separate break-out rooms are discouraged.
 - B. The Conference Facility should be far enough from participants' homes to encourage an overnight stay, if the budget and local circumstances allow. Such an arrangement will encourage development of new relationships within each team. However, the distance should not be so great that the participants feel their travel needs have not been considered.
 - C. Assure the availability of sufficient audio-visual equipment and support, meal and refreshment services, a business center, and parking.
 - D. Determine conference dates in collaboration with planning team and the teaching faculty.
 - E. Develop contract/commitment with the conference facility.
 - F. Advise partners/co-sponsors and key stakeholders of date and location for the conference.
- VII. Organize the Conference logistics.
 - A. Confirm and secure handout materials (journal articles, reports, charts, etc.) and PowerPoint/slide presentations with presenters. ASAM has a ready-made package of handouts available.
 - B. Collect, copy and assemble handout materials and copies of slide presentations into binders. Tips for building a complete package of materials:
 - 1. Notify presenters well in advance of the date that electronic copies of their slide presentations are due.

2. Carefully number pages and create a table of contents that allows for clear and easy access during the conference.
3. Allow sufficient time for photocopy and assembly prior to the conference. The package potentially includes:
 - a. Presenter slides.
 - b. Handouts (copies of the law, case studies, worksheets, etc.).
 - c. Journal articles and bibliography.
 - d. Curriculum materials supplied by ASAM.
 - e. Conference evaluation forms (color coded pre- and post-).
 - f. Presenter biographies.
- C. Create and duplicate a CD containing Buprenorphine Office Tools as a handout for each participant. Appendix 7 includes a set of sample tools, which are also available on the California ASAM Chapter Website (<http://www.csam-asam.org>). Create a hard copy Table of Contents for the CD as a handout.
- D. Initiate procedures to secure CME for physicians and CE hours for other disciplines (pharmacy, addiction treatment, nursing) who will be attending the conference.
- E. Prepare participant recruitment materials, including a letter of invitation, brochure, registration form and other pre-conference materials. The letter might anticipate the following:
 1. What will attract this group of professionals to give-up their time? Offer CME/CE, help with expediting the waiver process for physicians and food during the conference.
 2. See Appendix 2 for a sample letter.
- F. Distribute the materials 10-12 weeks prior to the conference (see Step Three below).
- G. Organize a conference registration process that will record participants, produce receipts for any fees paid, develop name tags and prepare certificates of completion.
- H. Confirm attendance with participants via letters, e-mail and telephone calls.

Step Three – Creating Local Teams

- I. Contact the following via telephone and e-mail and request names/phone numbers of physicians, addiction treatment professionals, pharmacists and others who might be interested in buprenorphine as a new tool in treating opiate dependence.
 - A. Addiction Treatment providers.
 - B. Medical Directors of local organizations (medical association, hospital, group practices, emergency rooms).
 - C. State alcohol and drug authorities.

- D. Mental Health agencies.
 - E. County mental health and alcohol and drug authorities.
 - F. Medical School (Family Medicine, Internal Medicine, Psychiatry, Addiction Medicine).
- II. Finalize the list of physicians, treatment providers and pharmacists who will be invited to be local delegates to a training conference on buprenorphine and office-based treatment of opiate dependence. Compile contact information in a standardized spreadsheet. (ASAM can provide the link to American Institute of Research who maintains the list of all certified physicians.)
- III. Recruit several physicians (perhaps from the medical school or members of your planning team) who are willing to call the physicians on your list and invite them personally to become involved in the project. Physicians with a specialty in family practice, internal medicine or psychiatry might be most willing to help. Having physicians contact other physicians is preferable to cold calls from a non-physician. Such cold calls are not effective. Often the caller, even a physician, has difficulty getting past the receptionist, secretary or nurse.
- A. Initial invitations and phone calls should be done 10-12 weeks in advance of the training conference. For those who express interest in the project, indicate a local breakfast meeting that will introduce them further to the project.
 - B. Secure e-mail addresses for those expressing interest in the project.
- IV. Recruit pharmacists and treatment providers through mailings and follow-up telephone calls, if necessary. Introductory materials should explain the scope of the project, the projected dates of the training conference and the intention to hold a pre-conference meeting of conference delegates approximately 2-4 weeks prior to the event. See Section 2 below for a description of the pre-conference meeting of local delegates or teams.

Step Four – Conference Design

- I. The purpose of the training conference is twofold: provide training on buprenorphine and office-based treatment of opioid dependence and to further develop linkages between physicians, treatment providers and pharmacists. The linkages develop during the course of case discussions and activities focused on developing local guidelines for treating opioid dependent individuals.
- II. Faculty lectures are the primary instruction method during the conference. The topics are prescribed by CSAT and ASAM. Presentations are interspersed with periodic case discussions, allowing participants time to engage with each other in exploring answers to case discussion questions. Faculty members circulate to assist and encourage groups.
- III. If possible, locate and interview a local physician within the target community who is prescribing buprenorphine. If appropriate, invite him/her to describe his/her experience.
- IV. Invite a State government official who can address how buprenorphine is considered in the State's health program or pharmacy benefits package.

- V. Time is also provided during the two-day event for each local multi-disciplinary group to begin drafting their own guidelines or protocol for how they will identify, assess, intake and develop a treatment plan for potential buprenorphine patients. A collaborative effort that works for all participants is the goal.
- VI. Specific dates for a post-conference meeting should be established prior to conclusion of the event. An interval of about three-four weeks is very appropriate. This allows participants to consult with colleagues, develop additional questions and bring information to the next meeting.
- VII. Appendix 6 provides a Process Guide for the development of the local protocols.
- VIII. Appendix 4 illustrates the Conference Agenda, including the specific topics and timeline for the two-day event.

Step Five – Conference Follow-Up

- I. Following the conference, local teams meet at least once more to finalize their local practice protocol/guidelines.
 - A. Project coordinator calls and sends e-mail to attendees as a reminder of the time and location for meeting.
 - B. Anticipate some local guidelines will be well-done and others will be less developed.
- II. Project coordinator or local leader facilitates the meeting. The purpose is to clarify each participant's role in the screening, referral, assessment and treatment process. For more information on this meeting see Section 2.
 - A. Prior to the meeting the facilitator secures electronic copy of the local guidelines draft.
 - B. Project coordinator brings hard copy of the team's most recent draft to the meeting.
 - C. Project coordinator provides coaching and information from other teams.
 - D. Team makes decisions regarding necessary further action.
- III. Some teams will decide to not move forward with providing opiate dependency services. Issues may include a shortage of professional resources, lack of leadership, community sentiment regarding medication-assisted opiate dependency treatment or perceived lack of need for the service.
- IV. Some teams will continue the development process. Key factors for those who decide to further develop their service system appear to be:
 - A. Presence of a committed addiction professional or physician champion.
 - B. Presence of a heroin task force or planning committee of non-physicians.
 - C. Availability of a support group for buprenorphine patients.
 - D. Supportive drug treatment agency that serves as a catalyst.
 - E. Supportive public health officer.

- V. Project coordinator next synthesizes local protocols/guidelines from each team into one document and shares it with all teams as well as with other communities that are interested in embarking upon a similar mission. The synthesized document for the OMIROR project appears in Section 3.

Section 2—Developing Local Teams

Local teams should meet at least four times: once prior to the training, a minimum of twice during the training and once post-training. During the course of those meetings the team evolves a set of *Clinical Practice Guidelines* for their local area, based upon the process outline that appears below.

The first meeting occurs prior to the training conference on “Buprenorphine and Office-Based Treatment of Opiate Dependence.” The project coordinator focuses the discussion on how each team might utilize buprenorphine in providing care for their patients/clients. The typical team consists of physicians, community treatment providers and a pharmacist. Together they identify existing systems that could be utilized, obstacles, and create new links and processes.

The project coordinator shares with each group the processes and models being developed by other teams. An improved fused product will be the result.

At, and perhaps prior to, the training conference, each team focuses on preparing a locally tailored set of *Clinical Practice Guidelines*. During the initial gathering people may be meeting each other for the first time. As they discuss common issues and share ideas for solving community wide (and often State-wide) problems, they will begin to shape their *Guidelines* for providing integrated office-based treatment for opiate dependent patients.

Step One – Preparing for and Holding the First Meeting

- I. Contact and invite potential participants (physicians, treatment providers, pharmacists and nurse practitioners).
- II. During the initial contact discuss the initial meeting of interested parties. If possible, obtain a commitment to attend that meeting. If a potential participant refuses to attend the meeting, they may not be appropriate for this type of process. The first meeting is critical to the success of this project. Obtaining a commitment from physicians to attend the first meeting may meet with resistance – but it is well worth the additional time required to sell them on the importance of the meeting. **That first meeting, in each county, made the difference!**
- III. Prior to the first meeting, send all interested persons a letter of invitation and registration forms for the training conference. See Appendix 2 for sample copies.
- IV. Intense follow-up will be required. Make repeat calls to all potential participants, send information and facsimiles again, if necessary.
- V. Collect materials for an educational kit to be distributed at the first team meeting. Potential sources: ASAM, faculty, SAMSHA/CSAT Internet sites. The goal here is to provide sufficient material to orient team members and help them understand the

potential benefits of incorporating buprenorphine into their practice. A sample table of contents is in Appendix 3.

- VI. The agenda for the first meeting might include:
 - A. Administer pre-event assessment – if required by CME agency.
 - B. Distribute Pre-Conference Reader of Buprenorphine-related information.
 - C. Begin discussing the group’s current understanding of buprenorphine and its role in treating opiate dependence.
 - D. Begin developing questions the group has about buprenorphine. These questions can be given to the training faculty and answered at the conference. In addition, the questions provide the faculty with important information about the attendees - the degree of expertise available in the audience and the level to which they should address their lectures.

Step Two – Further Team Development at the Conference

- I. Teams meet at least twice during the actual training conference to begin developing their guidelines.
 - A. Instructor presentations, interaction with other teams and discussions about the practical aspects of using buprenorphine frame the work done by the teams and produce positive results.
 - B. A suggested process and outline for the contents of a practice guideline are given to each team to guide their work. A copy of that document is included as Appendix 6.
 - C. Notes for the local protocol are recorded by the team. The incomplete draft is submitted to the Project Coordinator at the conclusion of the conference.
 - D. The protocol draft is duplicated and distributed for each team member.
- II. Teams establish a date for another meeting following the conference. The Project Coordinator makes plans to attend those meetings.

Step Three – Continuing Team Meetings and Product

- I. Teams meet to finalize their clinical practice guidelines.
- II. The Project Coordinator facilitates the meeting by preparing an agenda and guiding the discussion.
- III. Teams develop action plans for implementation of their guidelines.
- IV. Guidelines are synthesized by the Project Coordinator and distributed to all Conference participants. That synthesis appears here as Section 3.

Section 3—A Synthesis of Local Practice Guidelines

This section provides practical steps, processes and issues for all collaborators in the delivery of office-based treatment for opioid dependence to consider as part of the treatment regimen. These guidelines are a synthesis of documents developed in several rural Oregon counties as part of the Opiate Medication Initiative for Rural Oregon residents (OMIROR), a project funded by the SAMHSA Center for Substance Abuse Treatment and implemented by the Oregon Health & Science University Department of Public Health and Preventive Medicine.

Introduction

- I. Buprenorphine hydrochloride is a prescription drug approved in 2002 for the treatment of opiate addiction. It is a partial opiate agonist, which satisfies the dependent patient's need for an opiate to avoid painful withdrawal. At the same time, it does not provide the user with the psychoactive effect typically associated with opiate drugs. It can, therefore, be a useful adjunct to treatment for those addicted patients wanting to establish a more normal lifestyle without the need to constantly be seeking the next high to forestall withdrawal. This is the first such medication available to physicians for use in their office-based practice.
- II. There are a number of issues that need to be addressed and resolved before buprenorphine finds its way into common practice in rural areas. Some of those issues are:
 - A. Cost of the medication. Will insurance cover the cost? Medicaid? What will be the monthly cost for patients who pay their own way?
 - B. Collaboration between physician and addiction treatment agency. Buprenorphine is not sufficient treatment for opiate dependence. Typically, counseling and other related services are needed to assure minimum standards for opiate dependency treatment are met.
 - C. Treatment planning and case management. Who is going to work with the patient to develop a full spectrum treatment plan? How will the ongoing progress of the patient be monitored and by whom?
- III. Resources for the practitioner. In preparing to implement a buprenorphine regimen, the following references will be useful to the practitioner:
 - A. McNicholas, Laura and Howell, Elizabeth (2000). *Buprenorphine Clinical Practice Guidelines (BCPG)*. Draft document submitted to the Center for Substance Abuse Treatment.
 - B. American Society of Addiction Medicine (ASAM). *Clinical Practice Guidelines* and assessments.

- C. American Psychiatric Association (2000). Diagnostic and Statistical Manual-IV. Criteria for Opioid Intoxication and Withdrawal (292.89 and 292.0).

Preparation for Treatment

- I. Physicians, community treatment providers and pharmacists meet and discuss which office assumes responsibility for the various tasks included in the buprenorphine protocol.
- II. Physicians and community treatment providers agree upon a prompt referral system, allowing the prospective patient a medical appointment within an agreed-upon number of days from the initial contact.
- III. A flowchart is developed, with names assigned to each task in the protocol. The flowchart is shared with each partner, modified when appropriate (based upon experience) and re-published.
- IV. Partners set aside a regular “staffing” time to discuss mutual buprenorphine patients.
- V. Communities develop an education campaign to inform medical and other professionals about the availability and use of buprenorphine in the treatment of opiate dependence. Included in this effort (but not limited to it) would be physician organizations, community addiction treatment providers, methadone clinics, Narcotics Anonymous, law enforcement personnel, detoxification facilities, local hospitals and Urgent Care Centers.
- VI. Patients come from any source, including, but not limited to, other physicians, community treatment providers, law enforcement, local hospitals, Narcotic Anonymous, methadone clinics, etc. Encourage a “No Wrong Door” philosophy. Treatment personnel should reference the *BCPG* for a more detailed discussion.
- VII. Narcotics Anonymous is contacted and requested to establish a buprenorphine-only group. The position against opiate pharmacotherapy of some NA members may be challenging.

Patient Screening and Enrollment

- I. Not all patients are appropriate for buprenorphine. Determine eligibility criteria. Some resources that might be useful include Buprenorphine Office Tools (BOT), which can be found in Appendix 1, ASAM forms and the DSM-IV criteria for opiate dependence.
- II. Consistent with “No Wrong Door,” screening is done at community drug treatment facilities, medical clinics, physician offices or other participating agencies. Screening forms can be found in the BOT. Screening instruments are described in the *BCPG* (McNicholas and Howell, 2000). Phone screening may be done by front office personnel or by the clinician. Training of personnel to do phone screening is a key factor in initial patient selection.

- III. Availability of benefits to cover the cost of treatment is determined. Insurance compensation, State support, patient financial commitment must be ascertained as part of the assessment process to ensure continuity of care.
- IV. The patient, family members and significant others are educated about buprenorphine. The benefits and risks, including a review of treatment options and a discussion of contractual compliance, should be explained in full. Patients that decline family involvement or the family that refuses involvement may indicate the patient is not appropriate for buprenorphine.
- V. Special care is taken regarding confidentiality issues, especially in small rural communities. HIPAA requirements are understood and met.
- VI. Patients agree to each organization's contracts, including (but not limited to) compliance with confidentiality issues and sharing of information between the physician, addiction treatment provider, pharmacist and others with a need to know. Patients who do not make such a commitment are probably not good buprenorphine candidates. Likewise, patients that have transportation problems, personality disorders or are evasive in answering questions on the screening tools may not be appropriate for this drug.

Patient Assessment

- I. Clarify who will do what portions of the assessment and which instruments or diagnostic tools will be utilized.
- II. Conduct urine toxicology screen for opiates, methadone, benzodiazepines, cocaine, amphetamines and other drugs of abuse in the patient's community.
- III. Clarify assessment guidelines for special populations including adolescents, pregnant patients, the elderly, and patients with renal failure or compromised hepatic functions, HIV-positive and healthcare professionals. The *BCPG* includes some helpful information about special populations.
- IV. After the assessment and screening procedures are complete, the physician and addiction treatment provider conference to decide appropriateness of buprenorphine and potential treatment plan. The initial medical assessment is described in the *BCPG*.

Treatment Plan

- I. Team members consult the *BCPG*, *ASAM*, and *DSM-IV* references as they develop the patient diagnosis, determining appropriateness of treatment, identifying medical or psychiatric disorders, assessing withdrawal potential and formulating an initial treatment plan including contraindications. In the event that additional addiction expertise is required, a clinician reference line is available (Reckitt Benckiser Healthcare - 1.877.782.6966). Additional buprenorphine support is also available within the *ASAM* membership and a discussion board is available at the California *ASAM* website (www.csam-asam.org).

- II. The treatment plan indicates which community partner provides each service included in the plan.
- III. Treatment plan includes activities and assignments consistent with immediate and long-term goals. The *BCPG*'s section on treatment protocols provides a valuable outline for understanding the options available to the patient. Treatment goals are linked to issues and problems described in the patient's assessment and could include:
 - A. Detoxification.
 - 1. Manage withdrawal from opiates by using buprenorphine for a limited period of time, then gradually reducing buprenorphine dosing schedule. Rule out patient need for detoxification facility and/or addiction specialist for support during managed withdrawal.
 - 2. Transition from methadone maintenance to buprenorphine maintenance. Gradually reduce methadone dosage to the recommended amount prior to the transition to buprenorphine.
 - B. Stabilization/Maintenance.
 - 1. During the first three or four office physician office visits, the patient begins to participate in professional addiction treatment activities from a community provider.
 - 2. A plan for monitoring treatment progress is established by the treatment team, including urine analysis testing.
 - 3. Frequency of visits to the community treatment provider will be established as appropriate for the patient.
 - 4. Physician sees patient at least monthly for first six months.
 - 5. If appropriate, the patient may have up to one month of "Take-Home" medications.
 - 6. If a prescription is not refilled, the pharmacist will advise the community treatment provider.
 - 7. In some cases observed dosing may be indicated. This could be carried out at the physician's office, at the treatment agency or in the pharmacy.
 - C. Long-Term Management.
 - 1. Referral to Narcotics Anonymous or other 12-step program.
 - 2. Assess patient's ability to continue on take-home medications.
 - 3. Minimum of monthly check-in with community treatment provider. If and when appropriate, the counselor refers the patient to the physician.
 - 4. Plan for monitoring progress, including making adjustments to the treatment plan, is in place.
 - 5. Consult the *BCPG* for more details and options.

- D. The patient accepts the treatment plan. The plan anticipates barriers to treatment, including family dynamics, economic issues, transportation problems and other potential problems the patient identifies.
- E. Patient appointments with treatment provider and physician are coordinated to support the patient.
- F. Staffing-time is regularly scheduled.
- G. Patient induction protocol, as described in the *BCPG*, is conducted in the physician's office.
- H. Referrals are made for patients who need a higher level of care, or who are not making progress in treatment. Patient agreements guide discontinuation of services for non-adherence or aberrant behavior

Section 4—Lessons Learned

Recruiting Participants

It is important to leave no stone unturned as participants are recruited for the project. Here are some professional groups whose members might have special interest in the project:

- I. Nurse practitioner organizations and their members often know which professionals in the community might be interested.
- II. Behavioral health specialists found in some health, mental health and substance abuse agencies will be potential participants.
- III. Pharmacists should be included in the training. In addition, they will know which physicians are prescribing for the treatment of pain or substance use disorders. Those doctors are potential recruits.
- IV. Local chapters of the American Society of Addiction Medicine (ASAM) will have interested members.
- V. ASAM’s national buprenorphine sub-committee may have members from the local area or may know of local physicians with potential interest in the use of buprenorphine.

These are only some of the groups to consider, in addition to family practice physicians, internists, psychiatrists, addiction treatment agencies and state/county substance abuse authorities. Recruitment should begin at least 3-4 months prior to the training conference.

Project Coordinator

Consider a coordinator who is not a treatment provider, someone who is considered neutral by all groups. The coordinator can serve as a meeting facilitator and a neutral avenue for the sharing of information during the course of the project. While electronic communication is becoming ubiquitous among health professionals, do not overlook the importance of personal contact and service. Making telephone calls, assisting trainers with travel arrangements, securing a quality training facility and other “value added” activities can pay big dividends.

Importance of Teams

Relationships among some team members will not have existed previously. The creation of a local network is a positive and forward-looking model for public health. Collaborating on a set of Clinical Practice Guidelines may break new ground for the physicians, community treatment providers and pharmacists. Typically, these are the individuals who are committed and often acknowledged by their peers as leaders in the field. They bring expertise and a unique focus to a

consideration of office-based treatment. Some have a broad understanding of the multi-layered health care system and issues involved in treating addictive disease. They are the opinion-shapers and leaders in the medical community. They are often the early adopters of new technology.

Project Planning

The following are important steps to take and issues to address when formulating a technology transfer plan for a rural setting:

- I. Consider what the keys might be to relationship building and to preparing the community to consider enhancements to available resources for the treatment of opioid dependency?
- II. Identify potential community champions from different professional groups.
- III. Identify health care providers in each community who are likely to be early adopters of new technology.
- IV. Consider the time and financial resources needed to develop an initiative like this.
- V. Use *The Change Book* processes as a way of building community ownership for the changes the project is targeting.
- VI. Define the financial issues related to the use of buprenorphine.
 - A. Insurance coverage.
 - B. Medicaid coverage.
 - C. Chemical dependency treatment availability and cost.
 - D. How to overcome the financial challenges.
- VII. Develop a calendar of planning mileposts and project events. Allow extra time for recruiting and the resolution of unanticipated problems. The schedule should accommodate any grant-associated deadlines, initial local team meetings, conference planning and implementation, post-conference meetings, evaluation processes and documentation of the project.
- VIII. Anticipate addressing and observing the following:
 - A. Identifying the events that result in behavior change in practitioners.
 - B. Documenting local meetings.
 - C. Tracking enrollment of patients in buprenorphine-assisted treatment following the training conference and receipt by physicians of the federal waiver allowing them to prescribe.
 - D. Degree to which treatment processes are seamless.
 - E. How assessment and treatment practices change as a result of the project.
 - F. How relationships are established and maintained during the course of the project.

Section 5—Evaluation Report for the Opiate Medication Initiative for Rural Oregon Residents (OMIROR)

Prepared by:

Dennis McCarty, Traci Rieckmann, Carla Green and Steve Gallon
Oregon Health & Science University, Portland, Oregon

Jeff Knudsen and Roy Gabriel
RMC Research, Portland, Oregon

Linda Clary
Adapt, Inc., Roseburg, Oregon

The black Pathfinder crawled away from Portland International Airport in stop and go rush hour traffic. The trip south skirted Salem an hour later, by-passed Eugene and rooster-tailed on new Michelins toward Roseburg and beyond. Nightfall, combined with relentless rain, reduced visibility to nil and made driving treacherous; the trip seemed unending. Canyonville was four hours, plus a stop for dinner, away from Portland at exit 99 on Interstate 5. This tiny community served as the site for an event designed to enhance rural health services for years to come.

Seven Feathers Casino dominates the village squeezed between the Cascades and the Coast Range. The casino's conference facilities were convenient to practitioners collected from seven counties (Coos, Deschutes, Douglas, Jackson, Josephine, Klamath Falls and Lane) in Central and Southwestern Oregon; it was west of the Cascades so snowy mountain passes were a minimal problem, and it was an attractive location for a weekend training focused on the use of a new medication to help patients dependent on opiate drugs. The presenters, weary from their cross-country travel, straggled in Friday evening. They tumbled out of the SUV and made their way through a smoke filled glitter gulch of slot machines and table games to the hotel registration where they sought respite from the road and the solace of sleep.

Participants gathered quietly the next morning in the conference center for a 12 hour (1.5 day) training titled "Buprenorphine and Office-Based Treatment of Opiate Dependence: A Conference for Rural Health Care Providers." County teams assembled to learn about the newly approved medication, develop treatment protocols, and promote linkages among counselors, physicians and pharmacists. Fifty-one participants (17 physicians, 4 pharmacists, 2 nurse practitioners, and 28 drug abuse counselors and administrators) were eager to begin. The formal training started when Laura McNicholas (Philadelphia VA Medical Center), Judy Martin (14th Street Clinic in Oakland California), and Andy Saxon (University of Washington and the VA Puget Sound Health Care System) were introduced. Informal training had already begun during participant recruitment.

Participant Recruitment and the Formation of County Teams

The Opiate Medication Initiative for Rural Oregon Residents (OMIROR) promoted office-based treatment and access to care for heroin (and other opioid) dependent individuals in rural communities. Methadone services are unavailable in much of the state and methadone patients often drive 100 or more miles (one-way) on mountain roads for daily medication visits. Changes in federal legislation coupled with the Food and Drug Administration's approval of Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride in combination with naltrexone) for the treatment of opioid dependence fostered a moment to engage primary care physicians more directly in drug abuse treatment, especially for opiate dependence.

The Canyonville event trained primary care physicians and forged linkages with local drug abuse treatment programs and pharmacists. County teams crafted strategies to support physicians treating opiate dependent patients and to provide patients with counseling in addition to medication. Collaboration between drug abuse treatment services and primary care clinics was encouraged to enhance treatment effectiveness.

Physicians, pharmacists and counselors, however, did not spontaneously volunteer to assume additional responsibility. Two recruitment strategies seemed most fruitful. First, two OHSU physicians (from family practice and psychiatry) contacted health officers in the targeted counties and the federally qualified health centers where OHSU supported residents and trainees. Second, the local drug abuse treatment centers encouraged the physicians they worked with to participate. Potential participants received information on buprenorphine and its value in treating opiate dependence in rural communities.

Linda Clary, the project manager from ADAPT a southern Oregon drug abuse treatment agency serving several counties, met with each county team prior to the training, provided an overview of buprenorphine, described the training and facilitated the drafting of a county protocol to connect pharmacy, counselors and primary care physicians. Binders were distributed with 15 journal articles on buprenorphine, a copy of the Drug Abuse Treatment Act of 2000 and explanation, information posted on the suboxone.com website and instructions for using the CSAT web pages. Participants reviewed the material prior to arriving at the Conference and identified issues of concern. County teams, as a result, entered the training with a sense of how buprenorphine could be used and understood that the county opiate treatment protocol would be developed during the conference in Canyonville.

Although recruitment was challenging, the project team identified a wide range of potential participants. After committing to participate, only two physicians dropped out. Physicians from around the country, moreover, sought to attend the training; the requests were denied because the training was specifically focused on a small region of Oregon. Thus, the teams arrived at the casino eager and ready.

Training

The curriculum reviewed the context, described the pharmacology, discussed patient selection and use of buprenorphine in practice settings. Training continued with an overview of co-morbidity (medical and psychiatric) and presentation of case studies. During breakout periods, county teams developed protocols for referral and treatment of patients.

Judy Martin summarized the Drug Addiction Treatment Act of 2000 and the Food and Drug Administration's approval for Suboxone and Subutex; the legislation and approval set the stage for the use of buprenorphine in office-based practice. Andy Saxon's overview of the pharmacology and neurobiology of opioid dependence helped trainees appreciate Laura McNicholas' presentation on the pharmacology of buprenorphine and its use in the treatment of opioid dependent patients. After lunch, Dr. Saxon used a patient video to guide the group through a discussion of the diagnostic criteria to assess and select patients appropriate for buprenorphine treatment. Dr. McNicholas continued the training with a pragmatic discussion of inducting patients onto buprenorphine and a review of common mistakes and problems. Near the end of the day, Dr. Martin's experience treating patients with buprenorphine provided a framework for discussing buprenorphine maintenance and practical considerations in managing patients on buprenorphine. A review of clinical case studies closed the day. Teams worked on how the cases might be handled within their communities; the cases helped structure team thinking on assessment, referral and continuing care. Discussions continued over dinner.

Next morning county groups convened early to refine their treatment protocols. Dr. David Pollack, the Medical Director for the Oregon Office of Mental Health and Addiction Services and his colleague, Jim Bradshaw, began the day with an overview of changes in the Oregon Health Plan. Because of a budget deficit, the state legislature eliminated outpatient substance abuse and mental health treatment benefits and medication benefits (effective March 1, 2003) for a large portion of the individuals enrolled in Oregon's Medicaid program (perhaps 60 to 70 percent of the individuals being treated in publicly funded drug abuse services in Oregon). For the moment, therefore, the Oregon Health Plan would cover only the individuals who meet traditional federal Medicaid eligibility standards. Treatment providers throughout the state are challenged to provide care for many indigent men and women and to survive the loss of revenues.

Discussions of medical (HIV/AIDS, HCV, and TB) and psychiatric co-morbidity among opiate dependent patients outlined treatment challenges and pointed to the advantages of coordinated care. The final presentation reviewed special populations and included discussions of the use of buprenorphine with adolescents, pregnant women, elders, patients with chronic pain and patients with renal failure. After lunch, training concluded with questions and answers. Post-test GPRA forms and attitude surveys were distributed and collected. County teams continued to work on their community treatment protocols if they needed more time.

Physicians completed waiver applications for permission to write buprenorphine prescriptions and the applications were submitted to CSAT. Continuing medical education units were provided through Oregon Health & Science University; 21 counselors and two nurse

practitioners received continuing education credits from the Northwest Frontier Addiction Technology Transfer Center.

Bright sun accompanied the return drive to Portland International Airport. The presenters tasted early spring in the Willamette Valley—bright green grass, lambs gamboling in pastures and hazelnut trees about to burst into leaf. All were willing to return in the fall for an ASAM-sponsored buprenorphine training in Portland.

Protocols

Six of the eight counties drafted local assessment, referral and treatment protocols. The protocols addressed nine elements:

- I. Screening (who, where, how).
- II. Assessment (withdrawal potential, primary and co-occurring diagnoses, treatment planning).
- III. Treatment supports (motivation for treatment, family).
- IV. Willingness to comply with treatment requirements.
- V. Treatment goals (maintenance versus detoxification).
- VI. Immediate objectives (withdrawal management).
- VII. Maintenance procedures (induction, treatment schedule, stabilization, long-term medication management).
- VIII. Patient management (linkages with counseling, urine screens).
- IX. Confidentiality requirements.

Protocols were generally built on existing relationships and procedures focused assessment and treatment procedures on local drug abuse treatment centers and community health centers. Douglas County, for example, centered its plan on ADAPT, the Roseburg-based drug abuse treatment center, while Klamath County focused on their health center (Klamath Community Treatment Center). ASAM patient placement criteria and DSM-IV diagnostic interviews were the core of the assessment and planning processes. Mechanisms were devised to link primary care physicians, pharmacists and drug abuse treatment counselors. The Josephine County protocol, for example, directs the pharmacist to call the physician if a patient fails to refill a prescription. Confidentiality issues included HIPAA regulations as well as 42CFR Part II (the federal confidentiality regulation for alcohol and drug abuse treatment). Lane County planned physician training on the federal confidentiality standards for alcohol and drug abuse treatment.

Protocol development continued as teams returned to their communities. Linda Clary scheduled follow-up meetings with each group and facilitated the completion of local plans.

Assessment of the Training

Data from the post-test GPRA and ASAM evaluation forms suggest that most participants were pleased with the training. Trainees indicated that the combination of counselors, pharmacists and physicians worked well and fostered communication among the groups. An evaluation form required for ASAM sponsorship rated each presentation on a 7-point scale (1 = very poor; 7 = superlative). Table 1 summarizes the presentation ratings from the ASAM evaluation forms and records the percent of responses that were 1 – 4 (negative or neutral) and 6 – 7 (very good or superlative).

Table 1. Summary Scores From the ASAM Evaluation Forms

Presenter	Topic	% Score LE 4 (Negative or Neutral)	% Score 6 or 7 (Very Positive)
Saturday Morning			
Gallon (<i>n</i> =47)	Introduction	9	51
Martin (<i>n</i> =48)	Legislation and Regulation	17	52
Saxon (<i>n</i> =48)	Opioid Pharmacology	4	54
McNicholas (<i>n</i> =48)	Pharmacology of Buprenorphine	2	75
Saturday Afternoon			
Saxon (<i>n</i> =48)	Patient Assessment	8	56
McNicholas (<i>n</i> =48)	Clinical Use of Buprenorphine	6	71
Martin (<i>n</i> =48)	Office Management	21	60
All Faculty (<i>n</i> =44)	Case Study	18	54
Gallon (<i>n</i> =43)	Local Collaboration	12	63
Sunday			
Pollack (<i>n</i> =44)	Oregon Health Plan Status	11	70
Martin (<i>n</i> =31)	Medical Co-Morbidity	6	77
Saxon (<i>n</i> =42)	Psychiatric Co-Morbidity	19	59
McNicholas (<i>n</i> =41)	Special Populations	32	58
All Faculty (<i>n</i> =35)	Case Discussion	9	54
Gallon (<i>n</i> =33)	Local Protocol Review	6	57

Responses suggested strong overall satisfaction with the presentations. On each presentation or facet of the training more than half of the participants used the highest possible ratings (6 or 7). Four presentations recorded at least 70 percent high ratings (Medical Co-Morbidity, Pharmacology of Buprenorphine, Clinical use of Buprenorphine and the Update on the Oregon Health Plan. Conversely, negative and neutral ratings exceeded 20 percent on only two presentations—the discussions of Special Populations and Office Management. For both

discussions, time was limited and comments indicated that practitioners were looking for more detail on both topics.

Respondents generally believed that the conference goals were met completely. Three items assessed the extent to which the training achieved its goals:

- I. “Link physicians with pharmacists and chemical dependency treatment professionals in developing protocols for providing therapeutic services to opiate dependent patients” (**79 percent** said this goal was met completely: $n = 38$ total respondents).
- II. “Assist physicians in gaining approval to prescribe opiate agonist and partial opiate agonist medications” (**89 percent** said this goal was met completely: $n = 35$ total respondents).
- III. “Inform interested health and substance abuse professionals about the use of buprenorphine hydrochloride in the treatment of opioid dependence” (**97 percent** said this goal was met completely: $n = 38$ total respondents).

Trainees also noted aspects of the program that should be changed or retained. The primary request was a change in location; the casino was seen as a poor choice because of the heavy smoke on the casino floor, the poor quality of the sound system and that casinos were an inappropriate site for addictions treatment training. Additional suggestions were to hold the training on week days (rather than use weekend time), offer more guidance on protocol development, add a trainer who is an active family practice/primary care practitioner and using buprenorphine in their practice, and provide more details on specific aspects of caring for opioid dependent patients. Suggestions also recommended continued use of teams of counselors, pharmacists, and physicians, retention of the faculty, and affirmed the value of the videotaped patient interview.

Government Performance Results Act Evaluation

CSAT requires grantees to complete evaluation forms and report data for compliance with the Government Performance Results Act (GPRA). Participants were invited to fill out a training satisfaction survey at the end of the event. Satisfaction ratings are outlined in Table 2 and suggest high rates of satisfaction. On three of the four measures more than 50 % of the participants reported they were “Very Satisfied”; and nearly 100 % were “Satisfied” or “Very Satisfied” on all of the items.

Table 2. Percent Satisfied With Training (How satisfied are you with...)

Satisfaction Item	Respondents	% Very Satisfied	% Satisfied or Very Satisfied
The overall quality of this training?	47	46.8	100
The quality of the instruction?	47	54.4	100
The quality of the training materials?	47	55.3	100
Your training experience?	47	51.1	95.8

Respondents also indicated agreement or disagreement with a series of statements related to the training. Results are summarized in Table 3.

Table 3. Percent Agreement With Statements About the Training

Please Indicate Your Agreement With These Statements About the Training	Respondents	% Strongly Agree	% Agree or Strongly Agree
The training class was well organized	47	55.3	95.7
The material presented in this class will be useful to me ...	47	44.7	91.5
The instructor(s) was knowledgeable about the subject matter	47	85.1	100
The instructor(s) was well prepared for the course	47	85.1	100
The instructor(s) was receptive to participant comments and questions	47	89.4	100
I am currently effective when working in this topic area	46	8.7	52.7
The training enhanced my skills in this topic area	47	51.1	97.9
The training was relevant to my career	47	53.2	93.6
I expect to use the information gained from this training	47	59.6	97.9
I expect this training to benefit my clients	46	56.5	97.9
This training was relevant to substance abuse treatment	46	65.2	95.8
I would recommend this training to a colleague	46	69.6	100

Instructors were rated as knowledgeable, receptive and prepared – more than 80 percent of the respondents “Strongly Agreed” with these statements. Seven of ten respondents “strongly agreed” that they would recommend the training and 65 % “strongly agreed” that the training was relevant (nearly 100 percent either agreed or strongly agreed with these statements). The high rates of strong agreement reinforce the sense that training participants were pleased with the event. The one item with little strong agreement (9 percent) (“I am currently effective when working in this topic area.”) suggests that physicians and counselors in the rural counties recognize the need for additional training and expertise in treating opioid dependent patients.

Table 4. Percent Positive Ratings

Rating of Training Facets	Respondents	% Excellent or Strongly Agree	% Positive Ratings
General (Poor to Excellent)			
Registration Process	45	44.4	91.1
Program Format	45	48.9	93.3
Quality of the Facilities	45	40.0	73.3
Program (Strongly Disagree to Strongly Agree)			
Trainers were knowledgeable about subject matter	45	82.2	97.8
Presentations were clear/easy to understand	45	60.0	93.3
Core curriculum was covered concisely	45	55.6	92.8
Presentations increased my knowledge	45	71.1	97.8
Sufficient time was allowed for questions/answers	45	57.8	92.8
Program Materials (Strongly Disagree to Strongly Agree)			
Materials were clear/easy to understand	45	57.8	92.8
Materials were useful and informative	45	60.0	97.8
Next Steps (Strongly Disagree to Strongly Agree)			
Training clearly identified the waiver notification submission process	42	33.3	78.5
Training clearly identified the physician qualifications to receive a bup waiver	41	43.9	82.9
Overall Seminar Rating (Poor to Excellent)	46	60.9	97.9

Participants in the training also completed a page specifically rating aspects of the event on five-point scales (endpoints were either labeled “poor” to “excellent” or “strongly disagree” to “strongly agree”). Ratings are summarized in Table 4 and are consistent with the other measures – participants were pleased with the delivery and quality of the training. Trainers were rated as knowledgeable (82 percent strongly agreed) and trainee knowledge increased (60 percent strongly agreed).

Two aspects received lower ratings. First, participants were not clear about the waiver process – 33 percent strongly agreed that “training clearly identified the waiver notification submission process” and 44 percent strongly agreed that the qualifications for the waiver were clear. Second, 40 percent rated the “quality of the facilities” as “excellent.”

GPRA Follow-Up 30 Days Post Training

GPRA includes requirements to complete a 30-day follow-up interview with training participants who provide permission for a post-training contact. GPRA follow-up surveys were mailed 30 days following the training. Non-respondents were contacted and interviewed by phone. Completed interviews were obtained from 34 of the 42 participants (81 percent) who agreed to a follow-up contact within 90 days of the training. Overall satisfaction ratings are summarized in Table 5 and remain at high levels

Table 5. Percent Satisfied With Training (How satisfied are you with ...) (30 days post)

Satisfaction Item	Respondents	% Very Satisfied	% Satisfied or Very Satisfied
The overall quality of this training?	34	44.1	94.1
The quality of the instruction?	34	61.8	94.2
The quality of the training materials?	33	50.0	93.9
Your training experience?	33	50.0	94.1

Table 6 reviews levels of agreement with descriptive statements about the training. Participants remain enthusiastic about the training but, compared to the forms completed immediately at the end of training, the zeal is more muted.

Table 6. Percent Agreement With Statements About the Training (GPRA 30 days post)

Please Indicate Your Agreement With These Statements About the Training	Respondents	% Strongly Agree	% Agree or Strongly Agree
The material presented in this class will be useful to me ...	34	35.3	62.7
The training enhanced my skills in this topic area	34	70.6	88.2
The training was relevant to my career	34	26.5	85.3
I expect this training to benefit my clients	34	20.3	55.9
This training was relevant to substance abuse treatment	28	42.9	89.1
I would recommend this training to a colleague	34	38.2	91.1

Most of the respondents reported that they shared information (94 percent) and materials from the training (62 percent). More than half (56 percent) indicated that they applied the information in their current work. The barriers to application included a lack of patient interest, a lack of access to physicians willing to treat opioid dependent patients and concerns with the financial resources required for purchasing buprenorphine.

Attitude Change

Attitudes, beliefs, social norms associated with the use of three medications (methadone, buprenorphine and clonidine) to treat opiate dependence were assessed along with intentions to use the medications. Before and after the training, attitudes, beliefs and social norms toward the use of these medications were generally supportive. Because the participants were self-selected and interested in learning more about the use of a medication (buprenorphine) to treat opiate dependence, the favorable ratings are not surprising. Participants were expected to be predisposed to the use of medications and specifically buprenorphine – they came to learn how to use the medication. Table 7 provides the mean pre- and post-test ratings. Means are based on respondents with complete data for both the pre-test and the post-test.

Table 7. Mean Attitudes, Social Norms and Intentions to Use Buprenorphine

Measure	N	Before Training		After Training		p <
		Mean	SD	Mean	SD	
Attitude						
Buprenorphine	33	4.61	3.05	5.67	2.26	.062
Physicians	12	5.00	3.01	5.17	2.89	
Clinicians	11	3.55	3.27	5.45	1.86	
Social Norm						
Buprenorphine	35	0.69	1.71	0.80	1.66	ns
Physicians	12	-0.08	2.15	-0.08	2.15	
Clinicians	11	1.45	1.21	1.72	1.10	
Intention						
Buprenorphine	35	1.14	1.48	1.26	1.36	ns
Physicians	12	1.54	1.13	1.31	1.70	
Clinicians	11	0.55	1.92	1.18	0.98	

Attitude toward using buprenorphine (“For me, working with clients who take buprenorphine to treat heroin dependence is ...”) was measured as the sum of responses (scaled -3 to +3) to three semantic differential items that assess affect (bad-good; useless-useful; and sad-happy) (potential range: -9 to +9). Attitudes were positive prior to the training (pre mean = 4.6) and were more positive following the training (post mean = 5.7). The small sample size limits the statistical power so the trend toward standard significance levels ($p < .06$) suggests that the training had substantial impact on attitudes. A subanalysis comparing physicians and clinicians suggests that the counselors accounted for the majority of the improvement in attitudes. Sample size is too small for reliable tests of significance.

Measures of social norms (“People important to me think I should work with clients taking buprenorphine”) and intention (“I intend to tell my heroin-dependent clients to take buprenorphine”) did not show evidence of significant change following the training.

A review of beliefs associated with the use of medications found evidence of significant change on four beliefs: 1) Buprenorphine is an effective heroin treatment, 2) Buprenorphine saves patient lives, 3) Patients taking buprenorphine have better health and 4) Buprenorphine blocks craving for heroin. The significant changes in these beliefs contributed to the positive change in attitudes. Table 8 presents pre and post means on the belief items. Physician and counselor data are presented for items with significant pre-post change.

Table 8. Mean Beliefs Toward the Use of Buprenorphine Pre and Post Training

Belief Items	N	Before Training		After Training		p<
		Mean	SD	Mean	SD	
<u>Bup is effective</u>	38	1.74	1.11	2.32	0.62	.001
Physicians	12	2.14	0.99	2.54	0.52	
Clinicians	11	1.33	1.55	2.17	0.72	
<u>Bup saves patient lives</u>	38	1.87	1.04	2.21	0.91	.017
Physicians	12	2.00	1.00	2.31	0.85	
Clinicians	11	2.00	0.74	2.17	0.94	
<u>Pts taking bup have better health</u>	38	1.82	1.11	2.24	0.82	.006
Physicians	12	2.23	0.83	2.53	0.88	
Clinicians	11	1.58	1.08	2.00	0.85	
<u>Bup block heroin craving</u>	37	1.84	1.26	2.16	0.87	.07
Physicians	12	2.23	0.73	2.38	0.65	
Clinicians	11	1.50	1.68	2.00	1.21	
<u>Pts report few side effects</u>	37	0.86	1.25	1.22	1.25	ns
<u>Bup requires daily visits</u>	37	-0.95	1.47	-0.86	1.72	ns
<u>Bup is long-lasting</u>	38	1.89	1.20	2.05	1.31	ns
<u>Bup reduces heroin withdrawal symptoms</u>	37	2.14	0.82	2.21	0.82	ns
<u>Bup is easy to administer</u>	37	1.30	1.29	1.24	1.04	ns

Access to Care

Treatment system data from the State's Office of Mental Health and Addiction Services will be monitored to assess increased access to care for opiate dependent patients in the seven counties that participated in the training. The elimination of benefits for outpatient services in the Oregon Health Plan, however, may make it difficult to detect enhancements in access. An inquiry of physicians and pharmacists four months after completion of the training, found two counties serving 12 patients with buprenorphine. Some physicians were waiting for their formal waiver

notification and others decided not to request the waiver. Two counties are using the change teams to examine the county service delivery system and to suggest recommendations for improvement

Next Steps

The OMIROR project has been completed successfully. Its influence, moreover, will continue. Relationships were built between primary care physicians in health clinics and private practices with counselors in drug abuse treatment services and pharmacists in community pharmacies. Opioid dependent women and men in central and southwestern Oregon have a better likelihood of being treated in their home town and of having both medical and drug use problems addressed conjointly.

OMIROR demonstrated the feasibility of a 12-hour training that combines physicians, pharmacists and counselors. Each group gained from participation with the others. The physicians are more confident of their capacity to work with local drug abuse treatment centers and to care for the patients most effectively. Pharmacists understand their role in effective care for opioid dependent patients and how to work collaboratively with physicians and drug treatment services. Drug abuse treatment clinics and their counselors developed and reaffirmed relationships with primary care practitioners in their communities; these relationships will be useful for all their patients not just those being treated with buprenorphine. The nurse practitioners also advocated for access to the trainings because they would ultimately be expected to provide much of the service for opioid dependent patients being cared for in primary care.

As a result of the experience with the OMIROR training, we encourage CSAT and ASAM to format trainings for 1.5 days and to invite pharmacists and drug abuse counselors to participate together with primary care physicians. This combination appears to be effective and to reduce the risks of treating opioid dependent individuals without all of the linkages in place. Such training will help build collaborative relationships and promote coordination between health providers and chemical dependency treatment agencies. Buprenorphine offers a unique opportunity to expand the armamentarium of drug abuse treatment and to reorganize and to improve treatment for the adolescents, women and men using heroin and other opiates.

Section 6—References for Continued Learning

Addiction Technology Transfer Center, National Office. Available WWW.<http://www.nattc.org>

American Academy of Addiction Psychiatry. Available WWW.<http://www.aaap.org>

American Psychiatric Association (2000). *Diagnostic and Statistical Manual of Mental Disorders – 4th Edition* (DSM-IV).

American Society of Addiction Medicine. Available WWW.<http://www.asam.org>

California Chapter of the American Society of Addiction Medicine. Available WWW.<http://www.csam-asam.org>

Center for Substance Abuse Treatment. Available WWW.<http://www.samhsa.gov>

Center for Substance Abuse Treatment–Buprenorphine Information and Physician Locator: Available WWW.<http://www.buprenorphine.samhsa.gov>

The Change Book: A Blueprint for Technology Transfer. Addiction Technology Transfer Centers, 2000.

Manufacturer of Buprenorphine (Suboxone and Subutex): Reckitt Benckiser Healthcare - (1.877.782.6966). Available WWW.<http://www.suboxone.com>

McNicholas, Laura M.D, Ph.D. and Howell, Elizabeth MD (2000). *Buprenorphine Clinical Practice Guidelines*. Field review draft submitted to the Center for Substance Abuse Treatment.

Appendix 1

Project Plan

Quarter 1

- I. Project staffing.**
 - A. Identify Project Coordinator.
- II. State government coordination, Office Medical Assistance Programs.**
 - A. Identify potential stakeholder in State offices of Mental Health (generally State offices have staff members who will want to participate and contribute).
- III. Buprenorphine course.**
 - A. Complete on-line course via Danya International, if appropriate for educational purposes.
- IV. Develop recruitment tools.**
 - A. Create materials describing project.
 1. Submit draft to principals.
 2. Incorporate changes.
 3. Submit final to principals.
 - B. Identify State and other policy-makers/influencers that should be invited to training. (Advise the Project Coordinator.)
 - C. Develop marketing flyers.
- V. Buprenorphine status.**
 - A. Determine if State insurance plan includes buprenorphine. If not, develop and implement strategy to have this included in the State plan.
- VI. Plan 2-day training.**
 - A. Selection of CSAT-approved curriculum.
 - B. Selection of training organization. Schedule and hold a conference call to develop curriculum.
 - C. Develop training agenda.
 - D. Contact ASAM re: curriculum, trainers, CME.
 - E. Apply for CME, 6-month lead with ASAM, or use other medical teaching university.

- F. Selection of training facility.
- G. Gather materials for conference (buprenorphine-related articles, etc.).
- H. Obtain ASAM curriculum, power point presentations from trainers, ASAM evaluation forms, other evaluation forms. Collate, duplicate, place in binders.
- I. Obtain Buprenorphine Office tools and "burn" onto master CD. Duplicate CD. Place in storage containers for distribution at conference.

VII. Contact stakeholders.

- A. Develop a list of interested physicians/providers/pharmacists/practitioners.
 - 1. Contact county contacts/physicians from MH and A/D Directors.
 - 2. Contact community health centers and family physicians-introduce them to project.
 - 3. Obtain names of drug treatment centers-contact person.
 - 4. Contact county health person.
 - 5. Contact State Health Plan person in each county.
- B. Send recruiting information to each potential participant/attendee.

VIII. Pre-conference reader.

- A. Gather materials for inclusion in reader. Include conference agenda and other conference-related logistical details.
- B. Reading materials gathered, organized, duplicated, placed in binders.

IX. Evaluation plans.

- A. Finalize materials.
- B. Begin collecting data.
- C. Data sent to principal investigator.

X. Correspondence.

- A. E-mail project status/questions to principals.
- B. Set up e-mail list of participants/interested people.

Quarter II

I. Recruiting efforts.

- A. Finalize list of participants.
- B. Send list of physicians to medical recruiters. (Doctors call doctors.)
- C. Project Coordinator contacts all others.
- D. Obtain contact information for all participants, send information/invitation.

E. Follow-up for confirmation of attendance, establish first group meeting.

F. Follow-up reminders for first meeting.

II. First Group meeting.

A. Distribute pre-conference reading materials.

B. Discuss conference, answer questions.

C. Distribute discussion outline (Appendix 5).

III. Buprenorphine status.

A. Continue to monitor State Health Plan regarding coverage of buprenorphine.

B. Be prepared to discuss the status of the drug at the training event.

IV. Training event.

A. Mail event reminders to participants.

B. E-mail event reminders.

C. Continue developing training materials.

D. 2-day training event: training.

E. Groups develop Clinical Practice Guidelines based upon a specific process guide (Appendix 6).

F. Establish date for last meeting.

G. Administer both pre & post evaluation tests.

V. Analysis of data.

A. Principal Investigator starts analysis.

VI. Correspondence.

A. E-mail project status/questions to principals.

Quarter III

I. Clinical Practice Guidelines.

A. To be completed by groups in local meetings.

B. County teams review guidelines they developed at conference.

C. Finalize guidelines for their community.

II. Evaluation data.

A. Continue to collect.

B. Send and collect 30-day (after the conference) follow-up evaluations.

III. Correspondence.

- A. E-mail project status/questions to principals.

Quarter IV

I. Protocols/Guidelines.

- A. Synthesize community-crafted guidelines into one document and submit to participants.
- B. Distribute throughout the State to rural practitioners.
- C. E-mail project status/questions to principals.

II. Correspondence.

- A. E-mail project summary to participants.

III. Evaluation data.

- A. Gather evaluation data (surveys, interviews, and focus groups).
- B. Data sent to Principal Investigator.
- C. Develop final report and include lessons learned.

Appendix 2

Information/Invitation Letter

November 2003

Xxxx

Xxxx

Dear xxxx:

You are invited to participate in an emerging new opportunity to improve treatment for men and women in your community who are dependent on heroin and other opioid medications. Oregon Health & Science University, in collaboration with the Oregon Office of Mental Health and Addiction Services, has received federal funding to train physicians and substance abuse treatment professionals in the use of buprenorphine hydrochloride (a new medication for treating opiate dependence). The OHSU Northwest Frontier Addiction Technology Transfer Center (NFATTC) is responsible for implementing the project, which focuses on eight counties in Central and Southwestern Oregon.

Recent changes in federal law make it possible to improve access to care for individuals using heroin and other opiates. The *Drug Addiction Treatment Act of 2000* permits qualified physicians to prescribe Schedule III, IV or V narcotic drugs for the treatment of narcotic dependence if the Food and Drug Administration (FDA) approves the medication for opiate maintenance or detoxification. Buprenorphine hydrochloride (buprenorphine) received FDA approval in October for use in the treatment of opiate dependence. Buprenorphine has many positive benefits: as a partial agonist it is effective for up to 48 hours (longer than methadone), it has minimal impact on respiration, the patient can seek help in your office instead of traveling many hours to a methadone clinic, withdrawal from buprenorphine is easier than withdrawal from opiates or methadone and the stigma of treatment is reduced. For the first time, qualified physicians will be authorized to prescribe an opiate agonist therapy and opiate dependent patients will have an opportunity to receive treatment from local primary care and substance abuse treatment professionals rather than in specialized narcotic treatment programs (i.e., methadone clinics).

The goals of the current project are:

1. To inform interested health and substance abuse professionals about the use of buprenorphine hydrochloride in the treatment of opiate dependence.

2. To assist physicians in gaining approval to prescribe opiate agonist and partial agonist medications.
3. To link physicians with pharmacists and chemical dependency treatment professionals in developing local protocols for providing therapeutic services to opiate dependent patients.

Participants in the project will receive training on the use of buprenorphine and work collaboratively to develop local treatment protocols. Linkages between primary care providers, pharmacists and local alcohol and drug abuse treatment programs will be emphasized. Physicians who complete the training will be qualified to apply for the federal authorization required before the medication can be prescribed.

The training will be a two-day event for physicians, pharmacists, and substance abuse treatment providers on February 1-2, 2003 at the Seven Feathers Resort/Casino in Canyonville, Oregon. It will be co-sponsored by the American Society of Addiction Medicine. For individuals selected to participate, the cost of accommodations, meals and the training will be covered by OHSU. Prior to the training you will be asked to meet with other local physicians, pharmacists and treatment providers to learn more about opiate agonist treatment and about this project. We anticipate that each county will develop a protocol for the implementation of office-based opiate agonist treatment and assume that each county has unique needs and circumstances that will determine recommended treatment practices and procedures.

In terms of objectives, at the end of this project, participants will have:

- 1) Received Federally approved training on buprenorphine.
- 2) Obtained Category 1 CME hours or NAADAC/ACCBO approved CE hours.
- 3) Established relationships with other interested individuals in the community.
- 4) Contributed to the development of a local treatment protocol that will improve public health in the county.
- 5) Attended training with nationally recognized addiction medicine educators.
- 6) Enjoyed a weekend in a pleasant Southern Oregon location.

We hope you will consider being part of our efforts to improve treatment for opiate dependence in your area. ADAPT, our partner in this project, is coordinating the Conference (the training) and separate team meetings. Their Project Manager, Linda Clary, will be in touch with you to provide more information and invite you to a local meeting of interested health care professionals. Her contact information is: commsolutions@starband.net or you can reach her at (541) 464-8883. Thank you for your time today.

Sincerely,

Steven L. Gallon, Ph.D.
Project Director

Appendix 3

Pre-Conference Reader

OMIROR

Buprenorphine and Office-Based Treatment of Opioid Dependence A Conference for Rural Health Providers

Pre-Training Information

Articles:

DiClemente, Carlo C.; Norcross, John C; et al. "In Search of How People Change." *American Psychologist*, September 1992.

Fiellin, David A.; O'Connor, Patrick G. "Clinical Practice." *New England Journal of Medicine*, September 12, 2002. Vol. 347, No. 11.

Fiellin, David A.; O'Connor, Patrick G. "Pharmacologic Treatment of Heroin-Dependent Patients." *Annals of Internal Medicine*, July 2000. Vol. 133. No.1.

Kleber, Herbert D; Lewis, David C.; et al. "Drug Dependence, a Chronic Medical Illness." *JAMA*, October. 4, 2000.

General Information:

Drug Label – <<http://www.fda.gov/cder/foi/label/2002/20732161.pdf>>. Downloaded 11/03/02.

"FDA Approves Two Forms of Buprenorphine for Opiate Treatment." Press Release. <<http://www.csam-asam.org>>. Downloaded 11/03/02.

"Fighting Addiction." Physicians and Health Care Professionals. <<http://www.suboxone.com/suboxone/phys/pharmfaqs.html>>. Downloaded 11/03/02.

New Treatment for Heroin Addiction approved by FDA, 10/8/02. Calif. SAM Information paper. <<http://www.csam-asam.org>>. Downloaded 11/03/02.

"NIDA Research and SAMHSA Physician Training Combine to Put Care for Opiate Dependence in Hands of Family Doctor." NIDA and SAMSHA Press Advisory. October 9, 2002.

Patient Information – Suboxone and Subutex.

<<http://www.fda.gov/cder/foi/label/2002/20732/ppi.pdf>>. Downloaded 11/03/02.

Pharmacists – Information for Pharmacists on Suboxone and Subutex.

<http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.html>. Downloaded 11/03/02.

Physicians Information – Answers to Frequently Asked Questions.

<<http://www.fda.gov/cder/foi/label/2002/20732mdinfo.pdf>>. Downloaded 11/03/02.

“Subutex and Suboxone Approved to Treat Opiate Dependence.”

<<http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01165.html>>. Downloaded 11/03/02.

Subutex and Suboxone – Questions and Answers.

<http://www.fda.gov/cder/drug/infopage/subutex_suboxone/subutex-qa.html>. Downloaded 11/03/02.

Appendix 4

Conference Agenda

BUPRENORPHINE and OFFICE-BASED TREATMENT OF OPIOID DEPENDENCE A Conference For Rural Health Providers

**SPONSORED BY
OREGON HEALTH & SCIENCE UNIVERSITY and
THE AMERICAN SOCIETY OF ADDICTION MEDICINE**

**Seven Feathers Resort—Canyonville, Oregon
February 1-2, 2003**

February 1

9:00 a.m.	Registration and Continental Breakfast Pre-Test	Linda Clary
9:30 a.m.	Welcome and Introductions of Staff and Guests Legislation and Prescribing Regulation Opiate Dependence/Pharmacology Buprenorphine Pharmacology	Steve Gallon Laura McNicholas Andrew Saxon Laura McNicholas
Noon	Lunch Break	
1:00 p.m.	Patient Assessment and Selection Clinical Use of Buprenorphine Office Management Case Study Discussions	Andrew Saxon Laura McNicholas Judith Martin All Faculty
4:00 p.m.	Break	
	Small Group Case Discussion/Local Teams Local Teams Collaborate on a Protocol for Referrals and Case Management Summary of the day	Steve Gallon Laura McNicholas
6:00 p.m.	Conference Dinner	

February 2

9:00 a.m.	County Meetings to Articulate Local Protocols Presentation of Protocols to Conference Delegates Update on Oregon Formulary and Insurance Coverage	Steve Gallon David Pollack
10:30 a.m.	Medical Co-Morbidity Case Study Presentations and Discussion Psychiatric Co-Morbidity Special Treatment Populations Case Study Presentation and Discussion	Judith Martin All Faculty Andrew Saxon Laura McNicholas All Faculty
1:00 p.m.	Lunch Break	
2:00 p.m.	Local Teams Continue Work on a Local Protocol Select a Representative for a Regional Protocol Committee Schedule Next Local Meeting to Finalize Protocol and Procedures Questions/Answers, Evaluations and Post-Test Certification Paperwork	Steve Gallon All Faculty Linda Clary
3:30 p.m.	Adjourn	

Faculty:

Laura F. McNicholas, MD, PhD, University of Pennsylvania, Philadelphia VAMC.
 Andrew J. Saxon, MD, Veterans Administration Medical Center, Seattle, WA.
 Judith Martin, MD, The 14th Street Clinic, Oakland, CA.
 David Pollack, MD, Oregon Office of Mental Health and Addiction Services.
 Linda Clary, ADAPT, Roseburg, OR.
 Steve Gallon, Ph.D., OHSU, Northwest Frontier Addiction Technology Transfer Center.

Appendix 5

First Local Team Meeting Outline

Discussion Outline/Template for Use in Developing Local Team Clinical Practice Guidelines

Agenda

- I. Introductions.
- II. Background of the project.
- III. Answer any questions about the conference.
- IV. Distribute Pre-Conference Reader.
- V. Distribute the following outline and begin discussion.

Each team can use the following suggested outline to customize their Clinical Practice Guidelines. It encourages consideration of key issues prior to the training conference and promotes descriptions of multiple aspects of patient treatment. It also facilitates involvement and participation by all members of the team.

Screening Procedures

Determining the potential presence of alcohol and/or related problems through the use of objective questions, lab tests and interview.

- I. Who will be screened? Everyone? Only those that exhibit specific indicators? How will at-risk populations be screened? Special populations include adolescents, pregnant patients, the elderly, patients with renal failure or compromised hepatic function and health care professionals.
- II. How will the screening function be conducted?
- III. Who will do the screening? Will you have a “No Wrong Door” philosophy, meaning that patients can get started with their physician, with the substance abuse treatment agency, or with their pharmacist?
- IV. What will be done and by whom?

Assessment

Establishing the diagnosis, determining appropriateness of treatment, identifying related medical or psychiatric diagnoses, assessing withdrawal potential and formulating an initial treatment plan:

- I. Establishing the diagnosis.
- II. Determining appropriateness of treatment.
- III. Identifying related medical or psychiatric diagnoses.
- IV. Assessing withdrawal potential.
- V. Formulating initial treatment plan.

Interest in Treatment

Educating the patient, family and significant others regarding the benefits and risks of treatment and reviewing all treatment options.

Assessing the Willingness of the Patient to comply with treatment options.

Determining Treatment Goals

Detoxification from opiate drugs, abstinence from substances of abuse/drug-free, maintenance on an agonist (methadone) or partial agonist (buprenorphine).

Identifying Immediate Treatment Objectives

- I. Detoxification/withdrawal management.
- II. Stabilization/maintenance.
- III. Long-term management.

For a Stabilization/Maintenance Objective identify how you will approach:

- I. Induction into treatment.
- II. Schedule of treatment activities.
- III. Stabilization plan (1-2 months).
- IV. Maintenance plan (2+ months).
- V. Long-term medication management plan.

For Long-Term Patient Management Objective identify how the following will be approached:

- I. Psychosocial treatment.
- II. Treatment monitoring.
- III. Urine testing.

Compliance with confidentiality regulations.

Appendix 6

Conference Process Guide for Team Members

Developing Local Clinical Practice Guidelines

Introduction

Each county team is asked to begin developing at the conference a set of local practice guidelines for the treatment of opioid dependence when buprenorphine is used as part of the treatment plan. For most patients, drug abuse counseling and participation in 12-step or other self-help programs are considered necessary components of the treatment plan. Pharmacotherapy alone is rarely sufficient treatment for drug dependency. To the extent possible counseling and education should be included in the patient's plan, either through the physician's own practice or through referral. Most often, such psychosocial services will be available from reputable substance abuse treatment agencies in the local area.

The degree to which opiate dependent patients receive adequate care depends on how issues like the following are managed:

- I. Development of an adequate treatment plan.
- II. Coordination of key services.
- III. Communication between members of the treatment team.
- IV. Protection of patient privacy rights.

All these issues could be addressed in a local protocol that serves as a practice guide for managing these patients. The following outline is meant to help you identify key issues and build a comprehensive approach to a patient's care in your area.

Developing Local Guidelines

Session 1

- I. Start by making sure that everyone on your team has been introduced to one another. Take some time to share where you work, your interests in attending this conference and any concerns you have about developing local treatment options for opiate dependent patients.

- II. As a second task, please identify:
- A. A **facilitator** for your group. A facilitator is someone who understands the tasks to be accomplished and is willing to move the group along to complete the task in the allotted time. The facilitator puts personal issues and concerns aside in order to assist the group; the facilitator's personal concerns can be shared but not in a way that dominates the discussion.
 - B. It would also be helpful to identify a **recorder**. The recorder takes notes and fills in the Protocol Outline form.
 - C. Finally, it is suggested you have a **timekeeper** to help assure the group gets through each of the assigned tasks during the time you have available.
- III. The final task for this session is to review this Protocol Outline. Note the topics that need to be addressed in a local set of practice guidelines and discuss any that are of particular concern to you. Before ending this session decide when you will meet in the morning to begin working on your formal responses to the protocol outline. We will begin the morning presentations at 10 a.m. You have until that time to get a significant amount of work done on your plan.

Session 2

Your **objective** this morning is to **discuss and begin drafting local practice guidelines** for the issues in the protocol outline below. It is important to be as specific as possible in drafting your guidelines. Consider the Who-What-When-Where model as you work on each issue identified in the outline below. If you force yourself to be specific about what will be done, when, by whom and where, then the guide you create will be far more useful to you following the conference.

Please **assist your recorder** in documenting accurately the decisions you make as you think about working collaboratively in delivering care to this group of patients.

Here is the outline of issues to consider in developing your guidelines:

Local Guidelines

- I. **Screening Procedures**—Determining the potential presence of alcohol and/or related problems through the use of objective questions, lab tests and interview.
 - A. Who will be screened? Everyone? Only those that exhibit specific indicators? How will at-risk populations be screened? Special populations include adolescents, pregnant patients, the elderly, patients with renal failure or compromised hepatic function, and healthcare professionals.

B. How will the screening function be conducted?

C. Who will do the screening? Will you have a “No Wrong Door” philosophy, meaning that patients can get started with their physician, with the substance abuse treatment agency or with their pharmacist?

D. What will be done and by whom?

1. Objective measures.

2. Lab tests.

3. Interview.

II. **Assessment**—Who will be responsible for establishing the diagnosis, determining appropriateness of treatment, identifying related medical or psychiatric diagnoses, assessing withdrawal potential and formulating an initial treatment plan including contraindications.

A. Establishing the diagnosis.

B. Determining appropriateness of treatment.

C. Identifying related medical or psychiatric diagnoses.

D. Assessing withdrawal potential.

E. Formulating initial treatment plan.

- III. **Interest in Treatment**—Educating the patient, family and significant others regarding the benefits and risks of treatment, and reviewing all treatment options.
- A. **Assessing the willingness of the patient** to comply with treatment options.
- B. **Determining treatment goals**—Detoxification from opiate drugs, abstinence from substances of abuse/drug-free, maintenance on an agonist (methadone) or partial agonist (buprenorphine).
- C. **Identifying immediate treatment objectives.**
1. Detoxification/withdrawal management.
 2. Stabilization/maintenance.
 3. Long-term management.
- D. **For a stabilization/maintenance objective** identify how the following will be approached:
1. Induction into treatment.
 2. Schedule of treatment activities.
 3. Stabilization plan (1-2 months).
 4. Maintenance plan (2+ months).
 5. Long-term medication management plan.
- E. **For long term patient management objective** identify how the following will be approached:
1. Psychosocial treatment.
 2. Treatment monitoring.

3. Urine testing.

F. **Compliance** with confidentiality regulations.

Session 3

The **objective** for this final work session at the conference is to **continue working** on your practice guidelines. The **recorder prepares a copy of your work** to date to submit to the conference manager prior to departing the conference.

Prior to finishing this session, please **select a representative of your group for a regional protocol committee**. A synthesis of the county practice guidelines will be prepared for your review prior to submitting those guidelines to the Center for Substance Abuse Treatment. Our goal is to develop a single set of guidelines as a prototype that could be shared in other areas of the country.

As a final activity, if necessary please identify a date and time for a local meeting to finalize your protocol and procedures. Linda Clary is planning to meet with each team in your local county to provide closure to your process and to assure that the conference organizers have a clear understanding of your work and the issues you have identified as you plan for the implementation of office-based treatment of opioid dependence.

Congratulations on your good work!

Appendix 7

Buprenorphine Office Tools

Forms and patient information in Appendix 7.

- I. Initial Patient Contact About Buprenorphine
- II. Buprenorphine Maintenance Treatment—General Information
- III. Buprenorphine Maintenance Treatment—Specific Information
- IV. Buprenorphine Maintenance Treatment—Information for Family Members
- V. Consent for Treatment With Buprenorphine
- VI. DSM-IV Criteria for Substance Dependence and Abuse
- VII. Worksheet for DSM-IV Criteria for Diagnosis of Opiate Dependence
- VIII. Clinical Opiate Withdrawal Scale
- IX. Buprenorphine Maintenance Treatment—Intake History and Physical
- X. Buprenorphine Maintenance Treatment—Patient Responsibilities
- XI. Buprenorphine Maintenance Treatment—Intake Questionnaire for Patient Treatment-Planning Questions
- XII. Commonly Abused Drugs
- XIII. Buprenorphine Maintenance Treatment—Protocol for Follow-Up Appointments
- XIV. Consent for Release of Information

Initial Patient Contact About Buprenorphine

Checklist

For use by treatment program personnel who answer inquiries about buprenorphine.

Requirements (Check if discussed with patient.)

The following are required of patients who are admitted to buprenorphine treatment slot:

- Actively addicted to heroin or currently taking methadone.
- Initial long appointment, includes physical.
- Daily follow-up visits at first.
- At least monthly visits thereafter.
- Random urine and breath testing.
- Regular attendance to group or 12-step recovery program.
- Release to talk to all other doctors and counselors.
- Fees at time of visit, cash or money order.

Patient Information

Name _____ DOB _____

Address for Mail:

Telephone:

Home _____ Work _____

O.K. to leave a message? _____ Does your phone require caller ID? _____

Confidentiality (Check if discussed with patient.)

Patient confidentiality discussed.

Instructions for Initial Appointment (Check when discussed with patient.)

___ Full bladder.

___ Bring completed forms or come early.

___ Withdrawal, (if methadone, more than 24 hours since dose).

___ Bring ALL pill bottles.

___ Valid photo ID.

___ Will be breath tested for alcohol.

Appointment date and time _____ Mailed packet date _____

Buprenorphine Maintenance Treatment

General Information

New Treatment for Heroin Addiction

We would like to inform our patients about a new treatment for heroin addiction which has recently become legal, but is not yet available. The Drug Addiction Treatment Act of 2000 was signed by President Clinton on October 17. This law has several “firsts.” For the first time, a physician in the office setting will be able to prescribe a narcotic for treatment of addiction - following certain guidelines and restrictions. For the first time a patient who is addicted to heroin will be able to receive opioid medication for detoxification or for maintenance - again with certain restrictions - in a regular office setting, outside of the methadone treatment program. The only medication which is allowed is buprenorphine. Methadone and LAAM still may not be prescribed in California in an office setting for the treatment of addiction.

The New Law: The Drug Addiction Treatment Act of 2000 (Data)

The new law has the following restrictions:

- I. The physician has to have training in opioid addiction treatment.
- II. The physician has to register with the Secretary of Health and Human Services.
- III. The physician will receive a special number to add to his or her DEA license to prescribe scheduled drugs.
- IV. The drug prescribed has to be approved by the FDA as useful in the treatment of addiction. (Buprenorphine has been shown to be effective for heroin addiction, and is expected to be approved by FDA.)
- V. The drug prescribed may not be a Schedule II narcotic, but only III, IV or V. (Buprenorphine is not Schedule II. Methadone and LAAM are.)
- VI. The physician may only have 30 patients on this treatment at one time.
- VII. The physician must have access to counseling services for the addicted patient.

The New Medication: Buprenorphine

Buprenorphine is an opioid medication which has been used as an injection for treatment of pain while patients are hospitalized, for example for surgical patients. It is a long acting medication, and binds for a long time to the “*mu*” endorphin receptor. This means most patients do not have to take medication every day. It is not absorbed very well orally (by swallowing), so a

sublingual (dissolve under the tongue) tablet has been developed for treatment of addiction. One form of this sublingual tablet also contains a small amount of Naloxone (Narcan), which is an opioid antagonist and will cause withdrawal if injected. Buprenorphine without Naloxone has been available in other countries, and has been used illicitly by addicted persons, but so far it has not been abused when combined with Naloxone.

Aside from being mixed with Naloxone to discourage needle use, buprenorphine itself has a “ceiling” of narcotic effects (it is considered a “partial agonist”) which makes it safer in case of overdose. This means that by itself, even in large doses, it does not suppress breathing to the point of death in the same way that heroin, methadone and LAAM could do in huge doses. If a child swallowed a whole bottle of buprenorphine tablets (remember they are not absorbed very well by swallowing) it would probably not be lethal, whereas a single dose of methadone might be lethal to a child. These are some of the unusual qualities of this medication which make it safer to use outside of the usual strict methadone regulations at a clinic, and after stabilization, most patients would be able to take home as much as four weeks’ worth of buprenorphine at a time.

Will Buprenorphine Be Useful for Patients on Methadone?

Our methadone maintenance patients may be interested in whether this medication might help them. Unfortunately, because of the partial agonist nature of the medication, buprenorphine is not equivalent in maintenance strength to methadone and LAAM. In order to even try buprenorphine without going into major withdrawal, a methadone-maintained patient would have to taper down to 30mg. of methadone or lower. We are concerned that this medication may not be strong enough for most of our patients, and might lead to dangerous relapses if attempted. **If you decide to try it, please be aware of this danger of relapse** and keep the door open for resuming methadone immediately if necessary.

There are also some studies which show that detoxification from buprenorphine is effective. Some patients may decide to use buprenorphine to detoxify from heroin, instead of the usual methadone detoxification treatment. So far we don’t know whether buprenorphine will be “covered” under Medi-Cal (Medicaid) the way methadone detoxification frequently is.

So far remember the following tips:

- I. If you are offered buprenorphine by a “friend” and you are taking methadone or LAAM, the buprenorphine will push the other opioids off the receptor site and you may be in withdrawal and very uncomfortable.**
- II. If you dissolve and inject the buprenorphine-Naloxone sublingual tablet it may induce severe withdrawal because of the Naloxone, which is an antagonist.**
- III. If you are on methadone treatment and wish to transfer to buprenorphine, your dose has to be at or below 30mg.**
- IV. There have been deaths reported when buprenorphine is combined with benzodiazepines. (This family of drugs includes: Klonopin, Ativan, Halcion,**

Valium, Xanax, Librium, etc.) If you are taking any of these drugs, either by prescription or on your own, buprenorphine is may not be a good treatment for you.

More Information to Come

We will keep you posted as more practical facts develop about the use of this new treatment.

Buprenorphine Maintenance Treatment

Specific Information

Buprenorphine—A New Treatment for Heroin Addiction

Addiction medicine doctors consider addiction to be a chronic disease and treat it accordingly. Buprenorphine is one of the medications which can be used to treat opioid addiction. Opioids are drugs like heroin, opium, morphine, codeine, oxycodone, hydrocodone, etc., which can be abused and lead to tolerance and dependence. This means that the user's body becomes accustomed to ever-higher amounts, and, when the drug is stopped, there are symptoms of withdrawal. Even after the worst physical part of withdrawal is over, some patients still do not feel right for a long time and may relapse to using drugs again, just to "feel normal."

Some of the medical research shows that after abusing drugs for a long time, the brain is thrown off balance and the goal of treatment is to encourage stability, both in the body and in the patient's life.

Not all patients who abuse opioids need medication to treat their addiction. Many addicted persons do very well with counseling or residential therapeutic treatment or in NA groups. But in some cases these approaches alone are not enough to keep the person stable and maintenance medication is used. Maintenance medication is slower and longer acting in its effects on the brain than heroin or other drugs of abuse. This allows for a steadying of brain function which is part of treatment. So the best way to use buprenorphine in maintenance treatment is to find the correct dose, where the patient feels normal, and keep that dose steady for a long time. This means taking the medication on a regular schedule as prescribed, in the same way as taking a blood pressure medication or diabetes treatment.

Besides buprenorphine, there are two other maintenance medications which are used to treat addiction: methadone and LAAM. These medications are also long acting and work by stabilizing the brain. These medications are given in specially licensed clinics called Opioid Treatment Programs, and their use is carefully regulated by federal and state agencies.

Buprenorphine also is bound by some regulations. For this reason, patients on buprenorphine will be asked to give urine for drug screens and bring their bottles in for pill counts.

Buprenorphine is best started when the patient is suffering withdrawal, and the dose is adjusted over several days. It is given as a pill which dissolves under the tongue. The take-home buprenorphine pills also have a small amount of Naloxone (Narcan) in them, which is an opioid antagonist. The purpose of the Naloxone is to discourage illicit injection of the pill. The patient would not feel the effects of Naloxone by mouth, but if it were dissolved and injected it might cause severe withdrawal.

What Happens When Treatment With Buprenorphine Does Not Work?

Buprenorphine treatment may be discontinued for several reasons. Here are some examples:

- I. Buprenorphine controls withdrawal symptoms and is an excellent maintenance treatment for many patients, but some patients may need a stronger maintenance medication. If you are unable to control your heroin abuse, or if you continue to feel like using, even at the top doses of buprenorphine, then the doctor may advise you to transfer to methadone or LAAM at a clinic licensed to give those treatments.
- II. There are certain rules and patient agreements that are part of buprenorphine treatment, which are signed by all patients on admission. If you do not keep these agreements, you may be discharged from buprenorphine treatment.
- III. Prompt payment of clinic fees is part of buprenorphine treatment. If you cannot pay your fees, please discuss arranging a payment plan. If you still cannot pay, you will be discharged from buprenorphine treatment.
- IV. Dangerous or inappropriate behavior that is disruptive to the clinic or to other patients will result in discharge from buprenorphine treatment. This includes patients who come to the clinic intoxicated or loaded.
- V. Obviously, in the rare case of allergic reaction to the medication, it has to be discontinued.

The usual method of ending treatment is a taper, which means a decreasing dose of buprenorphine over a two-week period. After this time, you would no longer be enrolled in the buprenorphine program, and your treatment slot would be used for another patient. In some cases, a direct transfer to another kind of maintenance treatment can be made, such as to methadone maintenance at a clinic with a special license to use methadone to treat addiction.

In the case of dangerous behavior, there will be no two-week taper, and the patient will be summarily discharged and asked not to return.

Buprenorphine Maintenance Treatment

Information for Family Members

Family members of patients who have been prescribed buprenorphine for treatment of addiction often have questions about this treatment.

What Is an Opioid?

Opioids are addictive narcotics in the same family as opium and heroin. This includes many prescription pain medications, such as Codeine, Vicodin, Demerol, Dilaudid, Morphine, Oxycontin and Percodan. Methadone, LAAM (short for levo-alpha-acetyl methadol), and buprenorphine are also opioids.

Why Are Opioids Used to Treat Addiction?

Many family members wonder why doctors use buprenorphine to treat opiate addiction, since it is in the same family as heroin. Some of them ask, “Isn’t this substituting one addiction for another?” But the three medications used to treat addiction to heroin—methadone, LAAM and buprenorphine—are not “just substitution.” Many medical studies since 1965 show that maintenance treatment helps keep patients healthier, keeps them from getting into legal troubles, and prevents them from getting AIDS.

What Is the Right Dose of Buprenorphine?

Family members of patients who have been addicted to heroin have watched as their loved ones use a drug that makes them high or loaded or have watched the painful withdrawal which occurs when the drug is not available. Sometimes the family has not seen the ‘normal’ person for years. They may have seen the patient misuse doctors’ prescriptions for narcotics to get high. They are rightly concerned that the patient might misuse or take too much of the buprenorphine prescribed by the doctor. They may watch the patient and notice that the patient seems drowsy or stimulated or restless and think that the buprenorphine will be just as bad as heroin.

Every opioid can have stimulating or sedating effects, especially in the first weeks of treatment. The ‘right’ dose of buprenorphine is the one that allows the patient to feel and act normally. It can sometimes take a few weeks to find the right dose. During the first few weeks, the dose may be too high or too low which can lead to withdrawal, daytime sleepiness or trouble sleeping at night. The patient may ask that family members help keep track of the timing of these symptoms and write them down. Then the doctor can use all these clues to adjust the amount and time of day for buprenorphine doses.

Once the right dose is found, it is important to take it on time in a regular way so the patient's body and brain can work well.

How Can the Family Support Good Treatment?

Even though maintenance treatment for heroin addiction works very well, it is NOT a cure. This means that the patient will continue to need the stable dose of buprenorphine with regular monitoring by the doctor. This is similar to other chronic diseases such as diabetes or asthma. These illnesses can be treated, but there is no permanent cure so patients often stay on the same medication for a long time. The best way to help and support the patient is to encourage regular medical care, and encourage the patient not to skip or forget to take the medication.

Regular Medical Care

Most patients will be required to see the physician for ongoing buprenorphine treatment every two to four weeks, once they are stable. If they miss an appointment, they may not be able to refill the medication on time and may even go into withdrawal, which could be dangerous. The patient will be asked to bring the medication container to each visit and may be asked to give urine, blood or breath samples at the time of the visit.

Special Medical Care

Some patients may also need care for other needle-related problems such as hepatitis or HIV disease. They may need to go for blood work, or see several physicians for these illnesses.

Counseling

Most patients who are recovering from addiction need counseling at some point in their care. The patient may have regular appointments with an individual counselor, or for group therapy. These appointments are key parts of treatment and work together with the buprenorphine treatment to improve success in treatment for addiction. Sometimes family members may be asked to join in family therapy sessions, which also are geared to improve addiction care.

Meetings

Most patients use some kind of recovery group to maintain their sobriety. It sometimes takes several visits to different groups to find the right 'home' meeting. In the first year of recovery some patients go to meetings every day or several times per week. These meetings work to improve success in treatment, in addition to taking buprenorphine. Family members may have their own meetings such as Al-Anon or ACA to support them in adjusting to life with a patient who has addiction.

Taking the Medication

Buprenorphine is unusual because it must be dissolved under the tongue, rather than swallowed. Please be aware that **this takes a few minutes**. While the medication is dissolving, the patient will not be able to answer the phone or the doorbell or speak very easily. This means that the family will get used to the patient being 'out of commission' for a few minutes whenever the regular dose is scheduled.

Storing the Medication

If buprenorphine is lost or misplaced, the patient may skip doses or go into withdrawal, so it is very important to find a good place to keep the medication safely at home—away from children or pets and always in the same location, so it can be easily found. The doctor may give the patient a few ‘backup’ pills, in a separate bottle, in case an appointment has to be rescheduled or there is an emergency of some kind. It is best if the location of the buprenorphine is NOT next to the vitamins or the aspirin or other over-the-counter medications to avoid confusion. If a family member or visitor takes buprenorphine by mistake, he or she should be checked by a physician immediately.

What Does Buprenorphine Treatment Mean to the Family?

It is hard for any family when a member finds out he or she has a disease that is not curable. This is true for addiction as well. When chronic diseases go untreated, they have severe complications which lead to disability and death. Fortunately, buprenorphine maintenance can be a successful treatment, especially if it is integrated with counseling and support for life changes that the patient has to make to remain ‘clean and sober.’

Chronic disease means the disease is there every day and must be treated every day. This takes time and attention away from other things, and family members may resent the effort and time and money that it takes for buprenorphine treatment and counseling. It might help to compare addiction to other chronic diseases like diabetes or high blood pressure. After all, it takes time to make appointments to go to the doctor for blood pressure checks, and it may annoy the family if the food has to be low in cholesterol or unsalted. But most families can adjust to these changes when they consider that it may prevent a heart attack or a stroke for their loved one.

Another very important issue for family members to know about is: addiction can be partly inherited. Research is showing that some persons have more risk for becoming addicted than others and that some of this risk is genetic. So when one member develops heroin addiction, it means that other blood relatives should consider themselves ‘at risk’ of developing addiction or alcoholism. It is especially important for young people to know that alcohol or drugs at parties might be dangerous for them, even more than to most of their friends.

It is common for people to think of addiction as a weakness in character, instead of a disease. Perhaps the first few times the person used drugs it was poor judgment. However, by the time the patient is addicted and using every day and needing medical treatment, it can be considered to be a ‘brain disease’ rather than a problem with willpower. In fact, research brain scans that are done in patients who are on maintenance start to look normal again with treatment.

Sometimes when the patient improves and starts feeling normal, the family has to get used to the new “normal” person. The family interactions (sometimes called ‘family dynamics’ or ‘system’) might have been all about trying to help this person in trouble, and now he or she is no longer in so much trouble. Some families can use some help themselves during this change and might ask for family therapy for a while.

In Summary

Family support can be very helpful to patients on buprenorphine treatment. It helps if the family members understand how addiction is a chronic disease that requires ongoing care. It also helps if the family gets to know a little about how the medication works, and how it should be stored at home to keep it safe. Family life might have to change to allow time and effort for ‘recovery work’ in addiction treatment. Sometimes family members themselves can benefit from therapy.

Consent for Treatment With Buprenorphine

The statement on the reverse was drafted to describe elements that should be explained clearly to patients as part of the information given to enable them to give an informed consent to treatment.

This draft can be modified for the types of opiate dependent patients you are treating. For example, if the patients are heroin dependent then the word opiate can be replaced with heroin.

You may also modify the language to convert medical terms or phrases into lay terms.

At this time (October, 2002), buprenorphine is not approved by the FDA for treatment of opioid dependence. The forms of the drug developed for that indication are not yet available outside of clinical trial settings. Thus, the cost of any dosage form or the cost per day of buprenorphine maintenance is not known

Consent for Treatment With Buprenorphine

Buprenorphine is an FDA approved medication for treatment of people with opiate dependence. Qualified physicians can treat up to 30 patients for opiate dependence. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary.

Sample

Buprenorphine itself is an opiate, but it is not as strong an opiate as heroin or morphine. Buprenorphine treatment can result in physical dependence of the opiate type. Buprenorphine withdrawal is generally less intense than with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps or diarrhea lasting several days. To minimize the possibility of opiate withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

If you are dependent on opiates, you should be in as much withdrawal as possible when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine can cause severe opiate withdrawal. For that reason, you should take the first dose in the office and remain in the office for at least two hours. After that, you will be given some tablets to take at home. Within a few days, you will have a prescription for buprenorphine that will be filled in a pharmacy.

Some patients find that it takes several days to get used to the transition from the opiate they had been using to buprenorphine. During that time, any use of other opiates may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opiates will have less effect. Attempts to override the buprenorphine by taking more opiates could result in an opiate overdose. You should not take any other medication without discussing it with me first.

Combining buprenorphine with alcohol or some other medications may also be hazardous. The combination of buprenorphine with medication such as Valium, Librium, Ativan has resulted in deaths.

The form of buprenorphine (Suboxone) you will be taking is a combination of buprenorphine with a short-acting opiate blocker (Naloxone). If the Suboxone tablet were dissolved and injected by someone taking heroin or another strong opiate, it would cause severe opiate withdrawal.

Buprenorphine tables must be held under the tongue until they dissolve completely. Buprenorphine is then absorbed over the next 30 to 120 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed.

Buprenorphine will cost \$5 to \$10 per day just for the medication. If you have medical insurance, you should find out whether or not buprenorphine is a benefit. In any case, my office fees must be kept current.

Alternatives to Buprenorphine

Some hospitals that have specialized drug abuse treatment units can provide detoxification and intensive counseling for drug abuse. Some outpatient drug abuse treatment services also provide individual and group therapy, which may emphasize treatment that does not include maintenance on buprenorphine or other opiate like medications. Other forms of opiate maintenance therapy include methadone maintenance. Some opiate treatment programs use Naltrexone, a medication that blocks the effects of opiates but has no opiate effects of its own.

Print Name _____ Signature _____ Date _____

DSM-IV Criteria for Substance Dependence and Abuse

Once a thorough patient assessment has been performed, a formal diagnosis of either opiate dependence or abuse can be made. A substance dependence or abuse diagnosis, according to current DSM-IV diagnostic schema, is based on clusters of behaviors and physiological effects occurring within a specific time frame. The diagnosis of dependence always takes precedence over that of abuse, e.g., a diagnosis of abuse is made only if DSM-IV criteria for dependence have never been met.

Table 1. DSM-IV Criteria for Substance Dependence and Substance Abuse

<p style="text-align: center;"><i>Dependence</i></p> <p style="text-align: center;"><i>(3 or more in a 12-month period)</i></p>	<p style="text-align: center;"><i>Abuse</i></p> <p style="text-align: center;"><i>(1 or more in a 12-month period)</i></p> <p style="text-align: center;"><i>Symptoms must never have met criteria for substance dependence for this class of substance.</i></p>
<p>Tolerance (marked increase in amount; marked decrease in effect).</p> <p>Characteristic withdrawal symptoms; substance taken to relieve withdrawal.</p> <p>Substance taken in larger amount and for longer period than intended.</p> <p>Persistent desire or repeated unsuccessful attempt to quit.</p> <p>Much time/activity to obtain, use, recover.</p> <p>Important social, occupational, or recreational activities given up or reduced.</p> <p>Use continues despite knowledge of adverse consequences (e.g., failure to fulfill role obligation, use when physically hazardous).</p>	<p>Recurrent use resulting in failure to fulfill major role obligation at work, home or school.</p> <p>Recurrent use in physically hazardous situations.</p> <p>Recurrent substance related legal problems.</p> <p>Continued use despite persistent or recurrent social or interpersonal problems caused or exacerbated by substance.</p>

In using the DSM-IV criteria, one should specify whether substance dependence is with physiologic dependence (i.e., there is evidence of tolerance or withdrawal) or without physiologic dependence (i.e., no evidence of tolerance or withdrawal). In addition, patients may be variously classified as currently manifesting a pattern of abuse or dependence or as in remission. Those in remission can be divided into four subtypes -- full, early partial, sustained, and sustained partial -- on the basis of whether any of the criteria for abuse or dependence have been met and over what time frame. The remission category can also be used for patients receiving agonist therapy (e.g., methadone maintenance) or for those living in a controlled drug-free environment.

Patient's Name:

Worksheet for DSM-IV Criteria for Diagnosis of Opiate Dependence

Diagnostic Criteria* (Dependence Requires Meeting Three or More Criteria.)	Meets Criteria		Notes/Supporting Information
	Yes	No	
(1) Tolerance, as defined by either of the following: (a) A need for markedly increased amounts of the substance to achieve intoxication of desired effect.			
(b) Markedly diminished effect with continued use of the same amount of the substance.			
(2) Withdrawal, as manifested by either of the following: (a) The characteristic withdrawal syndrome.			
(b) The same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.			
(3) The substance is often taken in larger amounts or over a longer period of time than intended.			
(4) There is a persistent desire or unsuccessful efforts to cut down or control substance use.			
(5) A great deal of time is spent in activities necessary to obtain the substance, use the substance or recover from its effects.			
(6) Important social, occupational or recreational activities are given up or reduced because of substance use.			
(7) The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.			

Signature

Date

*Criteria from American Psychiatric Association (2000). Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision. Washington, DC, American Psychiatric Association, p. 197.

Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptoms. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name: _____ Date and Time ____/____/____ _____:_____	
Reason for This Assessment: _____	
Resting Pulse Rate: _____beats/minute <i>Measured after patient is sitting or lying.</i> 0 Pulse rate 80 or below 1 Pulse rate 81-100 2 Pulse rate 101-120 4 Pulse rate greater than 120	GI Upset: <i>Over last ½ hour.</i> 0 No GI symptoms 1 Stomach cramps 2 Nausea or loose stool 3 Vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting
Sweating: <i>Over past ½ hour not accounted for by room temperature or patient activity.</i> 0 No report of chills or flushing 1 Subjective report of chills or flushing 2 Flushed or observable moistness on face 3 Beads of sweat on brow or face 4 Sweat streaming off face	Tremor: <i>Observation of outstretched hands.</i> 0 No tremor 1 Tremor can be felt, but not observed 2 Slight tremor observable 4 Gross tremor or muscle twitching
Restlessness: <i>Observation during assessment.</i> 0 Able to sit still 1 Reports difficulty sitting still, but is able to do so 3 Frequent shifting or extraneous movements of legs/arms 5 Unable to sit still for more than a few seconds	Yawning: <i>Observation during assessment.</i> 0 No yawning 1 Yawning once or twice during assessment 2 Yawning three or more times during assessment 4 Yawning several times/minute
Pupil Size: 0 Pupils pinned or normal size for room light 1 Pupils possibly larger than normal for room light 2 Pupils moderately dilated 5 Pupils so dilated that only the rim of the iris is visible	Anxiety or Irritability: 0 None 1 Patient reports increasing irritability or anxiousness 2 Patient obviously irritable anxious 4 Patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint Aches: <i>If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored.</i> 0 Not present 1 Mild diffuse discomfort 2 Patient reports severe diffuse aching of joints/muscles 4 Patient is rubbing joints or muscles and is unable to sit still because of discomfort	Gooseflesh Skin: 0 Skin is smooth 3 Piloerection of skin can be felt or hairs standing up on arms 5 Prominent piloerection
Runny Nose or Tearing: <i>Not accounted for by cold symptoms or allergies.</i> 0 Not present 1 Nasal stuffiness or unusually moist eyes 2 Nose running or tearing 4 Nose constantly running or tears streaming down cheeks	The Total Score Is the Sum of All Eleven Items. Total Score: _____ Initials of Person Completing Assessment: _____

Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal

Buprenorphine Maintenance Treatment

Intake History and Physical

Patient's Name: _____ Date: _____

CC: _____

Opiate Abuse History:

Yrs./Mos. of Use: _____ Type of Use: _____ Current Run of Continuous Use: _____

Amount of Current Use: _____ Last Use Date/Time: _____

Present Symptoms: _____

History of Drug Abuse Treatment: _____

Medical History:

Allergies: _____ Current Meds: _____

Medical/ Psychiatric Problems: _____

Hospitalization/Surgery: _____

Hepatitis: _____ SBE: _____ HIV: _____ TB: _____ STD: _____

(Women) LMNP: ___ G: ___ P: ___ TAB: ___ SAB: ___ Contraception: _____

ROS: _____

Other Drug Abuse History:

Cocaine/Stimulant: _____ Alcohol: _____

Valium/Sedatives: _____ Caffeine: _____

Marijuana: _____ Nicotine/Cigarettes: _____ Quit/Cut Down? _____

Nutrition History: _____

Routine Screening History (Pap, Chol, Etc.): _____

Physical Examination:

T: ___ P: ___ BP: ___ R: ___ WT: ___ HT: ___ General Appearance: _____

HEENT: _____ ABD: _____

Thyroid/Neck: _____ Back: _____

Heart: _____ Neuro: _____

Lungs: _____ Extrem: _____
Chest/Breast: _____ Skin: _____

Signs Withdrawal: _____ Sketch of Tracks, Needle Marks and Scars: _____

Pupils: _____
Rhinorrhea: _____
Lacrimation: _____
Perspiration: _____
Piloerection: _____
Increase Temp: _____
Increase BP: _____
Tachycardia: _____
Vomiting: _____
Diarrhea: _____

Office-Based Opioid Maintenance Assessment:

_____ Opioid Dependence
_____ Withdrawal: Degree: _____

Plan:

_____ Admit to Maintenance Treatment; Initial Dose Order: _____
_____ Routine Labs; Other Labs: _____
_____ TB Test; Placed Date: _____ To Be Read Date: _____
Other TB Status Checks: _____
_____ Drug Screen Schedule: _____

Next Visit: _____

Counseling Plans: _____

Signed: _____ Date: _____

Patient Name: _____

Buprenorphine Maintenance Treatment

Patient Responsibilities

_____ **The patient will agree to store medication properly.** Medication may be harmful to children, household members, guests and pets. The pills should be stored in a safe place, out of reach of children. If anyone besides the patient ingests the medication, the patient must call the poison control center or 911 immediately.

_____ **The patient will agree to take the medication only as prescribed.** The indicated dose should be taken daily, and the patient must not adjust the dose on his or her own. If the patient wishes a dose change, he or she will call the clinic for an appointment to discuss this, and the physician can change the order.

_____ **The patient will agree to comply with the required pill counts and urine tests.** Urine testing is a mandatory part of office maintenance, and the patient must be prepared to give a urine sample for testing at each clinic visit, as well as to show the medication bottle for a pill count, including reserve medication.

_____ **The patient will agree to notify the clinic immediately in case of lost or stolen medication.** If a police report is filed, patient must bring in a copy for the record.

_____ **The patient will agree to notify the clinic immediately in case of relapse to drug abuse.** Relapse to opiate drug abuse can be life threatening and an appropriate treatment plan has to be developed as soon as possible. The physician should be informed about a relapse before any urine test shows it.

_____ **The patient will review the description of office maintenance at this site.** This description includes the hours, the phone numbers, the procedure for making appointment, the fees, the relationship to the methadone maintenance program, the requirements for participation in office maintenance and the clinic's responsibilities for patient care.

Signature _____
(Patient Signature)

Dated _____

Witness _____

Dated _____

Buprenorphine Maintenance Treatment

Intake Questionnaire for Patient Treatment-Planning Questions

Name _____ Date _____

Please answer the following questions which will help us design your plan of treatment:

What is the best time of day, and day of the week for you for clinic visits?

Are there any months out of the year when you may have difficulty making it in for a monthly appointment?

Is there any problem that makes it hard for you to give routine urine specimens?

Do you have any disabilities that make it hard for you to read labels or count pills?

What are your reasons for being interested in buprenorphine treatment?

When was the last time you relapsed to drug abuse? _____

What 'Triggers' do you know which have put you in danger of relapse in the past or which might in the future?

What coping methods have you developed to deal with these triggers to relapse?

What plans do you have for the coming year?

Work? _____

Home? _____

Other? _____

What medical care will you have in the coming year?

How will you comply with the annual examination and laboratory and TB testing requirements?

What kind of help would you like from your clinic counselor?

What are your strengths and skills to handle take-home buprenorphine?

What worries do you have about extended take-homes?

Is anyone in your home actively addicted to drugs or alcohol? _____

What are the major sources of stress in your life?

Commonly Abused Drugs

Substance	Examples of Proprietary or Street Names	Medical Use	Route of Administration	DEA Schedule	Period of Detection
<i>Stimulants</i>					
Amphetamine	Biphetamine, Dexedrine; <i>Black Beauties, Crosses, Hearts</i>	ADHD* obesity, narcolepsy	injected, oral smoked, sniffed	II	1-2 days
Cocaine	<i>Coke, Crack, Flake, Rocks, Snow</i>	local anesthetic, vasoconstrictor	injected, smoked, sniffed	II	1-4 days
Methamphetamine	Desoxyn; <i>Crank Crystal, Glass, Ice, Speed</i>	ADHD, obesity, narcolepsy	injected, oral sniffed, smoked	II	1-2 days
Methylphenidate	Ritalin	ADHD, narcolepsy	injected, oral	II	1-2 days
Nicotine	Habitrol patch, Nicorette gum, Nicotrol spray, Prostep patch; <i>Cigars, Cigarettes, Smokeless Tobacco, Snuff, Spit Tobacco</i>	treatment for nicotine dependence	transdermal smoked, sniffed, oral	not scheduled	1-2 days
<i>Hallucinogens and Other Compounds</i>					
LSD	<i>Acid, Microdot</i>	none	oral	I	8 hours
Mescaline	<i>Buttons, Cactus, Mesc, Peyote</i>	none	oral	I	2-3 days
Phencyclidine & Analogs	PCP; <i>Angel Dust, Boat, Hog, Love Boat</i>	anesthetic (veterinary)	injected, oral, smoked	I, II	2-8 days
Psilocybin	<i>Magic Mushroom, Purple Passion, Shrooms</i>	none	oral	I	8 hours
Amphetamine variants	DOB, DOM, MDA, MDMA <i>Adam, Ecstasy, STP, XTC</i>	none	oral	I	1-2 days
Marijuana	<i>Blunt, Grass, Herb, Pot, Reefer, Sinsemilla</i>	none	oral, smoked	I	1 day - 5 wks
Hashish	<i>Hash</i>	none	oral, smoked	I	1 day - 5 wks
Tetrahydrocannabinol	Marinol, THC	antiemetic	oral, smoked	I, II	1 day - 5 wks
Anabolic Steroids	Testosterone (T/E ratio), Stanozolol, Nadrolene	hormone replacement	oral, injected	III	Oral: up to 3 wks ** Injected: up to 3 mos (Nandrolene, up to 9 mos)
<i>Opioids and Morphine Derivatives</i>					
	Examples of Proprietary	Medical Use	Route of	DEA	Period of

Commonly Abused Drugs

	or Street Names		Administration	Schedule	Detection
Codeine	Tylenol w/Codeine, Robitussin A-C, Empirin with Codeine, Fiorinal with Codeine	analgesic, antitussive	injected, oral	II, III, V	1-2 days
Heroin	Diacetylmorphine <i>Horse, Smack</i>	none	injected, smoked, sniffed	I	1-2 days
Methadone	Amidone, Dolophine, Methadose	analgesic, treatment for opiate addiction	injected, oral	II	1 day - 1 wk
Morphine	Roxanol, Duramorph	analgesic	injected, oral, smoked	II, III	1-2 days
Opium	Laudanum, Paregoric; <i>Dover's Powder</i>	analgesic, antidiarrheal	oral, smoked	II, III, V	1-2 days
<i>Depressants</i>					
Alcohol	Beer, Wine, Liquor	methanol poisoning antidote	oral	not scheduled	6-10 hours
Barbiturates	Amytal, Nembutal, Seconal, Phenobarbital; <i>Barbs</i>	anesthetic, anticonvulsant, hypnotic, sedative	injected, oral	II, III, IV	2-10 days
Benzodiazepines	Ativan, Halcion, Librium, Rohypnol, Valium; <i>Roofles, Tranks, Xanax</i>	antianxiety, anticonvulsant, hypnotic, sedative	injected, oral	IV	1-6 weeks
Methaqualone	<i>Quaalude, Ludes</i>	none	oral	I	2 weeks

* ADHD - Attention Deficit Hyperactivity Disorder

** For Testosterone and Other Anabolic Steroids

Buprenorphine Maintenance Treatment

Protocol for Follow-Up Appointments

Follow-up appointments will be at least monthly.

The activities at follow-up appointments are focused on evaluating adequacy of treatment and danger for relapse. They should include:

- I. Pill counts, including reserve tablets.
- II. Urine testing for drugs of abuse and alcohol.
- III. Prescription of medication.
- IV. An interim history of any new medical problems or social stressors.

Dangerous Behavior, Relapse and Relapse Prevention

The following behavior ‘red flags’ will be addressed with the patient as soon as they are noticed:

- I. Missing appointments.
- II. Running out of medication too soon.
- III. Taking medication off schedule.
- IV. Not responding to phone calls.
- V. Refusing urine or breath testing.
- VI. Neglecting to mention new medication or outside treatment.
- VII. Appearing intoxicated or disheveled in person or on the phone.
- VIII. Frequent or urgent inappropriate phone calls.
- IX. Neglecting to mention change in address, job or home situation.
- X. Inappropriate outbursts of anger.
- XI. Lost or stolen medication.
- XII. Frequent physical injuries or auto accidents.
- XIII. Non-payment of visit bills.

These behaviors will be brought to the patient’s attention, and he or she will be supported in making appropriate responses to them. Additional care or monitoring may or may not be indicated

Consent for Release of Information

I, _____, born on _____
(Patient Name) (Patient Birth Date)

SSN _____, authorize _____ to
(Patient Social Security #) (Clinic or Doctor's Name)

disclose to _____
(Name and Location of Person/Organization to Receive Information)

the following information: _____.

The purpose of this disclosure is: _____.

This authorization expires on: _____, or

whenever _____ is no longer providing me with services.

I understand that my records are protected under the Federal regulations and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it.

Signature of Patient _____ Dated _____

Signature of Witness _____ Dated _____

ATTENTION RECIPIENT: Notice Prohibiting Redisclosure

This information has been disclosed to you from the records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of this information to criminally investigate or prosecute any alcohol or drug abuse patient.