

Quick Guide

For Clinicians

Based on TIP 43

**Medication-Assisted
Treatment for Opioid**

**Addiction
in Opioid
Treatment
Programs**



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Contents

Why a Quick Guide?	2
What Is a TIP?	3
Introduction	4
Screening, Admission, and Assessment	5
Pharmacology	8
Pharmacotherapy	12
Phases of Treatment	17
Patient Retention	23
Drug Testing	25
Associated Medical Problems	29
Multiple Substance Use	31
Patients With Special Needs	33
Administrative Considerations	37

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in Opioid Treatment Programs

This Quick Guide is based entirely on information contained in TIP 43, published in 2005. No additional research has been conducted to update this topic since publication of TIP 43.

WHY A QUICK GUIDE?

This Quick Guide was developed to accompany *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, Number 43 in the Treatment Improvement Protocol (TIP) series published by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA). This Quick Guide is based entirely on TIP 43 and is designed to meet the needs of the busy clinician for concise, easily accessed how-to information.

The Quick Guide is divided into 13 sections (see *Contents*) to help readers quickly locate relevant material. It presents current information about the nature and dimensions of opioid use disorders and their treatment in the United States, including basic principles of medication-assisted treatment for opioid addiction (MAT), regulatory requirements, and evidence-based best practices in opioid treatment programs (OTPs).

For more information on the topics in this Quick Guide, readers are referred to TIP 43.

WHAT IS A TIP?

The TIP series has been in production since 1991. This series provides the substance abuse treatment and related fields with consensus-based, field-reviewed guidelines on substance abuse treatment topics of vital current interest.

TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*

- Is a guide to MAT in OTPs
- Is written for opioid addiction treatment providers and OTP administrators
- Revises TIPs 1, 10, 20, and 22
- Incorporates changes in MAT since publication of TIP 1 in 1993
- Examines related medical, mental, sociological, and substance use disorders and their treatment in a comprehensive maintenance treatment program
- Describes ethical considerations that arise in many OTPs
- Summarizes areas for emphasis in successfully administering MAT in OTPs

See the inside back cover for information on how to order TIPs and other related products.

INTRODUCTION

Opioid addiction

- Is physical dependence on and subjective need and craving for opioid drugs
- Has similarities to other chronic medical disorders
- Is treated most successfully with a combination of pharmacological and behavioral interventions

MAT

- Is any opioid addiction treatment that includes a U.S. Food and Drug Administration (FDA)-approved medication for the detoxification or maintenance treatment of opioid addiction (i.e., methadone, levo-alpha acetyl methadol [LAAM], buprenorphine, buprenorphine-naloxone, naltrexone)
- May be provided in an OTP, a medication unit affiliated with an OTP, a physician's office, or another health care setting
- Includes comprehensive maintenance, medical maintenance, interim maintenance, detoxification, and medically supervised withdrawal
- Increases the likelihood for cessation of illicit opioid use or of prescription opioid abuse
- Is adversely affected by stigma

(For more information, see TIP 43, Chapter 1.)

SCREENING, ADMISSION, AND ASSESSMENT

Initial screening of applicants for admission to an OTP includes

- Identification of and immediate assistance with crises
- Verification that applicants satisfy Federal and State regulations and OTP eligibility criteria
- Explanation of patient and program responsibilities
- Description of essential aspects of MAT and OTP operations
- Identification of treatment barriers for applicants

An applicant is eligible for admission to an OTP if all of the following are true:

- He or she is addicted to an opioid drug.
- He or she became opioid addicted at least 1 year before admission.
- He or she is at least 18 years old (or meets Federal and State requirements for younger admissions).

A physician can invoke an exception to the 1-year opioid addiction criterion for one of the following reasons:

- The applicant was released from a correctional facility within 6 months of applying for treatment admission.

6 Medication-Assisted Treatment

- The applicant is a previously treated OTP patient (up to 2 years after previous discharge).
- The program physician certifies that the applicant is pregnant.
- The underage applicant has undergone two attempts at detoxification or outpatient psychosocial treatment for addiction. (A parent, legal guardian, or other State-designated adult must provide written consent.)

Federal regulations provide for interim maintenance treatment—emergency dispensing of opioid medication by an OTP for up to 120 days before an individual is admitted to treatment (without formal screening and with only minimal drug testing)—if

- The individual is eligible for admission to an OTP (see above).
- There are no available programs within a reasonable geographic area or programs that will have openings for a new patient within 14 days of his or her applying.
- The OTP that will provide interim maintenance maintains reasonable criteria to prioritize admissions.

Types of assessment for MAT include

- **Medical assessment.** Opioid and other substance use and treatment history, medical history, physical exam, laboratory tests

(including initial and random drug tests and possibly tests for tuberculosis [TB], hepatitis, HIV, and sexually transmitted diseases [STDs]), and women's health assessment (including pregnancy testing). OTPs also must comply with State physical examination requirements.

- **Induction assessment.** At least daily checks for signs of overmedication or undermedication during initial dosing and to ensure that patient has not used benzodiazepines or alcohol recently, observed dosing to ensure that patient ingests medication, checks for dosage adjustment, and determination of steady-state dosage levels. *(For more information on induction with specific medications, see TIP 43, pages 65–70.)*
- **Comprehensive assessment.** Determination of patient motivation for treatment and substance use, cultural background, and psychosocial factors such as mental status and history, sociodemographic status, family and social networks, physical or sexual abuse history, housing situation, legal status, spirituality, employment and military history, sexual orientation, insurance and financial status, and recreational activities.

(For more information, see TIP 43, Chapter 4.)

PHARMACOLOGY

Five medications are available for MAT in OTPs: methadone, LAAM, buprenorphine (Subutex[®]), buprenorphine-naloxone (Suboxone[®]), and naltrexone.

Methadone

- Is the most frequently used medication for opioid addiction treatment in OTPs
- Is a full mu opioid agonist
- Is available as an oral solution, liquid concentrate, tablet/diskette, and powder (but is nearly always administered as an oral solution in U.S. OTPs)
- Suppresses pain for 4–6 hours; suppresses withdrawal and drug craving for 24–36 hours in most patients who are opioid addicted
- Is administered daily for opioid addiction treatment and may be given in split doses
- Has been shown to be safe and effective when used with appropriate safeguards and psychosocial services
- Has variable body clearance rates and elimination half-lives among individual patients
- Has an excellent safety profile when taken as directed by the manufacturer

LAAM

- Is a full mu opioid agonist
- Is provided in an oral solution, which is colored to distinguish it from methadone
- Is longer acting than methadone and cannot be administered daily
- Was the subject of an FDA warning in 2001 because of its association with potentially fatal cardiac arrhythmia in some patients
- Has not been manufactured since early 2004, and its continued availability is uncertain

Buprenorphine (Subutex)

- Was approved in 2002 for MAT in physicians' offices and other medical and health care settings and in 2003 for MAT in OTPs (physicians must obtain a waiver from SAMHSA; OTPs must receive SAMHSA certification to provide buprenorphine)
- May be used both for medical maintenance pharmacotherapy and for medically supervised withdrawal from an opioid addiction treatment medication
- Is available in sublingual tablets either alone (Subutex) or combined with naloxone (Suboxone [see below])
- Is a partial opioid agonist at the mu receptor and an antagonist at the kappa receptor

- Has a ceiling effect that prevents larger doses from producing greater agonist effects, although larger doses lengthen its duration of action
- Can be administered on a daily or less-than-daily basis
- Can precipitate opioidlike withdrawal symptoms in patients with high levels of physical dependence
- Generally is safe and well tolerated when used as recommended by the manufacturer

Buprenorphine-Naloxone Combination (Suboxone)

- Combines a partial mu opioid agonist (buprenorphine) and antagonist (naloxone)
- Was developed to prevent injection abuse of buprenorphine
- Is provided in tablet form for sublingual administration
- Has a ratio of 4 parts buprenorphine to 1 part naloxone

Naltrexone

- Is a full mu opioid antagonist
- Blocks the effects of heroin, morphine, and methadone
- Can precipitate opioid withdrawal but causes no withdrawal symptoms of its own when a patient stops using it
- Can block opioid effects for up to 72 hours
- Has had poor patient compliance

- Effectively prevents relapse in most patients when used as directed
- Generally is safe when used as recommended by the manufacturer

The most common side effects of these medications are

- Constipation
- Sweating
- Insomnia or early awakening
- Decreased libido or sexual performance
- Dizziness
- Nausea, vomiting, or stomach upset
- Anxiety, nervousness, headache, joint/muscle pain, or tiredness (naltrexone)

Drugs that inhibit or induce the activity of the cytochrome P34A enzyme system can cause clinically significant increases or decreases in serum and tissue levels of opioid medications. These include certain medications to treat HIV and some psychiatric medications.

(For more information on the pharmacology of MAT medications, see TIP 43, Chapter 3.)

PHARMACOTHERAPY

Contraindications to OTP Admission and Opioid Pharmacotherapy

Inclusion rather than exclusion should be the guiding principle in OTPs. People who possibly should not be admitted to an OTP for MAT include those who

- Are also dependent on central nervous system (CNS) depressants, based on *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR) criteria
- Have had allergic reactions to opioid medications
- Have cardiac abnormalities (for treatment with LAAM)
- Do not satisfy DSM-IV-TR criteria for opioid dependence
- Have been addicted to opioids for less than 1 year (except those receiving buprenorphine) and have no addiction treatment history
- Cannot attend treatment sessions regularly, especially for dosing (unless a clinical exception is obtained from SAMHSA or buprenorphine dosing will meet patient needs)

Stages of MAT in an OTP

Induction Stage

In general, induction procedures used for each patient depend on the unique properties of each medication, prevailing regulatory requirements, patient preferences, and safety.

- Initial goals are to eliminate opioid withdrawal symptoms and achieve steady-state medication levels in patients' blood between doses of medication.
- Induction normally begins when there are no signs of opioid intoxication or sedation and beginning signs of opioid withdrawal (especially for induction with buprenorphine).
- Presence of sedatives, tranquilizers, tricyclic antidepressants, benzodiazepines, alcohol, or CNS depressants should be ruled out before induction begins.
- Dosing should be observed.
- LAAM may not be used for induction.

With methadone. Initial dosing is typically 20–30 mg and cannot exceed 30 mg per dose and 40 mg on day 1, unless need is documented by a program physician.

With buprenorphine. Induction with buprenorphine monotherapy is effective for most patients. Typically, 4 mg is given, followed after 4 hours

with up to 4 mg if needed, but the total on day 1 should not exceed 8 mg.

With buprenorphine-naloxone. Induction with the buprenorphine-naloxone combination is not recommended for patients withdrawing from longer acting opioids (it can cause withdrawal symptoms). For others, an initial 4/1 mg (buprenorphine/naloxone) is recommended, followed in 2 to 4 hours with an additional 4/1 mg if indicated.

With naltrexone. Patients should be abstinent from short-acting opioids for 7 days and long-acting opioids for 10 days. Initial dosing is 25 mg followed by 50 mg on day 2 if no withdrawal symptoms occur, then 50 mg per day up to 350 mg per week.

Stabilization Stage

The goal is to eliminate the patient's drug-seeking behavior, craving, and illicit opioid use or prescription opioid abuse.

Optimal dosage should be determined by patient response, but some guidelines exist for the following medications (*for LAAM, see TIP 43, page 72*):

- **Methadone.** Evidence supports a daily dose of 80 mg or more, but some patients do well on

less than 80 mg per day, and some patients require more than 120 mg per day.

- **Buprenorphine.** For most patients, the stabilization dosage is 12–16 mg per day, although some patients may need up to 32 mg per day. Increasing the dosage to 24 mg or more per day is usually necessary for every-other-day dosing schedules.
- **Naltrexone.** A daily 50 mg or thrice weekly 100–150 mg dose (totaling 350 mg per week) is recommended.

Maintenance Stage

The goal is for the patient to resume normal functioning while continuing to receive regular medication dosages, without the need for routine dosage adjustments.

Patients in this stage

- Are responding well to treatment and dosage
- Have stopped substance abuse
- Have resumed productive lifestyles
- Typically have received take-home medication privileges
- May remain at the same dosage for many months or years

Medically Supervised Withdrawal

The goal is to taper the amount of maintenance treatment medication a patient is taking.

- The likelihood of long-term success depends on individual patient factors.
- The relapse rate is high (80 percent or more in some studies).
- Methadone or buprenorphine may be used for tapering after detoxification.
- A common methadone-tapering practice is 5- to 10-percent incremental reductions every 1–2 weeks.

(For information on tapering from LAAM, see TIP 43, page 79.)

Take-Home Medication

Take-home maintenance medication is permitted for patient self-administration under specific conditions. Any patient in MAT may receive take-home medication doses for days when the OTP or physician's office is closed. For other take-home medication privileges, SAMHSA regulations require

- Absence of recent drug and alcohol abuse
- Regular OTP attendance
- Absence of behavioral problems in the OTP
- Absence of recent criminal activity
- Stable home, family, and social relationships
- Acceptable time in comprehensive maintenance treatment
- Assurance of safe storage of medication

- Clear indicators that benefits of decreased OTP attendance outweigh risk of medication diversion

Physician's Office-Based Opioid Treatment With Methadone

An exception can be obtained from SAMHSA for patients to receive methadone maintenance via observed dosing by a private physician in cooperation with an OTP when the patient

- Has been stable in treatment for at least 1 year
- Has a history of negative drug tests
- Is socially stable
- No longer requires psychosocial services

Under this arrangement, the physician need not observe dosing for patients already on extended take-home medication schedules.

(For more on the stages of pharmacotherapy and common dosing considerations, see TIP 43, Chapter 5.)

PHASES OF TREATMENT

MAT in OTPs may be conceptualized in phases so that interventions are matched to levels of patient progress and expected outcomes. At any point, patients may encounter a setback requiring a

return to a previous phase. The consensus panel for TIP 43 identified the following phases.

Acute Phase

- The acute phase begins immediately on patient admission to an OTP.
- Patients in this phase may be admitted for either maintenance treatment or detoxification.
- Treatment services usually are more intensive during this phase.
- Phase duration ranges from days (up to 180 for opioid detoxification in an OTP) to months and focuses on eliminating illicit substance use (induction) and lessening the intensity of other immediate problems (e.g., co-occurring disorders; medical, legal, family, and psychosocial problems).
- Patient goals include eliminating withdrawal symptoms and opioid craving; feeling well throughout the day; abstaining from illicit opioid use and complying with treatment medication regimens, confirmed by drug tests; learning about drug and medication interaction risks; avoiding high-risk situations for relapse; actively engaging in recovery; satisfying food, shelter, and safety needs; completing medical and mental health assessments; and, for those entering maintenance treatment, developing a treatment plan.

- Patients in detoxification have immediate access to maintenance treatment if medication tapering is unsuccessful or they change their minds about the type of treatment they want.
- By the end of this phase, signs of opioid withdrawal are ameliorated, physical drug craving is reduced, illicit-opioid use is eliminated, other substance use is reduced, medical and mental health assessments are done, a treatment plan has been developed, and basic needs are satisfied.

Rehabilitative Phase

- Dosage stabilization is complete but may require adjustments; patients are comfortable at their established dosage for at least 24 hours before moving to this phase.
- Program policies, such as those about take-home medications and dosing hours, are more flexible, so patients can attend to other life domains.
- Frequency of drug testing depends on progress in treatment; consistent, negative drug tests lead to reduced random-testing frequency (e.g., once or twice per month).
- Efforts increase to promote patient participation in constructive activities such as employment, education, vocational training, child rearing, homemaking, and volunteer work.

- Information about outside support groups (i.e., faith-based, community, and mutual-help groups) is reviewed, and patients are urged to participate in them, assuming groups support MAT.
- Patients receive assistance in developing skills for coping with relapse triggers.
- The primary goal is to empower patients to cope with major life problems by discontinuing alcohol and prescription drug abuse and all illicit-drug use; recognizing and coping with relapse triggers; complying with medical/dental and mental health treatment and maintaining a stable health status; maintaining a positive social and family support system; accepting increased responsibility for dependents; resolving legal problems and ceasing all illegal activities; participating in support groups; and obtaining effective pain management treatment.
- By the end of this phase, patients are employed, seeking employment, or involved in constructive activities (e.g., school, child rearing, and volunteer work); legal problems are being resolved; co-occurring disorders are stabilized; a conflict-free social support system is in place; and alcohol abuse, illicit-drug use, and inappropriate use of other substances are eliminated.

Supportive-Care Phase

- Patients have discontinued alcohol and prescription drug abuse and all illicit-drug use, as well as any involvement in criminal activities.
- Patients receive take-home medication for longer periods and are permitted fewer OTP visits (as few as one visit every 2 weeks, if State policy allows).
- Patients continue counseling and other care as needed, but medical and mental health, family relationships, and financial and legal situations are stable.
- Care is often augmented through mutual-help, faith-based, community, and other groups.
- When ready, patients may progress to either the medical maintenance or tapering phase.

Medical Maintenance Phase

- Patients are allowed longer term supplies of take-home medication (up to 30 days, if State regulations permit, after patients have been substance free for 2 years of continuous treatment) and further reductions in treatment visits.
- Methadone maintenance may occur through OTPs, physicians' offices, or other health care settings that are SAMHSA-approved "medication units" formally linked to OTPs.
- Patients should have no alcohol use problems, live in a stable environment, have a stable

income, be involved in productive activities, have had no legal involvement for at least 3 years and have no current parole or probation status, and have adequate social support systems.

- Continuation of random drug testing, callbacks of medication, and monitoring for relapse risks are recommended during this phase.
- Positive drug tests should cause a return to the rehabilitative phase.
- Patients may remain in methadone maintenance, transition to buprenorphine maintenance (in the OTP or via an offsite physician's office or another health care facility), or enter the tapering and readjustment phase.
- Medication diversion by a patient in medical maintenance results in reclassification to the most appropriate previous phase and adjustment of treatment, other services, and privileges.

Tapering and Readjustment Phase

- Goal is gradual reduction or elimination of maintenance medication.
- Most patients try to taper from treatment medication at least once.
- Patients should continue receiving treatment support and assistance to adjust to a life free of both maintenance medication and substances of abuse.

- Patients should be advised that even gradual dose tapering will cause discomfort and that a return to treatment medication is not a failure.
- Major goals are to increase self-sufficiency, maintain a balanced lifestyle, and function well without medication.

Continuing-Care Phase

- Treatment comprises medical followup by a primary care physician, occasional check-ins with an OTP counselor, and participation in recovery groups.
- Appointments with the OTP should be scheduled for every 1–3 months.
- Some patients might need referral to a non-MAT outpatient program.

(For more information on treatment phases, see TIP 43, Chapter 7.)

PATIENT RETENTION

Retention may be the most important indicator of MAT outcomes. Patient characteristics, behavior, and other nontreatment-related factors appear to contribute relatively little to retention in MAT. Several treatment-related steps have been found to improve patient retention:

- Individualization of medication dosages
- Clarification of program goals and treatment plans

- Simplified admission process
- Attention to patient financial needs
- Reduced attendance burden when possible
- Early provision of useful, high-intensity services
- Good staff–patient interactions
- Staff knowledge of, positive attitudes about, and confidence in MAT

Mutual-help programs vary in attitudes toward treatment medications. Counselors should help patients find mutual-help groups that accept opioid pharmacotherapy or start a group at the OTP.

Patients need to develop relapse prevention skills by

- Making lifestyle changes to decrease the need for drugs
- Recognizing relapse warning signs
- Developing positive coping methods
- Increasing participation in healthy, rewarding activities as alternatives to drug use
- Avoiding people and situations that might trigger use

Involuntary (or Administrative) Discharge

- Should be avoided if possible
- Should be handled fairly and humanely, when unavoidable
- Is indicated by SAMHSA only for violence or threats, drug dealing, repeated loitering, flagrant noncompliance with treatment, nonpayment of fees, and incarceration or confinement
- Should be preceded by other strategies such as clear communication of program rules, dosage adjustment, treatment of co-occurring disorders, intensified counseling, alternative medications, inpatient detoxification from other substances of abuse, change of counselors, rescheduling of dosing times, and family intervention
- Should include procedures for review and appeal, dosage protocol for withdrawal from medication, and a readmission procedure

(For more on patient retention and involuntary discharge from treatment, see TIP 43, pages 122–124 and 138–141, respectively.)

DRUG TESTING

Drug tests are performed or results are used in OTPs to

- Detect substances of abuse in patients
- Guide patient care
- Modify treatment plans

- Confirm clinical impressions
- Monitor patients' compliance with medication
- Evaluate OTP effectiveness
- Fulfill program quality assurance requirements
- Detect and monitor emerging substance use trends

Urine Drug Tests

Urine drug testing is the dominant testing method in OTPs because

- Obtaining specimens is relatively easy.
- Testing is affordable.
- The method is well studied with well-established cutoff levels and use guidelines.

Drawbacks of urine drug testing include

- The need for observed specimen collection negates trust.
- The possibility of deliberate tampering exists.
- Patients with shy bladder syndrome need other arrangements.
- A patient's physical condition can affect test sensitivity and specificity.
- The method is not feasible if patient has renal failure or other bladder control problems.
- Some medications (e.g., HIV medications) can affect results.

Oral Drug Tests

Oral-fluid drug testing in OTPs

- Was approved in 2003
- Requires specimen analysis by a qualified offsite laboratory
- Must follow appropriate State laws and regulations
- Includes specimen collection with oral swabs, which most patients prefer to observed urine collection
- Is highly sensitive and specific for methadone and opioids of abuse
- Allows storage of samples
- Is less susceptible to tampering than urine testing
- Has lower detection limits than urine testing for some drugs
- Is recommended when specimen collection must be observed

Frequency of Drug Tests

SAMHSA requires eight drug tests per year for patients in long-term MAT, including one test at admission and random monthly tests. Patients in short-term detoxification must have one initial drug test. Some States require more frequent testing and may have specific drug-testing methodologies to follow. OTPs

- Should contact their State agency to determine their State's requirements

- Must follow the more stringent of either Federal or State regulations
- Should institute more frequent, random tests for patients who continue to abuse substances or test negative for treatment medication

Laboratory Considerations

A laboratory selected for specimen analysis should

- Be federally approved and in compliance with Clinical Laboratory Improvement Amendments and Health Insurance Portability and Accountability Act regulations
- Participate in external quality assessment
- Have adequately trained staff and supervisors, including a trained staff scientist
- Use appropriate analytical methods based on manufacturer's instructions
- Confirm positive findings and evaluate control samples for each analysis
- Collaborate with OTPs on confidentiality, reporting of and turnaround time for results (preferably within 2 or 3 days), and specimen retention for retesting

Interpreting and Using Drug Test Results

- Drug test results should not be the sole basis for treatment decisions, especially discharge.
- Numerous medications and substances can produce false-positive or false-negative results.

- Positive tests for substance abuse should be confirmed whenever possible.
- Patients should be informed of unfavorable test results as soon as possible.
- Patient denials should be taken seriously, and appropriate followups should be performed.
- Results and subsequent treatment decisions should be documented in patient records.
- Results never should be used punitively but should be used to explore different interventions and treatment plans to improve compliance.
- Onsite testing kits allow the admission process to proceed while results are pending, but some recent studies have found drawbacks, and some States disallow onsite analysis.

(For more information on drug testing, see TIP 43, Chapter 9.)

ASSOCIATED MEDICAL PROBLEMS

Integration of medical and addiction treatment in an OTP is preferable but often beyond the means of the OTP. Each OTP should clearly define and communicate to patients the medical services offered on site versus by referral and should establish sound links with medical providers.

The following medical problems are more prevalent and often more severe in people addicted to opioids than in the general population:

- **Acute, life-threatening infections.** Cellulitis, abscesses, wound botulism, necrotizing fasciitis, and endocarditis
- **Infectious diseases.** TB, STDs, hepatitis (particularly hepatitis C), and HIV/AIDS
- **Chronic diseases.** Diabetes, asthma, hypertension, chronic obstructive pulmonary disease, and coronary artery disease
- **Pain.** Acute and chronic

OTPs should screen patients for these problems (HIV testing requires a patient's written permission) and provide patient education and treatment if possible or refer patients for medical care. OTPs should establish protocols for medical assessment and periodic reassessment.

When a patient requires hospitalization, the OTP physician should communicate the following to the attending physician and other hospital health care professionals:

- The patient's addiction medication dosage
- The date on which addiction medication was last administered
- The patient's medical, co-occurring, or social problems

- That the patient may require larger doses of medication for anesthesia and pain relief
- Information about appropriate controls to prevent the patient from obtaining and abusing substances

(For more information on medical problems and their management in OTPs, see TIP 43, Chapter 10.)

MULTIPLE SUBSTANCE USE

Patients in MAT commonly use and may be dependent on one or more of the following:

- **Alcohol.** The effects of concomitant alcohol and MAT medication use are additive and more sedating than either alone. Patients who are alcohol dependent may have liver damage as well as more medical and mental disorders, greater criminality, and poorer social and family relationships than patients who are not alcohol dependent. Alcohol-related factors are a major cause of death in patients in MAT.
- **Benzodiazepines/prescription sedatives.** High doses can cause severe intoxication, high risks of injuries or fatal overdose, and sedation or respiratory depression. Patients have reported taking these drugs within 1 hour of their MAT medication to boost the treatment medication's

effect. When used in prescribed doses, benzodiazepines are not dangerous for patients in MAT.

- **Cocaine/other stimulants.** Patients in MAT who use stimulants may be disruptive and exhibit severe mood swings. Adequate doses of methadone have been found to reduce cocaine use in some cases.
- **Marijuana.** Some studies have found that marijuana use does not affect MAT outcomes adversely. Patients in MAT sometimes use marijuana to self-medicate for anxiety or insomnia. Marijuana use should be discouraged because it increases the likelihood of patients' engaging in activities that will lead to relapse.
- **Nicotine.** Although many OTPs avoid addressing nicotine dependence because it may create additional stress for patients, research has shown that a smoking intervention neither detracts from nor interferes with addiction recovery.

Patients stabilized on MAT medication are less likely to abuse other substances than individuals who are unmedicated. OTPs can address multiple substance use by

- Adjusting treatment medication dosages
- Increasing counseling and psychosocial services
- Increasing drug testing

- Detoxifying patients (through either outpatient or inpatient treatment) from other substances, especially from CNS depressants

Discharge from MAT because of other substance use should be done only when all reasonable alternatives have been exhausted.

(For more information on multiple substance use in MAT, see TIP 43, Chapter 11.)

PATIENTS WITH SPECIAL NEEDS

To ensure that a patient can be matched to treatment as soon as the assessment indicates the patient has a special need, treatment planning should involve a team of

- Physicians
- Counselors
- Nurses
- Case managers
- Social workers

Patients Who May Require Special Treatment Services

- Patients with serious medical disorders should receive treatment on site or by referrals to medical centers.
- Patients with housing, family, or social problems may need help meeting basic needs.

- Patients with disabilities may be served best through mobile medication units, home-nursing services, or take-home privileges.
- Adolescents and young adults may require youth-oriented psychosocial services.
- Lesbian, gay, and bisexual patients may require help coping with problems related to their sexual orientation and additional HIV/AIDS counseling.
- Aging patients may require increased monitoring for medication interactions and dosage adjustments because of slower metabolisms.
- Patients with pain may have a higher tolerance for opioids and need higher doses. (*For more information on pain management, see TIP 43, pages 174–178.*)

(*For more on these types of patients, see TIP 43, Chapter 6.*)

Patients With Serious Co-Occurring Disorders

Many people who are opioid addicted have co-occurring mental disorders. The co-occurring mental disorder

- May be caused by the patient's substance abuse (i.e., primary substance use disorder and secondary mental disorder)
- May exist independently and may or may not be a significant cause of the substance use

disorder (i.e., primary mental disorder and secondary substance use disorder)

These patients require more intensive services than most patients. It is best to stabilize patients' opioid addiction while addressing their co-occurring disorders because each can influence the other. Special care must be given to ensure that

- Patients' opioid addictions are stabilized to make accurate diagnosis possible.
- The disorders are diagnosed correctly.
- Treatment medication for one disorder does not interfere with medication for the other.

(For more information on co-occurring mental disorders, see TIP 43, Chapter 12.)

Pregnant Women and Newborns

Integration of a women's overall health initiative into MAT is recommended to improve an OTP's capacity to meet women's needs. OTPs should assess women for physical and sexual abuse in current relationships. Referrals should be made to ensure a safe place for a woman and her children.

All women of childbearing age admitted to an OTP must receive a pregnancy test. Methadone currently is the only opioid medication approved by FDA to treat pregnant women in MAT, although buprenorphine is sometimes used when the

prescribing physician believes that the potential benefits justify the risks. Several studies have found buprenorphine safe and effective for treating pregnant patients, but more research is needed.

A large percentage of pregnant women in MAT continue to use other substances that are harmful to maternal and fetal health, including alcohol, heroin, cocaine, barbiturates, and tranquilizers. Monitoring drug use and appropriate perinatal care are crucial.

Methadone dosages must be adjusted for women who are pregnant to prevent withdrawal symptoms in the patient and to minimize neonatal abstinence syndrome in the infant. Mothers maintained on methadone can breast-feed if they

- Are not HIV positive
- Are not abusing substances
- Have no other disease or infection for which breast-feeding is contraindicated

An abstinence scoring system is recommended to monitor opioid-exposed newborns to

- Assess onset, progression, and diminution of withdrawal symptoms
- Determine whether pharmacotherapy is needed
- Monitor responses to such therapy

Research indicates that developmental sequelae for infants exposed to methadone in utero are well within the normal range.

(For more information on pregnancy in MAT, see TIP 43, page 93 and Chapter 13.)

ADMINISTRATIVE CONSIDERATIONS

OTP staff members should meet the following qualifications:

- Appropriate licensing, certification, or credentialing under State regulations
- Evidence of empathy and sensitivity toward patients in MAT
- Recognition and avoidance of harmful transference relationships with patients
- Sensitivity to culture, gender, and age issues
- Multicultural and multilingual background when needed
- Flexibility in thinking, behavior, and attitudes

Staff retention should be a priority. Managers should do the following to retain staff:

- Maintain clear policies and apply them consistently
- Avoid excessive caseloads
- Encourage a team approach and a culture of mutual respect
- Establish clearly delineated job descriptions

- Establish objective performance standards
- Convene regular consulting sessions among program staff members
- Provide opportunities for professional training
- Establish personnel policies that reduce stress on staff (e.g., flexible work schedules)

OTP staff members should be kept up to date on the following:

- Facts about MAT and the health effects of treatment medications
- Drug abuse and communicable disease trends in the local community
- General skills training such as crisis management, communication, cultural diversity, and problemsolving
- Training in sensitivity to patients and their needs

OTPs must maintain diversion control plans to reduce the possibility of diversion by

- **Patients.** This can be through random callbacks that require patients to return with their remaining take-home medication so that staff can inventory it, random drug testing to ensure that patients are taking their medication as directed, and a no-loitering policy.
- **Staff members.** This can be through rigorous accounting and inventory policies, accurate recording in receipt and dispensing logbooks, and prompt investigation of any discrepancies in records.

Community resistance to OTPs can be addressed through

- Good community relations
- Community outreach to neighbors and local businesses
- Community education

Because SAMHSA-approved accrediting organizations require OTPs to demonstrate performance improvement, OTPs must establish procedures to monitor and evaluate program effectiveness. Several resources are available to assist administrators in setting up quality assurance procedures.

(For more information, see TIP 43, Chapter 14.)

Ordering Information

TIP 43

Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs

TIP 43-Related Products

KAP Keys for Clinicians Based on TIP 43

*Medication-Assisted Treatment for Opioid
Addiction in Opioid Treatment Programs
Inservice Training Curriculum*

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Three Ways to Obtain FREE Copies of All TIP Products:

1. Call SAMHSA's National Clearinghouse for Alcohol and Drug Information (NCADI) at **800-729-6686**, TDD (hearing impaired) **800-487-4889**.
2. Visit NCADI's Web site at **www.ncadi.samhsa.gov**.
3. Access TIPs online at **www.kap.samhsa.gov**.



Other Treatment Improvement Protocols (TIPs) that are relevant to this Quick Guide:

TIP 37: *Substance Abuse Treatment for Persons With HIV/AIDS (2000)* **BKD359**

TIP 40: *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (2004)* **BKD500**

TIP 42: *Substance Abuse Treatment for Persons With Co-Occurring Disorders (2005)* **BKD515**

See the inside back cover for ordering information for all TIPs and related products.