

5 Special Populations

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The presence of certain life circumstances or comorbid medical or psychosocial conditions warrant special attention during the evaluation and treatment of opioid addiction with buprenorphine. Patients with circumstances or conditions that require special attention include those with certain medical comorbidities (e.g., AIDS, tuberculosis), concurrent mental disorders, or concurrent alcohol or other substance abuse disorders, as well as pregnant women, adolescents, geriatric patients, patients under the jurisdiction of the criminal justice system, and health care professionals who are addicted. Because of the unique issues presented by these circumstances, addiction treatment for these patients may require additional training or specialty care and consultation. Before treating individuals with these circumstances for opioid addiction in an office setting, physicians should consider whether patient needs can be met with the resources at hand or if referral to specialized treatment programs or to addiction specialists is indicated.

Patients With Medical Comorbidities

Patients addicted to opioids who present for treatment often have other comorbid medical problems. These conditions are often a consequence of high-risk behaviors, including injection drug use (intravenous, intramuscular, or subcutaneous), or of the direct toxic effects of the active and inert ingredients in illicit drugs. The prevalence of infectious diseases (e.g., HIV/AIDS, hepatitis B and C, tuberculosis, skin and soft tissue infections, syphilis and other sexually transmitted diseases [STDs]) is increased in these patients and should be screened for, as outlined in Chapter 3, Patient Assessment. Other comorbid conditions (e.g., seizure disorders, valvular heart disease secondary to endocarditis, pulmonary hypertension secondary to talc granulomatosis, lymphedema, pseudoaneurysms of the neck and groin secondary to thrombophlebitis, and renal insufficiency secondary to

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heroin-associated nephropathy) are also seen in this population and may require special attention. Patients with a history of endocarditis need antibiotic prophylaxis before certain dental procedures. Patients with a history of hepatitis C may require hepatitis A and B vaccinations and may be intolerant of potentially hepatotoxic medications. One retrospective study found that liver function tests were significantly elevated in patients treated with buprenorphine who also had a history of hepatitis, suggesting that liver function tests should be monitored in these patients on a regular basis during buprenorphine treatment (Petry et al. 2000). A detailed discussion of medical comorbidities in addiction is beyond the scope of this chapter and is reviewed extensively elsewhere (Cherubin and Sapira 1993; Stein 1990).

Treatment of opioid addiction in patients with comorbid medical conditions is likely to result in better outcomes for the comorbid conditions than would be achieved in the absence of treatment of the substance use disorder. Moatti et al. (2000) found that patients on buprenorphine tended to be more compliant with highly active antiretroviral therapies (HAART) than patients who were not treated concurrently for opioid addiction.

Pharmacological treatments of comorbid medical disorders may have important drug interactions with buprenorphine, however, due to shared pharmacokinetic properties. Although Carrieri et al. (2000) found no detrimental short-term effect of buprenorphine treatment on the effect of HAART on viral load, buprenorphine is metabolized by the hepatic cytochrome P450 3A4 enzyme system and will likely interact with other medications metabolized by the same system. Certain antiretrovirals may occupy the cytochrome P450 3A4 system and thus inhibit the metabolism of buprenorphine. Other drugs that induce the cytochrome P450 3A4 system (e.g., certain antituberculosis, anticonvulsant, and antiretroviral medications) may decrease

serum concentrations of buprenorphine, resulting in opioid withdrawal or decreased effectiveness. Because the interactions of most medications with buprenorphine have not been systematically studied, physicians should monitor for any signs or symptoms of opioid side effects, loss of effectiveness, or withdrawal after a patient starts any new medications. Buprenorphine dose adjustments may be necessary after starting new medications, even for patients who have been on a stable maintenance dose.

Other potential, and as yet unknown, drug interactions include the possibility of buprenorphine increasing or decreasing metabolism of medications used in treating comorbid medical conditions. Informing patients of potential drug-drug interactions, especially sedation or precipitated opioid withdrawal, is important to prevent jeopardizing adherence with medical treatment and/or precipitating relapse to illicit opioid use.

In summary, it is important to screen for and manage common comorbid medical conditions in patients being treated with buprenorphine for opioid addiction and to anticipate known and potential drug interactions. For additional information on drug-drug interactions with buprenorphine, refer to Chapter 2, Pharmacology.

Pregnant Women and Neonates

The continued use of heroin during pregnancy, with its attendant risks of infection, overdose, and intra-uterine withdrawal, is life threatening to both the woman and the fetus. Research on the safety and efficacy of buprenorphine in pregnant women and neonates is scarce, however. If a patient is pregnant or is likely to become pregnant during the course of opioid addiction treatment, the physician must consider whether buprenorphine is an appropriate option for treatment. Physicians

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should weigh all the risks and benefits of treatment with buprenorphine against all the risks associated with the continued use of illicit opioids. Methadone is currently the standard of care in the United States for the treatment of opioid addiction in pregnant women. Methadone has been shown to be safe and effective for both pregnant women and neonates.

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 human prescription drug 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 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.

Effects of Buprenorphine in Pregnancy

Data on the pharmacokinetics of buprenorphine in pregnant women and neonates are extremely limited (Johnson et al. 2003a; Marquet et al. 1997). Likewise, data are limited regarding the clinical use of buprenorphine for the maintenance treatment of opioid addiction in pregnant women. The literature in this area generally consists of case reports and a small number of prospective studies; there have been no controlled clinical trials. In case reports from European and Australian sources on the use of buprenorphine in opioid-addicted pregnant women, doses have ranged from 0.4 to 24 mg per day. In these limited reports, pregnancies

have generally progressed normally, with low rates of prematurity or other problems. Maternal clinical laboratory data in these reports have generally been within normal limits; or they were deemed either clinically nonsignificant, at levels expected during pregnancy, or due to factors other than the medication when outside normal limits. For a complete review of the published literature on the use of buprenorphine in the treatment of opioid addiction in pregnant women, see Johnson et al. 2003a.

Infants of Mothers Treated With Buprenorphine

Buprenorphine and its metabolite norbuprenorphine have been found in high concentrations in the blood, urine, and meconium of the neonates of women maintained on buprenorphine (Johnson et al. 2003a; Marquet et al. 1997).

The published literature includes information on at least 309 infants born to women maintained on buprenorphine treatment. Although not systematically studied, a neonatal abstinence syndrome (NAS) has been reported in 191 of these 309 infants, with approximately one-half of those with NAS requiring treatment. In more than 40 percent of the cases, however, evaluation of the abstinence syndrome was confounded by other drug use by the mothers. Overall, although no randomized controlled trials have been reported, the NAS associated with buprenorphine has been reported to be less intense than that observed with methadone.

One prospective open-label study (Fischer et al. 2000) found signs of NAS in 7 of 15 neonates exposed to buprenorphine in utero. Of these 15 neonates, 3 had moderate signs of NAS that required treatment, 4 had mild signs of NAS that required no treatment, and 8 had no signs of NAS. A second prospective open-label study (Johnson et al. 2003a) reported NAS in 3 of 3 neonates; however, none required treatment with medications.

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NAS from buprenorphine generally appears within the first 2 days of life, peaks within 3 or 4 days, and lasts for 5 to 7 days. Few infants were reported to have had a withdrawal symptom for 6 to 10 weeks.

Similar to the treatment of NAS following exposure to methadone, several different medications (including chlorpromazine, phenobarbital, benzodiazepine, paregoric elixir, and morphine drops) have been used successfully to treat the NAS associated with buprenorphine. The American Academy of Pediatrics recommends tincture of opium as the medication of choice for treatment of neonatal opioid withdrawal symptoms (American Academy of Pediatrics Committee on Drugs 1998).

Breast Feeding While on Buprenorphine Treatment

The limited human pharmacokinetic data show that buprenorphine passes into the breast milk of lactating women at a plasma-to-milk ratio of approximately 1. As a result, and because of the poor oral bioavailability of buprenorphine, the nursing infant will be exposed to only 1/5–1/10 of the total amount of buprenorphine available.

The literature includes reports on approximately 40 to 50 women who were maintained on buprenorphine and breastfed after delivery (Johnson et al. 2003a; Lejeune et al. 2001; Loustauneau et al. 2002; Marquet et al. 1997). These reports indicate that buprenorphine present in breast milk does not appear to suppress NAS. Additionally, NAS has not been observed after the cessation of breastfeeding by women who were maintained on buprenorphine (Loustauneau et al. 2002).

Although the Subutex® and Suboxone® package inserts state that breastfeeding is not advised in mothers treated with these medications, it is the consensus of the panel

that any effects of these medications on the breastfed infant would be minimal and that breastfeeding is not contraindicated.

However, given the limited literature in this subject area, physicians are advised to use their professional judgment in their recommendations.

The Buprenorphine/Naloxone Combination in Pregnancy

The panel notes that there is a question whether the buprenorphine/naloxone combination is or is not recommended for use in pregnancy. Naloxone is labeled by FDA as a Pregnancy Category B drug. The FDA Pregnancy Labeling Task Force assigns a human prescription drug to Pregnancy Category B (1) if animal reproduction studies have 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 a Pregnancy Category B drug, 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 a pregnant patient, and the patient understands the issues and risks, then she should be treated with buprenorphine monotherapy so as not to risk 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 of their medication supplies. To prevent abuse and diversion of the buprenorphine monotherapy formulation, quantities of take-home supplies and quantities provided via prescription should be smaller compared to treatment with the buprenorphine/naloxone combination formulation.

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Summary

Buprenorphine is classified by FDA as a Pregnancy Category C drug. Data from controlled studies on the use of buprenorphine in pregnant women are needed but are lacking. The available evidence does not show any causal adverse effects on pregnancy or neonatal outcomes from buprenorphine treatment, but this evidence is from case series not from controlled studies. Methadone is currently the standard of care in the United States for the treatment of heroin addiction in pregnant women. Pregnant women presenting for treatment of opioid addiction should be referred to specialized services in methadone maintenance treatment programs. If such specialized services are refused by a patient or are unavailable in the community, maintenance treatment with the buprenorphine monotherapy formulation may be considered as an alternative. In such circumstances, it should be clearly documented in the medical record that the patient has refused methadone maintenance treatment, or that such services were unavailable; that the patient was informed of the risks of using buprenorphine, a medication that has not been thoroughly studied in pregnancy; and that she understands those risks.

Adolescents/Young Adults

The use of buprenorphine for the treatment of opioid addiction in adolescents has not been systematically studied. It is known, however, that patients younger than 18 years of age, with relatively short addiction histories, are at particularly high risk for serious complications of addiction (e.g., overdose deaths, suicide, HIV, other infectious diseases). Many experts in the field of opioid addiction treatment believe that buprenorphine should be the treatment of choice for adolescent patients with short addiction histories. Additionally,

buprenorphine may be an appropriate treatment option for adolescent patients who have histories of opioid abuse and addiction and multiple relapses but who are not currently dependent on opioids. Buprenorphine may be preferred to methadone for the treatment of opioid addiction in adolescents because of the relative ease of withdrawal from buprenorphine treatment. Because adolescents often present with short histories of drug use, detoxification with buprenorphine, followed by drug-free or naltrexone treatment, should be attempted first before proceeding to opioid maintenance. Naltrexone may be a valuable therapeutic adjunct after detoxification. Naltrexone has no abuse potential and may help to prevent relapse by blocking the effects of opioids if the patient relapses to opioid use. Naltrexone has been a valuable therapeutic adjunct in some opioid-abusing populations, particularly youth and other opioid users early in the course of addiction. Naltrexone is most likely to be effective for patients with strong support systems that include one or more individuals willing to observe, supervise, or administer the naltrexone on a daily basis. In those adolescent patients in whom detoxification is followed by relapse, buprenorphine maintenance may then be the appropriate alternative. Refer to Chapter 4, Treatment Protocols, for buprenorphine maintenance and detoxification procedures.

The treatment of patients younger than 18 years of age can be complicated due to psychosocial considerations, the involvement of family members, and State laws concerning consent and reporting requirements for minors. Ancillary counseling and social services are important to support cooperation and follow-through with the treatment regimen.

Parental Consent

Parental consent is a critical issue for physicians who treat adolescents addicted to opioids. In general, adult patients with

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“decisional capacity” have the unquestioned right to decide which treatments they will accept or refuse, even if refusal might result in death. The situation for adolescents is somewhat different, however. Adolescents do not have the legal status of adults unless they are legally “emancipated minors.”

Adolescents’ rights to consent to or to refuse medical treatment differ from those of adults. Rules differ from State to State regarding whether an adolescent may obtain substance use disorder treatment without parental consent. Some State statutes governing consent and parental notification specify consideration of a number of fact-based variables, including the adolescent’s age and stage of cognitive, emotional, and social development, as well as issues concerning payment for treatment and rules for emancipated minors.

More than one-half of the States permit individuals less than 18 years of age to consent to substance use disorder treatment without parental consent. In States that do require parental consent, providers may admit adolescents to treatment when parental consent is obtained. In States requiring parental notification, treatment may be provided to an adolescent when the adolescent is willing to have the program communicate with a parent. Histories of neglect or abuse may be revealed during the care of adolescent patients, and physicians must be aware of reporting requirements in their State. Mandatory child abuse reporting takes precedence over Federal addiction treatment confidentiality regulations, according to Title 42, Part 2 of the Code of Federal Relations (42 C.F.R. Part 2).

Additional difficulties may arise when adolescents requesting treatment refuse to permit notification of a parent or guardian. With one very limited exception, the Federal confidentiality regulations prohibit physicians (or their designees) from communicating substance abuse treatment information to any third parties, including parents, without patient consent. The sole exception allows a

“program director” (i.e., treating physician) to communicate “facts relevant to reducing a threat to the life or physical well-being of the applicant or any other individual to the minor’s parent, guardian, or other person authorized under State law to act in the minor’s behalf,” when the program director believes that the adolescent, because of extreme youth or mental or physical condition, lacks the capacity to decide rationally whether to consent to the notification of his or her parent or guardian (42 C.F.R. Part 2, Subpart B, Section 2.14d 2001). The program director must believe the disclosure to a parent or guardian is necessary to cope with a substantial threat to the life or physical well-being of the adolescent applicant or someone else. In some cases, communication with State child protection agencies or judicial authorities may be an acceptable alternative, or the required course of action, if the physician believes neglect or abuse to have already occurred.

Treatment Setting

The more intensive a proposed treatment is, the more risk a program assumes in admitting adolescents without parental consent. Outpatient programs may have a better justification for admitting adolescents without parental consent than do intensive outpatient or residential programs.

Summary

Buprenorphine can be a useful option for the treatment of adolescents who have opioid addiction problems. The treatment of addiction in adolescents is complicated by a number of medical, legal, and ethical considerations, however. Physicians intending to treat addiction in adolescents should be thoroughly familiar with the laws in their State regarding parental consent. Physicians who do not specialize in the treatment of opioid addiction or adolescent medicine should strongly consider consulting with, or referring adolescent addiction patients to,

such specialists. Additionally, State child protection agencies can be a valuable resource when determining the proper disposition for adolescent addiction patients.

Geriatric Patients

Literature on the use of buprenorphine in geriatric patients is extremely limited. Because of potential differences in rates of metabolism and absorption compared to the nonelderly, care should be exercised in the use of buprenorphine in elderly individuals. Particular care should be exercised during buprenorphine induction both because of differences in body composition and because of the possibility of medication interactions.

Patients With Significant Psychiatric Comorbidity

The association of psychopathology and opioid addiction is well established. Psychiatric symptoms and disorders may be drug-induced, independent, or interrelated. Substance use and addiction can mimic, exacerbate, or precipitate psychiatric symptoms and disorders. Most substances of abuse produce moderate-to-severe psychiatric symptoms, and there is a complex association between substance use and psychiatric status.

A study of rates of psychiatric disorders among 716 patients addicted to opioids seeking treatment with methadone (Brooner et al. 1997), found a lifetime rate of 47 percent, and a current rate of 39 percent. Of note, patients in this study were stabilized in treatment for 1 month before the psychiatric evaluation. Other, earlier studies have reported higher rates of depression, antisocial personality characteristics, schizophrenia or schizotypal features, manic symptomatology, and alcoholism in opioid-addicted patients. For example, in a study of 533 opioid-addicted patients in treatment for their drug problems, Rounsaville and

colleagues (1982) found that 86.9 percent met diagnostic criteria for some psychiatric disorder (including personality disorders) in their lifetimes, and 70.3 percent met criteria for a current psychiatric disorder. It should be noted, however, that, although the rates of major depressive disorder, alcoholism, antisocial personality, minor mood disorders, and anxiety disorders in this group exceeded those found in the general population, the rates of schizophrenia and mania did not.

Although the etiological significance of psychiatric disorders in the genesis of opioid addiction is not established, it is known that treatment for both conditions is necessary for substance abuse treatment to be effective. Therefore, the presence and severity of comorbid psychiatric conditions must be assessed in patients who are opioid addicted before, or while, initiating buprenorphine treatment, and a determination must be made whether referral to specialized behavioral health services is indicated.

Untreated or inadequately treated psychiatric disorders can interfere with the effective treatment of addiction. Polydrug use and psychiatric problems are both associated with negative treatment outcomes unless they are identified and treated appropriately. For example, patients with major depression or dysthymia are more likely to use illicit drugs during treatment than patients who do not suffer from depression. Assessment is critical to determine whether psychiatric symptoms represent primary psychiatric disorders or substance-induced conditions. Primary psychiatric disorders may improve but do not dissipate with abstinence or maintenance therapies, and these disorders may require additional treatment. The psychiatric disorders most commonly encountered in patients who are opioid addicted are other substance abuse disorders, depressive disorders, posttraumatic stress disorder, substance-induced psychiatric disorders, and antisocial and borderline personality disorders.

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The presence of comorbid psychiatric disorders should not exclude patients from admission to opioid addiction treatment. Diagnosis of psychiatric disorders is critical to matching patients to appropriate treatment services. In first encounters with patients, it is essential to evaluate for the presence of suicidal or homicidal ideations, signs or symptoms of acute psychosis, and other acute or chronic psychiatric problems that may render patients unstable. Initiation of antidepressant therapy, in conjunction with treatment for opioid addiction, may be considered in patients presenting with signs or symptoms of depression. If manic behavior is present, attempts should be made to determine whether it is substance induced or whether the etiology is a primary mood disorder.

When psychiatric symptoms are severe or unstable, hospitalization for protection and containment may be appropriate to ensure the safety of the patient and others. Patients who are considered actively suicidal should not receive buprenorphine on an outpatient, prescription basis. Rather, they should be referred immediately for appropriate treatment, which may include psychiatric hospitalization. Those who are not currently suicidal but who have a history of suicidal ideation or attempts should be monitored closely in terms of medication supply and followup.

Psychiatrically stable patients can be readily accepted into treatment and stabilized on buprenorphine; subsequently they may receive additional psychiatric assessment to identify conditions requiring treatment. Patients who present with depression during the maintenance phase of buprenorphine treatment require continued assessment and should be treated appropriately.

Polysubstance Abuse

The abuse of multiple drugs (polysubstance abuse) among individuals addicted to opioids is common. Although polysubstance abuse or

dependence may be identified during assessment, physicians should remain alert to their presence throughout the course of addiction treatment.

Pharmacotherapy with buprenorphine for opioid addiction will not necessarily have a beneficial effect on an individual's use of other drugs. It is essential that patients be referred for treatment of addiction to other types of drugs when indicated. In addition, care must be exercised in the prescribing of buprenorphine for patients who abuse alcohol and for those who abuse sedative/hypnotic drugs (especially benzodiazapines), because of the documented potential for fatal interactions. (See Chapter 2, Pharmacology, for further information.)

Patients With Pain

Patients Being Treated for Pain Who Become Dependent on Opioids

Patients who need treatment for pain *but not for addiction* should be treated within the context of their regular medical or surgical setting. They should not be transferred to an opioid maintenance treatment program simply because they are being prescribed opioids and have become physically dependent on the opioids in the course of their medical treatment.

It can be difficult to distinguish between the legitimate desire to use opioids for pain relief and the desire to procure them for purposes of obtaining a high. This may be especially true in patients who have become physically dependent on opioids in the course of the treatment of a pain condition when that pain has been undertreated and inadequately relieved. Figure 5–1 presents some distinguishing features in the use of opioids by patients who are not addicted and who are using opioids for pain relief versus their use by patients who are addicted.

Figure 5-1

Clinical Features Distinguishing Opioid Use in Patients With Pain Versus Patients Who Are Addicted to Opioids

Clinical Features	Patients With Pain	Patients Who Are Addicted to Opioids
Compulsive drug use	Rare	Common
Crave drug (when not in pain)	Rare	Common
Obtain or purchase drugs from nonmedical sources	Rare	Common
Procure drugs through illegal activities	Absent	Common
Escalate opioid dose without medical instruction	Rare	Common
Supplement with other opioid drugs	Unusual	Frequent
Demand specific opioid agent	Rare	Common
Can stop use when effective alternate treatments are available	Usually	Usually not
Prefer specific routes of administration	No	Yes
Can regulate use according to supply	Yes	No

Patients Who Are Addicted to Opioids and Who Require Treatment for Pain

Behaviors associated with drug abuse frequently result in the development of acute and chronic pain conditions. These conditions may be caused by the toxic effects of the drug(s) themselves, as well as by trauma and infection. Patients receiving addiction treatment also may experience pain due to illness or injury unrelated to drug use. Physicians must manage this pain efficiently and appropriately. Opioids are among the most effective available options for managing pain, but they are often not prescribed to patients receiving treatment for addiction out of fear of “feeding the addiction” or of triggering relapse in currently abstinent patients. State laws governing the prescription of opioids to known substance abusers may place prescribing physicians at risk for prosecution unless the medical record clearly distinguishes between treatment of

the addiction and treatment of the pain condition.

Treatment Approach. Little clinical experience is documented regarding the treatment of pain in patients receiving buprenorphine. Pain in patients receiving buprenorphine treatment initially should be treated with nonopioid analgesics when appropriate. Although buprenorphine itself has powerful analgesic properties, the once-daily administration of buprenorphine, as used for the treatment of opioid addiction, often does not provide sufficiently sustained relief of pain. Additionally, the onset of action of analgesia with buprenorphine may not be adequate for the treatment of acute pain. In a study of the use of buprenorphine for acute analgesia (Nikoda et al. 1998), the high analgesic activity of buprenorphine was comparable to that of morphine, but the onset of action was found to be inadequate for urgent care.

Patients maintained on buprenorphine whose acute pain is not relieved by nonopioid medications should receive the usual

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aggressive pain management, which may include the use of short-acting opioid pain relievers. While patients are taking opioid pain medications, the administration of buprenorphine generally should be discontinued. Note that, until buprenorphine clears the body, it may be difficult to achieve analgesia with short-acting opioids in patients who have been maintained on buprenorphine, and higher doses of short-acting opioids may be required. Noncombination opioid analgesics are generally preferred to avoid the risk of acetaminophen or salicylate toxicity when using combination products at the doses that are likely to be required for pain control in patients who have been maintained on buprenorphine. Analgesic dose requirements should be expected to decrease as buprenorphine clears the body.

When restarting buprenorphine administration, physicians should refer to Chapter 4, Treatment Protocols, for induction procedures. To prevent the precipitation of withdrawal, buprenorphine should not be restarted until an appropriate time period after the last dose of the opioid analgesic, depending on the half-life of the opioid analgesic used.

Patients who are receiving opioids for chronic severe pain may not be good candidates for buprenorphine treatment because of the ceiling effect on buprenorphine's analgesic properties. This rationale would also be applicable to terminally ill patients. In patients who are maintained on buprenorphine and require end-of-life opioid analgesia, buprenorphine administration should be discontinued, unless the buprenorphine provides adequate analgesia or the patient prefers buprenorphine for some other reason.

In patients who are opioid addicted and who have severe chronic pain, methadone several times per day or other "round the clock" (rather than as required) long-acting, full-agonist medications may be the best alternative for treatment. This form of treatment is often best undertaken in

conjunction with an Opioid Treatment Program (OTP). However, if the physician is (1) otherwise qualified to treat the condition causing the pain and (2) careful to document that the primary purpose of the opioid pharmacotherapy is the management of that pain condition, then it may be acceptable to treat that patient in the office setting without further referral. As long as this type of patient remains compliant and is not abusing the pain medication or other drugs, there is no legal need for the patient to be treated in an OTP or with buprenorphine for the preexisting or concurrent addictive disorder. However, the Drug Enforcement Administration (DEA) frowns on the use of this as a rationale to treat the "pain of withdrawal" or spurious and ill-defined pain conditions to justify unsanctioned opioid maintenance. Pain patients on chronic opioids who have a history of drug abuse or addiction can be referred to a 12-Step program or other self-help group to help them maintain their level of recovery. Random drug screening also can reassure the physician that both physician and patient are staying within lawful bounds.

Because all pharmacological treatment with opioids is highly regulated, physicians who desire to use opioids to treat chronic pain in patients who are at risk for opioid addiction or relapse are advised to consult with a colleague knowledgeable in opioid maintenance pharmacology.

Patients Recently Discharged From Controlled Environments

This section focuses on the assessment and treatment of patients with opioid addiction who are recently released from controlled environments (e.g., prison) and who would be presumed to have involuntarily detoxified from opioids while incarcerated. Other situations that may warrant special consideration include (1) patients discharged

from extended hospital or rehabilitation center stays, (2) patients returning from extended overseas travel/expatriate duty in countries without easy access to licit or illicit opioids, and (3) other conceivable situations that may have caused an involuntary break in active use of and addiction to opioids.

The findings on patient assessment will help to clarify the diagnosis of opioid dependence/addiction and whether a patient is at serious risk for resumption of an addiction lifestyle if not treated with a buprenorphine maintenance regimen. Other considerations for providers include possible psychosocial needs and issues, as well as collateral contacts that may be required when treating patients who may have continuing involvement with the criminal justice system.

Opioid Addiction in Patients Under the Jurisdictions of Criminal Justice Systems

It is well documented that the crimes committed by most of the more than 1 million individuals incarcerated in the United States are related to the abuse of or addiction to drugs. Opioids are the preferred contraband drugs of choice in prisons and can be relatively easy to obtain in some institutions. Prison environments and inmate culture reinforce the addiction cycle and addiction lifestyle. Recidivism rates are higher in patients with a history of opioid addiction, because they are typically reincarcerated after failing parole or drug-testing requirements.

Assessment of Patients Who Are Opioid Addicted and Who Are Recently Released From Controlled Environments

Physicians should consider the following factors when assessing for addiction in patients recently released from controlled

environments: length of incarceration; postrelease addiction patterns and cycles; addiction treatment history (drug-free, outpatient, recovery, or therapeutic community); self-help involvement (before, during, and since incarceration); and reported triggers of illegal drug use and addiction upon release. Physicians should evaluate for the presence of comorbid mental health issues or history of other drug or alcohol use that could complicate buprenorphine treatment. (See Chapter 3, Patient Assessment, for further information.) If office-based buprenorphine treatment is being considered, physicians should carefully assess the patient's level of commitment to treatment and the likelihood of self control.

Assessing Psychosocial Issues

Attention to psychosocial issues is important in patients who are coming out of controlled environments. Issues that often affect the success of addiction treatment include

- Number and/or length of incarcerations
- Types of crimes committed (e.g., violent offenses, drug-related)
- Gang affiliations
- Type and length of parole or probation (e.g., whether the patient will be given regular or random drug testing)
- The patient's collateral contacts and reporting requirements
- Prior and current involvement of the patient's social support system (e.g., the presence of opioid addiction problems or current use in family members)
- Recent changes in familial or marital relationships
- Whether permission from the criminal justice system is required for treatment with buprenorphine

Physicians should inquire as to whether a patient has a reasonable plan for a stable lifestyle (e.g., involvement in job, school, family), and whether the plan includes total

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abstinence from drug and alcohol use. If there is no plan, the physician should inquire as to why not and should offer to help the patient create one.

Final determination of a patient's appropriateness for buprenorphine treatment will involve analysis of the subjective assessment and disclosed information, as well as a review of medical records to determine treatment compliance and cooperation. Physicians should assess a patient's psychosocial needs and the compatibility of the patient with the potential limitations of an outpatient, office-based environment.

Determining Appropriateness for Buprenorphine Treatment

A number of issues should be considered in determining the most appropriate treatment modality for patients with addiction who are recently released from controlled environments. If a methadone clinic alternative is available, the physician should determine the factors that may preclude referral. The existing doctor/patient relationship should be assessed, as well as eligibility for other assistance, and the presence of a solid support system. A physician's limitations with regard to potentially intensive buprenorphine monitoring activities should be considered, as a treating physician may be called on to determine, verify, and explain a treatment regimen (e.g., to parole and probation officers); to document the patient's compliance; and to interact with the legal system, employers, and others. Physicians should consider potential issues associated with detoxification in jail if a patient is reincarcerated. The cost of treatment needs to be considered, as well as whether the costs are covered by a patient's health insurance. Additionally, potential risk issues need to be

considered (e.g., diversion, overdose, criminal activity while in a limited, professional care setting, mixing with other patients).

Health Care Professionals Who Are Addicted to Opioids

A substantial problem of addiction to prescription opioids exists among physicians and other health professionals, especially within certain specialties (e.g., anesthesiology) (Talbot et al. 1987). Prescription opioid addiction in health professionals should be viewed as an occupational hazard of the practice of medicine. Health professionals who have substance abuse disorders often require specialized, extended care.

If the addictive drug of choice is present in the workplace, reentry planning after initial treatment should consider relapse by the health professional who is in early recovery. The opioid antagonist naltrexone and other adjunctive medications are often required. Naltrexone has been a routine adjunct for the treatment of anesthesiologists who are addicted to opioids. The key to successful naltrexone utilization by a highly motivated patient is a strong social support system that includes a significant other, coworker, or health professional who directly observes the naltrexone administration on a regular basis.

Buprenorphine may be an appropriate treatment option for some health professionals who are opioid dependent, but the use of a partial agonist would need to be part of a comprehensive, monitored recovery plan. If the professional has already come under regulatory scrutiny, such a plan might require approval by the State authority to which the professional reports.