Buprenorphine: A Guide for Nurses

TAP 30

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Technical Assistance Publication Series

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

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Introduction

Purpose of This Guide

This guide is intended to provide nurses (including Registered Nurses (RNs), Licensed Practical Nurses (LPNs), and Nurse Practitioners (NPs)) with general information about buprenorphine products—Suboxone® (buprenorphine and naloxone) and Subutex® (buprenorphine)—for the pharmacological treatment of opioid addiction. The guide can also serve as a resource to help nurses working with community physicians to improve treatment outcomes for individuals receiving office-based treatment for opioid addiction.

Providing comprehensive services in conjunction with medication is the most effective method of treating opioid addiction. It is important that buprenorphine be administered in conjunction with behavioral therapy and psychosocial support to ensure medication compliance and to increase patient functioning (NAADAC, 2002). The ultimate success of buprenorphine will depend on its integration into a broader continuum of health care services that includes counseling for patients with substance use disorders.

Nurses in all settings may be called upon to work with individuals undergoing treatment for opioid addiction with buprenorphine products and with physicians to improve treatment outcomes by providing behavioral treatment and counseling.

Learning Objectives

The guide is intended to fulfill the following objectives:

1. To provide nurses with general information on the pharmacology, safety profile, adverse effects, interactions, cautions, contraindications, and abuse potential of buprenorphine products (note: Suboxone® and Subutex® are the registered names of these products).
2. To increase nurses' factual knowledge on protocols for the use of buprenorphine products in medically supervised withdrawal (detoxification) and maintenance treatment services.
3. To help nurses, in conjunction with authorized physicians, design strategies for providing comprehensive physical and psychosocial assessments, treatment monitoring, and appropriate referral for opioid addiction and co-occurring medical and psychiatric conditions.
4. To provide comprehensive and practical guidance for patient screening, assessment, induction, stabilization, and prevention of precipitated withdrawal in medically supervised withdrawal ("detoxification") or maintenance treatment services.

5. To educate nurses about effective communication, assessment of patients' readiness to change, and appropriate motivational enhancement interventions to ensure that psychosocial counseling is delivered concurrently with pharmacological interventions.
6. To enhance addiction recovery management by educating nurses about stigma, patient empowerment and the recovery partnership, evidence-based practices, the application of technology, and the importance of ongoing patient monitoring and support.

Background

Data 2000: Legislative Authority for Buprenorphine Treatment

Federal legislation—the Drug Addiction Treatment Act of 2000 (DATA 2000)—changed addiction treatment in the United States by permitting office-based physicians to treat addiction to opioid (narcotic) drugs, such as heroin and many prescription pain relievers, with Schedule III–V narcotic medications approved by the U.S. Food and Drug Administration (FDA). Under the statutory provisions of DATA 2000, physicians who wish to prescribe (or dispense) approved medications for opioid therapy must first obtain a waiver that releases them from the separate registration requirements of the Narcotic Addiction Treatment Act of 1974 and its enabling regulations for the provision of opioid addiction treatment. (One enabling regulation is Title 42 of the Code of Federal Regulations (CFR), Part 8: Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule.) The Department of Health and Human Services (HHS) responsibility for the waiver program is administrated by the Substance Abuse and Mental Health Services Administration (SAMHSA) in HHS and follows certain criteria specified in DATA 2000 by which physicians' qualifications are considered before a waiver is issued.

Before prescribing Suboxone® or Subutex®, qualified physicians must notify the Secretary of HHS of their intent by submitting applications for a waiver. To obtain a DATA 2000 waiver, a physician must send SAMHSA a notification of intent to begin practicing this form of therapy. The notification of intent may be submitted online at the SAMHSA Buprenorphine Web site (http://buprenorphine.samhsa.gov) or mailed or faxed to SAMHSA using a notification form, SMA-167, that can be downloaded from the Web site. The notification of intent must contain information on the physician's qualifying credentials, training certificates, and other information. Each physician must certify that the physician has the capacity to refer addiction patients for appropriate counseling and other nonpharmacological therapies. Physicians must also certify that they will use certain treatment medications and adhere to patient limits.

Physicians' Qualifications

Under DATA 2000, prescription of buprenorphine products (Suboxone® or Subutex®) for the treatment of opioid addiction is limited to physicians who meet qualifying requirements. Physician Assistants (PAs), Nurse Practitioners (NPs), and Advanced Practice Nurses (APNs) may not prescribe buprenorphine products for the treatment of addiction even in

States that allow them to prescribe Schedule III, IV, or V drugs.

Physicians may be considered qualified to prescribe buprenorphine products if they:

- Meet at least one of the following training requirements:
  - Hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;
  - Hold a certification from the American Society of Addiction Medicine (ASAM);
  - Hold a subspecialty board certification in addiction medicine from the American Osteopathic Association;
  - Have completed not less than 8 hours of authorized training on the treatment or management of opioid-dependent patients. This training may include classroom situations, seminars at professional society meetings, electronic communications, or other media;
- AND meet both of the following criteria:
  - Have the capacity to provide or to refer patients for necessary ancillary services, such as psychosocial therapy; and
  - Agree to treat the applicable numbers of patients (30 or 100) in their individual or group practice (DATA 2000; Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA—Public Law 109-469)).

Originally, waivered physicians were limited to treating no more than 30 patients with approved buprenorphine products at any one time under DATA 2000, and physician group practices were also limited to 30 patients. The physician group practice limit was eliminated by Public Law 109-56, effective August 2, 2005, so that each physician in a group practice, like a physician in solo practice, was permitted to treat up to 30 patients at any given time.

Under the ONDCPRA, effective December 29, 2006, physicians who meet the following criteria may notify the Secretary of HHS of their need and intent to treat up to 100 patients at any one time. To meet the requirements, (1) the physician must currently be qualified under DATA 2000, (2) at least 1 year must have elapsed since the physician submitted the initial notification for authorization, (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services, and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

The SAMHSA Buprenorphine Information Center has information specialists available to answer questions about buprenorphine and DATA 2000 on weekdays from 8:30 a.m. to 5:00 p.m., Eastern time. The Information Center may be reached by telephone at 866–287–2728 or by e-mail at info@buprenorphine.samhsa.gov.

SAMHSA will communicate with the Drug Enforcement Administration (DEA) in the Department of Justice, review the notification, and inform the DEA whether or not the physician is qualified as required by DATA 2000. The DEA will issue a unique

identification number that indicates that the physician is qualified under DATA 2000. The physician then will be authorized to dispense and/or prescribe under the authority of his or her DEA practitioner registration. CSAT will send the physician a letter with the newly assigned DEA identification number. A new DEA registration certificate will be issued to the physician that documents the new DEA number that must be written on buprenorphine prescriptions as well as the original DEA registration number assigned to the physician.

DATA 2000 only permits physicians to prescribe and dispense approved opioid medications for the treatment of addiction. At this time, only Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone) have been approved for office-based treatment. Physicians are specifically prohibited from delegating prescribing opioids for detoxification and/or maintenance purposes to nonphysicians (i.e., Advanced Practice Nurses (APNs), Nurse Practitioners (NPs), and Physician Assistants (PAs)).

Since 2001, SAMHSA has been responsible for monitoring and regulating the use of opioid medications in treatment with methadone and buprenorphine. Since the implementation of DATA 2000, SAMHSA can provide office-based physicians a waiver to prescribe Schedule III, IV, and V medications such as Subutex® (buprenorphine) and Suboxone® (buprenorphine and naloxone) in their office settings (CSAT, 2004).

Buprenorphine and the Role of the Nurse

Currently, advanced practice nurses and NPs may not prescribe or dispense buprenorphine products for the treatment of addiction even in States that allow them to prescribe scheduled medications under certain controls, supervisions, and other restrictions. This guide will highlight the addictions management skills of nurses and promote a mutually respectful team environment in which nurses and physicians collaboratively work to improve the care provided to individuals who are addicted to opioids. This care may include assessment, induction, stabilization, maintenance, monitoring, addiction counseling, and relapse prevention.

The nurse's roles with patients receiving buprenorphine for the treatment of addiction (1) may be subject to State practice regulations and (2) may include, but not be limited to:

- Conducting screening, assessment, treatment monitoring, counseling, and supportive services;
- Educating patients, their family members, or other supportive individuals about buprenorphine therapy as well as risks, benefits, potential side effects, interactions, program requirements, consents, and treatment contracts;
- Involving patients in the development of the treatment plan, and working with the patient and the interdisciplinary team to individualize the plan for meeting the patients' needs;
- Enhancing treatment readiness, supporting treatment completion, ensuring safety, and promoting sustained recovery outcomes for individuals undergoing buprenorphine treatment for opioid addiction;
- Improving access, identifying community resources, and providing information about them; and explaining reimbursement options for office-based buprenorphine treatment;
- Assisting patients in accessing care elsewhere when the present practice is not a suitable option for them; and
- Assisting patients in accessing other treatment options as needed (e.g., day treatment, residential, outpatient, methadone detoxification or maintenance, etc.).

More detailed information is available in *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, SAMHSA's Treatment Improvement Protocol (TIP) #40 (CSAT, 2004). The guidelines cover screening, assessment, and diagnosis of opioid dependence and its associated problems. The guidelines also contain detailed protocols for the use of buprenorphine under a variety of clinical scenarios, including the use of buprenorphine with patients who are experiencing co-occurring pain or psychiatric disorders, or chemical dependency involving more than one substance.

Buprenorphine Pharmacology

General Opioid Pharmacology

Opioid Receptors

Opioid receptors are molecules on the surface of cells to which opioid compounds attach and through which they exert their effects. Three different types of opioid receptors are present in the brain: mu, kappa, and delta. Two of these opioid receptors (mu and kappa) are also found in the spinal cord and mediate pain transmission at this level of the nervous system, i.e., from the periphery to the brain. The receptor most relevant to opioid abuse and treatment is the mu receptor. It is through activation of the mu receptor that opioids exert the majority of their analgesic (pain-relieving property), euphorigenic (euphoria or "high"), and addictive effects (CSAT, 2004). Although the mu receptor is, as noted, the most relevant to opioid abuse and treatment, the kappa and delta receptors are also responsible for opioid addiction.

The Functions of Opioids at Receptors

Opioids can interact with receptors in different ways. Three types of drug/receptor interactions are agonists (or full agonists), antagonists, and partial agonists (CSAT, 2004).

Full Agonists

Drugs that activate receptors in the brain are termed agonists. Agonists bind to receptors and turn them on, thereby producing an effect in the organism. Full mu opioid agonists activate mu receptors. Opioids with the greatest abuse potential are full agonists (e.g., morphine, heroin, methadone, oxycodone, hydromorphone) (CSAT, 2004).

Antagonists

Antagonists also bind to opioid receptors, but instead of activating receptors, they effectively block them. An antagonist is like a key that fits in a lock but does not open it and prevents another key from being inserted to open the lock. Examples of opioid antagonists are naltrexone and naloxone (CSAT, 2004).

Partial Agonists

Partial agonists possess some of the properties of both antagonists and full agonists. Partial agonists bind to receptors and activate them, but not to the same degree as do full agonists. At lower doses and in individuals who are not dependent on opioids, full agonists and partial agonists produce effects that are indistinguishable. As doses are increased, both full and partial agonists produce increasing effects. At a certain point, however, the increasing effects of partial agonists reach maximum levels and do not increase further, even if doses continue to rise—"the ceiling effect." As higher doses are reached, partial agonists can act like

antagonists—occupying receptors but not activating them (or only partially activating them), while at the same time displacing or blocking full agonists from receptors. Buprenorphine is an example of a mu opioid partial agonist (CSAT, 2004).

Consequences of Repeated Administration and Withdrawal of Opioid Drugs

The repeated administration of a mu opioid agonist results in tolerance and dose-dependent physical dependence. Tolerance is characterized by a decreased subjective and objective response to the same amount of opioids used over time or by the need to keep increasing the amount used to achieve the desired effect. In the case of abuse or addiction, the desired effect typically is euphoria. Physical dependence is manifested as a set of withdrawal signs and symptoms in response to reduction, cessation, or loss of the active compound at receptors (withdrawal syndromes). Typical signs and symptoms of the opioid withdrawal syndrome include lacrimation (tears), diarrhea, rhinorrhea, piloerection (goose flesh), yawning, cramps and aches, pupillary dilation, and sweating. In an individual who otherwise is in good general health (e.g., with no history of significant cardiovascular disease), opioid withdrawal is not life threatening. Patients with cardiovascular disease or other severe conditions will need comanagement involving the appropriate specialist, as well as consultation with an addiction specialist (CSAT, 2004). The primary distinguishing characteristic that differentiates dependence from addiction, as outlined in the *Diagnostic and Statistical Manual IV (Text Revision)* (DSM-IV-TR) (APA, 2000) criteria, is the behavioral component of continued use despite negative consequences.

Two types of withdrawal are associated with mu opioid agonists: spontaneous withdrawal and precipitated withdrawal.

Spontaneous Withdrawal

Spontaneous withdrawal can occur when an individual who is physically dependent on mu agonist opioids (e.g., has been using opioids on a daily basis) suddenly discontinues that opioid use. It also can occur if an individual who is physically dependent markedly decreases his or her daily opioid use. In an individual who is physically dependent on heroin, spontaneous withdrawal usually begins 6–12 hours after the last dose and peaks in intensity 36–72 hours after the last use. The spontaneous withdrawal syndrome from heroin lasts approximately 5 days, although a milder, protracted withdrawal may last longer. Other short-acting opioids, such as oxycodone and hydrocodone, have kinetic profiles that are similar to heroin, and the time course of spontaneous withdrawal for these agents should be similar to that documented for heroin. Opioids with longer half-lives have a longer period before the onset of spontaneous withdrawal (e.g., 24–72 hours for methadone) and a longer period before peak withdrawal is experienced (CSAT, 2004).

Precipitated Withdrawal

Precipitated withdrawal usually occurs when an individual who is physically dependent on opioids is administrated an opioid antagonist. In

an individual who is not physically dependent on opioids, the acute administration of an antagonist typically produces no effects. In an individual who is physically dependent on opioids, however, an antagonist produces a syndrome of withdrawal that is qualitatively similar to that seen with spontaneous withdrawal (although the onset is faster and the syndrome is shorter, depending on the half-life of the antagonist). One way to conceptualize precipitated withdrawal is that the antagonist displaces agonists from receptors, but because the antagonist does not activate the receptor, there is a net decrease in agonist effect, resulting in withdrawal. It is also possible for partial agonists to precipitate withdrawal. If an individual who is physically dependent on opioids receives an acute dose of a partial agonist, the partial agonist can displace the full agonist from the receptors, yet not activate the receptors as much as the full agonist had. The net effect would be a decrease in agonist effect and a precipitated withdrawal syndrome. Precipitated withdrawal with a partial agonist is more likely to occur in an individual who has a high level of physical dependence (e.g., high use of opioids each day), who takes the partial agonist soon after a dose of full agonist, and/or who takes a high dose of the partial agonist (CSAT, 2004).

Affinity, Intrinsic Activity, and Dissociation

The strength with which a drug binds to its receptor is termed its "affinity." The degree to which a drug activates its receptors is termed its "intrinsic activity." Affinity for a receptor and activation of the receptor are two different qualities of a drug. A drug can have high affinity for a receptor but not activate the receptor (e.g., an antagonist). Mu opioid agonists, partial agonists, and antagonists can vary in their affinity. In addition to variation in affinity and intrinsic activity, drugs also vary in their rate of dissociation from receptors. "Dissociation" is a measure of the disengagement or uncoupling of the drug from the receptor. Dissociation is not the same as affinity—a drug can have high affinity for a receptor (it is difficult to displace it from the receptor with another drug once the first drug is present), but it still dissociates or uncouples from the receptor with some regularity. Buprenorphine's slow dissociation contributes to its long duration of action (CSAT, 2004).

Characteristics of Abused Drugs

The rate of onset of the pharmacological effects of a drug, and thereby its abuse potential, is determined by a number of factors. Important among these are the drug's route of administration, its half-life, and its lipophilic property (which determines how fast the drug reaches the brain). A faster route of drug administration (e.g., injection, smoking), a shorter half-life, and a faster onset of action are associated with a higher abuse potential of a drug. With all classes of drugs of abuse, the likelihood of abuse is related to the ease of administration, the cost of the drug, and how fast the user experiences the desired results after the drug's administration (CSAT, 2004).

Pharmacological Properties

Buprenorphine is characterized pharmacologically as an *opioid partial agonist* with both agonist and antagonist properties, depending on dosage and clinical circumstances. It can be abused, particularly by individuals who are not physically dependent upon opioids, but its maximal effects are significantly less than those of full agonists such as heroin and methadone (CSAT, 2004).

At lower doses, buprenorphine acts as an opioid agonist, enabling opioid-dependent individuals to discontinue opioids without experiencing withdrawal. At moderate doses, the agonist effects reach a plateau (ceiling effect). At higher doses, the opioid antagonist properties dominate and, in certain circumstances, higher doses of buprenorphine can displace opioid agonists, precipitating withdrawal symptoms in acutely opioid-intoxicated individuals. (http://buprenorphine.samhsa.gov/about.html).

Buprenorphine's ceiling effect enhances its safety profile, making it less likely to produce opioid overdose and reducing its potential for diversion (National Association of State Alcohol and Drug Abuse Directors (NASADAD), 2002). The combination of buprenorphine (a partial agonist) and naloxone (a pure antagonist) in Suboxone® discourages patients dependent on mu opioid receptor agonists (heroin, methadone, hydrocodone, oxycodone, and the like) from injecting dissolved tablets and further decreases the likelihood of diversion and abuse.

Buprenorphine is also a long-acting agent, so many patients may not need to take medication every day. These properties may offer some treatment advantages over the use of methadone.

Monotherapy and Combination Therapy

In October 2002, the FDA approved two products for the treatment of opioid dependence:

1. **Subutex®:** buprenorphine monotherapy product; and
2. **Suboxone®:** buprenorphine and naloxone combination product.

Other forms of buprenorphine (e.g., **Buprenex®**) are NOT approved for opioid addiction treatment. *The Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, a consensus-based treatment guideline published by SAMHSA, recommends that the buprenorphine and naloxone (Suboxone®) combination product be used for most patients (CSAT, 2004).

Dosing

Subutex®, the buprenorphine-only formulation, is available as sublingual tablets in doses of 2 milligrams (mg) and 8 mg. Suboxone®, the buprenorphine and naloxone combination product, is available as sublingual tablets in doses of 2 mg buprenorphine/0.5 mg naloxone, and 8 mg buprenorphine/2 mg naloxone. Naloxone is added to buprenorphine to decrease the potential for abuse by the parenteral route. Usually dosage is adjusted over several days. Initial prescriptions may be limited to *1-day doses* for the first several days before providing a prescription for several days. Usually, 2–4 mg of buprenorphine are administered sublingually on the

first day of treatment, then the patient is monitored for 2 hours. If signs or symptoms of withdrawal develop after the first dose, another 2–4 mg may be administered. Typically, the total dose on the first day should not exceed 8 mg.

The FDA Web site at http://www.fda.gov/cder/drug/infopage/subutex_suboxone contains drug-labeling information for Subutex® and Suboxone®. If the patient continues to complain of withdrawal symptoms after receiving 8 mg of buprenorphine, symptoms may be managed with nonopioid over-the-counter medications. This phenomenon is not common, and most patients find that 8 mg alleviates withdrawal symptoms. The average maintenance dose is usually 16 mg. Some patients may need several days to stabilize on their dose, and they may have some discomfort for several days during the induction process. Although the treatment flow charts in appendix B include a maximum daily buprenorphine dose of 32 mg, more recent clinical data suggest that daily doses above 24 mg do not provide additional therapeutic benefit to the vast majority of patients. Clinical trials underway could establish an even lower maximum daily buprenorphine dose recommendation (Greenwald et al., 2003).

Abuse Potential

Because of its opioid-agonist effects, buprenorphine can be abused, particularly by individuals who are not physically dependent on opioids. However, the abuse potential is low in comparison with that of full agonists. In the Suboxone® product, the opioid-antagonist medication naloxone is combined with buprenorphine to decrease the likelihood that opioid-dependent patients will inject the medication.

Sublingual naloxone has relatively low bioavailability, while sublingual buprenorphine has good bioavailability. Both naloxone and buprenorphine have poor gastrointestinal bioavailability. Thus, if a tablet containing both buprenorphine and naloxone is taken sublingually, as directed, the patient will experience predominantly a buprenorphine effect. However, if an opioid-dependent person dissolves and injects the combination tablet, the antagonistic effect of naloxone will predominate because of the high parenteral bioavailability, and opioid-dependent patients will experience a precipitated withdrawal syndrome. Thorough counseling of buprenorphine therapy candidates about the risk of precipitated withdrawal if they crush and inject the combination tablet (Suboxone®) will decrease the likelihood of its misuse.

Under certain circumstances, buprenorphine by itself may also precipitate withdrawal in opioid-dependent individuals. This withdrawal is more likely to occur with higher levels of opioid dependence, with higher doses of buprenorphine, or with shorter time intervals between the dose of an opioid full agonist and a dose of buprenorphine (e.g., up to 6–8 hours for short-acting opioids or more than 24 hours for long-acting opioids).

Safety Profile

Because of buprenorphine's ceiling effect, the drug is less likely than opioid full agonists to produce respiratory depression and other adverse effects. The maximal agonist

effects of buprenorphine appear to occur in the dose range of 16–32 mg for sublingual tablets (CSAT, 2004).

However, according to FDA labeling (FDA, 2002), cases of cytolytic hepatitis and hepatitis with jaundice have been observed in the population of persons who are addicted to opioids and receiving buprenorphine, both in clinical trials and in postmarketing adverse event reports. The spectrum of abnormalities ranges from transient asymptomatic elevations in hepatic transaminases to case reports of hepatic failure, hepatic necrosis, hepatorenal syndrome, and hepatic encephalopathy. In many cases, the presence of pre-existing liver enzyme abnormalities, infection with hepatitis B virus (HBV) or hepatitis C virus (HCV), concomitant usage of other potentially hepatotoxic drugs, and ongoing injecting drug use may have played a causative or contributory role. In other cases, insufficient data were available to determine the etiology of the abnormality. The possibility exists that buprenorphine had a causative or contributory role in the development of the hepatic abnormality in some cases. Liver function tests, measured prior to initiation of treatment, are recommended to establish a baseline. Periodic monitoring of liver function tests during treatment is also recommended. A biological and etiological evaluation is recommended when a hepatic event is suspected. Depending on the case, the drug should be carefully discontinued to prevent withdrawal symptoms and a return to illicit drug use; strict monitoring of the patient also should be initiated.

Also, Suboxone® and Subutex® may impair the mental or physical abilities required for the performance of potentially dangerous tasks such as driving a car or operating machinery, especially during drug treatment induction and dose adjustment. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that buprenorphine therapy does not adversely affect their ability to engage in such activities. Like other opioids, Suboxone® and Subutex® may produce orthostatic hypotension in ambulatory patients (adapted from FDA labeling for Suboxone® and Subutex®, 2002, at http://www.fda.gov/cder/foi/label/2002/20732,20733lbl.pdf).

Pregnancy

Research on the safety and efficacy of buprenorphine in pregnant women and neonates is scarce, and data on the pharmacokinetics of buprenorphine in pregnant women and neonates are extremely limited (Johnson et al., 2003; Marquet et al., 1997). The FDA classifies buprenorphine as a Pregnancy Category C drug. The FDA Pregnancy Labeling Task Force, whose long-term goal is to determine how animal toxicologic information contributes to clinically meaningful information in pregnancy, assigns a prescription drug for humans to Pregnancy Category C (1) if animal reproduction studies have shown an adverse effect on the fetus, (2) if there are no adequate and well-controlled studies in humans, and (3) if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. In addition to considering the FDA warnings pertaining to the use of buprenorphine in pregnant women, physicians and other health care providers also must consider the risks

of infectious diseases and lifestyle issues (e.g., poor nutrition, lack of prenatal care) when addressing the needs of these patients (CSAT, 2004).

There is also a question whether the buprenorphine and naloxone combination is recommended for use in pregnancy. Naloxone is labeled by FDA as a Pregnancy Category B drug. The FDA Pregnancy Task Force assigns a prescription drug for humans to Pregnancy Category B (1) if animal reproduction studies failed to demonstrate a risk to the fetus and (2) if there are no adequate and well-controlled studies in pregnant women. Despite the fact that naloxone is classified as Pregnancy Category B, it should be used with caution in pregnant women who are addicted to opioids.

Because both mother and fetus will be dependent on the opioids used by the mother, administration of naloxone could precipitate withdrawal in both. If it is determined that buprenorphine is the only acceptable option for the treatment of the pregnant woman, and she understands the issues and risks, then she should be treated with buprenorphine monotherapy so as to avoid the risk of fetal exposure to naloxone. It should be noted that use of buprenorphine monotherapy, because of its greater potential for abuse, necessitates more frequent monitoring of patients and their medications (e.g., every 1–2 weeks) (CSAT, 2004).

Adverse Effects

The adverse effects of buprenorphine are similar to those of other opioids, but usually these effects are less intense than those seen with full agonists. The most common adverse effects of buprenorphine are nausea, vomiting, headaches and constipation, which can be severe enough to make some patients not want to continue with induction. It can be difficult in the beginning to distinguish between ongoing, unresolved withdrawal from the abused opioid drug and withdrawal that is precipitated by the buprenorphine. *Please refer also to the section on Precipitated Withdrawal and Withdrawal Symptoms.*

Interactions, Cautions, and Contraindications

For a complete list of drug interactions, contraindications, warnings, and precautions, please refer to the Subutex® and Suboxone® package inserts (http://www.suboxone.com/pdfs/SuboxonePI.pdf).

- In some instances, relapse to opioid drug use may be life threatening. A number of deaths have occurred when individuals have misused buprenorphine intravenously, particularly when there is concomitant use of benzodiazepines, alcohol, or other opioids. Patients should be warned of the potential danger of self-administration of benzodiazepines or other central nervous system depressants while under treatment with Subutex® or Suboxone®.
- Patients should tell their family members and friends that, in the case of emergency, the treating physician or emergency room staff should be informed that the patient is physically dependent on opioids and that the patient is being treated with Subutex® or Suboxone®.

- In the case of overdose, primary management should be the re-establishment of adequate ventilation with mechanical assistance of respiration, if required. Naloxone may not be effective in reversing respiratory depression produced by buprenorphine.
- Patients with hepatic (liver) disease may not properly metabolize these drugs; their doses may need to be adjusted, and these patients should be observed for opioid toxicity or precipitated opioid withdrawal.
- Drugs that require extra precautions and may require dosage adjustments include ketoconazole, an antifungal medication frequently used with patients with HIV/AIDS; certain antibiotics; HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors; and certain barbiturates used to control epilepsy (seizures).
- Buprenorphine products should be administered with caution in elderly or debilitated individuals, and in those with severe impairments in hepatic, pulmonary, or renal function.

Allergic Reactions

Cases of acute and chronic hypersensitivity to buprenorphine have been reported both in clinical trials and in the postmarketing experience. The most common signs and symptoms include rashes, hives, and pruritus. Cases of bronchospasm, angioneurotic edema, and anaphylactic shock have been reported. A history of hypersensitivity to buprenorphine is a contraindication to Subutex® or Suboxone® use. A history of hypersensitivity to naloxone is a contraindication to Suboxone® use. (Adapted from FDA labeling for Suboxone® and Subutex®, 2002, at http://www.fda.gov/cder/foi/label/2002/20732,20733lbl.pdf.)

Several medical conditions and medications, as well as concurrent abuse of other drugs and alcohol, necessitate caution or are relative contraindications to buprenorphine treatment. Examples include (CSAT, 2004):

- **Seizures.** Caution should be taken when buprenorphine is used concurrently with antiseizure medications (e.g., carbamazepine). In addition, the relative risk of interaction between buprenorphine and sedative hypnotics (e.g., phenobarbital) should be kept in mind. Monitoring for therapeutic plasma levels of antiseizure medications should be considered.
- **HIV.** Caution should be taken when buprenorphine is used in combination with HIV antiretroviral medications, because they may inhibit, induce, or be metabolized by the cytochrome P450 3A4 enzyme system. These patients may require dosage adjustment.
- **Hepatitis and impaired hepatic function.** Viral hepatitis, such as infection with HBV and HCV, is common among individuals who abuse opioids and should be evaluated and treated appropriately. Although pharmacotherapy with buprenorphine is not contraindicated on the basis of mildly elevated liver enzymes, liver enzymes should be evaluated prior to induction of treatment and monitored frequently; dosage modifications may be necessary.
- **Pregnancy.** Risks and benefits of buprenorphine treatment must be

considered if the patient is pregnant or likely to become pregnant during the course of treatment with buprenorphine. Detoxification should not be considered for women who become pregnant while on buprenorphine products; this could be harmful to the fetus. If these women continue with buprenorphine therapy (as opposed to switching to methadone), they should be switched from Suboxone® to Subutex®.

- **Use of other drugs.** Buprenorphine is a treatment for opioid addiction, not for addiction to other classes of drugs. Patients who use or abuse more than one substance present unique problems and may need referral to resources outside the office setting for more intensive treatment.
- **Alcohol.** Since alcohol is a sedative-hypnotic drug, patients should be advised to abstain from alcohol while taking buprenorphine. Patients may present with withdrawal symptoms from other drugs at the same time they are experiencing opioid withdrawal symptoms. Buprenorphine will not control seizures caused by withdrawal from alcohol or other sedative-hypnotic substances.

Cost and Supply

Prescriptions written by qualified physicians will be valid at any pharmacy, but not all pharmacies carry these medications. If qualified physicians treat patients with buprenorphine products but do not maintain supplies of tablets for induction, they must establish relationships with one or more specific pharmacies that can provide initial doses and provide specific instructions for patients to return to the office setting for induction and follow-up prescriptions. Prescribers of buprenorphine are responsible for familiarizing themselves with all pertinent Federal regulations as well as State-specific requirements for the maintenance of buprenorphine products in office settings.

For more information about State-specific requirements for maintenance of buprenorphine products in office settings, or for instructions on establishing relationships with suppliers of the medication for induction use, refer to the Suboxone® Web site (http://www.suboxone.com) or call 1–877–SUBOXONE.

The cost of therapy may be a major limitation to the use of buprenorphine products (Suboxone® and Subutex®). Nurses who work with opioid-dependent individuals should become familiar with State and local resources and funding requirements for reimbursement through both public and private payers. State substance abuse treatment directors may provide more information about specific State and local resources to fund buprenorphine therapy. Refer to the National Association of State Alcohol/Drug Abuse Directors (NASADAD) Web site at http://www.nasadad.org/index.php?base_id=283 for information about how to contact substance abuse directors in particular States.

Buprenorphine Treatment Protocols—Office-Based Treatment

Office-based treatment of opioid dependence, in contrast to federally regulated opioid treatment programs (OTPs), is now permitted by DATA 2000. Office-based treatment involves the coordination of services by a physician's office as opposed to OTPs in which physicians have limited involvement (Fiellin & O'Connor, 2002).

Advantages and challenges are associated with providing office-based treatment. The advantages include (1) increasing the availability of treatment, (2) the ability to tailor services to the needs of patients, (3) minimization of the potential stigma associated with treatment, and (4) limiting patients' contact with drug-abusing patients.

Challenges to implementing office-based treatment include (1) the need for health care providers to acquire clinical experience with a new population of patients who abuse or are addicted to opioids and other drugs, and (2) the ability to provide or recommend appropriate psychosocial services (such as counseling, educational, and vocational services). In addition, issues such as inappropriate prescribing, medication diversion, and patient confidentiality must be addressed properly (CSAT, 2004; Fiellin &and O'Connor, 2002). It is vital for nurses to seek educational courses (such as buprenorphine courses offered by the ASAM) to improve their professional skills and prepare them for best practices in the addiction settings. For more information on buprenorphine treatment training please visit the following Web site: http://buprenorphine.samhsa.gov/pls/bwns/training.html.

Medically Supervised Withdrawal (Opioid Detoxification With Buprenorphine)

The term "medical withdrawal" has been chosen by experts in the field because it more accurately reflects the physician's role in withdrawal. (adapted from *CSAT Guidelines for the Accreditation of Opioid Treatment Programs 1999* at http://www.dpt.samhsa.gov/pdf/guidelines.pdf).

For patients who are physically dependent on heroin or other short-acting opioids, buprenorphine may be initiated at least 6–8 hours, but preferably 12–24 hours, after the patient last used opioids (CSAT, 2004). Optimally, buprenorphine should be administered when the patient exhibits definite signs of withdrawal. The maximal recommended induction dose of buprenorphine is 8 mg on day 1 (given at once or in divided doses, as clinically indicated) (CSAT, 2004).

Precipitated withdrawal may occur in switching from methadone or other long-acting medication to buprenorphine. Therefore, patients who are physically dependent on methadone or other long-acting opioids must be carefully selected for buprenorphine therapy. Appropriate patients may include those who have had difficulty adhering to scheduled visits at OTPs due to personal conflicts and work schedules or travel, as opposed to those who have been noncompliant with methadone treatment appointments. Other appropriate candidates include patients who have a history of uncontrollable adverse effects or true hypersensitivity to methadone.

Patients who are stable on methadone maintenance and who do not have a compelling reason to switch therapy should continue methadone maintenance because of the elevated risk for precipitated withdrawal during the conversion from methadone to buprenorphine. This risk is especially significant when buprenorphine is started shortly after the last methadone dose, and in patients maintained on methadone doses greater than 30–40 mg daily. To avoid precipitous onset of withdrawal symptoms, long-acting opioids should be tapered to the equivalent of 30–40 mg of methadone daily, and the last dose of methadone should be taken at least 24 hours prior to initiation of the buprenorphine therapy for methadone and at least 48 hours for levomethadyl acetate (LAAM). Note that this *conversion* dose of methadone should not be considered as the dose *equivalent* to a starting dose of buprenorphine. The induction dose of buprenorphine should start at 2 mg and may be repeated, as needed, up to 8 mg in a 24-hour period (CSAT, 2004).

Medically supervised withdrawal is only the first stage of addiction treatment and by itself often does little to change long-term drug use. The goal of medically supervised withdrawal is to manage the acute physical symptoms of withdrawal safely. Medically supervised withdrawal is strongly indicated as a precursor to effective drug-addiction treatment for some individuals. However, medically supervised withdrawal alone is rarely sufficient to achieve long-term abstinence (CSAT, 2004; CSAT, 2005*a*). Providers must help patients avoid withdrawal symptoms while making a smooth transition from a physically dependent to a physically nondependent state, so patients can then engage in further rehabilitation to prevent relapse without opioid-agonist treatment. To be effective, medically supervised withdrawal should be followed by long-term drug treatment therapy or naltrexone therapy to minimize the risk of relapse to opioid abuse (CSAT 2004).

> [A]bsent a compelling need for the complete avoidance of all opioids, long-term maintenance treatment with buprenorphine is to be preferred in most instances to any form of detoxification or withdrawal treatment. The literature suggests that the use of buprenorphine for gradual detoxification over long periods is probably more effective than its use for rapid medically supervised withdrawal over short or moderate periods (CSAT, 2004, page 59).

The optimal rate at which buprenorphine should be reduced is a matter of ongoing research. However, the dose may be decreased by as much as 50 percent per day, with a mild withdrawal syndrome that generally becomes manifest several days after the last dose and that can be treated with non-opioid, over-the-counter symptomatic remedies.

The best method is one that is slow, easy, and comfortable for patients. Medical withdrawal of compliant patients should proceed slowly at a rate that the prescriber determines to be therapeutic (for example, at 2 mg per month until the patient feels ready to discontinue buprenorphine altogether).

Noncompliant patients may need to be transferred to other medical treatment, such as methadone programs, or to nonmedical treatment programs where they can receive more structure and supervision.

Classifications of Medically Supervised Withdrawal

- **Short-term medically supervised withdrawal.** Patients with a compelling reason to be opioid-free quickly (impending incarceration, foreign travel, job requirement, etc.) will be considered for this method, in which the buprenorphine dose is reduced over 3 days or longer and then discontinued. This method is better accepted and more effective in relieving withdrawal symptoms than is clonidine (Cheskin, Fudala, & Johnson, 1994). However, data are insufficient about relapse rates and long-term outcomes for patients who undergo short-term withdrawal (CSAT, 2004).
- **Mid-term medically supervised withdrawal.** Patients without a compelling need to undergo short-term medically supervised withdrawal, but with a desire to be opioid free and to engage in rehabilitation, may be placed in a moderate-period reduction. Patients in this group may be withdrawn over a period of 10–14 days or more (up to 30 days) (CSAT, 2004).
- **Long-term medically supervised withdrawal.** Patients who are unwilling or unable to engage actively in rehabilitation services without agonist support may not be good candidates for short-term detoxification, but they may benefit from a long period of reduction, which may last between 30 and 180 days. These patients may also be suitable candidates for maintenance therapy (CSAT, 2004).

Few patients are likely to maintain abstinence without medication, so medically supervised withdrawal is considered only for patients with evidence of sustained medical and psychosocial stability. Patients should be encouraged to continue with buprenorphine maintenance therapy if medically supervised withdrawal is unsuccessful.

Maintenance Treatment

The three phases of buprenorphine therapy include *induction, stabilization,* and *maintenance.* Maintenance is reached when the patient is doing well on a steady dose of buprenorphine—preferably Suboxone®, the buprenorphine and naloxone combination product.

- **Induction phase.** The induction phase is the medically monitored

and supervised start-up of buprenorphine therapy. The goal of induction is to find the minimum dose at which the patient markedly reduces or eliminates use of other opioids and experiences no withdrawal symptoms, side effects, or cravings. Induction can be initiated in the physician's office, with induction doses administered as observed treatment, and subsequent doses provided through prescription (CSAT, 2004). Most patients can be inducted into treatment over 2–3 days by using the combination product Suboxone®. During the induction phase, buprenorphine products are administered when an opioid-dependent individual has abstained from using short-acting opioids for at least 6–8 hours, and when individuals on long-acting opioids have abstained for more than 24 hours and are in the early stages of withdrawal. Buprenorphine treatment cannot begin until patients are exhibiting objective signs and symptoms of opioid withdrawal. If patients are not in the early stages of withdrawal (i.e., when they have other opioids in the bloodstream), the administration of buprenorphine may precipitate withdrawal (FDA, 2002; HRSA-BPHC, 2003).

Patient education is very important in the induction phase. Withdrawal involves extreme discomfort, and patients may act to avoid it. It may be particularly helpful to ask patients about their typical first three signs of withdrawal and when they occur, so that the patient and provider can work together to prevent withdrawal.

One exception to the rule about adequate objective withdrawal signs is the highly motivated patient who has already detoxified himself several days before beginning induction. This patient may not exhibit significant objective withdrawal symptoms but may be dealing with significant cravings (Kathleen Thompson-Gargano, personal communication, October 2006).

- **Stabilization phase.** The stabilization phase begins when patients who have discontinued or greatly reduced the use of their drug of abuse no longer have cravings and are experiencing few or no side effects. The buprenorphine dose may need to be adjusted during this phase. Once stabilization has been achieved, the long half-life of buprenorphine sometimes makes it possible to switch patients to alternate-day dosing (HRSA-BPHC, 2003). Psychosocial counseling is a priority during the stabilization phase (HRSA-BPHC, 2003).
- **Maintenance phase.** The maintenance phase is reached when the patient is doing well on a steady dose of buprenorphine (preferably Suboxone®, the buprenorphine and naloxone combination product). The length of time of maintenance therapy is individualized, and it may be indefinite (CSAT, 2004). Patients should receive ongoing assessments and urine drug screens (CSAT, 2004).

  Initially, patients should be seen daily or have daily phone contact while induction is being completed. Then they should be seen at least weekly until they are well stabilized, when they may be seen no less frequently than every 4 weeks (CSAT, 2004).

Physicians should determine the length of treatment on buprenorphine according to the individual patient's needs and be sure to involve patients in the development of their treatment plans. The length of treatment may be as short as a few days for medical withdrawal (detoxification) services to as long as several years for maintenance therapy.

Precipitated Withdrawal and Withdrawal Symptoms

Avoiding Precipitated Withdrawal

Precipitated withdrawal is more likely to occur with higher levels of opioid dependence, with short-time intervals (e.g., less than 2 hours) between a dose of a full opioid agonist and a dose of buprenorphine, and with higher doses of buprenorphine. Withdrawal may be intense and of rapid onset. The best way to avoid precipitated withdrawal is to assess accurately the individual's patterns of opioid use, to determine whether the patient was on short- or long-acting opioid medications before initiating buprenorphine, and to monitor trial dosing (http://www.pbm.va.gov/criteria/BuprenorphineCriteriaForUse.pdf; CSAT, 2004).

Buprenorphine can precipitate an opioid withdrawal syndrome if administered to a patient who is opioid dependent and whose receptors are currently occupied by opioids. Therefore, a patient should no longer have any residual opioid effect from his or her last dose of opioid before receiving a first dose of buprenorphine. This condition is of particular importance for patients on long-acting opioid agonists (e.g., methadone). Due to this required abstinence before the initiation of buprenorphine treatment, it is likely that patients will feel that they are experiencing the early stages of withdrawal when they present for buprenorphine induction treatment. If a patient has early symptoms of withdrawal, the opioid receptors are unlikely to be occupied fully; precipitated withdrawal from administration of buprenorphine will be avoided, and the efficiency of buprenorphine in alleviating withdrawal symptoms can be assessed more easily (CSAT, 2004).

Assessment of Withdrawal Symptoms

Common signs and symptoms of opioid withdrawal include: (http://buprenorphine.samhsa.gov/about.html)

Objective	Subjective
· Elevated pulse and blood pressure · Vomiting/diarrhea · Diaphoresis (sweating) · Lacrimation (tears) · Rhinorrhea (runny nose) · Dilated pupils · Piloerection ("goose flesh") · Yawning · Mild fever	· Dysphoric mood · Nausea · Muscle aches/cramps/bone pain · Low back pain · Abdominal pain · Insomnia · Craving · Anxiety/irritability/restlessness

Figure 1. Staging and Grading Systems of Opioid Withdrawal

Stage	Grade	Physical Signs and Symptoms
Early Withdrawal (8–24 hours after last use)	1	Lacrimation Rhinorrhea Diaphoresis Yawning Restlessness Insomnia
	2	Piloerection Muscle twitching Myalgia Arthralgia Abdominal pain
Fully Developed Withdrawal (1–3 days after last use)	3	Tachycardia Hypertension Tachypnea Fever Anorexia Nausea Extreme restlessness
	4	Diarrhea Vomiting Dehydration Hyperglycemia Hypotension Curled-up position

HIV Web Study (http://www.HIVwebstudy.org) Supported by HRSA

As individuals progress through the following stages of opioid withdrawal, they progressively have more severe symptoms: (CSAT, 2004)

Signs and symptoms of withdrawal may be assessed by using standardized instruments such as the Clinical Opiate Withdrawal Scale (COWS) (Wesson & Ling, 2003), the Subjective Opiate Withdrawal Scale (SOWS) (Handelsman et al., 1987), or the Objective Opiate Withdrawal Scale (OOWS) (Handelsman et al., 1987) (see Appendix D: Assessment Instruments).

Helping Patients Manage Mild Withdrawal Symptoms

Usually, medically supervised withdrawal from Suboxone® causes mild, transitory withdrawal symptoms. Patients should be prepared for the occurrence of possible symptoms such as reduced energy, reduced appetite, irritability, or insomnia. It is also important for patients to understand that they can halt the medical withdrawal at any time and return to a higher dose. (See Suboxone® Treatment Walkthrough: http://www.suboxone.com/hcp/opioiddependence/suboxone_treatment.aspx.)

Tapering

The patient's Suboxone® dose should be tapered slowly at a rate that both the prescriber and the patient consider acceptable. Patients commonly want to taper more quickly, so helping patients set realistic goals at the outset is important. Some patients will ask to proceed directly from stabilization to medically supervised withdrawal. However, unless there is a compelling reason to discontinue Suboxone® quickly (e.g., travel), a slow taper is usually encouraged, because it is associated with a higher likelihood of treatment success (CSAT, 2004).

Although no standard dosing protocol exists for medically supervised withdrawal, sample protocols are provided in the Suboxone® and Subutex® Dosing Guide at http://www.suboxone.com/hcp/opioiddependence/ dosing_guide.aspx.

Self-Management of Mild Withdrawal Symptoms With Over-the-Counter or Prescription Medications

Medical withdrawal from Suboxone® causes mild withdrawal symptoms, such as muscle pain, nausea, gastrointestinal (GI) distress, and insomnia. Patients may benefit from over-the-counter medications or prescribed medications to alleviate symptoms.

Over-the-counter medications for symptom relief include those listed in Erickson (2006) and at http://www.fda.gov/cder/Offices/OTC/default.htm.

- Ibuprofen, 800 mg by mouth every 6 hours as needed for muscle aches
- Acetaminophen, 1,000 mg by mouth every 4 hours as needed for pain
- Maalox®, 30 cc by mouth every 2 hours as needed for GI distress
- Diphenhydramine, 50 mg by mouth at bedtime as needed for severe insomnia

The following prescribed medications may be helpful at controlling withdrawal symptoms (see Erickson, 2006; and http://www.fda.gov/ohrms/dockets/dailys/03/jul03/072503/072503.htm and http://www.fda.gov/cder/Offices/OTC/default.htm).

- Dicyclomine, 40mg by mouth every 6 hours as needed for abdominal pain
- Promethazine, 25 mg intramuscularly every 6 hours as needed for nausea and vomiting
- Promethazine, 25 mg by mouth every 6 hours as needed for nausea
- Lopermide, 2 mg by mouth every 6 hours as needed for diarrhea
- Clonidine, 0.1 mg by mouth every 2 hours as needed for severe anxiety

Management of Patients With Co-Occurring Pain

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (Merskey, 1979). Pain may be classified as either acute or chronic. Acute pain is associated with injury to body tissue, often accompanied with objective signs of sympathetic nervous system activity, and generally subsides as the injury heals. Chronic pain extends beyond a normal healing period, or in some cases the underlying cause of the pain cannot be identified. Chronic pain usually persists longer than 3 months and is rarely accompanied by symptomatic nervous system activity. Lack of objective signs may prompt the clinician

to conclude that the patient doesn't appear to be in pain (APS, 2003; Loeser & Melzack, 1999). Both acute and chronic pain can have an impact on the dimensions of the patient's quality of life including physical, social, psychological, and spiritual well-being (Ferrell et al., 1999).

Pain Assessment

The purpose of pain assessment is to (1) identify the pain level at which pain does not interfere with activities related to recovery or quality of life (QOL) level at which the patient can perform activities of daily living (ADLs); and (2) effectively measure interventions used in each patient's pain management plan (Grimes, 2006). The criteria of pain assessment are as follows:

Onset and treatment pattern	· When did the pain start? · How often does the pain occur? · Has pain intensity changed?
Location	· Where is the pain? · Is there more than one site of pain?
Description	· What does the pain feel like? · What words describe the pain?
Aggravating	· What makes the pain better? Worse?
Previous treatment	· What treatment have you tried to relieve the pain? · Were these effective?
Effect	· How does the pain affect physical and social function?
Intensity	· Using a pain scale, rate the intensity of the pain.

(AHCPR, 1994)

Multimodal Approach to the Treatment of Pain

The first approach to the treatment of pain is pharmacologic intervention. Carr and Goudas (1999) state that patients with moderate to severe acute pain often require opioid analgesics while they are receiving regular opioid-agonist therapy. If acute pain remains undertreated, it will decrease a patient's responsiveness to opioid analgesics; thus, controlling the subsequent pain will be far more difficult (Collett, 1998; Mao, Price, & Mayer, 1995). Multimodal analgesia, such as nonsteroidal anti-inflammatory drugs (NSAIDs), and acetaminophen and adjuvant analgesics, such as tricyclic antidepressants that enhance opioid effects, may be an appropriate pain therapy to decrease the total amount of opioid provided to patients (Kehlet & Dahl, 1993; Mitra & Sinatra, 2004). Meanwhile, clinicians must continue the opioid-agonist treatment for the patient before prescribing analgesia to avoid the increased pain sensitivity associated with opioid withdrawal (Jasinski, 1997).

The second approach is nonpharmacological interventions including physical and cognitive behavioral modalities. Cutaneous (skin) stimulation, exercise, immobilization, and acupuncture are examples of physical intervention. Cognitive behavioral modalities include relaxation and imagery, distraction and reframing, patient education, structured support, hypnosis, and pastoral counseling (Simon et al., 2002).

Finally, ongoing assessment and documentation of pain management intervention are crucial. Nurses

should periodically assess the four "**A's**" of pain management. Those include (1) **A**nalgesia, (2) **A**ctivities of daily living, (3) **A**dverse effects, and (4) **A**berrant drug-related behaviors (APS, 2003).

Management of Acute Pain in Patients on Buprenorphine Maintenance Therapy

If the patient requires opioid analgesics while receiving buprenorphine maintenance therapy, the following options may be appropriate (Alford, Compton, & Samet, 2006):

1. Provide titrated short-acting opioid analgesics (for short-duration pain only) while continuing buprenorphine maintenance therapy.
2. Administer opioid analgesics while discontinuing buprenorphine maintenance therapy. Return to buprenorphine therapy when acute pain is less intense and does not require opioid analgesics.
3. Divide buprenorphine dose, and administer every 6–8 hours.
4. Discontinue buprenorphine in case of hospitalization, and provide methadone (20–40 mg) for treating opioid dependence and short-acting opioid analgesics for treating pain. Availability of naloxone as an opioid antagonist in this situation is also necessary in case of emergency.

Physicians' and Patients' Responsibilities

To improve outcomes of pharmacologic therapies provided in office-based settings, practitioners must be clear about their treatment philosophy, expectations, and office rules. They must manage medication accurately during all stages of treatment. Providers should inform patients of clinic procedures and protocols, hours of operation, phone numbers, procedures for making appointments, fees, proper medication administration and storage, side effects and precautions, rights and responsibilities, and other practice-specific protocols or guidelines. In many States, physicians can periodically check Prescription Monitoring Programs (PMPs).

The following "red flag" behaviors should be addressed with patients immediately, and nurses should support patients in making appropriate responses to them (OMIROR, 2003):

- Missing appointments
- Refusing urine testing or breathalyzer
- Running out of medications too soon
- Taking medications off schedule
- Not responding to phone calls
- Neglecting to mention new medication or outside treatment
- Appearing intoxicated or disheveled in person or sounding intoxicated on the phone
- Making frequent, urgent, or inappropriate phone calls
- Neglecting to mention change in address, job, or home situation
- Having inappropriate outbursts of anger
- Reporting lost or stolen medication
- Having frequent physical injuries or auto accidents
- Not paying bills

Other warning signs include: (LaBelle, 2006)

- Drug screens positive for opioids or illicit drugs
- Request for higher doses after stabilization
- Evidence of tampering with drug tests
- Drug screens negative for buprenorphine (point of collection tests are available)
- Changes in behavior
- No engagement in counseling or self help
- Depression, withdrawal, or social isolation
- Weight loss

Information about patient responsibilities should be clearly articulated in a "treatment contract" that should be signed by both the patient and the physician. At a minimum, the treatment contract should cover components discussed below: (McCance-Katz, 2004; OMIROR, 2003)

- **Voluntary participation.** Patients should freely and voluntarily agree to receive buprenorphine products for the treatment of opioid addiction, provided that they accept the conditions of the treatment contract.
- **Pregnancy.** Women of childbearing age should receive a pregnancy test (urine human chorionic gonadotropin (HCG) test) before treatment is initiated and monthly or intermittently thereafter. Female patients should tell the physician if they are pregnant, plan to become pregnant, or are breastfeeding. It is not known whether Subutex® or Suboxone® may harm unborn children or infants.
- **Use of other medications.** Patients should agree not to obtain medications (prescription or nonprescription, including vitamins and herbal supplements) from physicians, pharmacists, or any other source without the approval of the physician who provides the buprenorphine therapy. Mixing buprenorphine with other medications—especially benzodiazepines such as diazepam (Valium), clonazepam (Klonopin), lorazepam (Ativan), chlordiazepoxide (Librium), alprazolam (Xanax), midazolam (Versed), and other drugs of abuse—may be particularly dangerous and may cause death.
- **Use of alcohol and other illicit drugs.** Because alcohol is a sedative-hypnotic drug, its use is strongly contraindicated, and patients should be advised to abstain from alcohol while taking buprenorphine (CSAT, 2004). Furthermore, patients should be warned that the use of cocaine or other illicit drugs is contraindicated, because such use often leads to relapse.
- **Use of medications only as prescribed.** Patients should take their medications on time and should not adjust their dose on their own. If patients desire a dose change, they should call for an appointment to discuss this with their physician.
- **Scheduled appointments.** Patients should agree to keep and arrive on time for all scheduled appointments while taking buprenorphine products. Missed appointments may result in not being able to get medication until the next scheduled visit.
- **Compliance with required pill counts and drug tests.** Drug testing is a mandatory part of office maintenance. The physician should consider ordering drug testing (e.g., urine samples) and pill counts at each visit.
- **Counseling and other referrals.** Patients must agree to keep appointments for any recommended psychosocial counseling (including 12-step or other self-help programs) and to accept referrals for other ancillary services as mutually agreed upon by the prescriber, nurse/counselor, and the patient.
- **Under the influence.** Patients are instructed not to come to the program intoxicated or under the influence of alcohol or drugs, because it is very unsafe to do so. If

they do come to the program intoxicated or under the influence, they will not be medicated and may be discharged from buprenorphine treatment. However, patients who admit to drug use are asking for help and should be congratulated and acknowledged for this openness, because it is behavior conducive to recovery and health maintenance.

- **Recovery and relapse.** Relapse to opioid drug use can be life threatening, and the treatment plan should be adjusted accordingly. Trust should be established with the patient so that the patient may be more willing to notify the physician about a relapse before it is detected with a drug test. The physician and nurse should adopt a matter-of-fact and nonpunitive approach with the patient in response to relapse.
- **Diversion.** Patients must agree not to sell, share, or give any medication to other persons. Such mishandling is a serious violation that may result in discharge. Patients should notify the physician immediately in case of lost or stolen medication. If a police report is filed, the patient should bring in a copy for the record.
- **Safe storage.** Medication may be harmful to children, household members, guests, and pets. Patients should be instructed to store the medication in a safe place and to keep the medication in child safety containers, out of the reach of children. They should call the poison control center or 911 if anyone other than the patient ingests the medication. Lost medication will not be replaced. Medication should not be kept in places of temperature extremes such as a glove compartment, or in a bathroom medicine chest where it can become moist or be taken by others.
- **Other safety issues.** Patients should not drive, operate heavy machinery, or perform other dangerous activities until they know how the medication affects them. Dangerous or inappropriate behavior that is disruptive to the clinic and others will not be tolerated and may result in discharge from treatment.

Nurses' Responsibilities

In OTPs, nonphysician health care professionals such as nurses, nurse case managers, and NPs are permitted to conduct various activities under SAMHSA regulations. For example, under 42 CFR 8.12(f), an authorized health care professional under the supervision of the program physician may conduct the required initial physical examination. On the other hand, only a medical director or program physician shall determine a patient's eligibility for take-home medications under 42 CFR 8.12(i)(2) (http://www.dpt.samhsa.gov/regulations/legreg.aspx).

In office-based settings, nonphysician health care professionals such as nurses, nurse case managers, and NPs may be permitted to conduct physical examinations and other procedures. These procedures should be conducted under the supervision of the physician and documented in the job description, if they are permissible under the Nurse Practice Act in the State in which the nurse practices. However, the physician must determine the patient's dosage of buprenorphine medication and the amount of medication permitted for take-home medication or the amount of medication to be dispensed with a prescription.

Nursing Practice and the Use of Buprenorphine for the Treatment of Opioid Addiction

Screening and Assessment

Nurses have a great role in screening and assessing the health status of patients who have addiction problems. As a basic intervention, nurses can identify problems caused by drug use (Clancy, Coyne & Wright, 1997). Screening and assessment tools may be used to help nurses identify significant uncovered risks and problems with drug and alcohol use (Clancy, Coyne, & Wright, 1997).

Initial screening. Initial screening should consist of a combination of objective screening instruments, laboratory evaluations, and interview(s). If the buprenorphine prescriber suspects an addiction problem after reviewing the initial results, further assessment is indicated. Indepth interviews and standardized assessments are the most effective means of gathering further information. Several validated addiction screening instruments are available, such as the Drug Abuse Screening Test (DAST-10) (see Appendix C: Screening Instruments).

Screening for individuals at risk for undetectable health and mental health disorders. Nurses can assist in ruling out co-occurring disorders and can identify patients with comorbid conditions during their ongoing screening, assessment, monitoring, and recovery management.

Nurses may assist in:

- Ruling out comorbid acute or chronic pain disorders and opioid dependence.
- Ruling out polysubstance use—consider using the Readiness Ruler (see Appendix C: Screening Instruments).
- Ruling out co-occurring psychiatric disorders—consider using Mental Health Screening Form III (MHSF-III) *(*see Appendix D: Assessment Instruments*).*
- Questioning about potential pregnancy and child-bearing status.
- Screening for infectious diseases (hepatitis viruses, HIV, tuberculosis (TB), sexually transmitted diseases (STDs)).
- Screening out domestic violence or abuse. Please visit the following Web sites for more information on the domestic violence screening tools: American Council of Obstetricians and Gynecologists, http://www.acog.org/departments/dept_notice.cfm?recno=17&bulletin=585; and *Domestic Violence: What Clinicians Should Know* (2004), http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijapa/vol4n1/violence.xml.

- **Assessment.** If screening tests indicate the presence of an opioid use disorder, further assessment is necessary to delineate thoroughly the patient's problem severity, to identify comorbid or complicating medical or emotional conditions, and to determine the appropriate treatment setting and level of treatment intensity for the patient (CSAT, 2004). It is essential that nurses perform assessments in a safe, confidential environment and properly consider individuals' and families' race, gender, sexuality, religion, and age (Clancy, Coyne, & Wright, 1997).

A comprehensive biopsychosocial assessment is necessary to determine the appropriateness of office-based or other opioid-agonist treatment. The assessment may be accomplished in stages over a 3- to 4-week period, during initiation of treatment and gradual acquisition of increasingly detailed information. Several office visits may be required to obtain all the information necessary to make a comprehensive set of diagnoses and to develop an appropriate treatment plan, although these efforts also may be completed in a single, extended visit. Treatment should not be delayed, however, pending complete patient assessment. The goals of a medical assessment of a patient who is addicted to opioids are to (CSAT, 2004):

- Establish the diagnosis or diagnoses
- Determine appropriateness for treatment
- Make initial treatment recommendations
- Formulate an initial treatment plan
- Plan for engagement in psychological treatment
- Ensure that there are no contraindications to the recommended treatments
- Assess other medical problems or conditions that need to be addressed before or during early treatment
- Assess other psychiatric or psychosocial problems that need to be addressed before or during early treatment

Components of assessment. The components of assessment of a patient who is addicted to opioids should include (CSAT, 2004):

- **Complete history.** Complete history includes substance abuse history, addiction treatment history, psychiatric history, family history, medical history, social and employment history, and readiness for change.
- **Physical examination.** Physical examination should focus on physical findings related to addiction. The physical complications of opioid addiction should be identified and addressed as part of the overall treatment plan.
- Mental status examination to evaluate the patient's (CSAT, 2004):
  - General appearance
  - Behavior and interaction with interviewer
  - Speech and voice
  - Motor activity
  - Mood and affect
  - Perceptions, hallucinations, delusions
  - Thought process and content—suicidal ideation, homicidal ideation, etc.

- Insight and judgment
- Motivation and readiness to change—patient's stated goals and expectations
- Cognitive function—orientation, memory, attention, concentration, fund of information, literacy skills, abstraction, intelligence
- Personality characteristics
- Defense mechanisms
- Relevant laboratory testing
- Formal psychiatric assessment (if indicated) (CSAT, 2005b)

For additional information about components of a formal psychiatric assessment, refer to Mental Health Screening Form III (MHSF-III) (*see* Appendix D: Assessment Instruments).

Individuals who are addicted to opioids may have the same chronic diseases seen in the general population and should be evaluated, as appropriate, for diseases that require treatment (such as infectious diseases, TB, and HIV). In addition, a number of medical conditions are commonly associated with opioid and other drug addictions (e.g., nutritional deficiencies and anemia, caused by poor eating habits; hepatitis; and chronic obstructive pulmonary disease.)

Assessing intoxication and overdose. It is vitally important to assess for signs of opioid intoxication, overdose, or withdrawal during the physical examination. Opioid overdose should be treated as a medical emergency. Opioid withdrawal can be objectively assessed by using several instruments such as Clinical Institute Withdrawal Assessment for Alcohol, Revised (CIWA-Ar) and Clinical Institute Withdrawal Assessment for Benzodiazepines(CIWA-B) (Kathleen Thompson-Gargano, personal communication, October 2006) (see Appendix D: Assessment Instruments). For more information about screening tools, review the SAMHSA, CSAT, Treatment Improvement Protocol (TIP) 24, *A Guide to Substance Abuse Services for Primary Care Clinicians* (CSAT, 1997) (see http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.45293).

- Substances
- Typical first symptoms
- Patient education
- Last substance use (dig deep to determine what was used, how much, and when)
- Withdrawal instrument score (e.g., COWS, in appendix D)
- Precipitated withdrawal

Diagnosis of Opioid-Related Disorders

Health care providers should document that every patient who is prescribed buprenorphine for the treatment of opioid addiction has met the criteria for opioid addiction (compulsive use of opioids despite harm), otherwise known as opioid dependence as defined in the latest edition of the DSM-IV-TR (APA, 2000). After a thorough assessment of the patient has been conducted, a formal diagnosis may be made using the DSM-IV-TR criteria for opioid and other substance dependence, and these criteria should be documented in the patient record by the licensed clinician who establishes the diagnosis.

In rare cases, a patient may be physiologically dependent on opioids and meet DSM-IV-TR criteria for abuse but not for dependence. In such a case, a short course of buprenorphine may be considered for detoxification. Maintenance treatment with buprenorphine is not recommended for patients who do not meet DSM-IV-TR criteria for opioid dependence.

Determining Appropriateness for Buprenorphine Treatment

Several issues should be considered in evaluating whether a patient is an appropriate candidate for buprenorphine treatment of opioid addiction in the office or other settings. At a minimum, candidates for buprenorphine treatment should: (1) be interested in treatment for opioid addiction, (2) have no absolute contraindication to buprenorphine, (3) be expected to be reasonably compliant with such treatment, (4) understand the risks and benefits of buprenorphine treatment, (5) be willing to follow recommended safety precautions, and (6) consent to be treated with buprenorphine after a review of treatment options. It is critical that the treatment approach be appropriate to the individual's age, gender, ethnicity, and culture (CSAT, 2004).

Patients are less likely to be appropriate candidates for buprenorphine treatment for opioid addiction if they have (1) comorbid dependence on high doses of benzodiazepines or other central nervous system depressants (including alcohol), (2) significant untreated psychiatric comorbidity, (3) active or chronic suicidal or homicidal ideation or attempts, (4) multiple previous treatment episodes for drug abuse with frequent relapses (except that multiple previous detoxification attempts followed by relapse are a strong indication of the need for long-term maintenance treatment), (5) poor response to previous treatment attempts with buprenorphine, and (6) significant medical complications (CSAT, 2004).

Treatment Planning

Nurses may be instrumental in the development of a treatment plan that contains (1) clear and achievable targets and time scales (e.g., number of sessions that a patient attends), (2) the venue in which care/intervention will be offered, and (3) the involvement of other services such as counseling and psychotherapy (Clancy, Coyne, & Wright, 1997). Also, nurses must consider the patient's motivation and treatment accessibility throughout the treatment process.

Nurses should actively involve patients in development of the treatment plan, including discussing appropriate behavior, explaining reasons for which medication may be discontinued, making a psychiatric referral or referral for other ancillary service, and explaining what happens if a patient is noncompliant. Also, patient participation in self-help support programs during and after treatment often is helpful in maintaining abstinence (Clancy, Coyne and Wright, 1997).

Ongoing Treatment Monitoring

Treatment must be assessed continually to ensure that it meets changing needs. Matching treatment settings, interventions, and services to each individual's particular problems and needs is critical to his or her ultimate success in returning to productive functioning in the family, workplace, and society. No single treatment is appropriate for all individuals. Moreover, because individuals who are addicted to drugs may be uncertain about entering treatment, taking advantage of opportunities when they are ready for treatment is crucial. Treatment must be readily available. Potential treatment applicants can be lost if treatment is not immediately available or is not readily accessible (CSAT, 2004).

To be effective, treatment must address the individual's drug use and any associated medical, psychological, social, vocational, and legal problems. In addition to medication, the person may require varying combinations of services and treatment components, including counseling or psychotherapy, medical services, family therapy, parenting instruction, vocational rehabilitation, and social and legal services. Remaining in treatment for an adequate period of time is critical for treatment effectiveness. However, appropriate duration depends on problems and needs. For most patients, the threshold of significant improvement is about 3 months in treatment. Because people often leave treatment prematurely, it is necessary for the treatment team to plan strategies to engage and keep patients in treatment. (CSAT, 2004).

It is crucial for nurses to monitor patients before and during the induction phase. Possible drug use during treatment must be monitored continuously, as it is not unusual for relapses to occur during treatment. Objective monitoring (urinalysis and other tests) helps patients withstand urges to use. Monitoring can provide early evidence of drug use so that the treatment plan can be adjusted. Finally, feedback to patients who test positive for illicit drug use is an important element of monitoring (Clancy, Coyne, & Wright, 1997).

Before treatment induction, nurses should review the following instructions with patients to prepare them for the first day of induction:

- Come to the doctor's office in mild withdrawal.
- Dispose of all illicit drugs and paraphernalia before the visit.
- Do not plan to drive for 24 hours after receiving the first dose(s) of buprenorphine medication.
- Plan to be at clinic or office for up to 4 hours, because induction may involve monitoring and more than one dose of medication (patient may bring a sandwich, book, etc.).
- Be ready to give a urine sample.
- Put tablet(s) under tongue and allow the tablet(s) to dissolve slowly.
- Do not talk, eat, drink, or swallow while the medication is in mouth.
- May a use mirror and watch the tablet(s) gradually shrink as they dissolve (Labelle, 2006).

When dispensing the first medication dose, it is crucial that nurses (1) watch the patient put the tablet in the right place under the tongue, (2) check periodically to see the tablet

shrinking, and (3) check that the table is completely gone. This is the only way of telling that ingestion occurred, aside from urine testing for buprenorphine (LaBelle, 2006).

The patient should receive a daily dose until stabilized. Once stabilized, the patient may continue a single daily dose or may shift to alternate-day dosing (e.g., every other day or Monday, Wednesday, Friday) (Amass et al., 2001). Also, providers can increase the dose on the dosing day by the amount not received on intervening days. For example, if the patient stabilizes on 8 mg daily, and every-other-day dosing is desired, then the provider may change the dosage to 16 mg on Monday, 16 mg on Wednesday, and 24 mg on Friday (to provide medication coverage for the 2-day weekend).

Counseling and Referral for Psychosocial Treatment

DATA 2000 stipulates that when a physician submits a notification (form SMA-167) to SAMHSA for a buprenorphine waiver, the physician must attest to the capacity to refer patients for appropriate counseling and other nonpharmacological therapies. Physicians who are providing opioid treatment should ensure that they are capable of providing psychosocial services either in their own practices (including counseling and patient participation in self-help groups) or through referrals to reputable behavioral health practitioners in their communities.

During consultation, nurses and other health care providers must pay attention to all patients' medical and psychosocial comorbidities and address them comprehensively, as pharmacotherapy rarely achieves long-term success without concurrent psychosocial, behavioral therapies and social services. Also, special attention must be given to those patients at risk of misusing their medications or whose living arrangements pose increased risk for misuse or diversion.

Counseling (individual or group) and other behavioral therapies are critical components of effective treatment. In therapy, patients must be helped to (1) address motivation, (2) build skills to resist drug use, (3) replace drug-using activities with constructive and rewarding nondrug-using activities, (4) improve problemsolving abilities, (5) work on interpersonal relationships, and (6) improve family and community functioning.

Addicted or drug-abusing individuals with coexisting mental disorders should have both disorders treated in an integrated way since substance use disorders (SUDs) and mental disorders often co-occur. Additionally, patients presenting for either condition should be assessed and treated for the co-occurrence of the other type of disorder. Treatment providers should assess and counsel individuals about HIV/AIDS, hepatitis B and C, TB, and other infectious diseases in order to (1) avoid high-risk behavior and (2) help people who are already infected to manage their illness (CSAT, 2004).

Categories of special populations who are highly in need of consultation while in treatment include the following (CSAT, 2004):

- Patients with psychiatric comorbidity require specialized assessment and integrated

psychiatric and substance abuse treatment.

- Patients with pain need regular medical care (not an OTP) if they are diagnosed with a pain disorder but not with addiction. Patients with pain disorders are sometimes physically dependent on medication. Patients with pain and patients with co-occurring addiction and chronic or acute pain may need to be assessed by a pain management specialist as well as an addiction specialist.
- Patients with medical comorbidities (such as infectious diseases or other medical complications) may additionally require referrals to one or a number of medical specialties.
- Patients who are pregnant and have opioid or other addictions are high-risk patients and require specialized care to manage and reduce risks for both the mothers and the neonates. However, information on buprenorphine and pregnancy is limited.
- Adolescent patients have special psychosocial and educational needs, and they require special consent procedures for starting treatment.
- Geriatric patients have particular vulnerabilities, but information about buprenorphine and older adults is limited.
- Patients with polysubstance abuse should be referred to addiction specialists (buprenorphine is not known to be effective for treating addiction to drugs in other classes).
- Patients who are recently discharged from, or under the jurisdiction of, the criminal justice system require collateral and other reporting contacts (for example, phone calls or written reports for parole officers or the drug court). Additionally, these patients may have other comorbid health, mental health, or psychosocial issues; they should receive services to stabilize these aspects of their lives.
- Health care professionals with addiction require comprehensive, specialized care. Their recovery plan must be closely monitored, and reporting to State authorities may be required.

Treatment Retention and Relapse Prevention

Length of buprenorphine treatment may be as short as a few days for medically supervised withdrawal or as long as several years for maintenance therapy. Recovery from drug addiction can be a long-term process and frequently requires multiple episodes of treatment. As with other chronic illnesses, relapses may occur during or after successful treatment episodes. Individuals may require multiple episodes of prolonged treatment to achieve long-term abstinence and fully restored functioning. Nurses must continuously monitor urine drug testing or other toxicology testing, the number of pills in the patient's supply, medication dosage, and pharmacy checks to help prevent relapse.

Relapse can happen because of the presence of both physical and emotional triggers in the patient's life. Nurses must help patients understand those triggers and create strategies to avoid and manage them (Marlatt & George, 1984; Wanigaratne et al., 1990). Those strategies include (1) help patients develop an understanding of the stressful triggers in their lives, (2) help patients develop alternative adaptive responses to stresses, and (3) help them find

constructive ways of managing stress (Clancy, Coyne, & Wright, 1997).

Nurses and other health care providers must continuously ask patients open questions to facilitate constructive discussion rather than resistance. Examples of those questions are as follows:

- What do you think you will do?
- It must be uncomfortable for you. What is your next step?
- What are your options?
- What are some of the good things happening to you?
- What is changing in your life?
- How does it feel to be successful thus far? (Clancy, Coyne, & Wright, 1997)
- What can we do to help you in your recovery process?
- What has worked for you in the past?

The aim of nursing intervention in recovery management is to help patients prioritize their needs and maintain their motivation as well as to empower patients to achieve desired recovery outcomes (Clancy, Coyne, & Wright, 1997).

Nurses must focus on patients' empowerment and help them manage their lives in a constructive way (Seedhouse, 1986). Nurses also need to help patients (1) develop trust over time during their therapeutic visits, and develop further trust of the treatment program and providers; (2) identify their own needs, and verbalize their specific goals and objectives; and (3) achieve their plans successfully (Egan, 1990).

Confidentiality and Privacy

Title 42 Code of Federal Regulations, Part 2, Subpart C—Disclosures With Patient's Consent

Prior to initiating office-based opioid addiction treatment, practice policies and procedures should be established that will guarantee the privacy and confidentiality of patients treated for addiction. Providers must comply with all applicable laws and regulations regarding the privacy and confidentiality of medical records in general, and of information pertaining to addiction treatment services in particular. The privacy and confidentiality of individually identifiable information relating to patients receiving drug or alcohol treatment is protected by the SAMHSA confidentiality regulation, Title 42, Part 2 of the Code of Federal Regulations (42 CFR Part 2). This regulation mandates that addiction treatment information in the possession of substance abuse treatment providers be handled with a greater degree of confidentiality than general medical information. Occasionally, physicians will need to communicate with pharmacists and other health care providers about the addiction treatment of a particular patient (e.g., to verify a Suboxone® or Subutex® prescription). Regulation 42 CFR Part 2 requires physicians providing opioid addiction treatment to obtain a signed patient consent before disclosing individually identifiable addiction treatment information to any third party. A sample consent form with all the elements required by 42 CFR Part 2 is included in TIP 40, pages 119–120 (CSAT, 2004). Here is the link to the consent form: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.section.72974.

Physicians should have each new patient who is treated with buprenorphine sign a copy of this form to prevent confidentiality problems at pharmacies when patients present with buprenorphine prescriptions. It is particularly important to obtain patients' consent when telephoning or faxing prescriptions to pharmacies, as this information constitutes disclosure of the patient's addiction treatment. When physicians directly transmit prescriptions to pharmacies, further redisclosure of patient-identifying information by the pharmacy is prohibited, unless signed patient consent is obtained by the pharmacy. Regulation 42 CFR Part 2 does not apply to pharmacies, however, when the patient delivers a buprenorphine prescription without telephone confirmation or other direct communication from physicians to the pharmacist.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191 (http://aspe.hhs.gov/admnsimp/pl104191.htm), which amends the Internal Revenue Service Code of 1986, mandates standardization of exchange formats for patient health, administrative, and financial data; requires development of unique identifiers for individuals, employers,

health plans, and health care providers; and establishes security standards for protecting the confidentiality and integrity of individually identifiable health information. SAMHSA has prepared a document—*Comparison Between the Confidentiality of Alcohol and Substance Abuse Patient Records (42 CFR Part 2) and the Health Insurance Portability and Accountability Act 1996*—that is available, along with other HIPAA technical assistance tools, on the SAMHSA HIPAA Web pages at http://www.hipaa.samhsa.gov. See also the SAMHSA Treatment Assistance Publication (TAP) 13, *Confidentiality of Patient Records for Alcohol and Other Drug Treatment* (Lopez, 1994), available on the SAMHSA Treatment Improvement Exchange Web site at http://www.treatment.org/taps/index.html. The Subutex® and Suboxone® package labels (available on the FDA Web site at http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm) also contain information on Federal confidentiality rules and regulations.

Physicians, nurses, and other health care providers should also consult with their State medical authorities concerning privacy and confidentiality rules in their locales. Some of the privacy and confidentiality issues that can arise in the course of addiction treatment (CSAT, 2004) are:

- Information covered by the doctor/patient privilege
- Circumstances in which confidential information is protected from disclosure
- Exceptions to State laws protecting ethical information
- Duty to report potential threats of violence or child or elder abuse
- Communications with third parties (e.g., families, employers, allied health care providers, third-party payers, law-enforcement officers, responses to subpoenas)

Nurses are responsible for assuring patients that their personal information is safe and respected within the team and agency. Also, nurses must inform patients that their personal information can be provided to third parties on the patient's behalf only with written permission from the patient (Lambert & Coyne, 1993; UKCC, 1996).

For More Information

Center for Substance Abuse Treatment (CSAT) Buprenorphine Information Center
http://www.buprenorphine.samhsa.gov/
Telephone: 866–BUP–CSAT (866–287–2728); live operators are available to answer calls Monday through Friday from 8:30 a.m. to 5:00 p.m., EST.

SAMHSA Buprenorphine Physician Locator Web Site
http://buprenorphine.samhsa.gov/bwns_locator/index.html
E-mail: info@buprenorphine.samhsa.gov.

Federation of State Medical Boards (FSMB)
Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office
http://www.fsmb.org/grpol_policydocs.html

Food and Drug Administration (FDA)/Center for Drug Evaluation and Research (CDER)
Telephone: 888–INFO–FDA for consumer inquiries and 301–827–6242 for media inquiries.
http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm

Join Together: National Poll of Physicians on Barriers to Widespread Buprenorphine Use
http://www.jointogether.org/sa/issues/hot_issues/bupe/

National Association of State Alcohol and Drug Abuse Directors (NASADAD)
NASADAD Policy Paper 14 (Topic: The Use of Medications in Substance Abuse Treatment)
http://www.nasadad.org/resource.php?doc_id=35

NASADAD Policy Paper 15 (Topic: Physician Information—Answers to Frequently Asked Questions)
http://www.nasadad.org/resource.php?doc_id=75

Northwest Frontier Addiction Technology Transfer Center (ATTC), Opiate Medication Initiative for Rural Oregon Residents (OMIROR). November 2003.
Treating Opiate Dependence in Rural Communities: A Guide for Developing Community Resources.
http://www.ireta.org/opiates2005/10.pdf

Substance Abuse and Mental Health Services Administration (SAMHSA)
Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, Treatment Improvement Protocol (TIP #40), available through SAMHSA's National Clearinghouse on Alcohol and Drug Information (NCADI). To order, go to http://ncadistore.samhsa.gov/catalog/productDetails.aspx?ProductID=16829. Telephone: 1–800–729–6686.

Suboxone® Clinical Information Hotline and Website
Telephone: 877–SUBOXONE (1–877–782–6966); Web: http://www.suboxone.com

The National Alliance of Advocates for Buprenorphine Treatment (NAABT)
http://www.naabt.org

Resources for Buprenorphine Training Sessions

You may contact the Suboxone® help line (1–877–782–6966) or visit the Suboxone® Web site (http://www.suboxone.com), or you may contact any of the following organizations:

The American Academy of Addiction Psychiatry
7301 Mission Road, Suite 252
Prairie Village, KS 66208
Telephone: 913–262–6161
E-mail: info@aaap.org
Web site: http://www.aaap.org

The American Psychiatric Association
1400 K Street, NW.
Washington, DC 20005
Telephone: 888–357–7924
E-mail: apa@psych.org
Web site: http://www.psych.org

The American Society of Addiction Medicine
4601 North Park Avenue, Arcade Suite 101
Chevy Chase, MD 20815
Telephone: 301–656–3920
E-mail: email@asam.org
Web site: http://asam.org

American Osteopathic Association
142 East Ontario Street
Chicago, IL 60611
Telephone: 800–621–1773
E-mail: info@aoa-net.org
Web site: http://www.aoa-net.org

Appendix A: Buprenorphine Physician and Treatment Program Locator

Buprenorphine
PHYSICIAN & TREATMENT PROGRAM LOCATOR

Welcome to the Buprenorphine Physician and Treatment Program Locator

The Locator is a service of the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA).

The Locator is an online resource designed to assist States, medical and addiction treatment communities, potential patients, and/or their families in finding information on locating physicians and treatment programs authorized to treat opioid addiction with buprenorphine (Suboxone® and Subutex®).

The Locator lists:

- Physicians authorized to prescribe a class of medications for opioid (narcotic) addiction treatment, of which Suboxone® and Subutex® are the only ones approved at this time.
- Treatment programs authorized to dispense (but not prescribe) opioid treatment medications, including Suboxone® and Subutex®.

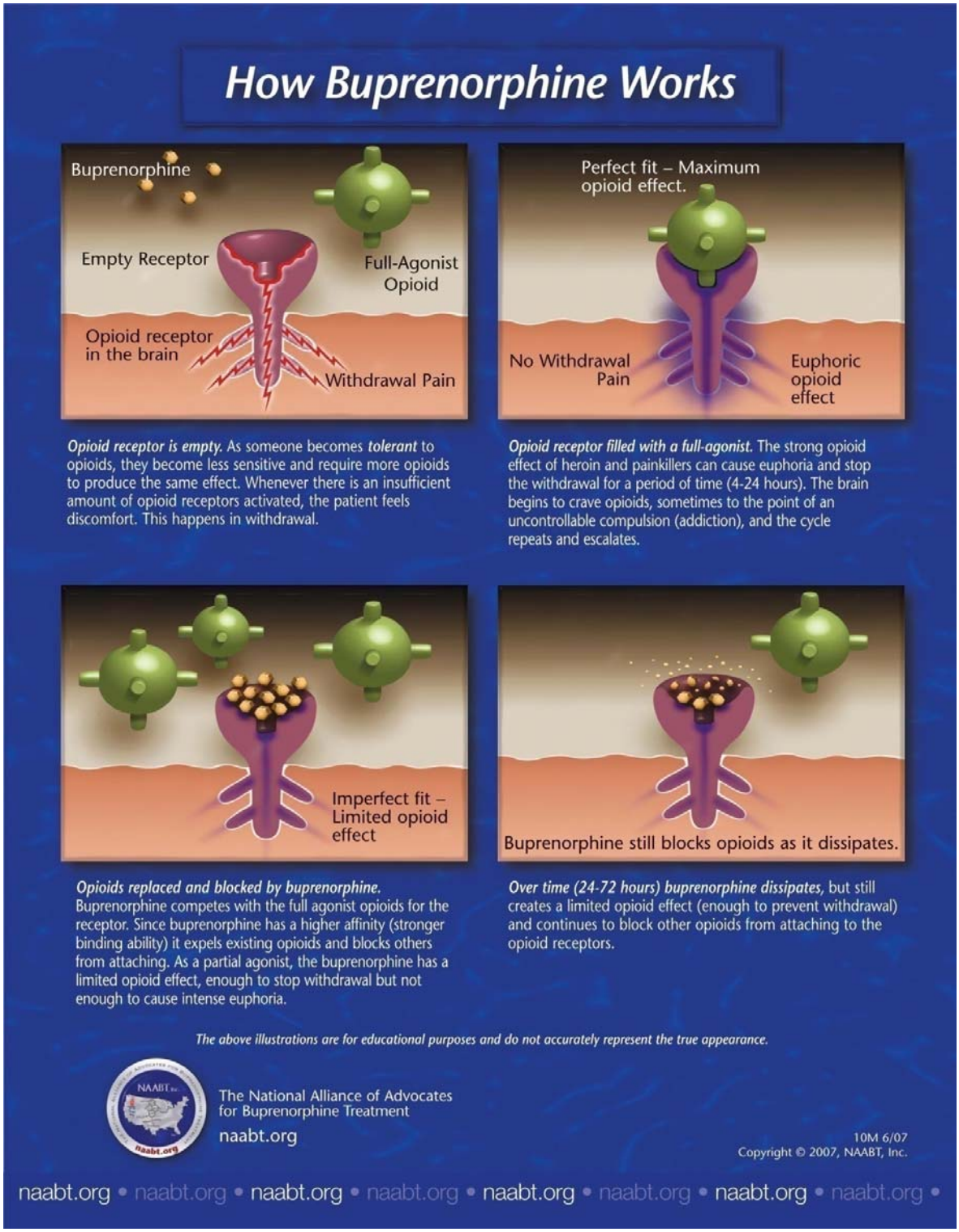
The treatment programs in the Locator are based on a list of treatment programs authorized under 21 U.S. Code (U.S.C.) Section 823(g)(1) to dispense (but not prescribe) opioid treatment medications. These treatment programs can admit patients and dispense methadone, Subutex®, or Suboxone®. Please note that CSAT is not a treatment referral agency and cannot make specific recommendations or endorsements regarding treatment programs on the Locator.

CSAT compiles the list of physicians in the Locator from its information on qualified physicians who have waivers to prescribe or dispense specially approved classes of narcotic medications for the treatment of narcotic addiction. Of these drugs, Subutex® and Suboxone® are the only ones approved by the U.S. Food and Drug Administration (FDA) thus far. The list includes only physicians who have met qualifications under the Drug Addiction Treatment Act of 2000 (DATA 2000) and who have authorized the use of their names in the Locator. As noted above for treatment programs, CSAT cannot make specific recommendations or endorsements regarding physicians on the Locator.

DATA 2000 allows qualified physicians to dispense or prescribe specially approved Schedule III, IV, and V drugs for medication-assisted opioid addiction treatment. In addition, DATA 2000 reduces the regulatory burden on physicians who choose to practice opioid therapy by permitting qualified physicians to apply for and receive waivers of the special registration requirements defined in the Narcotic Addiction Treatment Act and the Controlled Substances Act. Since DATA 2000 was enacted in October 2000, only the partial opioid agonist medication buprenorphine (Suboxone® and Subutex®) has received FDA approval.

To read the text of DATA 2000, to view what is required of "qualifying physicians" under the act, or to find out more about buprenorphine and DATA 2000, follow this link. http://www.buprenorphine.samhsa.gov/bwns_locator/aboutphysician.htm

How buprenorphine works is explained at http://www.naabt.org/education/images/Receptors_HiRes.jpg



(Illustration provided by the National Alliance of Advocates for Buprenorphine Treatment, copyright 2007, NAABT, Inc.)

Opioid receptor is empty. As someone becomes tolerant to opioids, they become less sensitive and require more opioids to produce the same effect. Whenever there is an insufficient amount of opioid receptors activated, the patient feels discomfort. This happens in withdrawal.

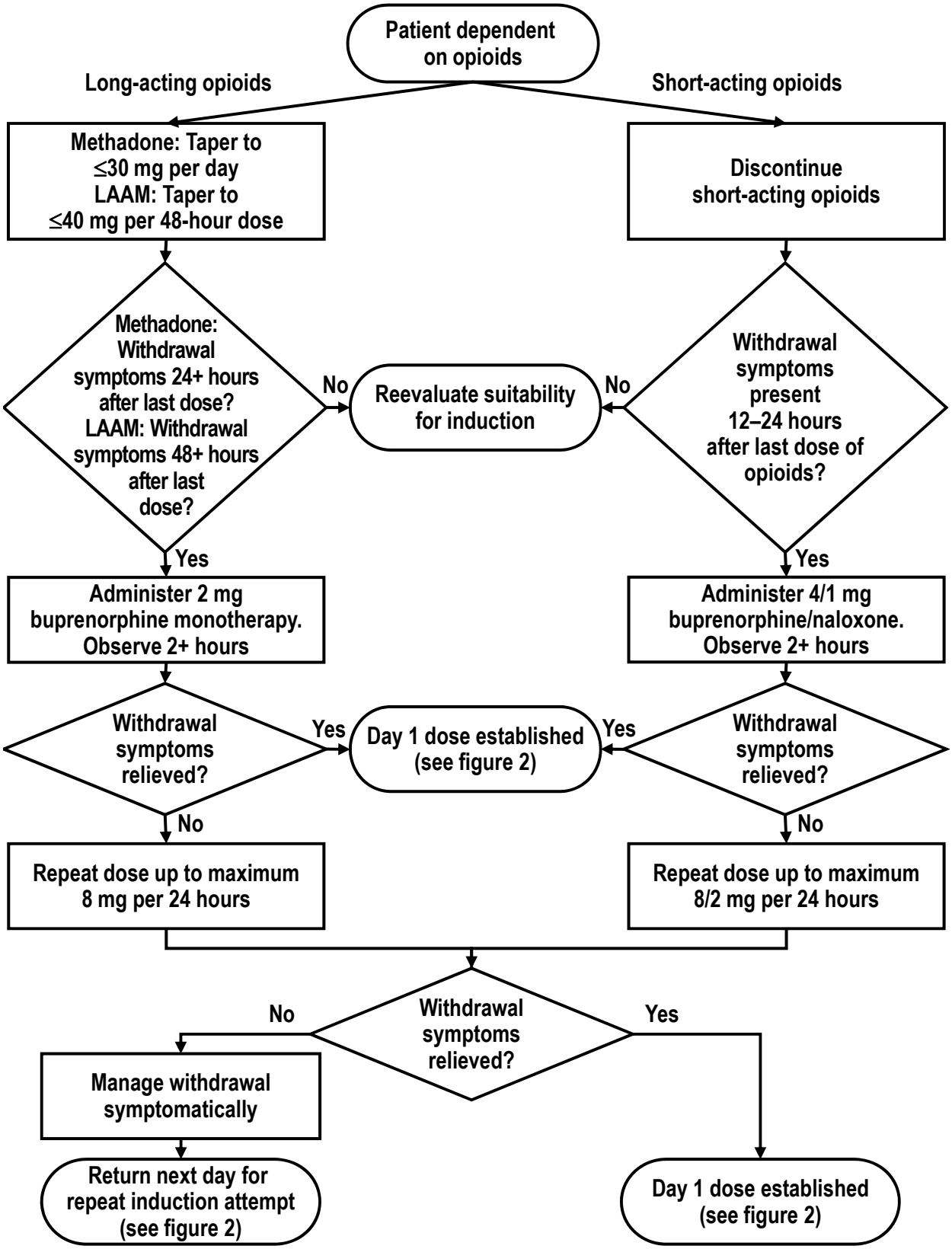
Opioid receptor filled with a full-agonist. The strong opioid effect of heroin and painkillers can cause euphoria and stop the withdrawal for a period of time (4-24 hours). The brain begins to crave opioids, sometimes to the point of an uncontrollable compulsion (addiction), and the cycle repeats and escalates.

Opioids replaced and blocked by buprenorphine. Buprenorphine competes with the full agonist opioids for the receptor. Since buprenorphine has a higher affinity (stronger binding ability) it expels existing opioids and blocks others from attaching. As a partial agonist, the buprenorphine has a limited opioid effect, enough to stop withdrawal but not enough to cause intense euphoria.

Over time (24–72 hours) buprenorphine dissipates, but still creates a limited opioid effect (enough to prevent withdrawal) and continues to block other opioids from attaching to the opioid receptors.

Appendix B:
Clinical Guideline Algorithms

Figure 1. Induction Days 1–2



When a patient dependent on opioids presents for treatment, determine whether the drug is a long-acting or short-acting opioid. The withdrawal and buprenorphine induction process is described here separately for these types of opioids.

If a patient presents who is taking the long-acting opioid methadone, taper the dose to 30 milligrams or less per day. If patient is taking the long-acting opioid levomethadyl acetate (LAAM), taper dose to 40 milligrams or less per 48 hours.

If a patient is not experiencing withdrawal symptoms 24 or more hours after the last dose of methadone or 48 hours or more after the last dose of LAAM, reevaluate the patient's suitability for induction of buprenorphine treatment. If the patient is experiencing symptoms of withdrawal from these drugs at these time intervals, administer 2 milligrams of buprenorphine monotherapy and observe the patient for 2 hours or longer.

If administering buprenorphine relieves withdrawal symptoms, the dose for day 1 is established (see figure 2 for details of further treatment).

If withdrawal symptoms are not relieved, repeat the dose of 2 milligrams of buprenorphine monotherapy, up to a maximum of 8 milligrams per 24 hours.

If the larger dose relieves withdrawal symptoms, the day 1 dose is established (continue treatment as described in figure 2).

If the larger dose does not relieve symptoms, manage withdrawal symptomatically and have the patient return the next day for a repeat of the attempt to induce buprenorphine treatment.

If a patient presents who is taking a short-acting opioid, discontinue the opioid.

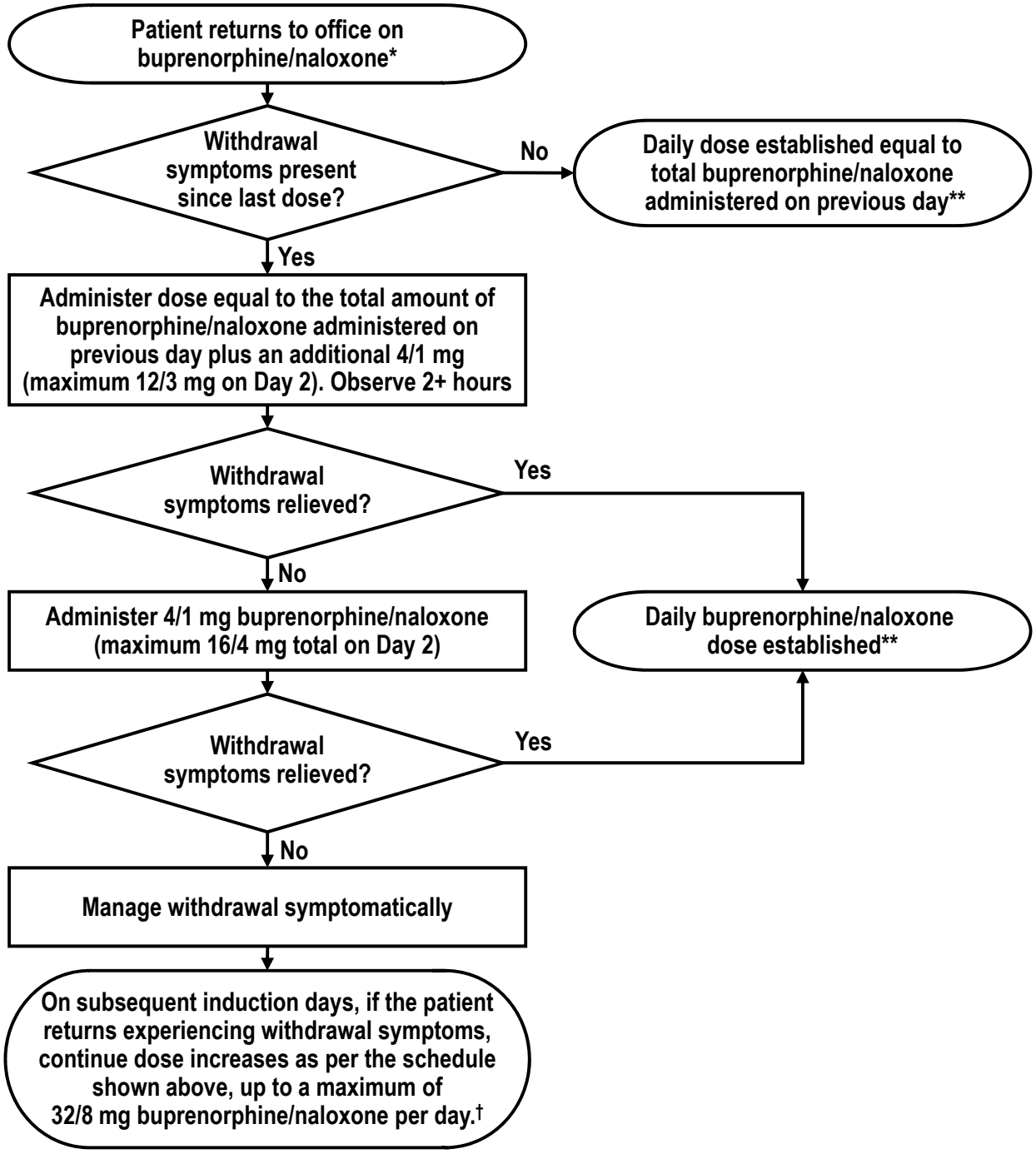
If withdrawal symptoms are not present 12–24 hours after the last dose of opioids, reevaluate the person's suitability for induction of buprenorphine treatment.

If withdrawal symptoms are present within 12–24 hours after the last dose of opioids, administer of a dose of 4 milligrams buprenorphine combined with 1 milligram of naloxone; observe the patient for 2 hours or longer. If withdrawal symptoms are relieved, the Day 1 dose has been established. Continue as described in figure 2.

If withdrawal symptoms are not relieved with the combined dose above, repeat the dose up to a maximum of 8 milligrams of buprenorphine combined with 2 milligrams of naloxone per 24 hours. If withdrawal symptoms are relieved with this higher dose, the day 1 dose is established. Continue treatment as described in figure 2.

If the larger dose does not relieve symptoms, manage withdrawal symptomatically and have the patient return the next day for a repeat of the attempt to induce buprenorphine treatment.

Figure 2. Induction Day 2 Forward



*If buprenorphine monotherapy was administered on Day 1, switch to buprenorphine/naloxone on Day 2 (for a patient who is not pregnant).

**Dose may be increased by 2/0.5–4/1 mg increments on subsequent days as needed for symptom relief. Target dose of 12/3–16/4 mg buprenorphine/naloxone per day by the end of the first week.

†More recent clinical data suggest that daily doses above 24 mg of buprenorphine do not provide additional therapeutic benefit to the vast majority of patients.

When a patient returns to the office on Day 2, having taken on Day 1 buprenorphine monotherapy (if formerly taking long-acting opioids) or combination buprenorphine and naloxone therapy (if formerly taking a short-acting opioid), switch to the combination therapy on Day 2 (if the patient is not pregnant).

If the patient is not having withdrawal symptoms since the last therapy (Day 1), administer the daily dose equal to the combination therapy administered on day 1. Note that the dose may be increased by 2–4 milligrams buprenorphine and 0.5–1 milligrams naloxone on subsequent days, as needed for symptom relief. Target a dose to reach 12–16 milligrams buprenorphine combined with 3–4 milligrams naloxone per day by the end of the first week.

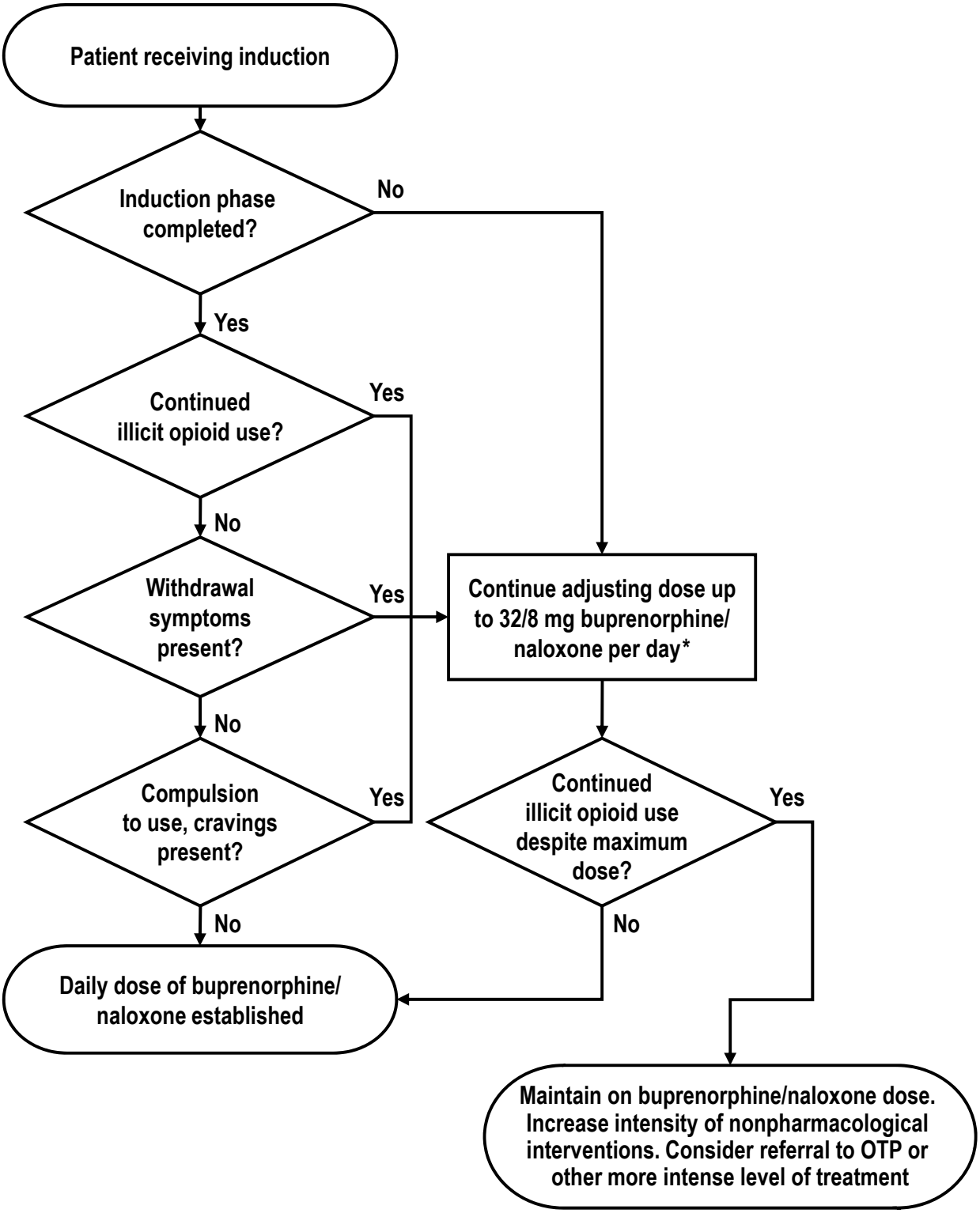
If the patient is having withdrawal symptoms since the last dose of therapy on Day 1, administer a dose equal to the total amount of combined therapy administered the previous day plus an additional 4 milligrams buprenorphine and 1 milligram naloxone. The maximum dose for Day 2 is 12 milligrams buprenorphine and 3 milligrams of naloxone. Observe the patient for 2 hours or longer.

If the withdrawal symptoms are relieved, the daily buprenorphine and naloxone combined dose is established. Again, note that the dose may be increased by 2–4 milligrams buprenorphine and 0.5–1 milligrams naloxone on subsequent days, as needed for symptom relief. Target a dose to reach 12–16 milligrams buprenorphine combined with 3–4 milligrams naloxone per day by the end of the first week.

If the withdrawal symptoms are not relieved with the dose given on Day 1, administer an additional dose of combined 4 milligrams buprenorphine and 1 milligram naloxone. The maximum total dose on day 2 is 16 milligrams buprenorphine and 4 milligrams naloxone. If withdrawal symptoms are relieved, the new daily dose is established. Again, note that the dose may be increased by 2–4 milligrams buprenorphine and 0.5–1 milligrams naloxone on subsequent days, as needed for symptom relief. Target a dose to reach 12–16 milligrams buprenorphine combined with 3–4 milligrams naloxone per day by the end of the first week.

If the increased dose on Day 2 does not relieve withdrawal symptoms, manage withdrawal symptomatically. On subsequent induction days, if the patient returns experiencing withdrawal symptoms, continue to increase the doses as per the schedule above up to a daily maximum of 32 milligrams buprenorphine and 8 milligrams naloxone combined.

Figure 3. Stabilization Phase



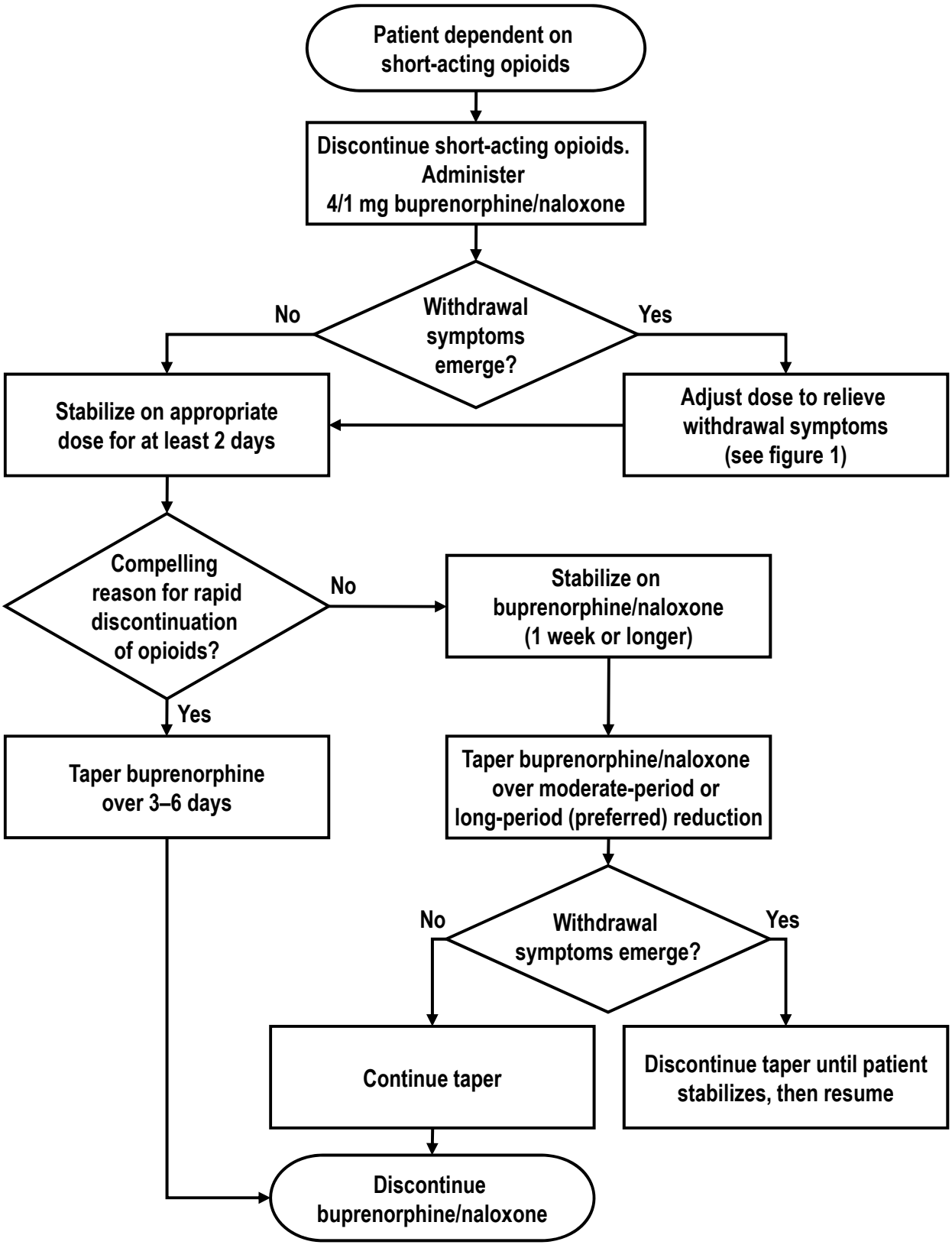
*More recent clinical data suggest that daily doses above 24 mg of buprenorphine do not provide additional therapeutic benefit to the vast majority of patients.

If a patient is receiving induction, this phase is completed when the daily dose of combined buprenorphine and naloxone is established and the patient has not continued illicit opioid use, withdrawal symptoms are not present, and neither the compulsion to use drugs nor cravings are present.

If a patient is receiving induction, this phase is not completed if the patient has continued illicit opioid use, withdrawal symptoms are present, and the compulsion to use drugs or cravings are present. If any of these conditions or more than one is present, continue adjusting the combined daily dose up to 32 milligrams buprenorphine and 8 milligrams naloxone. If the patient does not continue illicit opioids use, this dose becomes the established combined daily dose.

If the patient does continue illicit opioid use despite the maximum combined dose, maintain that combined dose. Increase the intensity of nonpharmacological interventions. Consider referral to Opioid Treatment Programs or other more intense levels of treatment.

Figure 4. Detoxification From Short-Acting Opioids



If a patient is dependent on short-acting opioids, discontinue those drugs and administer combined 4 milligrams buprenorphine and 1 milligram naloxone.

If withdrawal symptoms emerge, adjust the dose of combined buprenorphine and naloxone to relieve withdrawal symptoms, as described in figure 1.

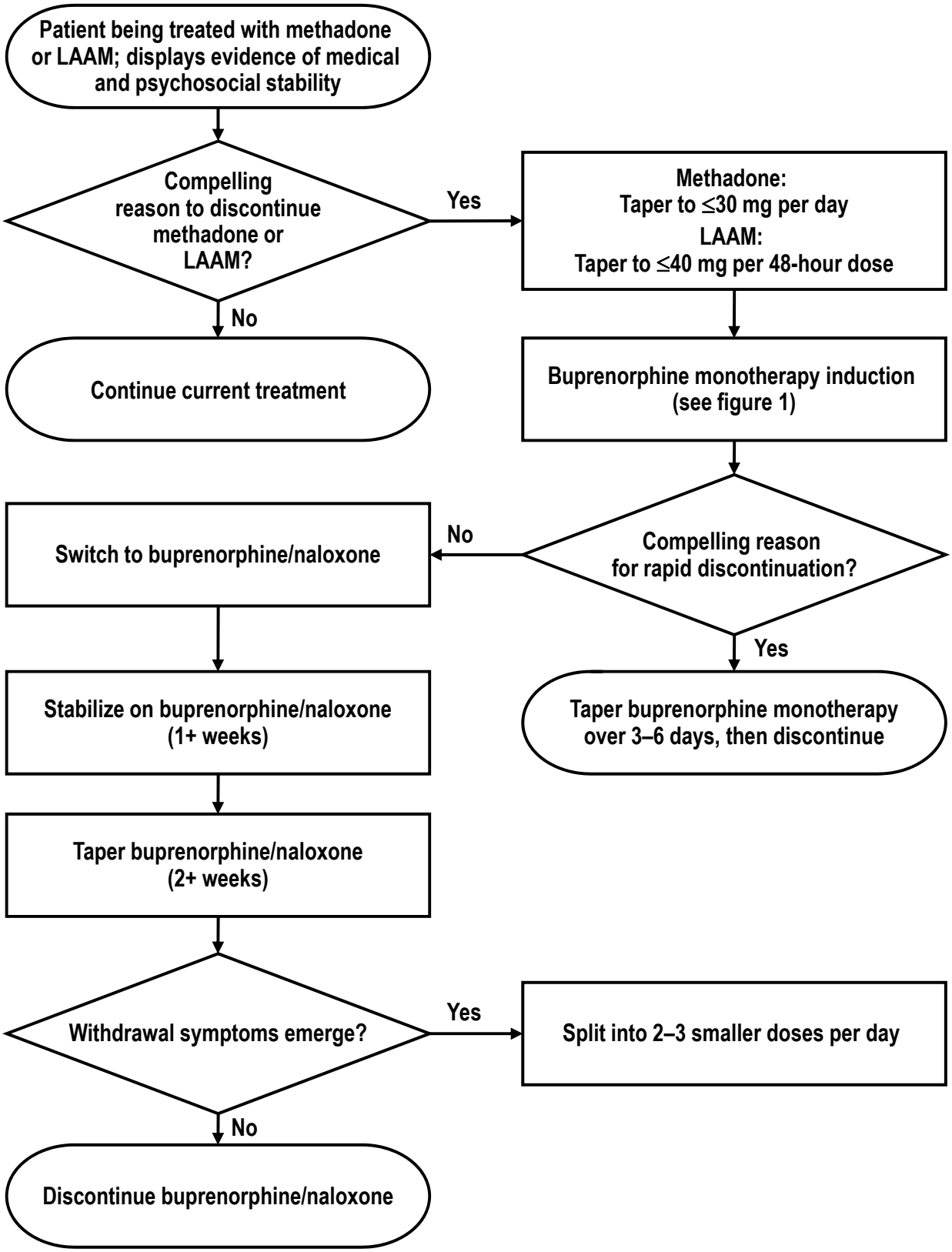
If withdrawal symptoms do not emerge (or the dose of combined drugs relieves withdrawal symptoms) stabilize the patient on the appropriate dose of buprenorphine/naloxone for at least 2 days.

If there is a compelling reason for rapid discontinuation of opioids, taper buprenorphine over 3–6 days, then continue buprenorphine/naloxone.

If there is not a compelling need for rapid discontinuation of opioids, stabilize the patient's dose of buprenorphine/naloxone for 1 week or longer. Taper the combined buprenorphine/naloxone over a moderate period, or preferably a long period, of reduction in dose.

If withdrawal symptoms emerge, discontinue the taper until the patient stabilizes, then resume tapering. If withdrawal symptoms do not emerge, or after taper is resumed, continue taper until buprenorphine/naloxone treatment is discontinued.

Figure 5. Discontinuing of Opioid Agonist Treatment (OAT) Using Buprenorphine



If a patient who is being treated with methadone or levomethadyl acetate (LAAM) displays evidence of medical and psychosocial stability, consider whether there is a compelling reason to discontinue that treatment. If not, continue with that treatment.

If there is a compelling reason to discontinue that treatment, taper doses (methadone to 30 milligrams or less per day or less; LAAM to 40 milligrams or less per day).

When the patient has tapered to those doses, begin buprenorphine monotherapy (see figure 1).

If there is a compelling reason for rapid discontinuation of therapy, taper buprenorphine monotherapy over 3–6 days, then discontinue.

If there is not a compelling reason for rapid discontinuation after induction of buprenorphine monotherapy, switch to combined buprenorphine/naloxone therapy and stabilize the dose over a period of 1 week or more.

Then taper the combined buprenorphine/naloxone therapy over 2 or more weeks. If withdrawal symptoms emerge, split the total amount into 2–3 smaller doses per day.

When withdrawal symptoms do not emerge, discontinue the combined buprenorphine/naloxone therapy.

Appendix C: Screening Instruments

Drug Abuse Screening Test (DAST-10), Drug Use Questionnaire

The following questions concern information about your possible involvement with drugs, not including alcoholic beverages, during the past 12 months. Carefully read each statement and decide if your answer is "Yes" or "No." Then circle the appropriate response beside the question.

In the following statements "drug abuse" refers to

- The use of prescribed or over-the-counter drugs in excess of the directions, and
- Any nonmedical use of drugs.
- The various classes of drugs may include cannabis (e.g., marijuana, hashish), solvents (e.g., paint thinner), tranquilizers (e.g., Valium), barbiturates, cocaine, stimulants (e.g., speed), hallucinogens (e.g., lysergic acid diethylamide [LSD]), or narcotics (e.g., heroin). Remember that the questions do not include alcoholic beverages.

Please answer every question. If you have difficulty with a question, then choose the response that is mostly right.

These Questions Refer to the Past 12 Months

1.	Have you used drugs other than those required for medical reasons?	Yes	No
2.	Do you abuse more than one drug at a time?	Yes	No
3.	Are you always able to stop using drugs when you want to?	Yes	No
4.	Have you ever had blackouts or flashbacks as a result of drug use?	Yes	No
5.	Do you ever feel bad or guilty about your drug use?	Yes	No
6.	Does your spouse (or parents) ever complain about your involvement with drugs?	Yes	No
7.	Have you neglected your family because of your use of drugs?	Yes	No
8.	Have you engaged in illegal activities in order to obtain drugs?	Yes	No
9.	Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	Yes	No
10.	Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding)?	Yes	No

Interpretation (Each "Yes" response = 1)

Score	Degree of Problems Related to Drug Abuse	Suggested Action
0	No Problems Reported	None At This Time
1–2	Low Level	Monitor, Reassess At A Later Date
3–5	Moderate Level	Further Investigation
6–8	Substantial Level	Intensive Assessment

Source: Adapted from Skinner, H. A. (1982). The drug abuse screening test. *Addictive Behaviors, 7*(4), 363–371. Copyright 2008. Reprinted with permission from Centre for Addiction and Mental Health. Available online at http://www.drugabuse.gov/Diagnosis-Treatment/DAST10.html.

The Alcohol Use Disorders Identification Test (AUDIT): Interview Version

1. How often do you have a drink* containing alcohol?
   - □ Never (0) [Skip to Questions 9–10]
   - □ Monthly or less (1)
   - □ 2 to 4 times a month (2)
   - □ 2 to 3 times a week (3)
   - □ 4 or more times a week (4)

2. How many drinks containing alcohol do you have on a typical day when you are drinking?
   - □ 1 or 2 (0)
   - □ 3 or 4 (1)
   - □ 5 or 6 (2)
   - □ 7, 8, or 9 (3)
   - □ 10 or more (4)

3. How often do you have six or more drinks on one occasion?
   - □ Never (0)
   - □ Less than monthly (1)
   - □ Monthly (2)
   - □ Weekly (3)
   - □ Daily or almost daily (4)

[Skip to Questions 9 and 10 if Total Score for Questions 2 and 3 = 0]

4. How often during the last year have you found that you were unable to stop drinking once you had started?
   - □ Never (0)
   - □ Less than monthly (1)
   - □ Monthly (2)
   - □ Weekly (3)
   - □ Daily or almost daily (4)

5. How often during the last year have you failed to do what was normally expected of you because of drinking?
   - □ Never (0)
   - □ Less than monthly (1)
   - □ Monthly (2)
   - □ Weekly (3)
   - □ Daily or almost daily (4)

6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?
   - □ Never (0)
   - □ Less than monthly (1)
   - □ Monthly (2)
   - □ Weekly (3)
   - □ Daily or almost daily (4)

7. How often during the last year have you had a feeling of guilt or remorse after drinking?
   - □ Never (0)
   - □ Less than monthly (1)
   - □ Monthly (2)
   - □ Weekly (3)
   - □ Daily or almost daily (4)

8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?
   - □ Never (0)
   - □ Less than monthly (1)
   - □ Monthly (2)
   - □ Weekly (3)
   - □ Daily or almost daily (4)

9. Have you or someone else been injured as the result of your drinking?
   - □ No (0)
   - □ Yes, but not in the last year (1)
   - □ Yes, during the last year (2)

10. Has a relative, friend, or a doctor or other health worker been concerned about your drinking or suggested you cut down?
   - □ No (0)
   - □ Yes, but not in the last year (1)
   - □ Yes, in the last year (2)

Record the total of the specific items. _____

* In determining the response categories it has been assumed that one drink contains 10 g alcohol. In countries where the alcohol content of a standard drink differs by more than 25 percent from 10 g, the response category should be modified accordingly.

Source: Babor, T. F., Higgins-Biddle, J. C., Saunders, J. B., & Monteiro, M. G. (2001*). AUDIT. The Alcohol Use Disorders Identification Test: Guidelines for use in primary care.* 2nd ed. Geneva: WHO, Department of Mental Health and Substance Dependence.

Available at http://whqlibdoc.who.int/hq/2001/WHO_MSD_MSB_01.6a.pdf

A self-report version of the AUDIT is also available in Babor et al. 2001.

Scoring and Interpretation of the AUDIT

The minimum score (for nondrinkers) is 0 and the maximum possible score is 40. A score of 8 is indicative of hazardous and harmful alcohol use, and possibly of alcohol dependence. Scores of 8–15 indicate a medium level and scores of 16 and above a high level of alcohol problems. Babor et al. (2001) recommend a cutoff score of 7 for women and individuals over 65 years of age; Bradley et al. (1998) recommended an even lower cutoff score of 4 points for women. For patients who are resistant, uncooperative, or noncommunicative, a clinical screening procedure (described by Babor et al., 2001) may be necessary.

Readiness Ruler

Readiness Ruler: How Ready Are You To Change Your Use of _____?

Circle one answer for each type of drug.

Types of Drugs	Answer: Not Ready to Change (1–3), Unsure (3–5), Ready to Change (5–8), Trying to Change (8–10)										Or: I don't use this type of drug
Alcohol	1	2	3	4	5	6	7	8	9	10	Don't Use
Tobacco	1	2	3	4	5	6	7	8	9	10	Don't Use
Marijuana/ Cannabis	1	2	3	4	5	6	7	8	9	10	Don't Use
Tranquilizers	1	2	3	4	5	6	7	8	9	10	Don't Use
Sedatives/ Downers	1	2	3	4	5	6	7	8	9	10	Don't Use
Steroids	1	2	3	4	5	6	7	8	9	10	Don't Use
Stimulants/ Uppers	1	2	3	4	5	6	7	8	9	10	Don't Use
Cocaine	1	2	3	4	5	6	7	8	9	10	Don't Use
Hallucinogens	1	2	3	4	5	6	7	8	9	10	Don't Use
Opiates	1	2	3	4	5	6	7	8	9	10	Don't Use
Inhalants	1	2	3	4	5	6	7	8	9	10	Don't Use
Other Drugs	1	2	3	4	5	6	7	8	9	10	Don't Use

http://casaa.unm.edu/inst.html; click on Readiness Ruler

Appendix D: Assessment Instruments

Buprenorphine Treatment Checklist

1. Does the patient have a diagnosis of opioid dependence?
2. Are there current signs of intoxication or withdrawal? Is there a risk for severe withdrawal?
3. Is the patient interested in buprenorphine treatment?
4. Does the patient understand the risks and benefits of buprenorphine treatment?
5. Can the patient be expected to adhere to the treatment plan?
6. Is the patient willing and able to follow safety procedures?
7. Does the patient agree to treatment after a review of the options?
8. Can the needed resources for the patient be provided (either on- or offsite)?
9. Is the patient psychiatrically stable? Is the patient actively suicidal or homicidal; has he or she recently attempted suicide or homicide? Does the patient exhibit emotional, behavioral, or cognitive conditions that complicate treatment?
10. Is the patient pregnant?
11. Is the patient currently dependent on or abusing alcohol?
12. Is the patient currently dependent on benzodiazepines, barbiturates, or other sedative-hypnotics?
13. What is the patient's risk for continued use or continued problems? Does the patient have a history of multiple previous treatments or relapses, or is the patient at high risk for relapse to opioid use? Is the patient using other drugs?
14. Has the patient had prior adverse reactions to buprenorphine?
15. Is the patient taking other medications that may interact with buprenorphine?
16. Does the patient have medical problems that are contraindications to buprenorphine treatment? Are there physical illnesses that complicate treatment?
17. What kind of recovery environment does the patient have? Are the patient's psychosocial circumstances sufficiently stable and supportive?
18. What is the patient's level of motivation? What stage of change characterizes this patient?

Mental Health Screening Form-III

Instructions: In this program, we help people with all their problems, not just their addictions. This commitment includes helping people with emotional problems. Our staff is ready to help you to deal with any emotional problems you may have, but we can do this only if we are aware of the problems. Any information you provide to us on this form will be kept in strict confidence. It will not be released to any outside person or agency without your permission. If you do not know how to answer these questions, ask the staff member giving you this form for guidance. Please note, each item refers to your entire life history, not just your current situation, this is why each question begins - "Have you ever ...."

1. Have you ever talked to a psychiatrist, psychologist, therapist, social worker, or counselor about an emotional problem?
   □ YES □ NO

2. Have you ever felt you needed help with your emotional problems, or have you had people tell you that you should get help for your emotional problems?
   □ YES □ NO

3. Have you ever been advised to take medication for anxiety, depression, hearing voices, or for any other emotional problem?
   □ YES □ NO

4. Have you ever been seen in a psychiatric emergency room or been hospitalized for psychiatric reasons?
   □ YES □ NO

5. Have you ever heard voices no one else could hear or seen objects or things which others could not see?
   □ YES □ NO

6. (a) Have you ever been depressed for weeks at a time, lost interest or pleasure in most activities, had trouble concentrating and making decisions, or thought about killing yourself?
   □ YES □ NO

   (b) Did you ever attempt to kill yourself?
   □ YES □ NO

7. Have you ever had nightmares or flashbacks as a result of being involved in some traumatic/terrible event? For example, warfare, gang fights, fire, domestic violence, rape, incest, car accident, being shot or stabbed?
   □ YES □ NO

8. Have you ever experienced any strong fears? For example, of heights, insects, animals, dirt, attending social events, being in a crowd, being alone, being in places where it may be hard to escape or get help?
   □ YES □ NO

9. Have you ever given in to an aggressive urge or impulse, on more than one occasion, that resulted in serious harm to others or led to the destruction of property?
   □ YES □ NO

10. Have you ever felt that people had something against you, without them necessarily saying so, or that someone or some group may be trying to influence your thoughts or behavior?
    □ YES □ NO

11. Have you ever experienced any emotional problems associated with your sexual interests, your sexual activities, or your choice of sexual partner?
    □ YES □ NO

12. Was there ever a period in your life when you spent a lot of time thinking and worrying about gaining weight, becoming fat, or controlling your eating? For example, by repeatedly dieting or fasting, engaging in much exercise to compensate for binge eating, taking enemas, or forcing yourself to throw up?
    □ YES □ NO

13. Have you ever had a period of time when you were so full of energy and your ideas came very rapidly, when you talked nearly non-stop, when you moved quickly from one activity to another, when you needed little sleep, and believed you could do almost anything?
    □ YES □ NO

14. Have you ever had spells or attacks when you suddenly felt anxious, frightened, uneasy to the extent that you began sweating, your heart began to beat rapidly, you were shaking or trembling, your stomach was upset, you felt dizzy or unsteady, as if you would faint?
    □ YES □ NO

15. Have you ever had a persistent, lasting thought or impulse to do something over and over that caused you considerable distress and interfered with normal routines, work, or your social relations? Examples would include repeatedly counting things, checking and rechecking on things you had done, washing and rewashing your hands, praying, or maintaining a very rigid schedule of daily activities from which you could not deviate.
    □ YES □ NO

16. Have you ever lost considerable sums of money through gambling or had problems at work, in school, with your family and friends as a result of your gambling?
    □ YES □ NO

17. Have you ever been told by teachers, guidance counselors, or others that you have a special learning problem?
    □ YES □ NO

Print client's name: _____

Program to which client will be assigned: _____

Name of admissions counselor: _____ Date: _____

Reviewer's comments: _____

_____

_____

_____

Total Score: _____ (each yes = 1 point)

Source: Carroll, J. F. X., & McGinley, J. J. (2000). Project Return Foundation, Inc. This material may be reproduced or copied, in entirety, without permission. Available at http://www.asapnys.org/resources/mhscreen.pdf

Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES 8D)

INSTRUCTIONS: Please read the following statements carefully. Each one describes a way that you might (or might not) feel about your drug use. For each statement, circle one number from 1 to 5 to indicate how much you agree or disagree with it right now. Please circle one and only one number for every statement.

Statement	NO! Strongly Disagree	No Disagree	? Undecided or Unsure	Yes Agree	YES! Strongly Agree
1. I really want to make changes in my use of drugs.	1	2	3	4	5
2. Sometimes I wonder if I am an addict.	1	2	3	4	5
3. If I don't change my drug use soon, my problems are going to get worse.	1	2	3	4	5
4. I have already started making some changes in my use of drugs.	1	2	3	4	5
5. I was using drugs too much at one time, but I've managed to change that.	1	2	3	4	5
6. Sometimes I wonder if my drug use is hurting other people.	1	2	3	4	5
7. I have a drug problem.	1	2	3	4	5
8. I'm not just thinking about changing my drug use, I'm already doing something about it.	1	2	3	4	5
9. I have already changed my drug use, and I am looking for ways to keep from slipping back to my old pattern.	1	2	3	4	5
10. I have serious problems with drugs.	1	2	3	4	5
11. Sometimes I wonder if I am in control of my drug use.	1	2	3	4	5
12. My drug use is causing a lot of harm.	1	2	3	4	5
13. I am actively doing things now to cut down or stop my use of drugs.	1	2	3	4	5
14. I want help to keep from going back to the drug problems that I had before.	1	2	3	4	5
15. I know that I have a drug problem.	1	2	3	4	5
16. There are times when I wonder if I use drugs too much.	1	2	3	4	5
17. I am a drug addict.	1	2	3	4	5
18. I am working hard to change my drug use.	1	2	3	4	5
19. I have made some changes in my drug use, and I want some help to keep from going back to the way I used before.	1	2	3	4	5

Source: Miller, W. R., & Tonigan, J. S. (1996). Assessing drinkers' motivation for change: The Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES). *Psychology of Addictive Behaviors, 10,* 81–89. SOCRATES 8D and SOCRATES 8D Scoring Sheet. Available at Center on Alcoholism, Substance Abuse, and Addictions (CASAA), Assessment Instruments. http://casaa.unm.edu/inst/SOCRATESv8.pdf. Reprinted with permission.

SOCRATES Scoring Form (19-Item Version 8.0)

Transfer the client's answers from questionnaire (see note below):

Recognition	Ambivalence	Taking Steps
1 _____	2 _____	
3 _____		4 _____
	5 _____	
	6 _____	
7 _____		8 _____
	9 _____	
10 _____	11 _____	
12 _____		13 _____
	14 _____	
15 _____	16 _____	
17 _____		18 _____
	19 _____	

TOTALS: **Recognition** _____ **Ambivalence** _____ **Taking Steps** _____

Possible Range: Recognition (7–35), Ambivalence (4–20), Taking Steps (8–40)

SOCRATES Profile Sheet (19-Item Version 8A)

INSTRUCTIONS: From the SOCRATES Scoring Form (19-Item Version) transfer the total scale scores into the empty boxes at the bottom of the Profile Sheet. Then for each scale, CIRCLE the same value above it to determine the decile range.

DECILE SCORES	Recognition	Ambivalence	Taking Steps
90 Very High		19–20	39–40
80		18	37–38
70 High	35	17	36
60	34	16	34–35
50 Medium	32–33	15	33
40	31	14	31–32
30 Low	29–30	12–13	30
20	27–28	9–11	26–29
10 Very Low	7–26	4–8	8–25
RAW SCORES (from Scoring Sheet)	**Re=**	**Am=**	**Ts=**

These interpretive ranges are based on a sample of 1,726 adult men and women presenting for treatment of alcohol problems through Project MATCH. Note that individual scores are therefore being ranked as low, medium, or high *relative to people already presenting for alcohol treatment*.

Clinical Opiate Withdrawal Scale (COWS)

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

Patient Name:	**Date:**	**Time:**
Reason for this assessment:		
1. Resting pulse rate: _____ beats/minute Measured after the patient is sitting or lying for one minute. 0 Pulse rate 80 or below 1 Pulse rate 81–100 2 Pulse rate 101–120 4 Pulse rate greater than 120	**7. GI upset:** *over last half hour* 0 No GI symptoms 1 Stomach cramps 2 Nausea or loose stool 3 Vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting	
2. Sweating: *over past half hour not accounted for by room temperature of patient activity* 0 No reports of chills or flushing 1 Subjective reports of chills or flushing 2 Flushed or observable moisture on face 3 Beads of sweat on brow or face 4 Sweat streaming off face	**8. Tremor:** *observation of outstretched hands* 0 No tremor 1 Tremor can be felt, but not observed 2 Slight tremor observable 4 Gross tremor or muscle twitching	
3. Restlessness: *observation during assessment* 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	**9. Yawning:** *observation during assessment* 0 No yawning 1 Yawning once or twice during assessment 2 Yawning three or more times during assessment 4 Yawning several times/minute	
4. 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	**10. 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	
5. Bone or joint aches: *if patient was having pain previously, only the additional component attributed to opiate withdrawal is scored.* 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	**11. Gooseflesh skin** 0 Skin is smooth 3 Piloerection of skin can be felt or hairs standing up on arms 5 Prominent piloerection	
6. Runny nose or tearing: *not accounted for by cold symptoms or allergies* 0 Not present 1 Nasal stuffiness or unusually moist eyes 2 Nose running or tearing 4 Nose constantly running or tears streaming down cheeks	**Total Score:** _____ [The total score is the sum of all 11 items.] Initials of person completing assessment: _____	

Score: 5–12 = Mild; 13–24 = Moderate; 25–36 = Moderately severe; >36 = Severe withdrawal
Source: California Society for Addiction Medicine. http://www.csam-asam.org/pdf/misc/COWS.doc. Reprinted with permission from the California Society of Addiction Medicine.

Subjective Opiate Withdrawal Scale (SOWS)

Instructions: Answer the following statements as accurately as you can. Circle the answer that best fits the way you feel now.

0 = not at all
1 = a little
2 = moderately
3 = quite a bit
4 = extremely

Statement	Not at all	A little	Moderately	Quite a bit	Extremely
1. I feel anxious.	0	1	2	3	4
2. I feel like yawning.	0	1	2	3	4
3. I'm perspiring.	0	1	2	3	4
4. My eyes are tearing.	0	1	2	3	4
5. My nose is running.	0	1	2	3	4
6. I have goose flesh.	0	1	2	3	4
7. I am shaking.	0	1	2	3	4
8. I have hot flashes.	0	1	2	3	4
9. I have cold flashes.	0	1	2	3	4
10. My bones and muscles ache.	0	1	2	3	4
11. I feel restless.	0	1	2	3	4
12. I feel nauseous.	0	1	2	3	4
13. I feel like vomiting.	0	1	2	3	4
14. My muscles twitch.	0	1	2	3	4
15. I have cramps in my stomach.	0	1	2	3	4
16. I feel like shooting up now.	0	1	2	3	4

The Subjective Opiate Withdrawal Scale (SOWS) consist of 16 symptoms rated in intensity by patients on a 5 point scale of intensity as follows: 0 = not at all, 1 = a little, 2 = moderately, 3 = quite a bit, 4 = extremely. The total score is a sum of item ratings, and ranges from 0 to 64.

Source: Reprinted from Handelsman, L., Cochrane, K. J., Aronson, M. J., Ness, R., Rubinstein, K. J., & Kanof, P. D. (1987). Two new rating scales for opiate withdrawal. *American Journal of Drug and Alcohol Abuse, 13*(3), 293–308. Table 1 on page 296. Reprinted by permission of the publisher, Taylor & Francis, Ltd., http://www.tandf.co.uk/journals.

The Clinical Institute Narcotic Assessment (CINA) Scale for Withdrawal Symptoms

The Clinical Institute Narcotic Assessment (CINA) Scale measures 11 signs and symptoms commonly seen in patients during narcotic withdrawal. This can help to gauge the severity of the symptoms and to monitor changes in the clinical status over time. To view the CINA scale, visit http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.section.72871 (CSAT, 2004).

Addiction Research Foundation Clinical Institute for Withdrawal Assessment (CIWA-Ar)

Patient:	**Date:**	**Time: (24 hour clock, midnight = 00:00)**
NAUSEA AND VOMITING—Ask "Do you feel sick to your stomach? Have you vomited?" *Observation.* 0 no nausea and no vomiting 1 mild nausea with no vomiting 2 3 4 intermittent nausea with dry heaves 5 6 7 constant nausea, frequent dry heaves and vomiting	**TACTILE DISTURBANCES**—Ask "Have you any itching, pins and needles sensations, any burning, any numbness, or do you feel bugs crawling on or under your skin?" *Observation.* 0 none 1 very mild itching, pins and needles, burning or numbness 2 mild itching, pins and needles, burning or numbness 3 moderate itching, pins and needles, burning or numbness 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations	
TREMOR—Arms extended and fingers spread apart. *Observation.* 0 no tremor 1 not visible, but can be felt fingertip to fingertip 2 3 4 moderate, with patient's arms extended 5 6 7 severe, even with arms not extended	**AUDITORY DISTURBANCES**—Ask "Are you more aware of sounds around you? Are they harsh? Do they frighten you? Are you hearing anything that is disturbing to you? Are you hearing things you know are not there?" *Observation.* 0 not present 1 very mild harshness or ability to frighten 2 mild harshness or ability to frighten 3 moderate harshness or ability to frighten 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations	
PAROXYSMAL SWEATS—*Observation.* 0 no sweat visible 1 barely perceptible sweating, palms moist 2 3 4 beads of sweat obvious on forehead 5 6 7 drenching sweats	**VISUAL DISTURBANCES**—Ask "Does the light appear to be too bright? Is its color different? Does it hurt your eyes? Are you seeing anything that is disturbing to you? Are you seeing things you know are not there?" *Observation.* 0 not present 1 very mild sensitivity 2 mild sensitivity 3 moderate sensitivity 4 moderately severe hallucinations 5 severe hallucinations 6 extremely severe hallucinations 7 continuous hallucinations	

ANXIETY—Ask "Do you feel nervous?" *Observation.* 0 no anxiety, at ease 1 mildly anxious 2 3 4 moderately anxious, or guarded, so anxiety is inferred 5 6 7 equivalent to acute panic states as seen in severe delirium or acute schizophrenic reactions.	**HEADACHE, FULLNESS IN HEAD**—Ask "Does your head feel different? Does it feel like there is a band around your head?" Do not rate for dizziness or lightheadedness. Otherwise, rate severity. 0 not present 1 very mild 2 mild 3 moderate 4 moderately severe 5 severe 6 very severe 7 extremely severe
AGITATION—*Observation.* 0 normal activity 1 somewhat more than normal activity 2 3 4 moderately fidgety and restless 5 6 7 paces back and forth during most of the interview, or constantly thrashes about	**ORIENTATION AND CLOUDING OF SENSORIUM**—Ask "What day is this? Where are you? Who am I?" 0 oriented and can do serial additions 1 cannot do serial additions or is uncertain about date 2 disoriented for date by no more than 2 calendar days 3 disoriented for date by more than 2 calendar days 4 disoriented for place and/or person
	Total CIWAr-Score _____ Rater's Initials _____ Maximum Possible Score 67

This scale is not copyrighted and can be reproduced freely.

Source: Sullivan, J. T., Sykora, K., Schneiderman, J., Naranjo, D., & Sellers, E. M. (1989). Assessment of alcohol withdrawal: The revised Clinical Institute Withdrawal Assessment for Alcohol Scale (CIWA-Ar). *British Journal of Addiction, 84*(11), 1353–1357.

Suggested Questions for Patient Interview Buprenorphine Treatment

Kathleen Thompson-Gargano, R.N., A.D.N. (October 2006)

Prior to Induction:	
What opiates do you use?	
Frequency, route, and amount	
What are your first symptoms of withdrawal?	
Will you be able to commit to appointments?	
Is there someone who can drive you in for your first appointment?	

Give specific appointment time and let patient know s/he should plan to be here for 2 hours on the first day only.

Nursing History and Assessment:	
When was the first time you used any substances of any kind including cigarettes, pot and alcohol?	
What was the next substance and at what age?	
Tell me about your current use, all substances, amounts, frequency, and route of administration.	
Have you ever shared a needle at any time?	
Tell me about your past treatment experiences.	
What was your longest clean time?	
What happened to make you go back to using?	
What was the most you ever used in a day?	
Have you ever overdosed?	
Have you ever been admitted to the ED or hospital because of your drug use?	
Have you ever been arrested or incarcerated? Are you currently on probation?	
What made you decide to come for treatment at this time?	
On a scale from 1 to 10, 1 being you are forced into coming here by court or a family member, and 10 being your life depends on it, where are you?	
Any family members addicted to substances of any kind?	
Tell me about your living situation?	
Does anyone you live or work with use opiates or cocaine?	
Are you scheduled to have surgery in the near future?	
Are you scheduled to go out of town or on vacation in the next 6 months?	

Principles of Effective Addictions Treatment (NIDA, 1999)

1. **No single treatment is appropriate for all individuals.** Matching treatment settings, interventions, and services to each individual's particular problems and needs is critical to his or her ultimate success in returning to productive functioning in the family, workplace, and society.

2. **Treatment needs to be readily available.** Because individuals who are addicted to drugs may be uncertain about entering treatment, taking advantage of opportunities when they are ready for treatment is crucial. Potential treatment applicants can be lost if treatment is not immediately available or is not readily accessible.

3. **Effective treatment attends to multiple needs of the individual, not just his or her drug use.** To be effective, treatment must address the individual's drug use and any associated medical, psychological, social, vocational, and legal problems.

4. **Treatment plan must be assessed continually to ensure that it meets changing needs.** In addition to medication, the person may require varying combinations of services and treatment components, including:
   - Counseling or psychotherapy;
   - Medical services;
   - Family therapy;
   - Parenting instruction;
   - Vocational rehabilitation; AND
   - Social and legal services.

5. **Remaining in treatment for an adequate period of time is critical for treatment effectiveness.**
   - Appropriate duration depends on problems and needs.
   - For most patients, the threshold of significant improvement is about 3 months in treatment.
   - Additional treatment can produce further progress toward recovery.
   - People often leave treatment prematurely, so plan strategies to engage and keep patients in treatment.

6. **Counseling (individual/group) and other behavioral therapies are critical components of effective treatment.** In therapy, patients:
   - Address motivation;
   - Build skills to resist drug use;
   - Replace drug-using activities with constructive and rewarding nondrug-using activities;
   - Improve problemsolving abilities;
   - Work on interpersonal relationships;
   - Improve family and community functioning.

7. **Medications are an important element of treatment for many patients, especially when combined with counseling and other behavioral therapies.**
   - Opioid replacement therapy can be very effective in helping individuals stabilize their lives and reduce their drug use.
   - Both behavioral treatments and medications can be critically important, especially for patients with mental disorders.

8. **Addicted or drug-abusing individuals with coexisting mental disorders should have both disorders treated in an integrated way.**
   - Substance use disorders (SUDs) and mental disorders often co-occur;
   - Patients presenting for either condition should be assessed and treated for the co-occurrence of the other type of disorder.

9. **Medical detoxification is only the first stage of addiction treatment and by itself does little to change long-term drug use.**
   - Detox safely manages acute physical symptoms of withdrawal;
   - Detox alone is rarely sufficient to achieve long-term abstinence;
   - Strongly indicated precursor to effective drug addiction treatment for some individuals.

10. **Treatment does not need to be voluntary to be effective.**
    - Strong motivation can facilitate the treatment process;
    - Sanctions or enticements in the family, employment setting, or criminal justice system can increase significantly:
      – Treatment entry and retention rates; and
      – Success of drug treatment interventions.

11. **Possible drug use during treatment must be monitored continuously.**
    - It is not unusual for lapses to occur during treatment.
    - Objective monitoring (urinalysis/other tests) helps patients withstand urges to use.
    - Monitoring can provide early evidence of drug use so that the treatment plan can be adjusted.
    - Feedback to patients who test positive for illicit drug use is an important element of monitoring.

12. **Treatment providers should assess and counsel individuals about HIV/AIDS, hepatitis B and C, tuberculosis, and other infectious diseases.**
    - Counsel to avoid high-risk behavior.
    - Counsel to help people who are already infected manage their illness.

13. **Recovery from drug addiction can be a long-term process and frequently requires multiple episodes of treatment.**
    - As with other chronic illnesses, relapses can occur during or after successful treatment episodes.
    - Individuals may require prolonged treatment and multiple episodes of treatment to achieve long-term abstinence and fully restored functioning.
    - Participation in self-help support programs during and following treatment often is helpful in maintaining abstinence.

Appendix E: References

Agency for Health Care Policy and Research (AHCPR). (1994). *Management of cancer pain. Clinical practice guideline* (Publication No. 94-0592 ed.). Rockville, MD: AHCPR.

Alford, D. P., Compton, P., & Samet, J. (2006). Acute pain management for patients receiving maintenance methadone or buprenorphine therapy. *Annals of Internal Medicine, 144*(2), 127–134.

Amass, L., Kamien, J. B., & Mikkulich, S. K. (2001). Thrice-weekly supervised dosing with the combination buprenorphine-naloxone tablet is preferred to daily supervised dosing by opioid-dependent humans. *Drug and Alcohol Dependence, 61*(2), 173–181.

American Pain Society (APS). (2003). *Principles of analgesic use in the treatment of acute pain and cancer pain* (5th ed.). Glenview, IL: American Pain Society.

American Psychiatric Association (APA). (2000). *Diagnostic and statistical manual of mental disorders* (4th ed., text revision). *(DSM-IV-TR).* Washington, DC: American Psychiatric Association.

Bradley, K. A., Badrinath, S., Bush, K., Boyd-Wickizer, J., & Anawalt, B. (1998). Medical risks for women who drink alcohol. *Journal of General Internal Medicine, 13*(9), 627–639.

Carr, D. B., & Goudas, L. C. (1999). Acute pain. *Lancet* [Review], *353*(9169), 2051–2058.

Center for Substance Abuse Treatment (CSAT). (n.d.). *About buprenorphine therapy*. http://buprenorphine.samhsa.gov/about.html [Accessed May 31, 2007].

Center for Substance Abuse Treatment (CSAT). (2007). *Buprenorphine: A guide for pharmacists.* SAMHSA Publication No. 07-4231. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration.

Center for Substance Abuse Treatment (CSAT). (2004) *Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction.* Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration. http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.72248 [Accessed November 5, 2008].

Center for Substance Abuse Treatment (CSAT). (1997). *A guide to substance abuse services for primary care clinicians.* Treatment Improvement Protocol (TIP) Series 24. http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.45293 [Accessed October 31, 2008].

Center for Substance Abuse Treatment (CSAT). (2005*a*). *Medication-assisted treatment for opioid addiction in opioid treatment programs.* Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 05-4048. Rockville, MD: Substance Abuse and Mental Health Services Administration. http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.82676 [Accessed October 31, 2008].

Center for Substance Abuse Treatment (CSAT). (2005*b*). *Substance abuse treatment for persons with co-occurring disorders.* Treatment Improvement Protocol (TIP) Series 42. DHHS Publication No. (SMA) 05-3992. Rockville, MD: Substance Abuse and Mental Health Services Administration. http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.74073 [Accessed November 6, 2008].

Cheskin, L. J., Fudala, P. J., & Johnson, R. E. (1994). A controlled comparison of buprenorphine and clonidine for acute detoxification from opioids. *Drug and Alcohol Dependence, 36*(2), 115–121.

Clancy, C., Coyne, P., & Wright, S. (1997). *Substance use: Guidance on good clinical practice for specialist nurses working with alcohol and drug users.* London: Association of Nurses in Substance Abuse (ANSA). http://www.ansauk.org/downloads/resource/ansabooklets/ansa_alcohol.pdf [Accessed October 28, 2008].

Collett, B. J. (1998). Opioid tolerance: The clinical perspective. *British Journal of Anaesthesia, 81,* 58–68.

Department of Health. (1996). *The Task Force to Review Services for Drug Misusers: Report of an independent review of drug treatment services in England.* London: HMSO.

Egan, G. (1990). *The skilled helper: A systematic approach to effective helping* (4th ed.). Monterey, CA: Brooks/Cole.

Erickson, P. (2006, October 9–10). *Buprenorphine: Detoxification/managed withdrawal*. Handout from the Buprenorphine Training of Trainers for Nurses, University of Maryland School of Nursing, Baltimore, MD.

Federal Register. (2001). http://www.gpo.gov/su_docs/fedreg/frcont01.html.

Ferrell, B. R., Rhiner, M., Cohen, M. Z., & Grant, M. (1991). Pain as a metaphor for illness: Part I, Impact of cancer pain on family caregivers. *Oncology Nursing Forum, 18*(8), 1303–1309.

Fiellin, D. A., & O'Connor, P. G. (2002). Office-based treatment of opioid-dependent patients. *New England Journal of Medicine, 347*(11), 817–823.

Goodman, F., Gordon, A., Kivlahan, D., Dalack, G., McNicholas, L., Oslin, D., Saxon, A., & Suchinsky R. (2006, March). *Criteria for use of buprenorphine/naloxone and buprenorphine sublingual tablets.* VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel. http://www.pbm.va.gov/criteria/BuprenorphineCriteriaForUse.pdf [Accessed October 28, 2008].

Greenwald, M. K., Johanson, C. E., Moody, D.E., Woods, J. H., Kilbourn, M. R., Koeppe, R. A., Schuster, C. R., & Zubieta, J. K. (2003). Effects of buprenorphine maintenance dose on mu-opioid receptor availability, plasma concentration, and antagonist blockage in heroin-dependent volunteers. *Neuropsychopharmacology, 28*(11), 2000–2009.

Grimes, T. (2006, October 9–10). *The culture of pain*. Handout from the Buprenorphine Training of Trainers for Nurses, University of Maryland School of Nursing, Baltimore, MD.

Handelsman, L., Cochrane, K. J., Aronson, M. J., Ness, R., Rubinstein, K. J., & Kanof, P. D. (1987). Two new rating scales for opiate withdrawal. *American Journal of Drug and Alcohol Abuse, 13*(3), 293–308.

Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC). (2003, December 5). *Use of buprenorphine in health center substance abuse treatment programs*. Program Assistance Letter, Document #2004-01. Rockville, MD: Health Resources and Services Administration. ftp://ftp.hrsa.gov/bphc/docs/2004pals/2004-01.htm. [Accessed May 31, 2007].

Jasinski, D. R. (1997). Tolerance and dependence to opiates. *Acta Anaesthesiologica Scandinavica, 41,* 184–186.

Johnson, R. E., Jones, H. E., & Fischer, G. (2003). Use of buprenorphine in pregnancy: Patient management and effects on the neonate. *Drug and Alcohol Dependence, 70*(2 Suppl), S87–S101.

Kehlet, H., & Dahl, J. B. (1993). The value of "multimodal" or "balanced analgesia" in postoperative pain treatment. *Anesthesia and Analgesia, 77*, 1048–1056.

LaBelle, C. (2006, October 9–10). *Buprenorphine: Induction, stabilization, maintenance and treatment monitoring*. Handout from the Buprenorphine Training of Trainers for Nurses, University of Maryland School of Nursing, Baltimore, MD.

Lambert, L., & Coyne, P. (1993). Confidentiality and the search for meaning and practice. *ANSA Journal, 13,* 26–28.

Loeser, J. D., & Melzack, R. (1999). Pain: An overview. *Lancet, 353*(9164), 1607–1609.

Lopez, F. (1994). *Confidentiality of patient records for alcohol and other drug treatment.* Technical Assistance Publication (TAP) Series, Number 13. DHHS Publication No. (SMA) 95-3018. Rockville, MD: Center for Substance Abuse Treatment.

Mao, J., Price, D. D., & Mayer, D. J. (1995). Mechanisms of hyperalgesia and morphine tolerance: A current view of their possible interactions. *Pain*, *62*, 259–274.

Marlatt, G. A., & George, W. H. (1984). Relapse prevention: introduction and overview of the model. *British Journal of Addiction, 79*(3), 261–273.

Marquet, P., Chevrel, J., Lavignasse, P., Merle, L., & Lachâtre, G. (1997). Buprenorphine withdrawal syndrome in a newborn. *Clinical Pharmacology and Therapeutics, 62*(5), 569–571.

McCance-Katz, E. (2004). Office-based buprenorphine treatment for opioid-dependent patients. *Harvard Review of Psychiatry, 12*(6), 321–328.

Merskey, H. (1979). Classification of chronic pain: Description of chronic pain syndromes and definitions of pain terms. *Pain* (Suppl 3), S217.

Mitra, S., & Sinatra, R. S. (2004). Preoperative management of acute pain in the opioid-dependent patient. *Anesthesiology, 101*, 212–227.

NAADAC, The Association for Addiction Professionals. (2002, October 12). NAADAC lauds buprenorphine launch: Association supports counselor involvement in new drug therapy. Press release. http://www.naadac.org/index.php?option=com_content&view=article&id=59:pr15&catid=37:press-releases&Itemid=68 [Accessed September 26, 2008].

Naegle, M. (2006, November/December). *Nurses and matters of substance.* Brooklyn, NY: National Student Nurses' Association (http://www.nsna.org). http://www.nsna.org/pubs/imprint/NovDec06/nov06_Feat_Naegle.pdf, pp. 58-63. [Accessed November 20, 2008].

National Association of State Alcohol and Drug Abuse Directors (NASADAD). (2002). *The use of medications in substance abuse treatment.* NASADAD Policy Paper. Washington, DC: NASADAD. http://www.nasadad.org/resource.php?doc_id=35. [Accessed September 26, 2008.]

National Institute on Drug Abuse (NIDA). (1999). *Principles of effective treatment.* NIH Publication No. 99-4180. Rockville, MD: National Institute on Drug Abuse. http://www.nida.nih.gov/PDF/PODAT/PODAT.pdf. [Accessed September 26, 2008].

Opiate Medication Initiative for Rural Oregon Residents (OMIROR). (2003, November). *Treating opiate dependence in rural communities: A guide for developing community resources*. Salem, OR: Northwest Frontier Addiction Technology Transfer Center (ATTC). http://www.ireta.org/opiates2005/10.pdf. [Accessed September 26, 2008.]

Pyne, R. H. (1998). Appendix 2: Guidelines for professional practice (UKCC Advisory Document). In *Professional discipline in nursing, midwifery, and health visiting: Including a treatise on professional regulation* (pp. 182–202). Oxford: Blackwell Science.

Seedhouse, D. (1986). *Health: The foundations for achievement*. Chichester, England: Wiley.

Simon, L. S., Lipman, A. G., Jacox, A. K., Caudill-Slosberg, M., Gill, L. H., Keefe, F. J., Kerr, K. L., Minor, M. A., Sherry, D. D., Vallerand, A. H., & Vasudevan, S. (2002). *Pain in osteoarthritis, rheumatoid arthritis, and juvenile chronic arthritis* (2nd ed.). Glenview, IL: American Pain Society.

Suboxone®/Subutex® dosing guide at http://www.suboxone.com/hcp/opioiddependence/dosing_guide.aspx. [Accessed October 28, 2008].

Substance Abuse and Mental Health Services Administration (SAMHSA). Trainings. http://buprenorphine.samhsa.gov/pls/bwns/training [Accessed October 28, 2008.]

Thompson-Gargano, K. (October 2006). Personal communications. Yale University, CT & co-founder of the National Alliance for Advocates for Buprenorphine Treatment (http://www.naabt.org/)

Trinkoff, A. M., & Storr, C. L. (1998). Substance use among nurses: Differences between specialties. *American Journal of Public Health*, *88*(4), 581–585.

U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER). (2002). FDA labeling for Suboxone® and Subutex®, NDA 20-732, NDA 20-733. Rockville, MD: Food and Drug Administration. http://www.fda.gov/cder/foi/label/2002/20732,20733lbl.pdf. [Accessed August 28, 2008].

Wanigaratne, S., Wallace, W., Pullin, F., Kearney, F., & Farmer, R. (1990). *Relapse prevention for addictive behaviors: A manual for therapists*. Oxford: Blackwell.

Wesson, D. R., & Ling, W. (2003). The clinical opiate withdrawal scale (COWS). *Journal of Psychoactive Drugs, 35*, 253–259.

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