Medication-Assisted Treatment
For Opioid Addiction in Opioid Treatment Programs

A Treatment Improvement Protocol

TIP 43

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
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MEDICATION-ASSISTED TREATMENT

Medication-Assisted Treatment For Opioid Addiction in Opioid Treatment Programs

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Disclaimer

The opinions expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of CSAT, SAMHSA, or DHHS. No official support of or endorsement by CSAT, SAMHSA, or DHHS for these opinions or for particular instruments, software, or resources described in this document is intended or should be inferred.

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What Is a TIP?

Treatment Improvement Protocols (TIPs), developed by the Center for Substance Abuse Treatment (CSAT), part of the Substance Abuse and Mental Health Services Administration (SAMHSA), within the U.S. Department of Health and Human Services (DHHS), are best-practice guidelines for the treatment of substance use disorders. CSAT draws on the experience and knowledge of clinical, research, and administrative experts to produce the TIPs, which are distributed to facilities and individuals across the country. The audience for the TIPs is expanding beyond public and private treatment facilities to include practitioners in mental health, criminal justice, primary care, and other health care and social service settings.

CSATís Knowledge Application Program (KAP) expert panel, a distinguished group of experts on substance use disorders and professionals in such related fields as primary care, mental health, and social services, works with the State Alcohol and Drug Abuse Directors to generate topics for the TIPs. Topics are based on the fieldís current needs for information and guidance.

After selecting a topic, CSAT invites staff from pertinent Federal agencies and national organizations to be members of a resource panel that recommends specific areas of focus as well as resources that should be considered in developing the content for the TIP. These recommendations are communicated to a consensus panel composed of experts on the topic who have been nominated by their peers. This consensus panel participates in a series of discussions. The information and recommendations on which they reach consensus form the foundation of the TIP. The members of each consensus panel represent substance abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A panel chair (or co-chairs) ensures that the contents of the TIP mirror the results of the groupís collaboration.

A large and diverse group of experts closely reviews the draft document. Once the changes recommended by these field reviewers have been incorporated, the TIP is prepared for publication, in print and on line. TIPs can be accessed via the Internet at www.kap.samhsa.gov. The

online TIPs are consistently updated and provide the field with state-of-the-art information.

Although each TIP strives to include an evidence base for the practices it recommends, CSAT recognizes that the field of substance abuse treatment is evolving, and research frequently lags behind the innovations pioneered in the field. A major goal of each TIP is to convey ìfront-lineî information quickly but responsibly. For this reason, recommendations proffered in the TIP are attributed to either panelistsí clinical experience or the literature. If research supports a particular approach, citations are provided.

This TIP, ***Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs***, incorporates the many changes in medication-assisted treatment for opioid addiction (MAT) that have occurred over the most active decade of change since the inception of this treatment modality approximately 40 years ago. The TIP describes the nature and dimensions of opioid use disorders and their treatment in the United States, including basic principles of MAT and historical and regulatory developments. It presents consensus panel recommendations and evidence-based best practices for treatment of opioid addiction in opioid treatment programs (OTPs). It also examines related medical, psychiatric, sociological, and substance use disorders and their treatment as part of a comprehensive maintenance treatment program. The TIP includes a discussion of the ethical considerations that arise in most OTPs, and it provides a useful summary of areas for emphasis in successfully administering MAT in OTPs.

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Foreword

The Treatment Improvement Protocol (TIP) series supports SAMHSAís mission of building resilience and facilitating recovery for people with or at risk for mental or substance use disorders by providing best-practices guidance to clinicians, program administrators, and payers to improve the quality and effectiveness of service delivery and thereby promote recovery. TIPs are the result of careful consideration of all relevant clinical and health services research findings, demonstration experience, and implementation requirements. A panel of non-Federal clinical researchers, clinicians, program administrators, and client advocates debates and discusses its particular areas of expertise until it reaches a consensus on best practices. This panelís work is then reviewed and critiqued by field reviewers.

The talent, dedication, and hard work that TIPs panelists and reviewers bring to this highly participatory process have helped bridge the gap between the promise of research and the needs of practicing clinicians and administrators who serve, in the most current and effective ways, people who abuse substances. We are grateful to all who have joined with us to contribute to advances in the substance abuse treatment field.

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Executive Summary

Research supports the perspective that opioid addiction is a medical disorder that can be treated effectively with medications when they are administered under conditions consistent with their pharmacological efficacy and when treatment includes necessary supportive services such as psychosocial counseling, treatment for co-occurring disorders, medical services, and vocational rehabilitation. Medication-assisted treatment for opioid addiction (MAT) has been effective in facilitating recovery from opioid addiction for many patients.

This TIP provides a detailed description of MAT, especially in opioid treatment programs (OTPs). MAT includes optional approaches such as comprehensive maintenance treatment, medical maintenance treatment, detoxification, and medically supervised withdrawal. Some or all of these approaches can be provided in OTPs or other settings. With the approval of buprenorphine for physicianís office-based opioid treatment, MAT availability is expected to increase.

Growing understanding and acceptance of opioid addiction as a treatable medical disorder have facilitated advances in MAT. The effectiveness of MAT advanced significantly with the development of methadone maintenance treatment in the 1960s and the creation and expansion of publicly funded treatment programs in the 1970s. The first official Federal use of the term ìmaintenance treatmentî (referring to opioid addiction treatment) occurred in the Narcotic Addict Treatment Act of 1974. Perhaps the most important development in MAT during the 1990s was publication of recommendations by a National Institutes of Health consensus panel on Effective Medical Treatment of Opiate Addiction. The panel concluded that opioid addiction is a treatable medical disorder and explicitly rejected notions that addiction is self-induced or a failure of willpower. The panel called for a commitment to providing effective treatment for opioid addiction and for Federal and State efforts to reduce the stigma attached to MAT and to expand MAT through increased funding and less restrictive regulation. The implementation of an accreditation system for OTPs further serves to standardize and improve MAT.

Accompanying these improvements in opioid addiction treatment is an increasing emphasis on the concomitant treatment of diseases such as HIV/AIDS, hepatitis, and tuberculosis, all of which occur at higher rates among people who inject drugs than in the general population.

This TIP addresses a variety of issues and challenges in MAT, including

- ï Drug testing for screening and assessmentó how and when (chapters 4 and 9)
- ï Administrative dischargeóissues of safety and noncompliance (chapter 8)
- ï Use of other substances with opioids and resulting complications for MAT (chapter 11)
- ï Co-occurring mental disorders and their complications for MAT (chapter 12)
- ï Administration of staffs and procedures (chapter 14).

The following paragraphs summarize chapters in this TIP.

Chapter 1, Introduction, introduces MAT and provides important concepts for understanding this TIP. It describes opioid addiction as a medical disorder with similarities to other disorders. It outlines the main options for MAT, such as choices of medication and optional services. The chapter concludes by summarizing the greatest challenges facing OTPs and offering a vision of the future.

Chapter 2, History of Medication-Assisted Treatment for Opioid Addiction, provides the historical context for MAT. It details the history of the use of opioids in the United States; the political, legal, and regulatory responses to opioid abuse; treatment trends (including logistics and strategies); and development of modern medications available in MAT.

Chapter 3, Pharmacology of Medications Used To Treat Opioid Addiction, reviews the pharmacology and clinical applications of the medications used for treating opioid addiction. It focuses on the metabolic activity, dosage forms, efficacy, side effects, drug interactions, safety considerations, and current availability and restrictions for methadone, levo-alpha acetyl methadol (LAAM), buprenorphine, and naltrexone. The information will enable treatment providers to compare the benefits and limitations of available opioid addiction treatment medications.

Chapter 4, Initial Screening, Admission Procedures, and Assessment Techniques, describes screening and assessment procedures used with applicants for admission to treatment and with patients in MAT. The chapter describes components of the screening (or intake) process that provides a foundation for treatment and procedures used during the admissions process to ensure thorough, efficient data collection and to gather information for ongoing treatment intervention. Components of substance use, medical, medication induction, and comprehensive psychosocial assessments are used to determine MAT eligibility, individualize treatment plans, and monitor changes in patient status. The chapter also provides information on managing emergency situations during admission and treatment.

Chapter 5, Clinical Pharmacotherapy, explains opioid pharmacotherapy, focusing on the clinical use of methadone, buprenorphine, LAAM, and naltrexone. It details the discrete stages of opioid pharmacotherapy, each of which requires unique clinical considerations. It discusses factors that may affect individual responses to treatment medications and key considerations in determining individual dosages. For patients who must leave MAT, either voluntarily or involuntarily, the chapter explains methods of withdrawal from treatment medications. It also discusses important considerations in administering take-home medication.

Chapter 6, PatientñTreatment Matching: Types of Services and Levels of Care, describes a multidimensional, clinically driven strategy for matching patients in MAT with the types of treatment services and levels of care that optimize treatment outcomes, within or in

conjunction with OTPs. Patientñtreatment matching involves individualizing the choice and application of treatment resources to each patientís needs, abilities, and preferences. The chapter describes alternative types of treatment programs and settings for identified types of patients and recommends elements that should be included in patientñtreatment matching, including ways to accommodate patients with special needs. The chapter describes elements of a treatment plan and the planning process, including the roles of counselor and patient, the importance of cultural and linguistic competence, motivation for treatment, and the need for a multidisciplinary team.

Chapter 7, Phases of Treatment, describes phases of treatment for patients in MAT. These phases are conceptualized as parts of a dynamic continuum of patient progress toward intended treatment outcomes. Each patient progresses according to his or her capacity and needs. After an orientation to introduce patients to the program, successive treatment phases include (1) the acute phase, during which patients attempt to eliminate illicit-opioid use and lessen the intensity of other problems associated with their addiction, (2) the rehabilitative phase, during which patients continue to address addiction while gaining control of other major life domains, (3) the supportive-care phase, during which patients maintain their abstinence while receiving other interventions when needed, (4) the medical-maintenance phase, during which patients are committed to continuing pharmacotherapy for the foreseeable future but no longer rely on other OTP services, (5) the tapering and readjustment phase, an optional phase in which patients gradually reduce and eliminate opioid treatment medication, and (6) the continuing-care phase, in which patients who have tapered from treatment medication continue regular contact with their treatment program. Phases of treatment address the therapeutic relationship, motivation, patientsí use of alcohol and illicit drugs, their mental and medical disorders, legal problems, and basic needs (including housing, education, and vocational training). Most patients need more frequent, intensive services in the acute phase, careful monitoring and diversified services during rehabilitative and supportive-care phases, and less frequent services in subsequent phases.

Chapter 8, Approaches to Providing Comprehensive Care and Maximizing Patient Retention, describes the core- and extended-care services essential to MAT effectiveness in OTPs. It explains how a comprehensive treatment program improves patient retention in treatment and the likelihood of positive treatment outcomes. Patients who receive regular, frequent, integrated psychosocial and medical services along with opioid pharmacotherapy often realize better outcomes than those who receive only limited services. Counseling services are integral to comprehensive maintenance treatment and can be behavioral, psychotherapeutic, or family oriented. Strategies that target relapse prevention also should be part of any comprehensive treatment program. The chapter describes ways to increase patient retention and avoid administrative discharge. Administrative discharge usually results in rapid relapse and may lead to incarceration or death. Clear communication and awareness on the part of both patients and staff members help avoid administrative discharge.

Chapter 9, Drug Testing as a Tool, presents an overview of drug testing in OTPs. Drug testing provides an objective measure of treatment efficacy and a tool to monitor patient progress, as well as information for quality assurance, program planning, and accreditation. OTPs must ensure the clinical utility of test results and protect patientsí privacy. Several drug-testing methodologies are available or in development, including tests of urine, oral fluid, blood, sweat, and hair. The chapter describes the benefits and limitations of these tests. Most often, OTPs use urine drug testing by immunoassay or thin-layer chromatography because these methods are the least costly and best validated of all options, but the Center for Substance Abuse Treatment has indicated that

oral-fluid testing may be an alternative approach in OTPs. The chapter describes criteria that an OTP should use to collect specimens and how treatment providers should respond to test results that indicate possible treatment problems.

Chapter 10, Associated Medical Problems in Patients Who Are Opioid Addicted, focuses on diagnosis and treatment of the medical conditions most commonly seen in MAT patients. A primary issue in MAT is deciding which medical services patients should receive in house versus through referral to outside providers. Chapter 10 examines the factors that influence this determination and reviews the screening services and protocols OTPs should have in place to evaluate patientsí acute and chronic medical problems and to perform periodic reassessments.

Chapter 11, Treatment of Multiple Substance Use, discusses problems associated with patientsí continued abuse of other substances, which is likely to affect patientsí participation in MAT, proper use of medication, and mental and physical health. Some substances, such as alcohol and certain sedatives, have a potentially lethal effect when combined with an opioid agonist or partial agonist medication. A number of interventions can address the continued abuse of other substances, including increased drug testing and the use of disulfiram, contingency management, dose adjustments, and counseling.

Chapter 12, Treatment of Co-Occurring Disorders, addresses issues for patients who have substance use and co-occurring mental disorders. These patients often exhibit behaviors or experience emotions that interfere with treatment and require special interventions. The chapter describes the prevalence of co-occurring disorders, screening and diagnosis of these disorders, and the effects of such disorders on treatment outcomes. It discusses general issues, specific psychiatric diagnoses, and a range of interventions (including psychoeducation, psychotherapy, and pharmacotherapy) to treat co-occurring disorders. The chapter explores special issues such as acute psychiatric danger, how to handle emergencies, and the effect of co-occurring disorders on behaviors that increase the risk of infectious diseases.

Chapter 13, Medication-Assisted Treatment for Opioid Addiction During Pregnancy, describes the complications associated with pregnancy and opioid addiction and how pregnancy should be addressed during MAT to reduce the potential for harm to a pregnant woman in MAT and her fetus. Among the main concerns are those related to HIV/AIDS and hepatitis C. The chapter describes how to adjust methadone dosage and manage overdose and withdrawal and addresses the postpartum treatment of mother and child, including topics such as breast-feeding and neonatal abstinence syndrome. The chapter focuses on methadone, which has been accepted for treating opioid addiction during pregnancy since the late 1970s.

Chapter 14, Administrative Considerations, covers the challenging administrative aspects of managing and staffing the complex and dynamic environment of an OTP. Successful treatment outcomes depend on the competence, values, and attitudes of staff members. To develop and retain a stable team of treatment personnel, program administrators must recruit and hire qualified, capable, culturally sensitive individuals; offer competitive salaries and benefit packages; and provide good supervision and ongoing training. Implementing community relations and community education efforts is important for OTPs. Outreach and educational efforts can dispel misconceptions about MAT and people in recovery. Finally, the chapter provides a framework for gathering and analyzing program performance data. Program evaluation contributes to improved treatment services by enabling administrators to base changes in services on evidence of what works. Evaluation also serves as a way to educate and influence policymakers and public and private payers.

Appendix D, Ethical Considerations in MAT, explores ethical issues inherent in MAT and provides a structure that administrators and clinicians can use in considering how to resolve them.

1 Introduction

In This Chapter…

Opioid addiction is a problem with high costs to individuals, families, and society. Injection drug use-associated exposure accounts for approximately one-third of all AIDS cases diagnosed in the United States through 2003 (National Center for HIV, STD and TB Prevention 2005) and for many cases of hepatitis C (National Institute on Drug Abuse 2000; Thomas 2001). In the criminal justice system, people who use heroin account for an estimated one-third of the $17 billion spent each year for legal responses to drug-related crime. Indirect costs from lost productivity and overdose also are high (Mark et al. 2001), and people with opioid addictions and their families experience severe reductions in their quality of life. The increasing abuse of prescription opioids is another major concern, both for their damaging effects and as gateway drugs to other substance use (see chapter 2).

Purpose of This TIP

This Treatment Improvement Protocol (TIP) is a guide to medication-assisted treatment for opioid addiction (MAT) in opioid treatment programs (OTPs). Compared with MAT in other settings, such as physiciansí offices or detoxification centers, treatment in OTPs provides a more comprehensive, individually tailored program of medication therapy integrated with psychosocial and medical treatment and support services that address most factors affecting each patient. Treatment in OTPs also can include detoxification from illicit opioids and medically supervised withdrawal from maintenance medications.

This TIP combines and updates TIP 1 (***State Methadone Treatment Guidelines***, published in 1993), TIP 10 (***Assessment and Treatment of Cocaine-Abusing Methadone-Maintained Patients***, published in 1994), TIP 20 (***Matching Treatment to Patient Needs in Opioid Substitution Therapy***, published in 1995), and TIP 22 (***LAAM in the Treatment of Opiate Addiction***, published in 1995). It incorporates the many changes in MAT that have occurred since the publication of TIP 1, primarily as they are reflected in OTPs, and discusses the challenges that remain.

Key Definitions

The glossary (Appendix C) and list of acronyms (Appendix B) at the back of the book provide definitions of key words, terms, acronyms, and abbreviations. Particularly important distinctions among selected terms and phrases are discussed below.

Distinctions between dependence and addiction vary across treatment fields. This TIP uses the term ìdependenceî to refer to physiological effects of substance abuse and ìaddictionî for physical dependence on and subjective need and craving for a psychoactive substance either to experience its positive effects or to avoid negative effects associated with withdrawal from that substance.

The intended audience for this TIP is treatment providers and administrators working in OTPs.

MAT is any treatment for opioid addiction that includes a medication (e.g., methadone, buprenorphine, levo-alpha acetyl methadol [LAAM], naltrexone) approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment. MAT may be provided in an OTP or an OTP medication unit (e.g., pharmacy, physicianís office) or, for buprenorphine, a physicianís office or other health care setting. Comprehensive maintenance, medical maintenance, interim maintenance, detoxification, and medically supervised withdrawal (defined under ìTreatment Optionsî below and individually in the glossary) are types of MAT.

An OTP is any treatment program certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication-assisted treatment for patients who are opioid addicted. An OTP can exist in a number of settings, including, but not limited to, intensive outpatient, residential, and hospital settings. Types of treatment can include medical maintenance, medically supervised withdrawal, and detoxification, either with or without various levels of medical, psychosocial, and other types of care.

The term ìabstinenceî in this TIP refers to nonuse of alcohol or illicit drugs (drugs not approved by FDA), as well as nonabuse of prescription drugs. Abstinence does not refer to withdrawal from legally prescribed maintenance medications for addiction treatment (for which ìmedically supervised withdrawalî is the preferred term).

Terminology continues to evolve for describing the combination of substance use and mental disorders. In this TIP, ìco-occurringî is the preferred term, but others use ìcoexisting,î ìdual diagnosis,î and ìcomorbidî to describe the combination of current or former substance use disorders and any other Axis I or any Axis II mental disorders recognized by the ***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*** (American Psychiatric Association 2000). (See also TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** [CSAT 2005***b***].)

Audience for This TIP

The intended audience for this TIP is treatment providers and administrators working in OTPs. Other groups that want to understand the principles and procedures followed in MAT also will benefit.

A Decade of Change

Several forces are transforming the MAT field. The implementation of an accreditation system (***Federal Register*** 64:39814) is standardizing and improving opioid addiction treatment (for

details, see 42 CFR, Part 8). Choices of medication, including methadone, buprenorphine, LAAM, and naltrexone (see chapter 3), now are available to treat opioid addiction. Each has its own benefits and limitations. Continued research on opioid addiction and treatment is clarifying what works to improve treatment outcomes, with an emphasis on accelerating the incorporation of evidence-based methods into treatment. Changes in the health care system nationwide (e.g., the growth of managed care and effects of the Health Insurance Portability and Accountability Act) are having an effect on OTPs and other types of health care programs. Understanding and acceptance of opioid addiction as a medical disorder by patients, health care providers, the media, and the public have increased since the publication of TIP 1.

MATóA More Accepted Form of Treatment

Opioid addiction as a medical disorder

Discussions about whether addiction is a medical disorder or a moral problem have a long history. For decades, studies have supported the view that opioid addiction is a medical disorder that can be treated effectively with medications administered under conditions consistent with their pharmacological efficacy, when treatment includes comprehensive services, such as psychosocial counseling, treatment for co-occurring disorders, medical services, vocational rehabilitation services, and case management services (e.g., Dole and Nyswander 1967; McLellan et al. 1993).

Dole (1988, p. 3025) described the medical basis of methadone maintenance as follows:

> The treatment is corrective, normalizing neurological and endocrinologic processes in patients whose endogenous ligand-receptor function has been deranged by long-term use of powerful narcotic drugs. Why some persons who are exposed to narcotics are more susceptible than others to this derangement and whether long-term addicts can recover normal function without maintenance therapy are questions for the future. At present, the most that can be said is that there seems to be a specific neurological basis for the compulsive use of heroin by addicts and that methadone taken in optimal doses can correct the disorder.

Similarities to other medical disorders

McLellan and colleagues (2000) compared basic aspects of substance addiction with those of three disordersóasthma, hypertension, and diabetesówhich universally are considered ìmedicalî and usually chronic and relapsing and for which behavioral change is an important part of treatment. They found that genetic, personal-choice, and environmental factors played comparable roles in the etiology and course for these disorders and that rates of relapse and adherence to medication were similar, although substance addiction often was treated as an acute, not chronic, illness. Their review of outcome literature showed that, as with the other disorders, substance addiction has no reliable cure but that patients who comply with treatment regimens have more favorable outcomes. Fewer than 30 percent of patients with asthma, hypertension, or diabetes adhered to their medication regimens, prescribed diets, or other changes to increase their functional status and reduce their risk of symptom recurrence. As a result, 50 to 70 percent experienced recurrent symptoms each year to the point of requiring additional medical care to reestablish remission.

Another similarity found between opioid addiction and these medical disorders was their outcome predictors (McLellan et al. 2000). For example, patients who were older and employed with stable families and marriages were found to be more likely to comply with treatment and have positive treatment results than were younger, unemployed patients with less stable family support.

The concept of opioid addiction as a medical disorder was supported further by other treatment followup studies showing that opioid addiction has a reasonably predictable course, similar to such conditions as diabetes, hypertension, and asthma. For example, Woody and Cacciola (1994) found that the risk of relapse for a person who was opioid addicted was highest during the first 3 to 6 months after cessation of opioid use. This risk declined for the first 12 months after cessation and continued to decrease but at a much slower rate. Results from other posttreatment studies indicated that roughly 80 percent of patients who are opioid addicted but leave MAT resume daily opioid use within 1 year after leaving treatment (e.g., Magura and Rosenblum 2001).

Similar to patients with other chronic disorders, many who are opioid addicted have been found to respond best to treatment that combines pharmacological and behavioral interventions. As detailed throughout this TIP, treatment of opioid addiction with maintenance medication, along with other treatment services for related problems that affect patientsí motivation and treatment compliance, increases the likelihood of cessation of opioid abuse. Conversely, discontinuation of maintenance medication often results in dropout from other services and a return to previous levels of opioid abuse, with its accompanying adverse medical and psychosocial consequences (Ball and Ross 1991). Entry into comprehensive maintenance treatment provides an opportunity to prevent, screen for, and treat diseases such as HIV/AIDS, hepatitis B and C, and tuberculosis (see chapter 10) and to increase compliance with medical, psychiatric, and prenatal care (Chaulk et al. 1995; Umbricht-Schneiter et al. 1994). Recent data on buprenorphine indicate that treatment with this medication, like methadone, has similar positive outcomes (CSAT 2004***a***; Johnson et al. 2000; Kakko et al. 2003).

Viewing opioid addiction as a medical disorder is consistent with the idea that treatment of even severe cases improves outcomes, just as in other chronic and relapsing medical disorders, even before abstinence is achieved. For example, Metzger and colleagues (1998) found that substance abuse treatment was associated with a significantly lower risk of HIV infection than was nontreatment. Treatment also was associated with a significant reduction, but not necessarily cessation, of drug use for many individuals. Similar findings on the positive health outcomes associated with maintenance treatment of opioid addiction, regardless of whether abstinence was attained, were seen in studies finding that methadone maintenance decreases overdose death. Data on benefits of partial responses to maintenance treatment resemble the benefits of treatment for other chronic medical disorders in terms of symptom alleviation. An analogy with MAT would be the desirability of reducing the risk of HIV infection, overdose, and the many psychosocial complications of addiction, which is not as desirable as the benefits of attaining complete abstinence from opioids but is associated with significantly improved patient health and well-being. The goal is always reducing or eliminating the use of illicit opioids and other illicit drugs and the problematic use of prescription drugs.

The medical community recognizes that opioid addiction is a chronic medical disorder that can be treated effectively with a combination of medication and psychosocial services. An important development in MAT during the 1990s was the 1997 publication of recommendations by a National Institutes of Health consensus panel on effective medical treatment of opiate addiction. After hearing from experts and the public and examining the literature, the panel concluded that ì[opioid addiction] is a medical disorder that can be effectively treated with significant benefits for the patient and societyî (National Institutes of Health 1997***b***, p. 18). That panel explicitly rejected the notion ìthat [addiction] is self-induced or a failure of willpower and that efforts to treat it inevitably failî (p. 18). It called for ìa commitment to offer effective treatment for [opioid addiction] to all who need itî (p. 2). The panel also called for Federal and State efforts to reduce the stigma attached to MAT and to expand MAT through increased funding, less restrictive

regulation, and efforts to make treatment available in all States (p. 24). The consensus panel for this TIP further recommends that access to treatment with methadone and other FDA-approved medications for opioid addiction be increased for people who are incarcerated, on parole, or on probation.

The trend toward greater acceptance of MAT as an effective treatment for opioid addiction has resulted in fewer State-mandated restrictions for treatment. For example, many States have removed restrictions on the length of time that patients may remain in treatment.

More Treatment Programs and More Patients in Treatment

In 1993, when TIP 1 was published, approximately 750 registered OTPs were treating some 115,000 patients in 40 States, the District of Columbia, Puerto Rico, and the Virgin Islands (CSAT 1993***b***, p. 1). At this writing, more than 1,100 OTPs operating in 44 States, the District of Columbia, Puerto Rico, and the Virgin Islands are treating more than 200,000 patients (Substance Abuse and Mental Health Services Administration n.d.***b***; Nicholas Reuter, personal communication, June 2004). As of this writing, methadone treatment is not available in six States: Idaho, Mississippi, Montana, North Dakota, South Dakota, and Wyoming.

Most expansion in the treatment system in the past 10 years has occurred in the proprietary sector. Historically, most OTPs were funded publicly, whereas proprietary programs were in the minority. In the 1980s, public funding for methadone treatment began to be reduced, along with State, Federal, and local budgets, and increasingly was replaced by private fee-for-service treatment programs in which patients bore more of the costs (Knight et al. 1996***a***, 1996***b***; Magura and Rosenblum 2001).

Choices of Medications

The National Institute on Drug Abuse (NIDA) has been working to broaden the array of effective treatment medications for chronic opioid addiction. Just after the publication of TIP 1, FDA approved the use of LAAM, although its use has been curtailed substantially since then (see chapter 3). In October 2002, FDA approved two new formulations containing buprenorphine for treatment of opioid addiction. Buprenorphine is used to treat individuals who have been opioid addicted for less than 1 year, as well as patients for whom buprenorphineís unique properties are beneficial (CSAT 2004***a***). The opioid antagonist naltrexone is available to treat people who are opioid addicted and have undergone medically supervised withdrawal. These medications are discussed in chapter 3.

> The medical community recognizes that opioid addiction is a chronic medical disorder that can be treated effectively…

Treatment Options

OTPs can provide several treatment options:

- Maintenance treatment combines pharmacotherapy with a full program of assessment, psychosocial intervention, and support services; it is the approach with the greatest likelihood of long-term success for many patients.
- Medical maintenance treatment is provided to stabilize patients and may include long-term provision of methadone, buprenorphine, LAAM, or naltrexone, with a reduction in clinic attendance and other services. A patient can receive medical maintenance at an OTP, after he or she is stabilized fully. The patient usually must complete a comprehensive treatment program first. The decision about whether to provide medical maintenance must be made by a licensed practitioner. A designated medication unit

(e.g., physicianís office, pharmacy, long-term care facility) affiliated with an OTP can provide some medical maintenance services. To reduce clinic attendanceóa key feature of medical maintenanceópatients must qualify, subject to variations in State regulations (which may be more stringent than Federal regulations), to receive 7- to 14-day supplies of methadone for take-home dosing after 1 year of continuous treatment and 15- to 30-day supplies after 2 years of continuous treatment in an OTP (if additional criteria are satisfied [see chapter 5]) (42 CFR, Part 8 ß 12(h); ***Federal Register*** 66:4079).

- Detoxification from short-acting opioids involves medication and, perhaps, counseling or other assistance to stabilize patients who are opioid addicted by withdrawing them in a controlled manner from the illicit opioids.
- Medically supervised withdrawal treatment involves the controlled tapering of treatment medication for patients who want to remain abstinent from opioids without the assistance of medication.

Based on the framework provided by the Drug Addiction Treatment Act of 2000 (21 United States Code 823(g)), qualified practitioners are authorized to use Subutex® and Suboxone® (see chapter 3) to treat chronic opioid addiction in an office-based opioid treatment (OBOT) or other health care setting.

Dosage decisions should be appropriate and tailored to each patient.

These alternatives are increasing access to care as OTPs broaden their range of treatment options, more physicians offer OBOT and become better trained in MAT principles and methods, and individuals with opioid addiction seek new points of treatment entry. At this writing, the availability of these options varies, often because of individual State regulations.

Changes in the Federal Regulatory System

On May 18, 2001, SAMHSA promulgated a new accreditation oversight system. Its goal is to ìreduce the variability in the quality of opioid treatment services, and reform the treatment system to provide for expanded treatment capacityî (***Federal Register*** 64:39814). As OTPs meet these national standards, treatment improvement is expected to continue along with increased attention to program evaluation and quality improvement mechanisms. The consensus panel hopes that this TIP will contribute to the movement toward quality-driven treatment standards.

Remaining Challenges

Although important strides have been made, much remains to be done to improve and expand treatment and to address the stigma that affects patients and programs.

Administering Appropriate Dose Levels

The consensus panel believes that programs should monitor and adjust patientsí dose levels of methadone and other opioid treatment medications to ensure that they receive therapeutic dosages without regard to arbitrary dose-level ceilings that are unsupported by research evidence. Dosage decisions should be appropriate and tailored to each patient. Progress has been made to ensure that patients receive the therapeutic dosage levels they need to remain stabilized; however, the panel finds it troubling that some OTPs still fail to prescribe medication in adequate doses (DíAunno and Pollack 2002).

Treating Patients Who Have More Complex Problems

Complex problems can complicate patientsí diagnosis and treatment. When TIP 1 was published, the opioid addiction treatment system faced two major challengesóthe spread of HIV/AIDS and the problem of untreated co-occurring disorders. The consensus panel believes that the provision of psychiatric services at or through OTPs has not kept pace with best practices. It is critical that OTPs be prepared to diagnose and treat co-occurring disorders aggressively, either directly or by referral. This issue is discussed in chapter 12.

The treatment system is grappling with the implications of hepatitis C virus (HCV) infection among people who inject drugs, with estimates of HCV infection in this group ranging from 60 percent on average nationwide (National Institute on Drug Abuse 2000) to 90 percent in some regions (Thomas 2001). OTPs face the challenge of how to provide patient education and HCV testing for people who inject drugs.

Patterns of opioid abuse have changed in the past decade. For example, in some areas of the country, patients are presenting with addiction to pain management medications as a primary admission indication (CSAT 2001***a***; Office of National Drug Control Policy 2002). OTPs report that patients addicted to pain management medications require higher therapeutic methadone levels than other patients. Since the mid-1990s, the prevalence of lifetime heroin use has increased for both youth and young adults. From 1995 to 2002, the rate among youth ages 12 to 17 increased from 0.1 to 0.4 percent; among young adults ages 18 to 25, the rate rose from 0.8 to 1.6 percent (Substance Abuse and Mental Health Services Administration 2003***c***).

Promoting Evidence-Based Treatment Services

Throughout this TIP are many examples of types of interventionsócomprehensive MAT, medical maintenance, psychosocial interventions, and moreóand program characteristics that have been demonstrated to improve retention and outcomes for patients. The consensus panel recommends that program administrators and treatment providers compare their practices with these evidence-based practices and make necessary changes where appropriate. Moreover, OTPs should measure their outcomes continuously, using appropriate program evaluation tools, to improve treatment quality (see chapter 14). Finally, OTPs may want to partner with the research community to investigate and adopt new interventions for improving outcomes.

In addition, SAMHSA has established and funded the Addiction Technology Transfer Center (ATTC) Network, which is dedicated to improving the skills and knowledge of substance abuse treatment providers and increasing their awareness of research findings. Regional centers in the ATTC Network seek to accomplish this goal by identifying and advancing opportunities to improve addiction treatment through the dissemination of new information in response to emerging needs and developments in the treatment field. (For more information, visit the ATTC Web site at www.nattc.org.)

Expanding the Treatment System

Although the number of patients enrolled in OTPs for addiction treatment has almost doubled since 1993, an estimated 898,000 people chronically or occasionally use heroin in the United States (Office of National Drug Control Policy 2003). Only about 20 percent of people who use heroin are being treated. For people who abuse opioid medications normally obtained by prescription, the percentage in treatment is even lower.

Lack of funding for services remains a significant barrier to treatment. In many States, Medicaid does not reimburse MAT services; accordingly, patients, many of whom

have limited financial resources, are compelled to finance their treatment.

Making Treatment Available to Criminal Justice Populations

Criminal justice populations are in critical need of opioid addiction treatment, yet most do not have access to MAT (National Center on Addiction and Substance Abuse 1998; National Drug Court Institute 2002; U.S. Department of Justice 1999). Resistance to MAT by many in the criminal justice system may be rooted in the traditional view that medical maintenance treatment is substitution of one drug for another (National Center on Addiction and Substance Abuse 1998). The Rikers Island jail facility in New York City has been providing inmates access to methadone treatment since 1987 (National Drug Court Institute 2002). Rhode Island jail facilities offer a 30-day dose-tapering program. The consensus panel understands that few other correctional institutions have provided MAT services.

Promoting Comprehensive Treatment

In its 1999 publication, ***Principles of Drug Addiction Treatment: A Research-Based Guide***, NIDA stressed the importance of comprehensive treatment services by devoting 3 of the 13 principles of effective drug addiction treatment to comprehensive care (see Exhibit 1-1) (National Institute on Drug Abuse 1999).

The consensus panel believes that it is critical to emphasize the central importance of comprehensive care as more physicians begin to use buprenorphine to treat chronic opioid addiction in their private offices. Ideally, a full continuum of care should integrate the services of primary care physicians who dispense opioid treatment medications in private offices and other medication units with the services provided by counselors, case managers, and other essential staff in OTPs.

Combating Stigma

For almost a century, the predominant view of opioid addiction has been that it is a self-induced or self-inflicted condition resulting from a character disorder or moral failing and that this condition is best handled as a criminal matter (see chapter 2). Use of methadone and other therapeutic medications has been viewed traditionally as substitute therapyómerely replacing one addiction with another and the treatment of choice for those too weak to overcome temptation. The stigma associated with

Exhibit 1-1

NIDA Comprehensive Care-Related Principles of Effective Drug Addiction Treatment

- ï Effective treatment attends to multiple needs of the individual, not just his or her drug use.
- ï Counseling (individual and/or group) and other behavioral therapies are critical components of effective treatment for addiction.
- ï Medications are an important element of treatment for many patients, especially when combined with counseling and other behavioral therapies.

Source: National Institute on Drug Abuse 1999.

MAT has been unique in its permeation of community institutions, affecting the attitudes of medical and health care professionals; social services agencies and workers; paraprofessionals; employers, families, and friends of persons who are opioid addicted; and other people who formerly abused substances, as well as influencing criminal justice policies, creating political opposition, and limiting funding and space for OTPs.

Although diversion control is an important part of MAT, public policy sometimes has seemed to place greater emphasis on protecting society from methadone than on the addiction, violence, and infectious diseases that these medications help alleviate (Institute of Medicine 1995; Joseph et al. 2000; Nadelmann and McNeeley 1996). The cost-effectiveness of MAT often has been overlooked (see chapter 2).

Stigma affects patients in various ways. It discourages them from entering treatment and prompts them to leave treatment early. It creates a barrier for those trying to access other parts of the health care system. A striking example is the failure of many medical practitioners to medicate pain adequately in this group. In addition, the refusal of some organ transplant programs to provide liver transplants to patients maintained on methadone may be a result of stigma, as well as a lack of convincing data on outcomes for methadone patients who receive transplants.

Stigma affects programs too. It prevents new programs from opening when community opposition develops. It can affect a programís internal operations. Staff members who work in OTPs sometimes absorb societyís antipathy toward patients in MAT and may deliver program services with a punitive or countertherapeutic demeanor. OTPs must guard against these attitudes through supervision, education, and leadership efforts (see chapter 14).

Several factors have made the destructive force of stigma particularly intractable, including the isolation of MAT from mainstream medicine, negative media reports about treatment, and the public impressions made by poorly run programs. Fortunately, positive changes are occurring in each area.

Positive stories about MAT in the media are sometimes overshadowed by highly charged negative accounts, for example, stories about patients loitering outside OTPs or diversion of take-home doses. SAMHSA, recognizing that ì[s]ignificant reduction in stigma and changes in attitudes will require a concerted effort based on systematic researchî (CSAT 2000***b***, p. 4), has undertaken a national educational campaign, titled Partners for Recovery. Many OTP managers and staff members have isolated themselves from their communities, which contributes to negative stereotypes and media stories. Managers and staff members should develop effective skills for working with the media. The consensus panel believes that the patient advocacy movement also can advance a national educational campaign about MAT.

Managers and staff members should develop effective skills for working with the media.

Strong efforts are needed to eliminate stigma within OTPs as well. Staff members should treat patients with respect and pay attention to the terms they use. The term ìsubstitution treatmentî should be avoided because it incorrectly implies that long-acting opioid medications act like heroin and other short-acting opioids. Terms such as ìdirtyî and ìcleanî in reference to drug-test specimens should be replaced by more clinically useful terms such as ìpositiveî and ìnegative,î respectively. The use of criminal justice terms such as ìprobationary treatmentî should be replaced with clinically appropriate language (see chapter 14).

Finally, programs should become better neighbors. Idle, perhaps intoxicated, patients who

remain near an OTP can become, by default, the programís public representatives and easy targets for complaints from the community. Frequently, patient loitering is a result of insufficient program management. Patient conduct in and around OTPs should be considered both a treatment and a community relations concern.

The Future of MAT

This is an exciting and challenging time for the MAT field, as positive changes accelerate and reinforce one another. The consensus panel hopes that this publication will advance high-quality care in OTPs by providing up-to-date information on science-based, best-treatment practices and by highlighting sound ethical principles of treatment. Equipped with this TIP, the accreditation standards, and a developing alliance with the general medical community, OTPs should be able to improve and expand effective opioid addiction treatment throughout the country.

2 History of Medication-Assisted Treatment for Opioid Addiction

In This ChapterÖ

This chapter describes the history of opioid use and addiction in the United States; changes in the population groups affected by opioid addiction disorders; and this countryís social, political, legal, and medical responses. The chapter emphasizes factors affecting the development and course of medication-assisted treatment for opioid addiction (MAT) in opioid treatment programs (OTPs).

Opioid addiction has affected different population groups and socioeconomic classes in the United States at different times. Societyís response has changed along with changes in the groups or classes most affected, shifts in social and political attitudes toward opioid addiction, and the accumulation of more and better information about its causes and treatments (Musto 1999). The consensus panel for this TIP believes that an appreciation for the roots of opioid addiction and treatment is important because attitudes and beliefs about opioid use and addiction that are rooted in U.S. history over the past 150 years continue to influence policies governing MAT.

Emergence of Opioid Addiction as a Significant Problem and the Roots of Controversy

Many of todayís substances of abuse including the opioidsóprimarily opium, morphine, heroin, and some prescription opioidsógained their early popularity as curatives provided by physicians, pharmacists, and others in the healing professions or as ingredients in commercial products ranging from pain elixirs and cough suppressants to beverages. These products usually delivered the benefits for which they were used, at least initially, such as pain relief, increased physical and mental energy (or ìrefreshmentî), and reduced anxiety. For example, opioids were often the best available substances to relieve pain on Civil War battlefields. Unfortunately, the uncontrolled use of opioids either for prescribed and advertised benefits or for nonmedicinal effects leads to

increased tolerance and addiction. Tolerance increases the need for larger quantities of opioids, more frequent use, or combination with other substances to sustain their effects; it also increases the severity of withdrawal when addiction is not satisfied. Recognition of this problem has spurred a long-running debate among patients and people who use opioids, their families, physicians, researchers, community leaders, patient advocates, and government officials. This debate centers on two different views: (1) opioid addiction is a generally incurable disease that requires long-term maintenance with medication; or (2) opioid addiction stems from weak will, lack of morals, other psychodynamic factors, or an environmentally determined predilection that is rectified by criminalization of uncontrolled use and distribution and measures promoting abstinence.

[O]pioids were prescribed widely to alleviate acute and chronic pain, other types of discomfort, and stress.

The Changing Face of Opioid Addiction

Opioid addiction first emerged as a serious problem in this country during and after the Civil War, when opioids were prescribed widely to alleviate acute and chronic pain, other types of discomfort, and stress. Although a smaller pattern of nonmedical opioid use continued as well, mainly opium smoking among Chinese immigrants and members of the Caucasian ìundergroundî (e.g., prostitutes, gamblers, petty criminals), iatrogenic addiction was much more common (White 1998). By the late 19th century, probably two-thirds of those addicted to opioids (including opium, morphine, and laudanum) were middle- and upper-class White women, a fact Brecher and the Editors of Consumer Reports (1972, p. 17) attribute to ìthe widespread medical custom of prescribing opiates for menstrual and menopausal discomfort, and the many proprietary opiates prescribed for ëfemale troubles.íî Civil War veterans who were addicted by medical procedures composed another group, but their numbers were dwindling. By 1900, an estimated 300,000 persons were opioid addicted in the United States (Brecher and Editors 1972; Courtwright 2001; Courtwright et al. 1989).

During the late 19th and early 20th centuries, U.S. society generally viewed iatrogenic addiction among women and disabled war veterans sympatheticallyóas an unfortunate medical conditionóand treated these groups with tolerance and empathy, particularly because neither group presented major social problems (Courtwright 2001). Doctors usually prescribed more opioids for these patients, and sanatoriums were established for questionable ìcuresî of the resulting addictions. The chronic nature of opioid addiction soon became evident, however, because many people who entered sanatoriums for a cure relapsed to addictive opioid use after discharge. In Eugene OíNeillís autobiographical drama ìLong Dayís Journey Into Night,î for example, his father refuses to return OíNeillís mother, who is addicted, to a sanatorium because he is aware of the addictive qualities of morphine and is resigned to the inevitability of relapse (Courtwright 2001).

By the end of the 19th century, doctors became more cautious in prescribing morphine and other opioids, and the prevalence of opioid addiction decreased. Small groups still practiced opium smoking, but most Americans regarded it as socially irresponsible and immoral. It is noteworthy, however, that heroin, introduced in 1898 as a cough suppressant, also began to be misused for its euphoric qualities, gradually attracting new types of users. This development, along with diffusion of the hypodermic technique of drug administration, which gained popularity between 1910 and 1920, had a profound effect on opioid use and addiction in the 20th century and beyond (Courtwright 2001).

The size and composition of the U.S. opioid-addicted population began to change in the early 20th century with the arrival of waves of European immigrants. Courtwright (2001) portrays most users of opioids of this period as young men in their 20s: ìdown-and-outsî of recent-immigrant European stock who were crowded into tenements and ghettos and acquired their addiction during adolescence or early adulthood. They often resorted to illegal means to obtain their opioids, usually from nonmedical sources and specifically for the euphoric effects. ìGone was the stereotype of the addicted matron; in its place stood that of the street criminalî (Courtwright 2001, p. 1).

The initial treatment response in the early 20th century continued to involve the prescriptive administration of short-acting opioids. By the 1920s, morphine was prescribed or dispensed in numerous municipal treatment programs (Courtwright et al. 1989).

Addictive use of opium, cocaine, and heroin, along with drug-related crime, especially in poor urban communities, increasingly concerned social, religious, and political leaders. The tolerance and empathy shown toward Civil War veterans and middle-aged women evaporated; negative attitudes toward and discrimination against new immigrants probably colored views of addiction. Immigrants and others who trafficked in and abused drugs were viewed as a threat. As detailed below, societyís response was to turn from rudimentary forms of treatment to law enforcement (Brecher and Editors 1972; Courtwright 2001; Courtwright et al. 1989). For more on trends in the 1920s and 1930s, see ìEarly treatment effortsî below.

McCoy (n.d.) refers to a forced decline in opioid addiction during World War II, brought about by restrictions on shipping and strict port security, which produced a marked hiatus in global opium trafficking and caused the U.S. opioid-addicted population to drop to a historic low of about 20,000. Once smuggling resumed after the war, the population that had used opioids resumed the habit.

Another major change in the U.S. opioid-addicted population occurred after World War II. As many European immigrants moved from crowded cities, Hispanics and African-Americans moved into areas with preexisting opioid abuse problems, and the more susceptible people in these groups acquired the disorder (Courtwright 2001; Courtwright et al. 1989).

The post-World War II shift in the composition of opioid-addicted groups coincided with hardening attitudes toward these groups, leading some researchers to conclude that stigmatization of people with addiction disorders and their substances of abuse reflected, at least in part, class and ethnic biases. A portion of U.S. society appeared to view with disdain and fear the poor White, Asian, African-American, and Hispanic people with addiction disorders who lived in the inner-city ghettos (Courtwright et al. 1989).

Brecher and the Editors of Consumer Reports (1972) point out that, by the mid-1960s, the number of middle-class young White Americans using heroin was on the rise, as was addiction-related crime. By the 1970s, U.S. military involvement in Vietnam also was having an effect. From one-fourth (Brecher and Editors 1972) to one-half (Courtwright 2001) of American enlisted men in Vietnam were believed to have used or become addicted to heroin; however, White (1998) points out that the feared epidemic of heroin addiction among returning veterans did not materialize fully. He concludes, ìVietnam demonstrated that a pattern of drug use could emerge in response to a particular environment and that spontaneous remission could occur when the environment was changedî (p. 303).

By the 1980s, an estimated 500,000 Americans used illicit opioids (mainly heroin), mostly poor young minority men and women in the inner cities. Although this number represented a 66-percent increase over the estimated number of late 19th-century Americans with opioid addiction, the per capita rate was much less than in the late 19th century because the population had more than doubled

(Courtwright et al. 1989). Nevertheless, addiction became not only a major medical problem but also an explosive social issue (Courtwright 2001; Courtwright et al. 1989).

By the end of the 1990s, an estimated 898,000 people in the United States chronically or occasionally used heroin (Office of National Drug Control Policy 2003), and the number seeking treatment was approximately 200,000 (almost double the number during the 1980s). The abuse of opioids that normally were obtained by prescription was a growing concern because of both their damaging effects and their potential as gateway drugs to other substance use. Treatment admission rates for addiction to opioid analgesics more than doubled between 1992 and 2001 (Substance Abuse and Mental Health Services Administration 2004), and visits to emergency rooms related to opioid analgesic abuse increased 117 percent between 1994 and 2001 (Substance Abuse and Mental Health Services Administration 2003***b***).

Societyís Changing Response

The Harrison Narcotic Act of 1914

The Pure Food and Drug Act of 1906, which required medicines containing opioids to say so on their labels, was the first national response to the changing image of people with addictions (Brecher and Editors 1972). The Harrison Narcotic Act of 1914 was the earliest significant Federal attempt to place strict controls on opioids and other substances (Brecher and Editors 1972). Although U.S. mercantile and trade interests were also at stake, the widely held perception that people with addictions generally were members of a White criminal underclass or a Chinese minority has been portrayed as an underlying motivation for the statute (Courtwright 2001; Courtwright et al. 1989). The Harrison Act was conceived not as a prohibition law but as a measure to regulate the manufacture, distribution, and prescription of opioids, coca, and their derivatives. Under the actís provisions, manufacturers, pharmacists, and physicians had to be licensed, keep records for inspection, and pay modest fees to the U.S. Department of the Treasury, referred to hereafter as Treasury.

The act permitted physicians and dentists to dispense or distribute opioids ìto a patient . . . in the course of [the physicianís] professional practice onlyî (38 Stat. 786 [1914]). Although this provision permitted physicians to prescribe or dispense opioids so long as they kept the required records, Treasury interpreted the act as a prohibition on physiciansí prescribing opioids to persons with addictions to maintain their addictions. (Treasury was the agency responsible for enforcing the Harrison Act as well as prohibition laws.) Treasuryís position appeared to be that addiction is not a disease and the person with an addiction, therefore, was not a patient. It followed that any physician prescribing or dispensing opioids to such individuals was not doing so in the ìcourse of his professional practiceî (White 1998). In 1919, the United States Supreme Court upheld Treasuryís interpretation. This interpretation and enforcement of the Harrison Act effectively ended, until well into the 1960s, any legitimate role for the general medical profession in medication-assisted treatment for Americans who had drug addictions (White 1998).

Early treatment efforts

Until the 1919 Supreme Court decision upholding Treasuryís interpretation of the Harrison Act, numerous municipalities with large numbers of residents who were opioid addicted were operating treatment clinics in which morphine was prescribed or dispensed. Some clinics prescribed heroin and cocaine (Courtwright et al. 1989). These early OTPs varied in how they functioned; some provided detoxification treatment and others adopted a maintenance policy (Courtwright 2001; Gewirtz 1969). Perhaps the best known of these early OTPs were the Department of Health program in New York City, where those with addictions were detoxified with decreasing doses of heroin and morphine, and the program established by Dr. Willis Butler in Shreveport, Louisiana,

which not only detoxified patients but also maintained some of them on morphine (Courtwright et al. 1989).

Courtwright and others state that Treasury regarded these clinics as a threat to its anti-maintenance philosophy. By the early 1920s, it had succeeded in closing them through legal pressure, critical inspections, and threats. The last program to be closed was Dr. Butlerís in Shreveport (Courtwright 2001; Courtwright et al. 1989).

In the 1920s, an increase in crime related to the acquisition of illicit opioids was reported in cities throughout the country. In 1929, Congress appropriated funds to establish two new treatment facilities, initially called ìnarcotics farmsî (White 1998), in Fort Worth, Texas, and Lexington, Kentucky. The Lexington facility, which opened to patients in 1935, was renamed the U.S. Public Health Service Narcotics Hospital in 1936. These institutions detoxified patients with opioid addiction who entered voluntarily, and they also served as hospitals for prison inmates who had opioid addictions and were legally committed through a Federal court. The prescribed stay was about 6 months, although some patients stayed longer. Prisoners could stay for up to 10 years. These hospitals offered social, medical, psychological, and psychiatric services in addition to detoxification and had a low patient-to-staff ratio (about 2 to 1), but the atmosphere was described as prisonlike, especially at the Lexington facility (White 1998). Two major followup studies showed the program to be a failure. One reported a relapse rate of 93 percent in 1,881 former patients over a 1.0- to 4.5-year followup period (Hunt and Odoroff 1962). The second found a relapse rate of 97 percent in 453 former patients over followup periods of 6 months to 5 years (Duvall et al. 1963). The Lexington hospital facility was turned over to the Bureau of Prisons in 1974 (Courtwright et al. 1989). Despite the failure of these programs, White credits the research conducted there with providing ìmuch of the foundation upon which modern treatment advances were builtî (White 1998, p. 126).

The increase in heroin addiction in New York City after World War II led, in 1952, to the establishment of Riverside Hospital for adolescents with addiction disorders. This program also proved to be a failure. A followup study in 1956 showed a high posttreatment relapse rate (e.g., at least 86 percent of patients admitted in 1955), and the Riverside facility was closed in 1961 (Brecher and Editors 1972).

Experiment in civil commitment

Civil commitment is portrayed by Brecher and the Editors of Consumer Reports (1972) and White (1998) as legislation enabling those with substance addiction and those ìin imminent danger of becoming addictedî (White 1998, p. 250) to be confined in rehabilitation centers without having first committed or been convicted of a crime. Civil commitment was instituted in California and New York in the 1960s to allay fears about addiction-related crimes against people and property in the inner cities. People with addictions could be committed to facilities through a voluntary process that included a medical examination to validate the presence of an addiction, or they could be committed for 3 years when arrested on a misdemeanor charge, as an alternative to a jail sentence. The civil commitment program instituted in New York in 1966 turned out to be exceedingly expensive, and the positive results were minimal (Brecher and Editors 1972; Inciardi 1988). The great majority of those admitted, treated, and paroled to aftercare programs dropped out of these programs, and they usually could not be located. A review of Californiaís civil commitment experience in the

> Treasuryís position appeared to be that addiction is not a disease… and the personÖ not a patient.

1960s showed that five of every six patients committed for addictions and subsequently placed on aftercare relapsed, were rearrested, dropped out of treatment, died, or were removed from the program by writs of habeas corpus (Joseph 1988; Joseph and Dole 1970).

Although statutes permitting involuntary commitment might remain on the books in some States, such laws rarely have been used to commit people who abuse substances and who are not under criminal justice jurisdiction (Anglin 1988). Court decisions after the 1960s generally have required that an individual be a danger to himself or herself or others before the legal system can use involuntary commitment (e.g., ***OíConnor*** v. ***Donaldson***, 422 U.S. 563, 1975).

The search for alternatives

In New York, death rates associated with the injection of heroin increased from 7.2 to 35.8 per 10,000 deaths between 1950 and 1961 (Frank 2000; Joseph et al. 2000). In the 1960s and 1970s, more than 150,000 names were added to the Narcotics Register in New York City. (The Narcotics Register, active from 1967 to 1974, was a list of known or suspected persons with addictions.)

Support for opioid maintenance grew, especially because no effective psychosocial alternative existed to treat the large number of people with opioid addictions.

By the middle to late 1960s, illicitñopioid-related mortality had become the leading cause of death for young adults from ages 15 to 35 in New York City. The number of serum hepatitis (now called hepatitis B) cases related to contaminated needles also was increasing. Record numbers of people with opioid addictions were arrested for drug-related crimes (e.g., possession, sales, robbery, burglary), and overcrowded jails had no effective method to ease detoxification (Inciardi 1988; Joseph and Dole 1970). By 1968, the Manhattan County Jail for Men (also known as the Tombs) had been wracked by riots blamed on poor living conditions, severe overcrowding, and lack of medical care for inmates with drug addictions.

As the incidence of addiction and related criminal activity rose dramatically in urban areas, concern grew in the legal and medical communities because increased incarceration had failed to stem the tide. The legal and medical professions were perturbed by the post-World War II rise in opioid addiction in the United States and the ineffectiveness of Federal regulatory policy. In 1958, a joint committee of the American Bar Association and the American Medical Association (AMA) issued a report recommending that an outpatient facility prescribing opioids to treat addiction be established on a controlled experimental basis (Brecher and Editors 1972).

Other groups voiced support for the concept of opioid maintenance programs. The New York Academy of Medicine recommended, in 1955 and again in 1963, that clinics be established in affiliation with hospitals to dispense opioids in a controlled manner to patients addicted to illicit opioids. In 1956, the AMA advocated a research project to investigate the feasibility of dispensing opioids in an OTP. In 1963, the Kennedy administrationís Advisory Commission on Narcotic and Drug Abuse also recommended research to determine the effectiveness of outpatient OTPsí dispensing of opioids to people addicted to opioids (Brecher and Editors 1972). In the early 1970s, faced with increased opioid-related drug use and crimes, the Nixon administration greatly increased funding to stem the supply of illicit opioids, primarily heroin, entering the United States. It also greatly increased funding for methadone maintenance, and the number of patients receiving methadone increased from 9,000 in 1971 to 73,000 in 1973 (Courtwright 2001). Support for opioid

maintenance grew, especially because no effective psychosocial alternative existed to treat the large number of people with opioid addictions.

Origins of Opioid Maintenance Therapy

Development of Medications To Treat Opioid Addiction

Early rationale for methadone maintenance treatment

In 1962, Dr. Vincent P. Dole, a specialist in metabolism at The Rockefeller University, became chair of the Narcotics Committee of the Health Research Council of New York City. After studying the scientific, public health, and social ramifications of addiction in the city, he received a grant to establish a research unit to investigate the feasibility of opioid maintenance. In preparing for this research, he read ***The Drug Addict as a Patient*** by Dr. Marie E. Nyswander (Nyswander 1956), a psychiatrist with extensive experience treating patients who were addicted to opioids. She was convinced that these individuals could be treated within general medical practice. She also believed that many would have to be maintained on opioids for extended periods to function because a significant number of people who attempted abstinence without medication relapsed, in spite of detoxifications, hospitalizations, and psychotherapy (Brecher and Editors 1972; Courtwright et al. 1989). Dr. Nyswander joined Dr. Doleís research staff in 1964. Among others joining the team was clinical investigator Dr. Mary Jeanne Kreek.

These researchers realized that morphine, which is related to heroin, was not a good choice as an opioid maintenance drug because patientsí social functioning was impaired by morphineís sedating effects (White 1998). Also, the short half-life of morphine required several injections per day, and, as tolerance developed, increasing amounts were needed over a short time for patients to remain stable (Brecher and Editors 1972). Other short-acting opioids, such as heroin, codeine, oxycodone, and meperidine (Demerol®), showed similar results (Dole 1980, 1988).

Development of methadone

With short-acting opioids eliminated as options for maintenance therapy, research focused on methadone. Methadone appeared to be longer acting and effective when administered orally. It also was selected on the basis of observations of its use in patients withdrawing from heroin and as an analgesic in the experimental treatment of pain (Dole 1980, 1988). In 1964, technology was not available to measure blood levels of heroin, morphine, or methadone to assess duration of action. Proof of the efficacy of methadone maintenance treatment depended on observation and recognition by researchers.

In an initial study, methadone was administered to two patients previously maintained on morphine. Once tolerance for daily doses of 50 to 120 mg was established, patients could function normally without the anxiety associated with drug craving (White 1998). During this research, the following important findings about methadone maintenance were noted, all supporting its efficacy and benefits (Dole 1980, 1988):

- Patients did not experience euphoric, tranquilizing, or analgesic effects. Their affect and consciousness were normal. Therefore, they could socialize and work normally without the incapacitating effects of short-acting opioids such as morphine or heroin.
- A therapeutic, appropriate dose of methadone reduced or blocked the euphoric and tranquilizing effects of all opioid drugs examined (e.g., morphine, heroin, meperidine, and opium), regardless of whether a patient injected or smoked the drugs.
- No change usually occurred in tolerance levels for methadone over time, unlike for morphine and other opioids; therefore, a dose could be held constant for extended periods (more than 20 years in some cases).

- Methadone was effective when administered orally. Because it has a half-life of 24 to 36 hours, patients could take it once a day without using a syringe.
- Methadone relieved the opioid craving or hunger that patients with addiction described as a major factor in relapse and continued illegal use.
- Methadone, like most opioid-class drugs, caused what were considered minimal side effects, and research indicated that methadone was medically safe and nontoxic.

Expansion of methadone maintenance from research project to public health program

In 1965, the initial research project on methadone safety and efficacy was transferred to Manhattan General Hospital in New York City (Brecher and Editors 1972). Because Dole and his colleagues knew that an independent evaluation of this new treatment would be necessary, a team headed by Dr. Frances Rowe Gearing was formed at Columbia University School of Public Health to evaluate patient progress as this treatment expanded. In general, the team found that patientsí social functioning improved with time in treatment, as measured by elimination of illicit-opioid use and better outcomes in employment, school attendance, and homemaking. Most patients were stabilized on methadone doses of 80 to 120 mg/day. Most patients who remained in treatment subsequently eliminated illicit-opioid use. However, 20 percent or more of these patients also had entered treatment with alcohol and polysubstance abuse problems, despite intake screening that attempted to eliminate these patients from treatment (Gearing and Schweitzer 1974). Methadone treatment was continued for these patients, along with attempts to treat their alcoholism and polysubstance abuse. Further evaluation, research, and expansion of the program ultimately were recommended (Joseph and Dole 1970) and instituted. Methadone maintenance became a major public health initiative to treat opioid addiction under the leadership of Dr. Jerome Jaffe, who headed the Special Action Office for Drug Abuse Prevention in the Executive Office of the White House in the early 1970s. Dr. Jaffeís office oversaw the creation of a nationwide, publicly funded system of treatment programs for opioid addiction.

Development of LAAM

Like methadone, levo-alpha acetyl methadol (LAAM) was classified as a U.S. Drug Enforcement Administration (DEA) schedule II controlled substance (i.e., having a high potential for abuse but also a currently accepted medical use) that creates a pharmacologic cross-tolerance for other opioids and therefore blocks their euphoric effects while controlling opioid craving. Whereas methadone suppressed opioid withdrawal symptoms for 24 hours or longer, LAAM achieved this effect for 48 to 72 hours or longer.

LAAM was first developed in 1948 by German chemists as an analgesic (Finn and Wilcock 1997). By the late 1960s, interest arose in LAAM as an alternative to methadone (American Association for the Treatment of Opioid Dependence n.d.). Between 1969 and 1981, 27 separate studies of more than 6,000 patients established LAAMís safety and efficacy (National Institute on Drug Abuse 1993***a***). The U.S. Food and Drug Administration (FDA) approved LAAM for use in OTPs in July 1993 (National Institute on Drug Abuse 1993***a***).

Later studies continued to confirm that LAAM was an effective alternative to methadone and was preferred by some patients (Glanz et al. 1997). However, in April 2001, based on reported LAAM-related disturbances in cardiac function, FDA and Roxane Laboratories, Inc., manufacturer of ORLAAM®, strengthened the warnings in LAAM product labeling (Haehl 2001). The American Association for the Treatment of Opioid Dependence has issued clinical guidelines for LAAM (American Association for the Treatment of Opioid Dependence n.d.). At this writing, only 3

percent of patients enrolled in maintenance programs in the United States are receiving LAAM (Substance Abuse and Mental Health Services Administration 2002***a***).

In 2003, Roxane Laboratories announced that it would stop producing LAAM on January 1, 2004 (Schobelock 2003), making LAAMís continued availability doubtful. This TIP continues to include basic, limited coverage of LAAM in discussions of opioid medications because of its clinical significance and relevance in MAT.

Development of buprenorphine

Information on the development of the latest successful maintenance medication, buprenorphine, is in ìDEA classification of buprenorphineî below and TIP 40, ***Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*** (CSAT 2004***a***).

Development of naltrexone

Naltrexone is the only pure opioid antagonist of the medications described here (see chapter 3). In the early 1980s, the National Institute on Drug Abuse (NIDA) completed initial testing of naltrexone to treat opioid addiction, and FDA approved naltrexone for this use in 1984. In 1995, naltrexone also received FDA approval as a preventive treatment for relapse to alcohol use among patients dependent on alcohol. Some opioid treatment providers have found that naltrexone is most useful for highly motivated patients who have undergone detoxification from opioids and need additional support to avoid relapse or who desire an expedited detoxification schedule because of external circumstances. Naltrexone also may benefit some patients in the beginning stages of opioid use and addiction. Other patient groups frequently have demonstrated poor compliance with long-term naltrexone therapy, mainly because naltrexone neither eases craving for the effects of illicit opioids when used as directed nor produces withdrawal symptoms when discontinued (Tai et al. 2001).

Public Policy Studies and Reports Since 1993

Analyses since the publication of TIP 1 have shown that maintenance treatment for opioid addiction is effective in both treatment outcomes and costs.

California Drug and Alcohol Treatment Assessment

In 1994, the California Department of Alcohol and Drug Programs published the results of a pioneering large-scale study of the effectiveness, benefits, and costs of substance abuse treatment in California. Using State databases, provider records, and followup interviews with treatment participants, the study detailed the effects of treatment on participant behavior including drug and alcohol use, criminal activity, health, health care use, and income; the costs of treatment; and the economic value of treatment to society (Gerstein et al. 1994).

AnalysesÖhave shown that maintenance treatment for opioid addiction is effective in both treatment outcomes and costs.

Among the California Drug and Alcohol Treatment Assessmentís findings were the following:

- Treatment was cost beneficial to taxpayers, with the cost averaging $7 returned for every dollar invested (Gerstein et al. 1994). ìEach day of treatment paid for itself (the benefits to taxpaying citizens equaled or exceeded the costs) on the day it was received, primarily through an avoidance of crimeî (Gerstein et al. 1994, p. iv). ìRegardless of the modality of care, treatment-related economic savings outweighed costs by at least 4 to 1î (Gerstein et al. 1994, p. 90).

- Methadone treatment was among the most cost-effective treatments, yielding savings of $3 to $4 for every dollar spent. This was true for each major methadone treatment modality, but costs were lower in an outpatient OTP than in a residential or social modality (Gerstein et al. 1994).
- Patients in methadone maintenance showed the greatest reduction in intensity of heroin use, down by two-thirds, of any type of opioid addiction treatment studied.
- Patients in methadone maintenance showed the greatest reductions in criminal activity and drug selling, down 84 percent and 86 percent, respectively, of any type of opioid addiction treatment studied.
- Health care use decreased for all treatment modalities; participants in methadone maintenance treatment showed the greatest reduction in the number of days of hospitalization, down 57.6 percent, of any modality.

Institute of Medicine

In 1995, the Institute of Medicine (IOM) produced a study titled ***Federal Regulation of Methadone Treatment*** (Institute of Medicine 1995). This study concluded that FDA regulations were inhibiting physicians from exercising their professional judgment; isolating methadone treatment from mainstream medicine, thereby depriving patients of important ancillary services; and discouraging research into new medications. This IOM study recommended that the Federal regulatory process be modified to

For more than three decades, methadoneís use to treat addiction has been subjected to extensive Federal, State, and local regulation.

- Encourage programs to provide comprehensive services, such as individual and group counseling and medical care
- Emphasize the need for continuing clinical assessment throughout treatment
- End arbitrary restrictions on OTP practices.

National Institutes of Health

In 1997, a National Institutes of Health (NIH) consensus panel called for expansion of methadone maintenance treatment. It identified such barriers as the publicís misperception of persons who are opioid addicted not as individuals with a disease but as ìotherî or ìdifferent,î the misperception ìthat [addiction] is self-induced or a failure of willpower and that efforts to treat it inevitably fail,î and overregulation of methadone treatment that limits the flexibility and responsiveness of treatment programs (National Institutes of Health 1997***b***). That panel called for the following:

- Federal leadership to inform the public that opioid addiction is a medical disorder that can be treated effectively, with significant benefits for the patient and society
- Access to methadone treatment for persons under legal supervision (e.g., probation, parole, incarceration)
- Increase in funding for methadone maintenance treatment
- Reduction in unnecessary regulation of MAT, including
  - Replacement of FDA regulation and oversight of MAT with more effective, less expensive measures, such as accreditation, to improve the quality of methadone treatment
  - Revision of DEA regulations to eliminate the extra level of regulation placed on methadone compared with other schedule II opioids, thereby encouraging more physicians and pharmacies to prescribe and dispense methadone and making maintenance treatment available in more locations

- ñ Faster approval of new medications for MAT by FDA and the States
- ñ Expansion of the availability of maintenance pharmacotherapy to States and programs where it is currently unavailable.

Regulatory History

For more than three decades, methadoneís use to treat addiction has been subjected to extensive Federal, State, and local regulation. (For a detailed history of Federal regulation of methadone treatment, see chapter 5 in the IOM report [1995] edited by Rettig and Yarmolinsky.)

Laws Related to Controlled Substances as Addiction Treatment Medications

Congress has enacted several significant statutes since 1970 to limit and control the availability of psychoactive drugs and their use to treat addiction.

Controlled Substances Act (1970)

The Controlled Substances Act of 1970 (Public Law [P.L.] 91ñ513) requires all manufacturers, distributors, and practitioners who prescribe, dispense, or administer controlled substances to register with DEA. A physician seeking registration must meet certain standards established by the Secretary of Health and Human Services and must comply with regulations established by the U.S. Attorney General regarding security of opioid stocks and maintenance of records.

Narcotic Addict Treatment Act (1974)

In passing the Narcotic Addict Treatment Act of 1974 (P.L. 93ñ281), which amended the Controlled Substances Act, Congress recognized the use of an opioid drug to treat opioid addiction as critical and, for the first time in Federal law, defined ìmaintenance treatment.î To promote closer monitoring of programs that use opioids for maintenance treatment, the law required separate DEA registration by medical practitioners who dispense opioid drugs in the treatment of opioid addiction. Previously, any physician with a DEA registration could prescribe methadone for pain management or addiction treatment. This act also increased coordination between the U.S. Department of Health and Human Services (DHHS) and DEA. Under its provisions, before a practitioner can obtain registration from DEA, DHHS must determine that the practitioner is qualified according to established treatment standards.

The Narcotic Addict Treatment Act also established NIDA as an institute independent of the National Institute of Mental Health. Authority to regulate the treatment of opioid addiction was split between NIDA and FDA. NIDA became responsible for determining appropriate standards for medical, scientific, and public health aspects of drug abuse treatment. FDA received the authority to determine the safety and effectiveness of drugs and approve new drugs for opioid addiction treatment.

Drug Addiction Treatment Act (2000)

The Drug Addiction Treatment Act of 2000 (DATA [P.L. 106ñ310 div. B]) amended that portion of the Controlled Substances Act mandating separate registration for practitioners who dispense opioids in addiction treatment. It allows practitioners who meet certain qualifying criteria to dispense or prescribe schedule III, IV, or V controlled substances specifically approved by FDA for MAT. Chapter 3 describes the specific requirements that physicians must satisfy under DATA provisions, including the requirement that physicians must

have the capacity to refer patients for needed counseling and other ancillary services.

DEA classification of buprenorphine

On October 8, 2002, DEA completed its evaluation of buprenorphine, classifying it as a schedule III drug (i.e., having potential for abuse and a currently accepted medical use in treatment but less potential for addiction than schedule II drugs). FDA made buprenorphine the first drug approved for treatment of opioid addiction in physiciansí offices (CSAT 2004***a***; Substance Abuse and Mental Health Services Administration 2003***a***; see also chapter 3).

History of Methadone Regulation

Federal regulation

In 1972, FDA issued regulations governing eligibility, evaluation procedures, dosages, take-home medications, frequency of patient visits, medical and psychiatric services, counseling, support services, and related details for methadone treatment programs. Several modifications were made to these regulations during the 1980s. Until 2001, FDA was responsible for approving these programs and ensuring compliance with FDA regulations.

The new regulations acknowledged that addiction is a medical disorder not amenable to one-size-fits-all treatment.

As experience with the effectiveness of methadone grew, criticism of the 1972 FDA regulations increased from physicians, who complained that the regulations placed burdens on their practice of medicine, and from addiction treatment specialists, who pointed out that proscriptive regulations failed to leave room for treatment innovation. (See comments on the new rules in their proposed form [***Federal Register*** 64:39812ñ39814].)

The movement away from a compliance orientation and toward an accreditation model was supported by a number of reviews, including the 1997 NIH consensus development conference on Effective Treatment of Opiate Addiction and the review of 1972 FDA regulations by IOM (Institute of Medicine 1995). Interest in accreditation grew because of its emphasis on self-assessment and improvement and on integration of quality assurance and performance elements developed by expert accreditation organizations. In addition, trends in national health care fueled movement toward accreditation. Many managed care organizations require all accredited health care practitioners to demonstrate quality care. Several States grant exemptions from State licensing requirements (called ìdeemed statusî) to accredited health care facilities.

Final regulations issued by DHHS and the Substance Abuse and Mental Health Services Administration (SAMHSA) on January 17, 2001, effective May 18, 2001, govern the use of methadone and LAAM in both maintenance and detoxification treatments for opioid addiction. The 1972 FDA regulations were repealed, and a new accreditation-based regulatory system was created. The new system shifted administration and oversight from FDA to SAMHSA. The new regulations acknowledged that addiction is a medical disorder not amenable to one-size-fits-all treatment. They recognized that different patients, at different times, could need vastly different services.

Accreditation itself is a peer-review process that evaluates a treatment program against SAMHSAís opioid treatment standards and accreditation standards of SAMHSA-approved accrediting bodies (42 Code of Federal Regulations, Part 8). It includes site visits by

specialists with experience in opioid pharmacotherapy and related activities.

The new regulations establish an entirely different regulatory and oversight structure for MAT. The DEA role remains the same, but FDAís authority to approve and monitor programs has been transferred to SAMHSA. Instead of detailed proscriptive rules, the new regulations set forth general certification requirements and Federal opioid treatment standards. These are elaborated in best-practice guidelines and in accreditation ìelementsî (or standards) developed by the SAMHSA-approved accreditation bodies. SAMHSA has employed a series of expert panels to develop guidelines for an accreditation-based certification system. Placing detailed practice criteria in accreditation standards rather than in regulations permits SAMHSA and the accreditation bodies to update the standards as needed.

The new regulations provide that, once a program is accredited, SAMHSA uses accreditation results along with other data to determine whether the program is qualified to carry out treatment under the standards in the regulations. SAMHSA maintains oversight of accreditation elements in its review of accreditation bodiesí initial and renewal applications.

The consensus panel for this TIP expects the accreditation process to result in an integrated and individualized approach to services, increased patient satisfaction, better staff recruitment, enhanced community confidence and outcomes, and improvements in quality of care. The shift to accreditation enables SAMHSA to focus its oversight efforts on improving treatment rather than ensuring that programs are meeting regulatory criteria.

States

The new Federal regulations preserve Statesí authority to regulate OTPs. Oversight of treatment medications remains a tripartite system involving States, DHHS/SAMHSA, and the U.S. Department of Justice/DEA.

States can monitor the same areas as Federal agencies, but State rules do not always echo Federal regulations. Some States have established medical recertification requirements for continuation of comprehensive, long-term MAT after a specified period. Other State and local requirements, such as certificates of need, zoning, and licensure, can affect the number, size, and location of OTPs. These regulations are not affected by the change in Federal regulations.

3 Pharmacology of Medications Used To Treat Opioid Addiction

In This Chapter…

This chapter reviews the pharmacology and clinical applications of the principal medications used to treat opioid addiction in opioid treatment programs (OTPs), including the opioid agonists methadone and levo-alpha acetyl methadol (LAAM), the partial opioid agonist buprenorphine, and the opioid antagonist naltrexone. Coverage of LAAM is brief because its future availability is uncertain. Coverage of buprenorphine is short because TIP 40, ***Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*** (CSAT 2004***a***), discusses its pharmacology in more detail. Coverage of naltrexone is short because its use in the United States generally has been limited to easing withdrawal symptoms for a small portion of patients undergoing medically supervised withdrawal after maintenance treatment. Exhibit 3-1 provides information about these and other medications for opioid addiction treatment, including the year of their U.S. Food and Drug Administration (FDA) approval and their U.S. Drug Enforcement Administration (DEA) drug schedule assignment.

The most frequently used medication for opioid addiction treatment in OTPs is methadone, and much of this chapter focuses on methadone pharmacology. LAAM always has been used much less than methadone, and its use was reduced further in 2001, after it was associated with cardiac arrhythmia in some patients. That association led FDA to warn that LAAM be used only for patients not responding well to methadone. That warning and other factors led the manufacturer to cease production of LAAM on January 1, 2004 (Schobelock 2003), making its continued availability uncertain after depletion of existing stocks. Programs were encouraged to transfer patients using LAAM to other treatments. Another pharmaceutical company may manufacture and distribute LAAM in the future.

FDA approved buprenorphine on October 8, 2002, for use in medical maintenance treatment and medically supervised withdrawal. It is the first partial opioid agonist in recent U.S. history available for use by certified physicians outside the traditional opioid treatment delivery system and the strict requirements of the Narcotic Addict Treatment Act of 1974

Exhibit 3-1

Pharmacotherapeutic Medications for Opioid Addiction Treatment

Product	Formulations	Receptor Pharmacology	FDA Approval	DEA Schedule	Treatment Settings
Methadone	Oral solution, liquid concentrate, tablet/ diskette, and powder	Full mu opioid agonist	Never formally approved by FDA	II	OTP
LAAM	Oral solution	Full mu opioid agonist	1993	II	OTP
Buprenorphine (Subutex®)	Sublingual tablet	Partial mu opioid agonist	2002	III	Physicianís office, OTP, or other health care setting
Buprenorphine-naloxone (Suboxone®)	Sublingual tablet	Partial mu opioid agonist/mu antagonist	2002	III	Physicianís office, OTP, or other health care setting
Naltrexone	Oral tablet	Mu opioid antagonist	1984	Not scheduled	Physicianís office, OTP, any substance abuse treatment program

(see chapter 2). In addition, on May 22, 2003, an interim rule change made buprenorphine available for use in OTPs that receive certification from the Substance Abuse and Mental Health Services Administration (SAMHSA) to dispense buprenorphine. Physicians working in medical offices or other appropriate settings must obtain a waiver from SAMHSA to use buprenorphine to treat opioid addiction (see Exhibit 3-2). Qualified physicians may dispense or prescribe buprenorphine products for up to 30 patients at a time under the provisions of the Drug Addiction Treatment Act of 2000 (DATA). (More information about DATA and waivers can be found at www.buprenorphine.samhsa.gov; also see Boatwright 2002.)

The consensus panel for this TIP expects that the availability of buprenorphine in multiple settings will increase the number of patients in treatment and that its availability in physiciansí offices and other medical and health care settings should help move medical maintenance treatment of opioid addiction into mainstream medical practice.

Exhibit 3-2

Requirements for Physiciansí Waivers To Dispense or Prescribe Buprenorphine and Buprenorphine-Naloxone to Patients Who Are Opioid Addicted

ì To qualify for a waiver under DATA 2000 a licensed physician (MD or DO) must meet any one or more of the following criteria:

- ï The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- ï The physician holds an addiction certification from the American Society of Addiction Medicine.
- ï The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.
- ï The physician has, with respect to the treatment and management of opioid-addicted patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary [of Health and Human Services] determines is appropriate for purposes of this subclause.
- ï The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.
- ï The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients.
- ï The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the ***Federal Register*** by the Secretary during the 30-day period preceding the end of the 3-year period involved.î

Source: www.buprenorphine.samhsa.gov/waiver_qualifications.html.

Pharmacology and Pharmacotherapy

Methadone and LAAM

The synthetic opioids methadone and LAAM are the only long-acting full opioid agonists approved for opioid pharmacotherapy at this writing. Opioid agonists bind to the mu opiate receptors on the surfaces of brain cells, which mediate the analgesic and other effects of opioids. Methadone and LAAM produce a range of mu agonist effects similar to those of short-acting opioids. Therapeutically appropriate doses of these agonist medications produce cross-tolerance for short-acting opioids such as morphine and heroin, thereby suppressing withdrawal symptoms and opioid craving as a short-acting opioid is eliminated from the body. The dose needed to produce cross-tolerance depends on a patientís level of tolerance for short-acting opioids.

LAAM is longer acting than methadone. Unlike methadone, it cannot be administered daily because its longer duration of action would lead to accumulation of toxic levels in the body that could result in death (Roxane Laboratories, Inc., 2001). Articles by Oda and Kharasch (2001) and Walsh and colleagues (1998), as well as the manufacturerís package insert for ORLAAMÆ (Roxane Laboratories, Inc., 2001), provide more information on LAAMís pharmacology.

When given intramuscularly or orally, methadone suppresses pain for 4 to 6 hours. Intramuscular methadone is used only for patients who cannot take oral methadone, for example, patients in medication-assisted treatment for opioid addiction (MAT) who are admitted to a hospital for emergency medical procedures. Methadone should not be given parenterally in an OTP.

Because of its extensive bioavailability and longer half-life, an adequate daily oral dose of methadone suppresses withdrawal and drug craving for 24 to 36 hours in most patients who are opioid addicted. Patients with special needs may require split methadone doses given more than once daily. Methadone is metabolized chiefly by the cytochrome P3A4 (CYP3A4) enzyme system (Oda and Kharasch 2001), which is significant when methadone is co-administered with other medications that also operate along this metabolic pathway (see ìInteractions With Other Therapeutic Medicationsî below).

After patient induction into methadone pharmacotherapy, a steady-state concentration (i.e., the level at which the amount of drug entering the body equals the amount being excreted) of methadone usually is achieved in 5 to 7.5 days (four to five half-lives of the drug). Methadoneís pharmacological profile supports sustained activity at the mu opiate receptors, which allows substantial normalization of many physiological disturbances resulting from the repeated cycles of intoxication and withdrawal associated with addiction to short-acting opioids. Therapeutically appropriate doses of methadone also attenuate or block the euphoric effects of heroin and other opioids. ***Goodman and Gilmanís Pharmacological Basis of Therapeutics*** (Hardman et al. 2001) provides a comprehensive description of methadoneís pharmacological effects.

Methadone is up to 80 percent orally bioavailable, and its elimination half-life ranges from 24 to 36 hours. When methadone is administered daily in steady oral doses, its level in blood should maintain a 24-hour asymptomatic state, without episodes of over-medication or withdrawal (Payte and Zweben 1998). Methadoneís body clearance rate varies considerably between individuals. The serum methadone level (SML) and elimination half-life are influenced by several factors including pregnancy and a patientís absorption, metabolism and protein binding, changes in urinary pH, use of other medications, diet, physical condition, age, and use of vitamin and herbal products (Payte and Zweben 1998).

Measuring methadone via SMLs helps determine how much is circulating in patientsí

systems. In a typical 24-hour period after dosing, SMLs should peak after about 2 to 4 hours and decline gradually to trough levels thereafter (Payte and Zweben 1998). Although researchers have noted a strong correlation between methadone dosage and serum concentrations in some patients, the relationship is not necessarily linear, and a high degree of variation exists among patients (reviewed by Leavitt et al. 2000). The rate-of-change ratio between peak and trough SMLs can be useful clinically; Payte and Zweben (1998) suggested that peak SMLs should not exceed twice the trough levels.

Researchers have found that trough SMLs of 150 to 600 ng/mL are necessary to suppress drug craving (reviewed in Leavitt et al. 2000). Many treatment providers consider that trough SMLs of $400 ng/mL provide adequate opioid cross-tolerance, thereby controlling patientsí opioid abuse; however, Eap and colleagues (2002) found no studies that validated these minimum trough levels.

Methadone has two enantiomeric forms, ì(***R***)-î (also called ***levo***- or L-) methadone and ì(***S***)-î (***dextro***- or D-) methadone, which have the same chemical formula but different spatial arrangements. OTPs in the United States use a 50:50 racemic mixture of these two enantiomers. Only (***R***)-methadone has clinically significant mu receptor agonist activity, and its potency as an analgesic is 50 times greater than that of (***S***)-methadone (Eap et al. 2002). (***R***)-methadone also has a significantly higher mean clearance rate than (***S***)-methadone (Eap et al. 1999).

Methadone is metabolized into inactive metabolites, mainly in the liver by CYP450 enzymes, but probably also by enzymes in the intestines. These metabolites are then excreted. Drugs that induce or inhibit this enzyme activity can affect methadone metabolism. If these enzymes are stimulated by other medications, the duration of methadoneís effect and SMLs may be lowered, precipitating withdrawal symptoms. If these enzymes are inhibited by other medications, methadone metabolism may be slowed, and the SMLs and duration of methadoneís effect in patients may be increased (Eap et al. 2002; Leavitt et al. 2000; Payte and Zweben 1998).

Several CYP450 isoforms help metabolize methadone, including CYP3A4 (the most abundant), CYP2B6, CYP2D6, and possibly, but to a smaller extent, CYP1A2, CYP2C9, and CYP2C19 (Cozza and Armstrong 2001; Eap et al. 2002; Gerber et al. 2004). Different enzymes metabolize (***R***)- and (***S***)-methadone differently. Numerous genetic and environmental factors affect these enzymes and account for variations in methadone metabolism among individuals. Some enzymes also play a part in metabolizing other medications, such as benzodiazepines, antidepressants, anticonvulsants, antibiotics, and antiviral agents (e.g., HIV protease inhibitors). Through their effects on these enzymes, some medications can raise or lower patientsí SMLs. Especially during initiation of methadone maintenance, methadone can increase CYP3A4 activity, thereby accelerating its own metabolism in some individuals (Eap et al. 2002; Leavitt et al. 2000).

> [A]n adequate daily oral dose of methadone suppresses withdrawal and drug craving for 24 to 36 hours…

CYP2D6 selectively metabolizes the (***R***)-methadone enantiomer. Production of this enzyme is affected by genetic factors. A small portion of the population does not produce much CYP2D6, whereas others have very high CYP2D6 activity. The latter group may require much higher methadone doses to compensate for their high rate of (***R***)-methadone metabolism (Eap et al. 2002; Leavitt et al. 2000). Individuals also differ considerably in CYP3A4 and CYP1A2 activity, accounting in part for the wide variations in methadone metabolism (Eap et al. 2002).

Buprenorphine

Buprenorphine, a derivative of the opium alkaloid thebaine, is a synthetic opioid and generally is described as a partial agonist at the mu opiate receptor and an antagonist at the kappa receptor. Research has demonstrated that buprenorphineís partial agonist effects at mu receptors, its unusually high affinity for these receptors, and its slow dissociation from them are principal determinants of its pharmacological profile (Cowan 2003).

In the 1990s, researchers determined that, as a partial mu agonist, buprenorphine does not activate mu receptors fully (i.e., it has low intrinsic activity), resulting in a ceiling effect that prevents larger doses of buprenorphine from producing greater agonist effects (Walsh et al. 1994). As a result, there is a greater margin of safety from death by respiratory depression when increased doses of buprenorphine are used, compared with increased doses of full opioid agonists. Buprenorphine overdose is uncommon, although it has been reported in France, and it is associated almost always with injection of buprenorphine coupled with ingestion of high doses of benzodiazepines, alcohol, or other sedative-type substances (Kintz 2001, 2002). Another feature of buprenorphine is that it can be used on a daily or less-than-daily basis. Typically, the interdosing interval is extended by doubling or tripling the daily dose to permit alternate-day or thrice weekly dosing (Amass et al. 2000, 2001), which is possible because, although larger doses do not increase buprenorphineís agonist activity, they do lengthen its duration of action (Chawarski et al. 1999).

Buprenorphine also may be an excellent agent to facilitate detoxification from illicit opioids and abused prescription opioids. Although it has a relatively short plasma half-life (about 4 to 6 hours), buprenorphine has a long duration of action resulting from its high affinity for and correspondingly slow dissociation from the mu receptor (Cowan 2003). This slow dissociation likely reduces the magnitude of withdrawal symptoms during detoxification (Johnson et al. 2003***b***). Some evidence supports a short-term course of buprenorphine-naloxone therapy for detoxification from opioids.

Buprenorphine is metabolized in the liver by the CYP3A4 subgroup of CYP450 enzymes (Kobayashi et al. 1998), and, like methadone and LAAM, its rate of metabolism is affected by coadministration of other medications metabolized along this pathway.

Depending on the dosage, buprenorphine activity can be viewed as falling between that of full agonists, such as methadone and LAAM, and antagonists, such as naltrexone (Exhibit 3-3) (Johnson et al. 2003***b***). Because it is a partial agonist at higher doses, buprenorphine also can precipitate opioidlike withdrawal symptoms in patients with high levels of physical dependence on opioids, making it appear to function more like an antagonist under these conditions (see ìInductionî in chapter 5).

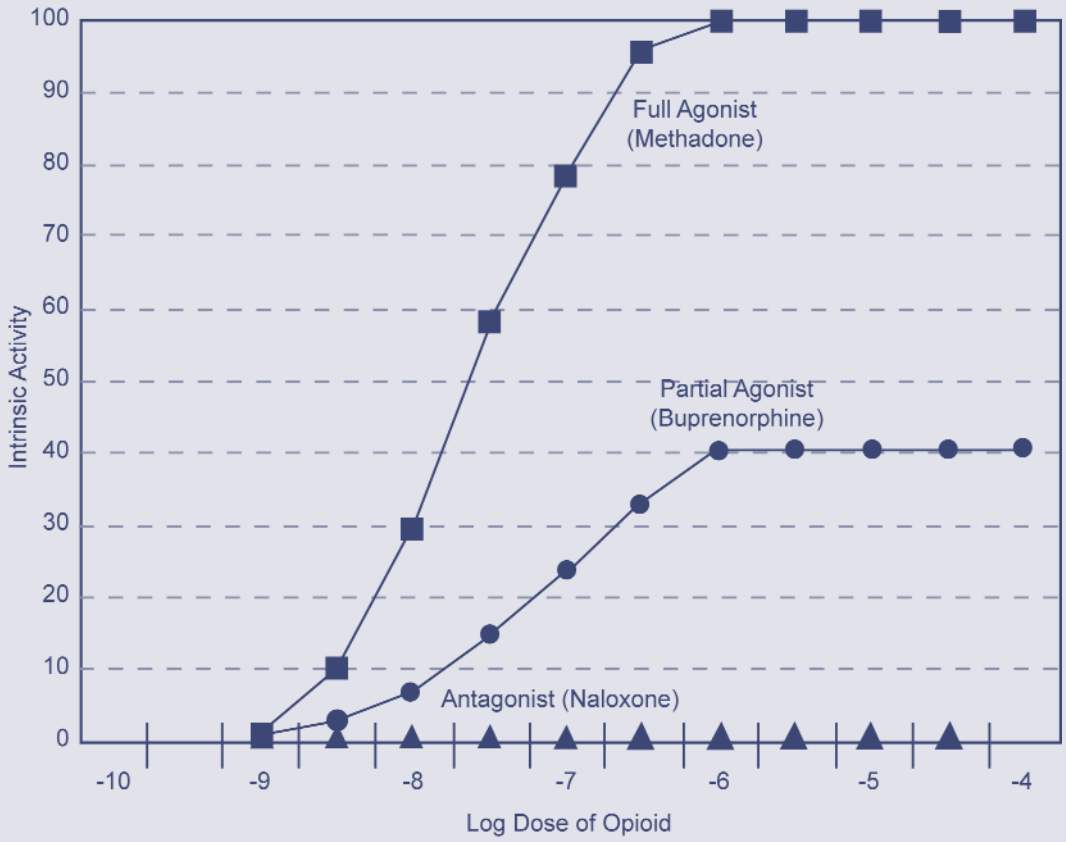
Naltrexone

Naltrexone is a highly effective opioid antagonist that tightly binds to mu opiate receptors. Because it has a higher affinity for these receptors than has heroin, morphine, or methadone, naltrexone displaces those drugs from receptors and blocks their effects. It can, therefore, precipitate withdrawal in patients who have not been abstinent from short-acting opioids for at least 7 days and have not been abstinent from long-acting ones, such as methadone, for at least 10 days (OíConnor and Fiellin 2000). Naltrexone displaces buprenorphine to a lesser degree, but, in high enough doses, it overrides buprenorphineís activity as well.

Because naltrexone has no narcotic effect, there are no withdrawal symptoms when a patient stops using naltrexone, nor does naltrexone have abuse potential. Early research concluded that tolerance does not develop for naltrexoneís antagonist properties, even after many months of regular use (Kleber et al. 1985). A 50 mg tablet markedly attenuates or blocks opioid effects for 24 hours, and a 100 to 150 mg dose can block opioid effects for up to 72 hours (OíBrien et al. 1975).

Exhibit 3-3

Intrinsic Activity of Full Agonist (Methadone), Partial Agonist (Buprenorphine), and Antagonist (Naloxone) Therapy



Source: Reprinted from ***Drug and Alcohol Dependence*** 70(Suppl.) Johnson et al. Buprenorphine: How to use it right. S59ñS77, 2003***b***, with permission from Elsevier.

The FDA approved naltrexone for maintenance treatment in 1984 based on its pharmacological effects, without requiring proof of its efficacy in clinical trials for opioid addiction treatment. Despite its potential advantages, it has had little impact on the treatment of opioid addiction in the United States, primarily because of poor patient compliance (OíConnor and Fiellin 2000).

Dosage Forms

Methadone

Methadone is provided in various forms, including diskettes, tablets, oral solution, liquid concentrate, and powder. In the United States, methadone used in MAT almost always

is administered orally in liquid form. Parenteral administration is prohibited in OTPs. Parenteral abuse of methadone is not widespread, and people rarely inject the methadone dispensed in U.S. OTPs because it is mixed with substances (e.g., flavored drinks) that make injection unattractive.

In a…study comparing the efficacy of LAAM…, buprenorphine…, and methadone…, all three medications substantially reduced illicit opioid use.

Approved forms of methadone for oral administration are supplied in various doses and concentrations, allowing OTPs to choose which to dispense on the basis of clinic and patient preferences, convenience, and cost. The diskette form comprises scored tablets, which are dissolved in water, mixed with a flavored liquid, and taken orally. Advantages are easy inventory and the ability for patients to see what they are taking before water is added. The diskette is not suited, however, for small dose increments and decrements. Methadone tablets, which dissolve in water, can be used in conjunction with diskettes for small dose changes; however, tablets normally are used only for analgesic applications; OTPs favor forms less subject to diversion. The liquid concentrate form offers complete dosing flexibility, particularly with a computer-assisted dispensing pump system. The powder form can be mixed with water into a solution.

LAAM

LAAM is supplied to OTPs as a colorless liquid to be taken orally. When LAAM was approved, Federal regulations required OTPs to ensure that ìdosage forms of LAAM and methadone are easily distinguishedî (21 Code of Federal Regulations, Part 291 ß 505). Therefore, OTPs color LAAM to distinguish it from methadone.

Buprenorphine

Buprenorphine is available in sublingual tablets containing either buprenorphine alone (sometimes called monotherapy tablets and marketed under the name Subutex) or combined with naloxone (called combination therapy tablets with the trade name Suboxone). For the combination therapy tablet, the ratio of buprenorphine to naloxone is 4 mg of buprenorphine to 1 mg of naloxone. The combination tablet was developed because of problems with injection abuse of buprenorphine reported outside the United States, where injection of buprenorphine is not permitted for treatment. Injected alone, buprenorphine precipitates withdrawal symptoms in most patients who are opioid addicted, and the addition of naloxone increases this likelihood. The combination tablet may precipitate acute withdrawal. Withdrawal also may be precipitated if too much or too little buprenorphine is given or if it is administered while the opioid receptors are highly occupied by an opioid agonist. Therefore, physicians need to be careful when timing the initiation of buprenorphine induction.

Naltrexone

Naltrexone was first produced by DuPont under the trade name Revia®. However, it is now produced by Mallinckrodt under the trade name Depade® and is supplied in 25, 50, and 100 mg tablets.

Efficacy

Methadone

Methadone maintenance has been demonstrated repeatedly to be safe and effective when used with appropriate safeguards and psychosocial

services (OíConnor and Fiellin 2000). Maintenance treatment typically leads to reduction or cessation of illicit opioid use and its adverse consequences, including cellulitis, hepatitis, and HIV infection from use of nonsterile injection equipment, as well as criminal behavior associated with obtaining drugs. Methadone pharmacotherapy has been shown to lead to improved overall adjustment, including reductions in psychiatric symptoms, unemployment, and family or social problems. Mattick and colleagues (2003) provide complete reviews of the effectiveness of methadone.

LAAM

Controlled clinical trials generally have established that LAAM is as effective as methadone and buprenorphine in reducing illicit-opioid use and retaining patients in treatment when equipotent doses are compared (e.g., Johnson et al. 2000; White et al. 2002). Appel and colleagues (2001) provide more information on LAAMís efficacy.

Buprenorphine

The primary efficacy of buprenorphine in clinical trials was demonstrated via patient retention and elimination of illicitñopioid-positive drug tests. Compared with equipotent doses of both methadone and LAAM, buprenorphine produced similar rates of treatment retention and abstinence from illicit opioids. In a controlled, randomized study comparing the efficacy of LAAM (75 to 115 mg), buprenorphine sublingual solution (16 to 32 mg), and methadone (60 to 100 mg), all three medications substantially reduced illicit opioid use (Johnson et al. 2000).

Johnson and colleagues (2003***b***) reviewed numerous studies evaluating the efficacy of buprenorphine for maintenance treatment lasting up to 1 year. These studies have shown that daily doses of 8 mg of sublingual solution or 8 to 16 mg of the buprenorphine tablet are safe and well tolerated. Most studies comparing buprenorphine and methadone have shown that 8 mg of sublingual buprenorphine or 16 mg of the tablet per day is equivalent to approximately 60 mg of oral methadone per day. A study by Fudala and colleagues (2003) demonstrated the efficacy and safety of the buprenorphine-naloxone combination tablet in office-based settings.

Naltrexone

Naltrexone is highly effective in preventing relapse when used as directed. However, most studies have indicated very high (70 to 80 percent) dropout rates from naltrexone therapy (Stine et al. 2003). A study by Rothenberg and colleagues (2002) found especially poor retention levels for patients who had received methadone before naltrexone treatment (none of them completed 6 months of treatment, compared with 31 percent of patients who had not received methadone before naltrexone therapy). Other studies have demonstrated better compliance when naltrexone therapy is supported with payment scheduling and vouchers (e.g., Preston et al. 1999***b***).

Side Effects

Long-term methadone, LAAM, or buprenorphine therapy is associated with few side effects. Although patients typically have high levels of medical and mental disorders, most result from preexisting problems or the consequences of addiction, not from the treatment medication (Institute of Medicine 1995). Chapter 10 provides a review of related medical problems in patients who are opioid addicted.

The most common adverse effects reported by patients receiving methadone or LAAM are constipation, which is caused by slowed gastric motility, and sweating; a similar side effect profile is seen for buprenorphine. Other side effects include insomnia or early awakening and decreased libido or sexual performance (Hardman et al. 2001). Possible side effects reported after regular use of these medications are listed in Exhibit 3-4.

Exhibit 3-4

Possible Side Effects of Opioid Agonist and Partial Agonist Therapy

Whole Body Effects

- ï Weakness, loss of energy (asthenia)
- ï Back pain, chills
- ï Fluid accumulation (edema)
- ï Hot flashes
- ï Flu syndrome and malaise
- ï Weight gain

Gastrointestinal Effects

- ï Constipation
- ï Dry mouth
- ï Nausea and vomiting
- ï Abdominal pain

Musculoskeletal Effects

- ï Joint pain (arthralgia)
- ï Muscle pain (myalgia)

Nervous System Effects

- ï Abnormal dreams
- ï Anxiety
- ï Decreased sex drive
- ï Depression
- ï Euphoria
- ï Headache
- ï Decreased sensitivity to tactile stimulation (hypesthesia)
- ï Insomnia
- ï Nervousness
- ï Somnolence

Respiratory Effects

- ï Cough
- ï Rhinitis
- ï Yawning

Cardiac Effects

- ï Electrocardiogram changes (possible QT prolongation with LAAM or high doses of methadone)
- ï Postural hypotension
- ï Slowed heart rate (bradycardia)

Hepatic Effects

- ï Abnormal liver function tests

Endocrine Effects

- ï Hyperprolactinemia
- ï Absence of menstrual periods (amenorrhea)

Skin and Appendage Effects

- ï Sweating
- ï Rash

Special Sensory Effects

- ï Blurred vision

Urogenital Effects

- ï Difficult ejaculation
- ï Impotence

Cardiovascular Effects

Methadone

Methadone has been shown to increase QT intervals in at least two studies (i.e., Krantz et al. 2003; Martell et al. 2003). A QT interval is that part of a patientís electrocardiogram reading that begins at the onset of the QRS complex and extends to the end of the T wave. The QT interval represents the time between the start of ventricular depolarization and the end of ventricular repolarization. The QT interval normally varies depending on heart rate, age, and gender. The QT interval may be influenced by electrolyte balance, medications, and ischemia. A prolonged QT interval increases the risk of developing a cardiac arrhythmia called torsade de pointes.

Cases of torsade de pointes have been reported in patients taking high doses of methadone (mean daily doses of approximately 400 mg). Although information about this effect is limited, 6 of 17 patients who developed torsade de pointes in one study had an increase in their methadone dose during the month preceding arrhythmia (Krantz et al. 2003). This finding supported the possibility that methadone contributed to the development of arrhythmia. Furthermore, Martell and colleagues (2003) showed that, regardless of dose, a statistically significant increase occurred in QT intervals during the first 2 months of treatment. Practitioners should be aware of potential QT-prolonging effects of methadone, especially at high doses, and should be aware of interactions with other medications that also have QT-prolonging properties or with medications that slow the elimination of methadone.

LAAM

LAAM has been associated with prolonged QT interval in some patients and, in rare cases, with death from torsade de pointes arrhythmia. As a result, it has been taken off the market in Europe, and it has been given a ìblack boxî warning (i.e., a required warning on the package insert and other product-related materials) in the United States by FDA. These findings have led to discontinuation of LAAM therapy for new patients by most American OTPs. Currently, it is labeled for use only when no other treatment option exists or for continuing use in patients who already have demonstrated tolerability for the medication (Roxane Laboratories, Inc., 2001).

Before a patient is started on LAAM, providers must follow informed-consent procedures about QT interval prolongation and provide information about the possibility of arrhythmia and sudden death (CSAT 1999***b***). Patients should be screened for cardiac risk factors, including preexisting prolonged QT intervals or other cardiac problems (Food and Drug Administration 2001; Schwetz 2001). More information about LAAM is available from Roxane Laboratories Technical Product Information at 800-962-8364 and in chapter 2.

Side Effects of Naltrexone

Approximately 10 percent of patients receiving naltrexone have gastrointestinal side effects (e.g., nausea and vomiting) that may necessitate stopping the medication. Most patients, however, experience only mild, transient stomach upset (Stine et al. 2003). Naltrexone also can cause anxiety, nervousness, insomnia, headache, joint or muscle pain, and tiredness in some patients (National Library of Medicine 1997).

Effects on the Immune System

Short-acting opioids such as heroin and morphine interfere with the normal activity of the immune system, perhaps through stress hormones such as cortisol, which are known to suppress immune function. These effects are not seen with methadone, which does not appear to affect natural killer cell activity, immunoglobulin, or T or B cells (Novick et al. 1989).

Effects on the Liver

Methadone, LAAM, and buprenorphine are metabolized by the liver, but no evidence exists

that they are hepatotoxic (Joseph et al. 2000). Because the liver is a major storage site for these medications, patients with liver disease should be expected to metabolize opioid-based medications more slowly, which might raise blood levels of these medications but lower their stores and shorten their duration of action. Abnormal liver functions among patients maintained on these drugs usually are caused by viral infections, most commonly hepatitis C acquired from contaminated needles, or by cirrhosis secondary to alcoholism (Marray 1992). Chapter 10 provides information on medical conditions commonly seen in patients who are opioid addicted.

Although the presence of liver disease is not a reason to exclude patients from MAT, severe persistent liver disease in these patients indicates the need to monitor liver functions regularly and to use caution in dosage adjustment. Severe liver impairment might result in toxic serum levels of an opioid medication. Symptoms of toxic levels include poor concentration, drowsiness, dizziness when standing, and excessive anxiety (sometimes called feeling ìwiredî). These effects usually can be managed by dose reduction. The consensus panel and the FDA labels on Subutex and Suboxone recommend baseline and periodic liver function testing for patients receiving buprenorphine.

In evaluating naltrexone to treat alcoholism, a Center for Substance Abuse Treatment consensus panel (CSAT 1998***a***) recommended caution in using naltrexone for patients who have high (three times normal) serum transaminase levels. OTPs should perform liver function tests before naltrexone therapy and periodically thereafter to ensure healthy liver function. For the relatively few cases in which liver toxicity occurs, treatment should be discontinued after determining that the liver problem has no other cause.

Side Effects of Buprenorphine

Johnson and colleagues (2003***b***) reported that buprenorphine in solution or tablet and the combination buprenorphine-naloxone tablet were well tolerated. Few serious side effects have been reported in studies involving more than 5,000 patients, although, like other opioids, buprenorphine can produce constipation, headache, nausea and vomiting, and dizziness (Fudala et al. 2003; Ling et al. 1998). Increases in liver enzymes (aspartate aminotransferase and alanine aminotransferase) were observed in individuals receiving buprenorphine who also were positive for hepatitis C (Petry et al. 2000). At this writing, 53 cases of buprenorphine-associated hepatitis have been reported in France since 1996 (Auriacombe et al. 2003). One report suggested an association between injection buprenorphine misuse and liver toxicity, possibly from buprenorphineís increased bioavailability when administered parenterally (Berson et al. 2001). The direct role of buprenorphine in these abnormalities is unclear because many individuals in these studies might have had hepatitis B or C. Additional studies are needed to clarify this issue.

Interactions With Other Therapeutic Medications

Because methadone, LAAM, and buprenorphine are metabolized chiefly by the CYP3A4 enzyme system (a part of the CYP450 system), drugs that inhibit or induce the CYP450 system can alter the pharmacokinetic properties of these medications. Drugs that inhibit or induce this system can cause clinically significant increases or decreases, respectively, in serum and tissue levels of opioid medications.

Drugs that induce the CYP450 enzyme system can precipitate withdrawal in patients receiving methadone, LAAM, or buprenorphine. Most notable are certain medications used to treat HIV infection, such as nelfinavir (McCance-Katz et al. 2000), efavirenz (Clarke, S.M., et al. 2001***b***), and nevirapine (Clarke, S.M., et al. 2001***a***; Otero et al. 1999). Other common inducers are carbamazepine, phenytoin, and phenobarbital (Michalets 1998).

Psychiatric medications sharing the same metabolic pathways as methadone and LAAM

include some selective serotonin reuptake inhibitors (SSRIs), which inhibit the isoenzymes that metabolize methadone and might increase SMLs (Nemeroff et al. 1996). Hamilton and colleagues (2000), who examined SMLs in patients who were depressed, receiving the SSRI sertraline, and undergoing methadone pharmacotherapy, found that sertraline produced modest increases in SMLs during the first 6 weeks of treatment. They concluded that patients who are methadone maintained and receiving SSRIs should be monitored for altered SMLs. However, because clinical experience with patients in MAT who take SSRIs has not indicated that these alterations are clinically significant, the consensus panel recommends careful monitoring of these patients but not routine testing of their SMLs. Of all the SSRIs, fluvoxamine likely has the most potential to cause excessive SMLs while patients are receiving it and decreased SMLs after patients discontinue it (Alderman and Frith 1999).

Fluvoxamine has been implicated in oversedation and respiratory depression when combined with methadone (Alderman and Frith 1999).

Earlier studies showed that methadone increased serum levels of tricyclic antidepressants, indicating that the oral doses required for a therapeutic response to tricyclics might be lower than those needed for a positive response in patients not addicted to opioids (Maany et al. 1989).

Finally, rifampin, carbamazepine, phenobarbital (used occasionally for the treatment of seizure disorders), and some medications to treat HIV infection (see chapter 10) also may induce liver enzymes that speed the bodyís transformation of methadone. Patients taking these medications might need increases in their methadone dosage or split doses to maintain stability.

Exhibit 3-5 summarizes other reported drug interactions with methadone.

Exhibit 3-5

Reported Drug Interactions With Methadone

Agent	Effect on Methadone	Possible Mechanism	Remarks
Amitriptyline	Decreased clearance	Inhibition of one or several CYP isozymes (1A2, 2C9, 2C19, 2D6, 3A4)	Clinical relevance unclear
Amprenavir	Decreased serum levels; possible decreased opioid effects	Induction of CYP3A	Median 65% decrease of SMLs in five patients; association of amprenavir and abacavir, with amprenavir the likeliest inducing agent
Amylobarbitone	Increased clearance	Induction of CYP3A	Clearance determined in patients receiving methadone for cancer pain

(continued on following page)

Exhibit 3-5

Reported Drug Interactions With Methadone (continued)

Agent	Effect on Methadone	Possible Mechanism	Remarks
Ciprofloxacin	Increased opioid effects	Inhibition of CYP1A2 and/or CYP3A4	One case report of sedation, confusion, and respiratory depression
Diazepam	Increased opioid effects	Mechanism unclear; probably not a pharmacokinetic interaction	Clinical relevance unclear
Efavirenz	Decreased plasma levels and opioid effects	Induction of CYP3A	Mean 57% decrease of AUC* in 11 patients; 1 case report of reduction of both enantiomers of methadone
Ethanol	Increased opioid effects and added sedation	Mechanism unclear	Clinical relevance unclear
Fluconazole	Decreased methadone clearance and increased SMLs	Inhibition of CYP3A4	Increased AUC by 35% in 13 patients after 200 mg/day for 14 days
Fluoxetine	Increased SMLs	Inhibition of CYP2D6 (stereoselectivity for (***R***)-methadone)	Increased plasma levels (mean increase 32%) for (***R***)- but not (***S***)-methadone in seven patients
Fluvoxamine	Increased SMLs and increased opioid effects	Inhibition of one or several CYP isozymes (1A2, 2C19, 3A4, 2C9)	One case report of hypoventilation, severe hypoxemia, and hypercapnia; two case reports of withdrawal symptoms when fluvoxamine stopped; one case report of fluvoxamine use to decrease methadone metabolism induced by barbiturate
Fusidic acid	Decreased opioid effects	Induction of CYP3A and CYP2C	Reports of withdrawal symptoms after 4-week therapy
Moclobemide	Increased opioid effects	Inhibition of CYP2D6 and/or CYP1A2	One case report of withdrawal symptoms when moclobemide stopped

*Area under the concentration-time curve.

Exhibit 3-5

Reported Drug Interactions With Methadone (continued)

Agent	Effect on Methadone	Possible Mechanism	Remarks
Nelfinavir	Decreased SMLs	Induction of CYP3A; possible induction of P-glycoprotein	Mean decrease about 55% in two patients
Nevirapine	Decreased SMLs and opioid effects	Induction of CYP3A	Case reports of very important decrease in SMLs and severe withdrawal symptoms
Paroxetine	Increased SMLs	Inhibition of CYP2D6 (stereoselectivity for (***R***)-methadone)	Increased (***R***)-methadone plasma levels in eight CYP2C6 extensive metabolizers (32%) but not in poor metabolizers (3%)
Phenobarbital	Decreased SMLs and opioid effects	Induction of CYP3A	One case report with a 31% reduction of trough SMLs
Phenytoin	Decreased SMLs and opioid effects	Induction of CYP3A	Mean 2.4-fold decrease of SMLs with moderately severe opioid withdrawal symptoms
Rifampin	Decreased SMLs and opioid effects	Induction of CYP3A	Cases of severe withdrawal symptoms
Ritonavir	Decreased SMLs and opioid effects	Induction of CYP3A, possible induction of P-glycoprotein; induction of CYP2C19 and/or CYP2B6 suggested to explain greater induction of metabolism of (***S***)- than (***R***)-methadone	Mean 36% decrease of the AUC in 11 patients after a 14-day treatment; high interindividual variability of decrease in SMLs
Sertraline	Increased SMLs	Inhibition of one or several CYP isozymes (3A4, 2D6, 1A2, 2C9, 2C19)	No side effects from excess dosage recorded
Spironolactone	Increased clearance	Induction of CYP3A	Clearance determined in patients receiving methadone for cancer pain

Adapted from Eap et al. 2002, by permission of Adis International.

Exhibit 3-6 provides a list of other substances that are known to induce or inhibit CYP3A4 and potentially could affect levels of methadone, LAAM, and buprenorphine.

Little information is available on the interaction of naltrexone with other medications. Lethargy and somnolence have been reported when naltrexone is used along with Thorazine® (chlorpromazine) or Mellaril® (thioridazine), and caution should be taken when naltrexone is used with other antipsychotic drugs. Patients taking naltrexone experience significant blockade of opioid effects from medications taken for analgesia. However, this blockade is present only when naltrexone is taken regularly; it will cease 24 to 72 hours after naltrexone is discontinued (OíConnor and Fiellin 2000).

Strategies To Prevent or Minimize Harmful Drug Interactions in MAT

To control patientsí vulnerability to adverse cardiac and other harmful effects of drug interactions with methadone or LAAM, the consensus panel recommends obtaining a thorough drug and medication history, including results of drug and other laboratory tests. In some cases, particularly when patients are treated in multiple settings, consolidating this information can be a challenge.

Treatment providers should rely on their experience, intuition, and common sense to anticipate and circumvent negative drug interactions. The traditional advice when adding drugs to a therapeutic regimen is to start with

Exhibit 3-6

Other Inducers and Inhibitors of CYP450 and CYP3A4

CYP3A4 Inducers Expected To Reduce Opioid Medication Levels		
Carbamazepine	Ethosuximide	Rifabutin
Dexamethasone	Primidone	Troglitazone
CYP3A4 Inhibitors Expected To Increase Opioid Medication Levels*		
Amiodarone	Itraconazole	Norfloxacin
Cannabinoids	Ketoconazole	Omeprazole (slight)
Clarithromycin	Metronidazole	Quinine
Erythromycin	Mibefradil	Saquinavir
Grapefruit juice	Miconazole	Troleandomycin
Indinavir	Nefazodone	Zafirlukast

*Although clarithromycin and erythromycin are CYP3A4 inhibitors, azithromycin does not inhibit CYP3A4.

Adapted from Michalets 1998, from ***Pharmacotherapy*** with permission; with additional information from Gourevitch and Friedland 2000 and McCance-Katz et al. 2000.

low doses, increase slowly, and monitor closely. In many cases, medication dosages lower than those recommended by the manufacturer may be sufficient for the desired therapeutic effect (Cohen 1999). This is especially prudent for patients receiving agonist medications who have a positive diagnosis for cardiac risk factors.

Educating patients about the risks of drug interaction is essential. The following information should be emphasized:

- During any agonist-based pharmacotherapy, abusing drugs or medications that are respiratory depressants (e.g., alcohol, other opioid agonists, benzodiazepines) may be fatal.
- Current or potential cardiovascular risk factors may be aggravated by opioid agonist pharmacotherapy, but certain treatment strategies reduce cardiovascular risk (and should be included as needed in patientsí treatment plans).
- Other drugsóillicit, prescribed, or over the counteróhave potential to interact with opioid agonist medications (specific, relevant information should be provided).
- Patients should know the symptoms of arrhythmia, such as palpitations, dizziness, lightheadedness, syncope, or seizures, and should seek immediate medical attention when they occur.
- Maintaining and not exceeding dosage schedules, amounts, and other medication regimens are important to avoid adverse drug interactions.

Researchers (e.g., Cohen 1999; Levy et al. 2000; Piscitelli and Rodvold 2001) have provided other suggestions for treatment providers to minimize harmful drug interactions in MAT:

- When possible, substitute alternative medications that do not interact with opioid treatment medications (e.g., azithromycin for erythromycin [because the latter is a strong CYP3A4 inhibitor] or divalproex for carbamazepine [because the latter is a potent CYP3A4 inducer]).
- When other medications must be coadministered with opioid treatment medications, select those that have the least potential for interaction.
- Consider whether significant adverse drug interactions might be ameliorated by administering a medication with or without food or by altering dosing schedules.
- Be aware that, the more complicated the medication regimen, the less likely patients will adhere to it, necessitating increased vigilance on the part of treatment providers as the complexity of medication treatment increases.
- When potentially interactive medications are coadministered, adjust the agonist or partial agonist dosage based on patient response, rather than prophylactically basing the dosage on expected interaction, because degrees of interaction vary dramatically; prejudging the amount of a necessary dosage adjustment is unlikely to work.
- When opioid medication dosage must be adjusted to compensate for the effects of interacting drugs, observe patients for signs or symptoms of opioid withdrawal or sedation to determine whether they are undermedicated or overmedicated.
- When a potentially interactive drug combination must be used and concerns exist about adverse effects if opioid medication is increased, for example, in patients with preexisting cardiovascular conditions, closely monitor drug serum concentrations or increase testing frequency. Advise patients of the physical signs or symptoms of adverse interactions, and tell them what to do if these indicators occur.
- Be aware of concomitant preexisting diseases (e.g., diseases that decrease renal or hepatic function) and preexisting cardiovascular conditions that might influence the potential for adverse drug interactions.

Knowledge about medication interactions with methadone and other medications used in the treatment of opioid addiction is changing

constantly. The reader is advised to check for the most current information on a regular basis. A useful Web site is medicine.iupui.edu/flockhart.

Safety

Methadone and LAAM

The safety profiles of methadone and LAAM are excellent when these drugs are taken as directed by the manufacturer and, for LAAM, when patients are screened carefully for any cardiac risk factors. However, because both methadone and LAAM are full mu opioid agonists, overdose and death can occur if they are taken in larger amounts than directed and in amounts exceeding patientsí tolerance levels. Unintended, possibly lethal respiratory depressant effects also can occur if these medications are used in combination with substances that depress the central nervous system, such as alcohol and benzodiazepines.

Buprenorphine

Like methadone, buprenorphine generally is safe and well tolerated when used as recommended by the manufacturer, and buprenorphineís partial agonist characteristics reduce the risk of respiratory depression from overdose. Buprenorphine overdose deaths reported in France generally have been attributed to the concurrent parenteral abuse of buprenorphine and benzodiazepines (Kintz 2001; Reynaud et al. 1998; Tracqui et al. 1998***a***, 1998***b***). Only two overdose deaths have been attributed to buprenorphine alone (Kintz 2002). The potential for injection abuse with buprenorphine is believed lower than with full agonists because, as a partial agonist, buprenorphine can precipitate withdrawal in individuals who are opioid addicted. Moreover, use of combination buprenorphine-naloxone tablets in the United States should mitigate further the risk of abuse. As with any agonist-based pharmacotherapy, however, it is extremely important to educate patients about the potential lethality of abusing treatment medication alone or in combination with respiratory depressants, especially benzodiazepines.

Naltrexone

Naltrexone generally is safe when used according to the manufacturerís directions. Hall and Wodak (1999) cautioned that overdose rates for patients on naltrexone who relapse to heroin use might be higher than among patients receiving other treatments for opioid addiction. Further investigation is needed to validate this concern.

4 Initial Screening, Admission Procedures, and Assessment Techniques

In This ChapterÖ

Initial screening or intake procedures determine an applicantís eligibility and readiness for medication-assisted treatment for opioid addiction (MAT) and admission to an opioid treatment program (OTP). Ongoing assessment should begin as soon as a patient is admitted to an OTP. It provides a basis for individualized treatment planning and increases the likelihood of positive outcomes.

No single tool incorporates all the important elements for assessing patients in MAT. The Addiction Severity Index (ASI) (McLellan et al. 1992), although not comprehensive, can guide collection of the basic information needed to measure patient conditions and progress objectively. Recent research (e.g., Bovasso et al. 2001) continues to support the validity of ASI composite scores. The consensus panel recommends that OTPs develop tools and methods for more extensive assessment. This chapter describes screening and assessment procedures and important considerations that might be made during and shortly after admission to an OTP, as well as assessment techniques and considerations that are important to ongoing MAT.

Initial Screening

First Contact

The screening process begins when an applicant or family member first contacts an OTP, often via telephone or a visit to the OTP. This contact is the first opportunity for treatment providers to establish an effective therapeutic alliance among staff members, patients, and patientsí families. Careful planning for and interaction with new applicants and their families contribute to positive MAT outcomes. Staff members should be prepared to provide immediate, practical information that helps potential applicants make decisions about MAT, including the approximate length of time from first contact to admission, what to expect during the admission process, and types of services offered. A brief exploration of

applicantsí expectations and circumstances can reveal other information they need for considering MAT.

Goals of Initial Screening

The consensus panel recommends the following goals for initial screening:

- ***Crisis intervention.*** Identification of and immediate assistance with crisis and emergency situations (see ìScreening of Emergencies and Need for Emergency Careî below)
- ***Eligibility verification.*** Assurance that an applicant satisfies Federal and State regulations and program criteria for admission to an OTP
- ***Clarification of the treatment alliance.*** Explanation of patient and program responsibilities
- ***Education.*** Communication of essential information about MAT and OTP operations (e.g., dosing schedules, OTP hours, treatment requirements, addiction as a brain disease) and discussion of the benefits and drawbacks of MAT to help applicants make informed decisions about treatment
- ***Identification of treatment barriers.*** Determination of factors that might hinder an applicantís ability to meet treatment requirements, for example, lack of childcare or transportation.

Along with these primary goals, initial screening can begin to identify other medical and psychosocial risk factors that could affect treatment, including factors related to mental disorders; legal difficulties; other substance use; and vocational, financial, transportation, and family concerns. Cultural, ethnic, and spiritual factors that affect communication and might affect treatment planning should be noted as early as possible. Staff members should obtain enough information from applicants to accommodate needs arising from any of these factors if necessary.

Screening of Emergencies and Need for Emergency Care

The consensus panel recommends that providers develop medically, legally, and ethically sound policies to address patient emergencies. Emergencies can occur at any time but are most common during induction to MAT and the acute treatment phase (see chapter 7). In particular, patients who exhibit symptoms that could jeopardize their or othersí safety should be referred immediately for inpatient medical or psychiatric care. If possible, staff members who conduct initial screening and assessment should make appropriate referrals before applicants are admitted to an OTP. Identifying and assessing emergencies may require staff familiarity with the components of a mental health status examination (see ìPsychosocial Assessmentî below).

Suicidality

In a study of population data from the U.S. National Comorbidity Survey, a significant association was found between opioid addiction and increased risk of suicide (Borges et al. 2000). Initial screening and periodic assessments should help determine whether those indicating risks of suicide need additional services (e.g., hospitalization for protection or treatment, outpatient mental treatment, or evaluation for antidepressant medication). Exhibit 4-1 lists some indicators of suicidality. Exhibit 4-2 lists recommended responses.

Homicidality and threats of violence

Threats should be taken seriously. For example, if an individual with knowledge of OTP procedures and schedules makes a threat, patterns of interaction between staff and this individual should be shifted. It might be necessary to change or stagger departure times, implement a buddy system, or use an escort service (National Institute for Occupational Safety and Health 1996). Counseling assignments can be changed, or patients can be transferred to another OTP.

Exhibit 4-1

Suicide Risk Factors

Behavioral and Circumstantial Indicators of Suicide Risk	
ï Talk about committing suicide	ï Giving away prized possessions
ï Trouble eating or sleeping	ï History of suicide attempts
ï Drastic changes in behavior	ï Unnecessary risk taking
ï Withdrawal from friends or social activities	ï Recent severe losses
ï Loss of interest in hobbies, work, or school	ï Preoccupation with death and dying
ï Preparations for death, such as making a will or final arrangements	ï Loss of interest in personal appearance
	ï Increased use of alcohol or drugs
Expressed Emotions That May Indicate Suicide Risk	
ï Canít stop the pain	ï Canít make the sadness go away
ï Canít think clearly	ï Canít see a future without pain
ï Canít make decisions	ï Canít see oneself as worthwhile
ï Canít see any way out	ï Canít get someoneís attention
ï Canít sleep, eat, or work	ï Canít seem to get control
ï Canít get out of depression	

Source: Adapted from American Association of Suicidology n.d.

Exhibit 4-2

Recommended Responses to Indicators of Suicidality

ï Be direct. Talk openly and matter-of-factly about suicide.

ï Be willing to listen. Allow expressions of feelings. Accept the feelings.

ï Be nonjudgmental. Donít debate whether suicide is right or wrong or feelings are good or bad. Donít lecture on the value of life.

ï Get involved. Become available. Show interest and support.

ï Donít dare an individual to do it.

ï Donít act shocked. This puts distance between the practitioner and the individual.

ï Donít be sworn to secrecy. Seek support.

ï Offer hope but not glib reassurances that alternatives are available.

ï Take action. Remove means, such as guns or stockpiled pills.

ï Get help from persons or agencies specializing in crisis intervention and suicide prevention.

Source: Adapted from American Association of Suicidology n.d.

The consensus panel recommends that OTP staff members receive training in recognizing and responding to the signs of potential patient violence. OTPs should develop policies and procedures for homicide and other violent situations. The OTPís policy on violence and threats of violence should be explained at the beginning of treatment. Emergency screening and assessment procedures should include the following:

- Asking the patient questions specific to homicidal ideation, including thoughts, plans, gestures, or attempts in the past year; weapons charges; and previous arrests, restraining orders, or other legal procedures related to real or potential violence at home or the workplace.
- Documenting violent incidents and diligent monitoring of these records to assess the nature and magnitude of workplace violence and to quantify risk. When a threat appears imminent, all legal, human resource, employee assistance, community mental health, and law enforcement resources should be readied to respond immediately (National Institute for Occupational Safety and Health 1996).

Admission Procedures and Initial Evaluation

After initial applicant screening, the admission process should be thorough and facilitate timely enrollment in the OTP. This process usually marks patientsí first substantial exposure to the treatment system, including its personnel, other patients, available services, rules, and requirements. The admission process should be designed to engage new patients positively while screening for and assessing problems and needs that might affect MAT interventions.

Timely Admission, Waiting Lists, and Referrals

The longer the delays between first contact, initial screening, and admission and the more appointments required to complete these procedures, the fewer the applicants who actually enter treatment. Prompt, efficient orientation and evaluation contribute to the therapeutic nature of the admission process.

If a program is at capacity, admitting staff should advise applicants immediately of a waiting list and provide one or more referrals to programs that can meet their treatment needs more quickly. A centralized intake process across programs can facilitate the admission process, particularly when applicants must be referred. For example, if an applicant accepts referral to another provider, telephone contact by the originating program often can facilitate the applicantís acceptance into the referral program. If an applicant goes willingly to another program for immediate treatment but prefers admission to the original OTP, the admission process should be completed and the applicantís name added to the waiting list.

Patients who prefer to await treatment at the original site should be added to the waiting list and contacted periodically to determine whether they want to continue waiting or be referred. For individuals who are ineligible, staff should assess the need for other acute services and promptly make appropriate referrals. The consensus panel recommends that each OTP establish criteria to decide which prequalified patients should receive admission priority, especially when a program is near capacity. For example, some programs offer high-priority admission to pregnant women, addicted spouses of current patients, applicants with HIV infection or other serious medical conditions, or former patients who have tapered off maintenance medication but subsequently require renewed treatment.

Interim Maintenance Treatment

For eligible individuals who cannot be admitted to a public or nonprofit program for comprehensive maintenance services within a reasonable geographic area and within 14 days of applying, 42 Code of Federal Regulations (CFR), Part 8 ß 12(j), provides for ìinterim maintenance treatment,î in which medication

is administered to patients at an OTP for up to 120 days without formal screening or admission and with only minimal drug testing, assuming the existence of reasonable criteria at the OTP to prioritize admissions.

Denial of Admission

Denial of admission to an OTP should be based on sound clinical practices and the best interests of both the applicant and the OTP. Admission denial should be considered, for example, if an applicant is threatening or violent. Continuity of care should be considered, and referral to more suitable programs should be the rule. Due process and attention to applicant rights (see CSAT 2004***b***) minimize the possibility that decisions to deny admission to an OTP are abusive or arbitrary.

Admission Team

OTPs should have qualified, compassionate, well-trained multidisciplinary teams (see chapter 6) that efficiently collect applicantsí information and histories, evaluate their needs as patients, and orient them to MAT. Team members should be cross-trained in treating addiction and co-occurring disorders. Those conducting admission interviews should be culturally competent, and their interactions with applicants should not be stigmatizing. They also should be able to communicate OTP policies and services and make appropriate referrals.

Information Collection and Dissemination

Collection of patient information and dissemination of program information occur by various methods, such as by telephone; through a receptionist; and through handbooks, information packets, and questionnaires. Medical assessments (e.g., physical examinations, blood work) and psychosocial assessments also are necessary to gather specific types of information. Although collection procedures differ among OTPs, the consensus panel recommends that the following types of information be collected, documented, or communicated to patients:

- **Treatment history.** An OTP should obtain a new patientís substance abuse treatment history, preferably from previous treatment providers, including information such as use of other substances while in treatment, dates and durations of treatment, patterns of success or failure, and reasons for discharge or dropout. Written consent from a patient is required to obtain information from other programs (see CSAT 2004***b***). (See below for details on other components to include in this history.)

> The admission process should be designed to engage new patients positively while screening for and assessing problems and needs…

- **Orientation to MAT.** All patients should receive an orientation to MAT, generally extending over several sessions and including an explanation of treatment methods, options, and requirements and the roles and responsibilities of those involved. Each new patient also should receive a handbook (or other appropriate materials), written at an understandable level in the patientís first language if possible, that includes all relevant program-specific information needed to comply with treatment requirements. Patient orientation should be documented carefully for medical and legal reasons. Documentation should show that patients have been informed of all aspects of the multifaceted MAT process and its information requirements, including (1) the consent to treatment (CSAT 2004***b***), (2) program recordkeeping and confidentiality requirements (e.g., who has access to records and when, who can divulge information

[A]ddressing concerns about and stressing the benefits of MAT …are essential to long-term treatment retention…

without patient consent [see CSAT 2004***b***]), (3) program rules, including patient rights, grievance procedures, and circumstances under which a patient can be discharged involuntarily, and (4) facility safety instructions (e.g., emergency exit routes). OTPs should require patients to sign or initial a form documenting their participation in the orientation process. Also, patients must receive and sign a written consent to treatment form (see Appendix 4-A; see also CSAT 2004***b***), which is kept on file by the OTP.

- **Age of applicant.** Persons younger than age 18 must meet specific Federal and State requirements (at this writing, some States prohibit MAT for this group), and an OTP must secure parental or other guardian consent to start adolescents on MAT (see discussion below of exemptions from the Substance Abuse and Mental Health Services Administrationís [SAMHSAís] 1-year dependence duration rule).
- **Recovery environment.** A patientís living environment, including the social network, those living in the residence, and stability of housing, can support or jeopardize treatment.
- **Suicide and other emergency risks.** (See above.)
- **Substances of abuse.** A patientís substance abuse history should be recorded, focusing first on opioid use, including severity and age at onset of physical addiction, as well as use patterns over the past year, especially the previous 30 days. A baseline determination of current addiction should meet, to the extent possible, accepted medical criteria. Many people who are opioid addicted use other drugs and alcohol; this multiple substance use has definite implications for treatment outcomes (see ìSubstance Use Assessmentî below and chapter 11). Therefore, screening and medical assessment also should identify and document nonopioid substance use and determine whether an alternative intervention (e.g., inpatient detoxification) is necessary or possible before an applicant is admitted to the OTP.
- **Prescription drug and over-the-counter medication use.** All prescription drug and over-the-counter medication use should be identified. Procedures should be in place to determine any instances of misuse, overdose, or addiction, especially for psychiatric or pain medications. The potential for drug interactions, particularly with opioid treatment medications, should be noted (see chapter 3).
- **Method and level of opioid use.** The general frequency, amounts, and routes of opioid use should be recorded. If opioids are injected, the risk of communicable diseases (e.g., HIV/AIDS, hepatitis C, endocarditis) increases. Patient reporting helps providers assess patientsí substance addiction and tolerance levels, providing a starting point to prescribe appropriate treatment medication for stabilization (American Psychiatric Association 2000; Mee-Lee et al. 2001***a***).
- **Pattern of daily preoccupation with opioids.** A patientís daily pattern of opioid abuse should be determined. Regular and frequent use to offset withdrawal is a clear indicator of physiological dependence. In addition, people who are opioid addicted spend increasing amounts of time and energy obtaining, using, and responding to the effects of these drugs.
- **Compulsive behaviors.** Patients in MAT sometimes have other impulse control disorders. A treatment provider should assess behaviors such as compulsive gambling or sexual behavior to develop a comprehensive perspective on each patient.
- **Patient motivation and reasons for seeking treatment.** Prospective patients typically present for treatment because they are in withdrawal and want relief. They often are

preoccupied with whether and when they can receive medication. Because successful MAT entails not only short-term relief but a steady, long-term commitment, applicants should be asked why they are seeking treatment, why they chose MAT, and whether they fully understand all available treatment options and the nature of MAT. Negative attitudes toward MAT may reduce patient motivation. However, concerns about motivation should not delay admission unless applicants clearly seem ambivalent. In such cases, treatment providers and applicants can discuss the pros and cons of MAT. The consensus panel believes that identifying and addressing concerns about and stressing the benefits of MAT as early as possible are essential to long-term treatment retention and maintaining patient motivation for treatment.

- **Patient personal recovery resources.** A patientís comments also can identify his or her recovery resources. These include comments on satisfaction with marital status and living arrangements; use of leisure time; problems with family members, friends, significant others, neighbors, and coworkers; the patientís view of the severity of these problems; insurance status; and employment, vocational, and educational status. Identification of patient strengths (e.g., stable employment, family support, spirituality, strong motivation for recovery) provides a basis for a focused, individualized, and effective treatment plan (see chapter 6).
- **Scheduling the next appointment.** Unless the program can provide assessment and admission on the same day, the next visit should be scheduled for as soon as possible. To facilitate an accurate diagnosis of opioid addiction and prompt administration of the initial dose of medication when other documentation of a patientís condition is unavailable, the applicant should be instructed to report to the OTP while in mild to moderate opioid withdrawal.

Medical Assessment

Medical assessment plays a substantial role in determining MAT eligibility. Some assessment tools and methods mentioned briefly in this chapter are explained further in chapter 10.

The results of medical assessment, including toxicology tests, other laboratory results, and psychosocial assessment, usually are reviewed by a program physician and then submitted to the medical director in preparation for pharmacotherapy. Programs should minimize delay in administering the first dose of medication because, in most cases, applicants will present in some degree of opioid withdrawal.

Determination of Opioid Addiction and Verification of Admission Eligibility

Federal regulations on eligibility

Federal regulations state that, in general, opioid pharmacotherapy is appropriate for persons who currently are addicted to an opioid drug and became addicted at least 1 year before admission (42 CFR, Part 8 ß 12(e)). Documentation of past addiction might include treatment records or a primary care physicianís report. When an applicantís status is uncertain, admission decisions should be based on drug test results and patient consultations.

Exemptions from SAMHSAís 1-year dependence duration rule

If appropriate, a program physician can invoke an exception to the 1-year addiction history requirement for patients released from correctional facilities (within 6 months after release), pregnant patients (program physician must certify pregnancy), and previously treated patients (up to 2 years after discharge) (42 CFR, Part 8 ß 12(e)(3)).

A person younger than 18 must have undergone at least two documented attempts at detoxification or outpatient psychosocial treatment within 12 months to be eligible for maintenance treatment. A parent, a legal guardian, or an adult designated by a relevant State authority must consent in writing for an adolescent to participate in MAT (42 CFR, Part 8 ß 12(e)(2)). Patients younger than 18 should receive age-appropriate treatments, ideally with a separate treatment track (e.g., young adult groups).

Cases of uncertainty

When absence of a treatment history or withdrawal symptoms creates uncertainty about an applicantís eligibility, OTP staff should ask the applicant for other means of verification, such as criminal records involving use or possession of opioids or knowledge of such use by a probation or parole officer. A notarized statement from a family or clergy member who can attest to an individualís opioid abuse might be feasible.

The consensus panel does not recommend use of a naloxone (Narcan®) challenge test (see chapter 5) in cases of uncertainty. Physical dependence on opioids can be demonstrated by less drastic measures. For example, a patient can be observed for the effects of withdrawal after he or she has not used a short-acting opioid for 6 to 8 hours. Administering a low dose of methadone and then observing the patient also is appropriate. Administering naloxone, although effective, can initiate severe withdrawal, which the consensus panel believes is unnecessary. It also requires invasive injection, and the effects can disrupt or jeopardize prospects for a sound therapeutic relationship with the patient. The panel recommends that naloxone be reserved to treat opioid overdose emergencies.

History and Extent of Nonopioid Substance Use and Treatment

The extent and level of alcohol and nonopioid drug use and treatment also should be determined, and decisions should be made about whether these disorders can be managed safely during MAT (see ìSubstance Use Assessmentî below and chapter 11).

Medical History

A complete medical history should include organ system diagnoses and treatments and family and psychosocial histories. It should cover chronic or acute medical conditions such as diabetes, liver or renal diseases, sickle cell trait or anemia, and chronic pulmonary disease. Documentation of infectious diseases, including hepatitis, HIV/AIDS, tuberculosis (TB), and sexually transmitted diseases (STDs), is especially important. Staff should note patientsí susceptibility to vaccine-preventable illnesses and any allergies and treatments or medications received for other medical conditions. Womenís medical histories also should document previous pregnancies; types of delivery; complications; current pregnancy status and involvement with prenatal care; alcohol and drug use, including over-the-counter medications, caffeine, and nicotine, before and during any pregnancies; and incidences of sudden infant death syndrome.

Complete Physical Examination

Each patient must undergo a complete, fully documented physical examination by the program physician, a primary care physician, or an authorized health care professional under the direct supervision of the program physician, before admission to the OTP. The full medical examination, including the results of the serology and other tests, must be documented in the patientís record within 14 days following admission. States may have additional requirements, and OTPs must comply with

these requirements. The examination should cover major organ systems and the patientís overall health status and should document indications of infectious diseases; pulmonary, liver, and cardiac abnormalities; dermatologic sequelae of addiction; vital signs; general appearance of head, eyes, ears, nose, throat, chest, abdomen, extremities, and skin; and physical evidence of injection drug use and dependence, as well as the physicianís clinical judgment of the extent of physical dependence. Women should receive a pregnancy test and a gynecological examination at the OTP site or by referral to a womenís health center. Again, the results of all tests, laboratory work, and other processes related to the initial medical examination are to be contained in the patientís file within 14 days following admission.

Laboratory Tests

Although Federal regulations no longer require OTPs to conduct a full panel of laboratory tests, some States do. The consensus panel recommends that laboratory tests include routine tests for syphilis, hepatitis, TB, and recent drug use. SAMHSA regulations stipulate ìat least eight random drug abuse testsî annually per patient, performed according to accepted OTP practice (CFR 42, Part 8 ß 12(f)(6)). Given that some drugs are metabolized extensively and excreted quickly, it is important that analytic procedures provide the highest sensitivity for substances of interest, such as breath testing for alcohol use.

TB testing

The risk of TB infection and disease is high among individuals involved with drugs (Batki et al. 2002). Rates of active TB among people who use substances and are HIV infected are high (Gourevitch et al. 1999), and cases of multidrug-resistant TB in this group are increasing. All patients should undergo screening and medical examination for TB every 12 months. Anergy panel tests should be administered to anergic patients (those with diminished reactivity to certain antigens). Patients who are immune system compromised might have a negative purified protein derivative test, even with active infection. A chest x ray or sputum analysis should be done if there is doubt. If a patient has a positive TB test, medical staff should treat the patient accordingly (see chapter 10) or refer him or her to a primary care clinic for treatment.

Hepatitis testing

People who inject drugs are at high risk for hepatitis virus infection (see chapter 10) and should be tested at admission to an OTP. Hepatitis A is an important liver infection that affects people who abuse drugs at higher rates than people who do not. Most patients in OTPs are seropositive for surface antigen or antibody to hepatitis B virus (HBV) core antigen, and some exhibit signs of chronic hepatitis. Any patients whose tests are negative for hepatitis A virus or HBV infection should be vaccinated for these infections at the OTP or by referral.

> [R]esults of…the medical examination are to beÖin the patientís file within 14 days following admission.

Hepatitis C virus (HCV) accounts for most new hepatitis cases among people who inject drugs, infects between 70 and 96 percent of this population, and is the countryís leading cause of chronic liver disease (Sylvestre 2002***b***). The consensus panel strongly recommends that HCV diagnosis and referral be an integral component of initial MAT assessment. Programs that do not offer onsite HCV antibody testing should provide appropriate referrals. (A simple blood test for hepatitis C antibodies is available; a positive result does not necessarily signal current infections, only that antibodies have developed.)

HIV testing

OTPs are required to provide adequate medical services, and the program sponsor must be able to document that these services are fully and reasonably available to patients. HIV testing on site or by referral, with pretest and posttest counseling, is a recommended medical service. OTPs should make HIV testing part of their medical services as recommended by the Centers for Disease Control and Prevention (2001***a***). Medical care and other supportive services can be offered if patientsí HIV and HCV statuses are known early in treatment and monitored continuously.

> Clinical examination and an applicantís medical history are keys to determine the appropriateness of MAT.

Rapid HIV tests have been approved by the U.S. Food and Drug Administration (FDA) and are recommended by the U.S. Public Health Service to facilitate early diagnosis of HIV infection among at-risk populations involved in substance abuse (Centers for Disease Control and Prevention 2002***a***). Rapid tests can detect antibodies to HIV in blood obtained by fingerstick or venipuncture, or in oral fluid and provide reliable and valid results in 20 minutes or less. Thus, the rapid HIV test provides a measure of exposure to HIV and requires confirmatory testing for a diagnosis of HIV infection. In studies by the manufacturer, the blood antibody test correctly identified 99.6 percent of people infected with HIV and 100 percent of those not infected, which is comparable to the results of FDA-approved enzyme immunoassays. FDA expects clinical laboratories to obtain similar results (Centers for Disease Control and Prevention 2003***b***). OTPs performing rapid HIV tests should comply with the guidelines provided in SAMHSAís Rapid HIV Testing Initiative (www. samhsa.gov/HIVHep/rhti_factsheet.aspx). As a preliminary positive test, positive results should be confirmed by supplemental HIV testing. In addition, some States have other requirements for laboratory testing in general and HIV testing specifically.

STD testing

Early testing for STDs in patients receiving MAT usually is a State health requirement. Persons who inject drugs are at higher risk of STDs, primarily from increased likelihood of involvement in sex trading to finance drug use and the disinhibiting effects of psychoactive substances (Sullivan and Fiellin 2004). Therefore, all patients in MAT should receive serologic screening for syphilis and, for women and symptomatic men, genital cultures for gonorrhea and chlamydia (Sullivan and Fiellin 2004). In the early stages of admission and treatment, patients should be educated about the effects of STDs and their correlation with other communicable diseases, such as HIV/AIDS and hepatitis C, to increase patientsí knowledge of the ways they can avoid these risks.

For many patients who are opioid addicted, sexual activities are intertwined with drug use behaviors (Calsyn et al. 2000***b***). Documenting the sexual histories of heterosexual and lesbian, gay, and bisexual (LGB) patients, in terms of timing of sexual encounters and partners, is essential to determine their potential exposure to HCV, HIV, and other STDs, as well as the risk of infection for other sexual partners. Several studies have pointed to increased high-risk sexual behavior among populations that are substance addicted, homeless, and mentally ill, in addition to higher levels of psychological distress and psychiatric symptoms (McKinnon et al. 2002; Stoskopf et al. 2001).

Additional drug testing

After initial drug testing, subsequent assessment should include further review of urine, blood, oral fluid, or other drug test results. Ideally, drug tests should be conducted regularly and

randomly during treatment. The first test is especially important because it is part of the initial evaluation and may serve as documentation of current opioid use. As noted in Federal regulations, the presence of opioids in test results does not establish a diagnosis of opioid addiction, and the absence of opioids does not rule it out. Clinical examination and an applicantís medical history are keys to determine the appropriateness of MAT. Chapter 9 discusses drug-testing procedures and Federal regulations governing these procedures.

Womenís Health

Women in MAT should receive information on their particular health needs, for example, family planning, gynecological health, and menopause (see the forthcoming TIP ***Substance Abuse Treatment: Addressing the Specific Needs of Women*** [CSAT forthcoming ***f***]). Women of childbearing age should be counseled on pregnancy testing during admission before making decisions about detoxification (42 CFR, Part 8 ß 12(e)(3)). Pregnancy testing, along with onsite access to or referral for family planning services, should be available in all OTPs as part of an overall womenís health initiative (see chapter 13).

Induction Assessment

Induction is the riskiest stage of MAT (see chapter 5), and proper medical assessment during induction requires an understanding of the pharmacology of treatment medication (see chapter 3). A patient should be assessed at least daily during induction for signs of overmedication or undermedication, and dose adjustments should be made accordingly.

Comprehensive Assessment

Completion of induction marks the beginning of stabilization and maintenance treatment and ongoing, comprehensive medical and psychosocial assessment conducted over multiple sessions. This assessment should include, but not be limited to, patient recollections of and attitudes about previous substance abuse treatment; expectations and motivation for treatment; level of support for a substance-free lifestyle; history of physical or sexual abuse; military or combat history; traumatic life events; and the cultural, religious, and spiritual basis for any values and assumptions that might affect treatment. This information should be included in an integrated summary in which data are interpreted, patientsí strengths and problems are noted, and a treatment plan is developed (see chapter 6) that matches each patient to appropriate services.

Data should be collected in a respectful way, taking into consideration a patientís current level of functioning. Motivational interviewing techniques (Miller and Rollnick 2002) can help engage applicants early. The information collected depends on program policies, procedures, and treatment criteria; State and Federal regulations; and the patientís stability and ability to participate in the process. The psychosocial history can reveal addiction-related problems in areas that might be overlooked, such as strengths, abilities, aptitudes, and preferences. Most information can be analyzed by using standardized comprehensive assessment instruments tailored to specific populations or programs, such as those described by Dodgen and Shea (2000).

SAMHSA regulations require that patients ìaccepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatmentî (42 CFR, Part 8 ß 12(f)(4) [***Federal Register*** 66(11):1097]). Treatment plans should be reviewed and updated, initially every 90 days and, after 1 year, biannually or whenever changes affect a patientís treatment outcomes. Ongoing monitoring should ensure that services are received, interventions work, new problems are identified and documented, and services are adjusted as problems are solved. Patientsí views of their progress, as well as the treatment teamís assessment of patientsí responses to

treatment, should be documented in the treatment plan.

Patient Motivation and Readiness for Change

Patient motivation to engage in MAT is a predictor of early retention (Joe et al. 1998) and is associated with increased participation, positive treatment outcomes, improved social adjustment, and successful treatment referrals (CSAT 1999***a***).

Starting with initial contact and continuing throughout treatment, assessment should focus on patient motivation for change (CSAT 1999***a***). OTP staff members help patients move beyond past experiences (e.g., negative relationships with staff, inadequate dosing) by focusing on making a fresh start, letting go of old grievances, and identifying current realities, ambivalence about change, and goals for the future. It often is helpful to enlist recovering patients in motivational enhancement activities. TIP 35, ***Enhancing Motivation for Change in Substance Abuse Treatment*** (CSAT 1999***a***), provides extensive information about stages of change, the nature of motivation, and current guidelines for enhancing patient motivation to change.

Substance Use Assessment

As discussed previously, a patientís lifetime substance use and treatment history should be documented thoroughly. The following areas should be assessed:

- Periods of abstinence (e.g., number, duration, circumstances)
- Circumstances or events leading to relapse
- Effects of substance use on physical, psychological, and emotional functioning
- Changing patterns of substance use, withdrawal signs and symptoms, and medical sequelae.

Reports of psychiatric symptoms during abstinence help treatment providers differentiate drug withdrawal from mental disorder symptoms and can reveal important clues to effective case management, for example, the need to refer patients for treatment of co-occurring disorders.

Chapter 11 discusses treatment methods and considerations for patients with histories of multiple substance abuse. Most of these patients fall into one of three groups, which should be determined during assessment: those who use multiple substances (1) to experience their psychoactive effects, (2) to self-medicate for clinically evident reasons (e.g., back pain, insomnia, headache, co-occurring disorders), or (3) to compensate for inadequate treatment medication (Leavitt et al. 2000). Multiple substance use should be identified and addressed as soon as possible because of the risk of possible overdose for patients who continue to abuse drugs or alcohol during treatment. Continued substance abuse while in MAT might indicate that another treatment option is more appropriate. A challenge in treating patients who abuse substances for clinically evident reasons is to determine whether the patients are attempting to medicate undiagnosed, misdiagnosed, or undertreated problems. If so, then effectively addressing these related problems may reduce or eliminate continuing drug or alcohol abuse and improve outcomes.

Cultural Assessment

A comprehensive assessment should include patientsí values and assumptions; linguistic preferences; attitudes, practices, and beliefs about health and well-being; spirituality and religion; and communication patterns that might originate partly from cultural traditions and heritage (Office of Minority Health 2001). Staff knowledge about diverse groups is important for effective treatment services. Of particular importance are experiences and coping mechanisms related to assimilation and acculturation of groups into mainstream American culture that may affect how they perceive substance abuse and MAT. Gathering pertinent information often must rely on subjective sources (e.g., interviews and

questionnaires). Even so, staff members involved in screening and assessment should be cautioned against making value judgments about cultural or ethnic preferences or assumptions about ìaverageî middle-class American values and beliefs. (See the forthcoming TIP ***Improving Cultural Competence in Substance Abuse Treatment*** [CSAT forthcoming ***b***].)

A shared staffñpatient cultural identity is attractive to some patients entering treatment. To the extent possible, patient preferences for staff members who share their cultural identity should be honored. Multilingual educational materials and displays of culturally diverse materials in the OTP help patients feel more at ease when English is not their primary language.

Psychosocial Assessment

The components and objectives of psychosocial assessment also are applicable to patients in MAT. A psychosocial assessment typically identifies the relevant dynamics of patientsí lives and functioning both before the onset of illness (e.g., depression, anxiety) and currently. It identifies patientsí specific strengths and resources (e.g., employment, supportive family relationships) as a basis for focused, individualized, effective treatment planning.

History of co-occurring disorders and current mental status

Mental status assessments identify the threshold signs of co-occurring disorders and require familiarity with the components of a mental status examination (i.e., general appearance, behavior, and speech; stream of thought, thought content, and mental capacity; mood and affect; and judgment and insight) as outlined in ***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*** (American Psychiatric Association 2000). A mental status assessment also should look for perceptual disturbances and cognitive dysfunction.

Qualified professionals should train all staff members involved in screening and assessment to recognize signs and symptoms of change in patientsí mental status. This training should be ongoing. After reviewing their observations with the program physician, staff members should refer all patients still suspected of having co-occurring disorders for psychiatric evaluation. This evaluation should identify the types of co-occurring disorders and determine how they affect patientsí comprehension, cognition, and psychomotor functioning. Persistent neuropsychological problems warrant formal testing to diagnose their type and severity and to guide treatment. Consultations by psychologists or physicians should be requested or referrals made for testing. (See chapter 12 for typical methods of psychiatric screening and diagnosis in an OTP.)

A psychosocial assessmentÖ identifies the relevant dynamics of patientsí lives and functioning both before the onset of illness and currently.

Sociodemographic history

Sociodemographic data about an applicant should include employment, educational, legal, military, family, psychiatric, and medical histories, as well as current information, and should be supplemented by documents for identification, such as a driverís license, birth or baptismal certificate, passport, Social Security card, Medicaid card, public assistance card, or identification card from another substance abuse treatment program.

Family and cultural background, relationships, and supports

The effect of substance use on a patientís family cannot be overestimated, and family problems should be expected for most patients entering treatment. The comprehensive assessment should include questions about family relationships and problems, including any history of domestic violence, sexual abuse, and mental disorders (see below). When possible, the assessment should include input from relatives and significant others. Because families with members who abuse substances have problems directly linked to this substance abuse, at least one staff member should be trained in family therapy or in making appropriate referrals for this intervention.

During assessment, program staff should be sensitive to various family types represented in the patient population. For example, programs treating significant numbers of single parents should consider onsite childcare programs. Structured childcare services also enable OTP staff to observe and assess a patientís family functioning, which can be valuable in treatment planning.

Any counselor or treatment provider who might confront emergencies related to child or spousal abuse should be trained in how to identify and report these problems. TIP 25, ***Substance Abuse Treatment and Domestic Violence*** (CSAT 1997***b***), provides screening, assessment, and response guidance when domestic violence is suspected. TIP 36, ***Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues*** (CSAT 2000***d***), focuses on screening and assessment when patients are suspected of being past victims or perpetrators of child abuse. Staff members should be trained to listen and prepared to hear traumatic stories and handle these situations, for example, by monitoring any intense symptoms and seeking special assistance when necessary (CSAT 2000***d***). Staff should be able to identify individuals who exhibit certain signs and symptoms associated with abuse (e.g., posttraumatic stress disorder [PTSD]) and provide or coordinate immediate services to address it (CSAT 1997***b***, 2000***d***).

Child abuse. All States require mandatory reporting of child abuse by helping professionals including OTP staffóparticularly State-licensed physicians, therapists, nurses, and social workers (CSAT 2000***d***). Most States require that this reporting be immediate and offer toll-free numbers. Most also require that reports include the name and address of a parent or caretaker, the type of abuse or neglect, and the name of the alleged perpetrator. Failure to report indications of abuse that results in injury to a child can lead to criminal charges, a civil suit, or loss of professional licensure. Mandated reporters generally are immune from liability for reports made in good faith that later are found to be erroneous (CSAT 2000***d***).

Staff members who suspect domestic violence should investigate immediately whether a patientís children have been harmed. Inquiries into possible child abuse can occur only after notice of the limitations of confidentiality in MAT (42 CFR, Part 8 ß 12(g)) has been given to the patient, who must acknowledge receipt of this notice in writing. Patients also must be informed, during orientation and when otherwise applicable, that substance abuse treatment providers are required to notify a childrenís protective services agency if they suspect child abuse or neglect.

Spousal or partner abuse. Generally, if a patient believes that she or he is in imminent danger from a batterer, the treatment provider should respond to this situation before addressing any others and, if necessary, suspend the screening or assessment interview to do so. Exhibit 4-3 summarizes the steps a treatment provider should follow. He or she should refer a patient to a shelter, legal services, or a domestic violence program if indicated. Providers should be familiar with relevant Federal, State, and local regulations on domestic violence (e.g., the 1994 Violence Against Women Act [visit www.ojp.usdoj.gov/vawo/laws/vawa/vawa.htm])

Exhibit 4-3

Recommended Procedures for Identifying and Addressing Domestic Violence*

- ï Look for physical injuries, especially patterns of untreated injuries to the face, neck, throat, and breasts, which might become apparent during the initial physical examination.
- ï Pay attention to other indicators: history of relapse or treatment noncompliance; inconsistent explanations for injuries and evasiveness; complications in pregnancy; possible stress- and anxiety-related illnesses and conditions; sad, depressed affect; or talk of suicide.
- ï Fulfill legal obligations to report suspected child abuse, neglect, and domestic violence.
- ï Never discuss a patient without the patientís permission; understand which types of subpoenas and warrants require that records be turned over to authorities.
- ï Convey that there is no justification for battering and that substance abuse is no excuse.
- ï Contact domestic violence experts when battery has been confirmed.

*State laws may include other requirements.

and the legal resources available (e.g., restraining orders, duty to warn, legal obligation to report threats and past crimes, confidentiality).

Romans and colleagues (2000) identified the following methods for exploring potential domestic violence situations, which can be incorporated into effective assessment tools:

- ï Always interview patients in private about domestic violence.
- ï Begin with direct, broad questions and move to more specific ones; inquire how disagreements or conflicts are resolved (e.g., ìDo you want to hit [him or her] to make [him or her] see sense?î); ask whether patients have trouble with anger or have done anything when angry that they regret; combine these questions with other types of lifestyle questions.
- ï Ask about violence by using concrete examples and specific hypothetical situations rather than vague, conceptual questions.
- ï Display information about domestic violence in public (e.g., waiting room) and private (e.g., restroom) locations.
- ï Use opportunities during discussions (e.g., comments about marital conflict situations or poor communication with partners) to probe further.
- ï Obtain as complete a description as possible of the physical, sexual, and psychological violence perpetrated by or on a patient recently; typically, those who commit domestic violence minimize, deny, or otherwise obscure their acts.

History of physical or sexual abuse

Some patients enter an OTP with a history of physical or sexual abuse, which frequently causes additional psychological distress (Schiff et al. 2002). Information about these types of abuse is important in treatment planning but not always easily accessible using specific assessment tools, especially early in treatment.

Some patients with abuse histories might deny their victimization. Many women are less likely to admit abuse to male counselors. Male staff should know when to request a staff change for counseling about physical or sexual abuse. Patients might not be ready to address the problem, think it is unrelated to substance abuse, or be ashamed. Gathering information from them about abuse, therefore, requires extreme care and respect during screening and assessment. Once patients are stabilized and their practical needs are addressed, counseling by qualified treatment providers can focus on this problem.

Peer relations and support

The extent of social deterioration, interpersonal loss, and isolation that patients have experienced should be documented thoroughly during screening and assessment. Assessment of a patientís support systems, including past participation in mutual-help groups (e.g., Alcoholics Anonymous, Methadone Anonymous [MA]), is critical to identifying peer support networks that provide positive relationships and enhance treatment outcomes. Some 12-Step groups are ill-informed about MAT and may be unaware of the treatment goals of MAT and less than supportive; in these cases, providers should help patients identify other sources of support (e.g., MA groups) and encourage continued development of some type of peer support network. In areas with limited resources, patients may be able to overcome initial discriminatory behavior in existing groups by increasing their knowledge of MAT and their ability to self-advocate.

[A]ssessment and treatment… should focus on stopping the substance abuse that interferes with patientsí well-being.

Housing status and safety concerns

Based on year 2000 estimates, approximately 10 percent of patients in MAT are homeless or living as transients when admitted to treatment (Joseph et al. 2000). Moreover, those who are not homeless often live with people who are addicted or in areas where substance use is common. In the opinion of the consensus panel, early intervention to arrange safe, permanent shelter for these patients should be a high priority, and a patientís shelter needs should be ascertained quickly during screening and assessment. OTPs should establish special support services to help patients secure appropriate living arrangements, such as referral agreements with housing agencies or other programs to locate housing that addresses the special needs of homeless patients.

Criminal history and legal status

Another purpose of screening and assessment is to identify legal issues that might interrupt treatment, such as outstanding criminal charges or ongoing illegal activity to support substance use; however, pending or unresolved charges are not a contraindication for MAT. Assessment may involve exploring personal circumstances such as child custody and related obligations. In the consensus panelís experience, many patients ignore legal problems during periods of substance use, but these problems pose a serious threat to recovery. In addition, a patientís arrest record, including age at first arrest, arrest frequency, nature of offenses, criminal involvement during childhood, and life involvement with the criminal justice system, should be clarified.

Insurance status

Patientsí resources to cover treatment costs should be determined during screening and assessment. Often they are uninsured or have not explored their eligibility for payment assistance. The consensus panel believes that OTPs are responsible for helping patients explore

payment options so that they have access to a full range of treatment services, including medical care, while ensuring payment to the OTP.

In situations of inadequate funding or patient ineligibility for funds, another source of payment should be identified. OTP staff can assist patients in applying for public assistance or inquiring whether personal insurance will reimburse MAT costs. Counselors can help patients make decisions about involving their insurance companies and address fears that employers will find out about their substance use or that benefits for health care will be denied.

Employment history

Another important component of psychosocial assessment is a patientís employment history. Based on year 2000 estimates, only 20 percent of patients in MAT were employed when admitted to an OTP (Joseph et al. 2000). Until they are stabilized, employed patients often experience substance-related difficulties at the workplace, including lack of concentration, tardiness and absences, inability to get along with coworkers, on-the-job accidents, and increased claims for workersí compensation. Early identification of these difficulties can help staff and patients create a more effective treatment plan.

Patients who are employed often are reluctant to enter residential treatment or take the time to become stabilized on medication; however, most of these patients would take medical or other leave time if they were hospitalized for other illnesses, and they should be encouraged to take their addiction as seriously. A physicianís note recommending time off work for some period might help, but it should be on letterhead that does not reference drug treatment.

Military or other service history

A patientís military or other service history can highlight valuable areas in treatment planning. In particular, was military service generally a positive or negative experience? If the former, treatment providers can help patients identify areas of strength or personal achievement, such as the ability to cope under stress, receipt of medals for service accomplishments, and honorable discharge; patients can learn to build on past strengths in current challenging situations and to progress in treatment. If the latter, providers should review patientsí negative military experiences, including loss of friends and loved ones, onset of substance use, war-related injuries, chronic pain, PTSD, and co-occurring disorders (e.g., depression). This information might indicate patterns of behavior that continue to affect recovery.

Patientsí military history also might reveal their eligibility for medical and treatment resources through U.S. Department of Veterans Affairs programs and hospitals or social service agencies.

Spirituality

ìSpiritualityî in this TIP refers to willing involvement in socially desirable activities or processes that are beyond the immediate details of daily life and personal self-interest. Attention to the ethics of behavior, consideration for the interests of others, community involvement, helping others, and participating in organized religion are expressions of spirituality.

A patientís spirituality can be an important treatment resource, and persons recovering from addiction often experience increased interest in the spiritual aspects of their lives. A study by Flynn and colleagues (2003) of 432 patients admitted to 18 OTPs found that those who remained in recovery for 5 years credited religion or spirituality as one factor in this outcome. Staff should assess patientsí connections with religious institutions because these institutions often provide a sense of belonging that is valuable in the rehabilitative process.

Miller (1998) found a lack of research exploring the association between spirituality and addiction recovery but concluded that spiritual engagement or reengagement appeared to be correlated with recovery. In studies reviewed by Muffler and colleagues (1992), individuals with a high degree of spiritual motivation to

recover reported that treatment programs that included spiritual guidance or counseling were more likely to produce positive outcomes than programs that did not. OTPs should assess spiritual resources adequately. Counselors and other mental health professionals could benefit from training in patient spirituality if it is difficult for them to explore.

Sexual orientation and history

The assessment and treatment needs of heterosexual and LGB populations are similar and should focus on stopping the substance abuse that interferes with patientsí well-being. Assessment of risk factors associated with sexual encounters and partners is essential. What often differs for an LGB population is the importance of assessing patientsí sexual or gender orientation concerns, such as their feelings about their sexual orientation (CSAT 2001***b***). OTP staff should pay strict attention to confidentiality concerns for LGB patients because they may be at increased risk of legal or other actions affecting employment, housing, or child custody. Treatment modalities and programs should be accessible to all groups, and programs providing ancillary services should be sensitive to the special needs of all patients regardless of sexual orientation (CSAT 2001***b***).

Patientsí ability to manage money

Financial difficulties are common among patients in MAT, who often have spent considerable money on their substance use that otherwise would have paid for rent, food, and utilities. Financial status and money management skills should be assessed to help patients understand their fiscal strengths and weaknesses as they become stabilized. Patients often need assistance to adjust to loss of income caused by reduced criminal activity and develop skills that enhance their legitimate earning power. Once financial factors are clarified, patients may be better prepared to devise realistic strategies to achieve short- and long-term goals.

Recreational and leisure activities

Recreational and leisure activities are important in recovery; therefore, assessment should determine any positive activities in which patients have participated before or during periods of substance use. Identifying existing recreational and leisure time preferences and gaining exposure to new ones can be significant steps in developing a recovery-oriented lifestyle.

Appendix 4-A. Example of Standard Consent to Opioid Maintenance Treatment

Consent to Participation in Opioid Pharmacotherapy Treatment

Patient's Name: _____ **Date:** _____

I hereby authorize and give voluntary consent to the Division and its medical personnel to dispense and administer opioid pharmacotherapy (including methadone or buprenorphine) as part of the treatment of my addiction to opioid drugs. Treatment procedures have been explained to me, and I understand that this will involve my taking the prescribed opioid drug at the schedule determined by the program physician, or his/her designee, in accordance with Federal and State regulations.

It has been explained that, like all other prescription medications, opioid treatment medications can be harmful if not taken as prescribed. I further understand that opioid treatment medications produce dependence and, like most other medications, may produce side effects. Possible side effects, as well as alternative treatments and their risks and benefits, have been explained to me.

I understand that it is important for me to inform any medical provider who may treat me for any medical problem that I am enrolled in an opioid treatment program so that the provider is aware of all the medications I am taking, can provide the best possible care, and can avoid prescribing medications that might affect my opioid pharmacotherapy or my chances of successful recovery from addiction.

I understand that I may withdraw voluntarily from this treatment program and discontinue the use of the medications prescribed at any time. Should I choose this option, I understand I will be offered medically supervised tapering.

For Female Patients of Childbearing Age: There is no evidence that methadone pharmacotherapy is harmful during pregnancy. If I am or become pregnant, I understand that I should tell my medical provider right away so that I can receive appropriate care and referrals. I understand that there are ways to maximize the healthy course of my pregnancy while I am in opioid pharmacotherapy.

_____	_____	_____
Signature of Patient	**Date of Birth**	**Date**

Witness: _____

Adapted with permission from Department of Psychiatry and Behavioral Sciences, Albert Einstein College of Medicine, Division of Substance Abuse, Bronx, NY.

5 Clinical Pharmacotherapy

In This Chapter…

This chapter describes pharmacotherapy in opioid treatment programs (OTPs), in particular the clinical use of methadone, with limited discussion of levo-alpha acetyl methadol (LAAM) and buprenorphine. More limited coverage is provided on the opioid antagonist naltrexone, which is not used widely for opioid addiction treatment in the United States. As explained in chapter 3, at this writing most OTPs have discontinued the use of LAAM for new patients, and its continued availability is uncertain. TIP 40, ***Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*** (CSAT 2004***a***), provides more detailed information about buprenorphine.

In general, the choice of medication used in medication-assisted treatment for opioid addiction (MAT) is based on safety and efficacy, patient preferences, and treatment goals. Methadone maintenance treatment has the longest successful track record in patients addicted to opioids for more than a year and has been shown to control withdrawal symptoms, stabilize physiologic processes, and improve functionality. Studies also have found that methadone maintenance treatment reduces criminality, noncompliance with HIV/AIDS therapy, seroconversion to HIV/AIDS, and mortality associated with opioid addiction (Appel et al. 2001; Ball and Ross 1991). Since 2001, LAAM, although effective in opioid pharmacotherapy, has carried a restrictive label precluding its use as the initial medication for MAT. As reviewed in chapter 3, the effectiveness of buprenorphine has been found to be similar to that of methadone and LAAM (Johnson et al. 2000). Sublingual buprenorphine formulations have been approved for use in OTPs and by physicians in office-based and other health care settings. Some patients prefer buprenorphine maintenance in an office-based opioid treatment (OBOT) setting to the daily observed dosing that is part of methadone maintenance in an OTP. However, patients who progress in MAT while in an OTP eventually may qualify for take-home medication lasting up to 30 days at a time, as detailed below, and patients desiring ongoing buprenorphine pharmacotherapy now can receive buprenorphine on a less-than-daily basis in either an OTP or OBOT setting. For some patients, these options may reduce the attendance requirements for MAT in an OTP.

For patients who do not qualify for or do not prefer opioid maintenance treatment (see ìContraindications to Opioid Pharmacotherapyî below), a primary issue during treatment is what to do about withdrawal symptoms. Naturally occurring opioid withdrawal is almost never life threatening, but it can produce discomfort severe enough to warrant urgent intervention. Treatment for withdrawal symptoms usually involves administration of a long-acting opioid medication such as methadone or buprenorphine, which can be followed by gradual tapering of the medication as withdrawal symptoms diminish.

Control of withdrawal symptoms often is insufficient treatment to prevent a relapse to opioid abuse, and detoxification alone may yield only short-term benefits. Research has shown that retention in treatment over an extended period is key to successful outcomes for opioid addiction in many patients, just as it is for other chronic diseases like hypertension, diabetes, and asthma (McLellan et al. 2000). Therefore, when detoxification from short-acting opioids is provided, the consensus panel recommends linkage to ongoing psychosocial treatment, with or without additional maintenance therapy with an opioid antagonist such as naltrexone. Comprehensive, long-term opioid agonist maintenance remains the treatment with the best track record of controlling opioid use and saving lives, although opioid partial agonist therapy is promising. Access and easy transfer to this care should remain available as part of any detoxification program.

Contraindications to Opioid Pharmacotherapy

The consensus panel believes that few psychiatric or medical diagnoses categorically should rule out admission to an OTP or access to opioid pharmacotherapy. Inclusion rather than exclusion should be the guiding principle. Types of people who possibly should not be admitted to an OTP and should receive other interventions include

- Individuals who abuse opioids but whose conditions do not meet criteria for opioid dependence outlined in the ***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*** (DSM-IV-TR) (American Psychiatric Association 2000). If a clear history of opioid abuse or addiction exists but a person currently is not addicted, regulations allow admission to an OTP in two cases in which a person might relapse without treatment: pregnancy and release from incarceration (42 Code of Federal Regulation [CFR], 8 Part ß 12(e)(3)).
- Individuals with less than 1 year of opioid addiction and no addiction treatment history, except patients receiving OBOT with buprenorphine. Detoxification might be attempted with applicants who have a shorter history of addiction. Applicants receiving buprenorphine may be admitted to an OTP for either medically supervised withdrawal or maintenance treatment.
- Applicants who cannot attend treatment sessions regularly, especially for medication dosing (unless a clinical exception can be obtained [see chapter 7]); this requirement is less of a hindrance for patients receiving OBOT with buprenorphine.
- Previous patients who have had allergic reactions to methadone, LAAM, or buprenorphine.
- For LAAM, applicants with cardiac abnormalities such as prolonged QT interval.

In addition, people who are opioid addicted and meet DSM-IV-TR criteria for alcohol or sedative dependence might be problematic candidates for opioid pharmacotherapy because the combined effects of alcohol or sedatives that depress the central nervous system (CNS) can cause serious adverse events during MAT (see discussion of drug interactions in chapter 3). Some treatment providers require detoxification from alcohol and sedatives before opioid pharmacotherapy, followed by careful monitoring such as daily Breathalyzer™ tests, ongoing drug tests, and reduction or withholding of medication if a test is positive. The consensus panel endorses this strategy, provided that adequate alcohol or sedative detoxification

facilities are readily available. If not, both opioid addiction and alcohol or sedative dependence should be treated concurrently at the OTP site with a combination of psychosocial and pharmacological interventions.

Stages of Pharmacotherapy

The stages of pharmacotherapy with methadone, LAAM, or buprenorphine include induction, stabilization, and maintenance. The stages of naltrexone pharmacotherapy may differ.

Induction

Induction procedures for methadone, LAAM, and buprenorphine depend on the unique pharmacologic properties of each medication, prevailing regulatory requirements, and patient characteristics. Regardless of the medication used, safety is key during the induction stage.

General considerations

Timing. When to begin the first dose of opioid treatment medication is important. Most treatment providers begin treating new patients when there are no signs of opioid intoxication or sedation and some beginning signs of opioid withdrawal. Administration of the first dose also should await a physical assessment to rule out any acute, life-threatening condition that opioids might mask or worsen (see chapter 4 for more information on medical assessment). For naltrexone, patients should be abstinent from all short-acting opioids for at least 7 days and from long-acting opioids, such as methadone, for at least 10 days before beginning the medication to prevent potentially severe withdrawal symptoms (OíConnor and Fiellin 2000).

Other substance use. The presence of sedatives such as benzodiazepines or alcohol should be ruled out before induction to minimize the likelihood of oversedation with the first dose. OTP staff should ensure that patients known to abuse sedatives, tranquilizers, tricyclic antidepressants, benzodiazepines, alcohol, or other CNS depressants are told in clear language of the dangers of adverse effects if they take these substances while being stabilized or maintained on methadone, LAAM, or buprenorphine.

Observed dosing. Observed dosing with methadone, LAAM, or buprenorphine should be part of the medical safety procedure and diversion control plan in an OTP and is recommended during induction with buprenorphine. Observed dosing is the only way to ensure that a patient ingests a given dose and to monitor a patientís response. In observed dosing, staff members who dispense medication first carefully identify patientsó sometimes by requiring them to remove hats or dark glasses, for exampleóand then provide the medication.

> Regardless of the medication used, safety is key during the induction stage.

To ensure that patients swallow oral doses of methadone or LAAM, they should be required to speak before and after ingesting at least 2 ounces of liquid in which an appropriate dose of medication is dissolved. For buprenorphine, a sublingual tablet should be observed to have dissolved completely under the tongue. After the first dose, patients should wait in an observation area and be checked 30 to 60 minutes later for acute adverse effects. If same-day dosing adjustments must be made, patients should wait 2 to 4 more hours after the additional dosing, for further evaluation when peak effects are achieved. The consensus panel recommends that patients be observed for several hours after the first dose of any opioid treatment medication. This observation is particularly important for patients at higher risk of overdose, including those naive to methadone, LAAM, and buprenorphine; those receiving other CNS-depressant medications or known to abuse CNS depressants; and severely medically

ill, frail, or elderly patients. Naltrexone typically is prescribed without observed dosing, but poor patient compliance with ongoing naltrexone therapy has led some investigators to look at using family members to ensure that patients take their medication (Fals-Stewart and OíFarrell 2003).

Initial dosing. The first dose of any opioid treatment medication should be lower if a patientís opioid tolerance is believed to be low, the history of opioid use is uncertain, or no signs of opioid withdrawal are evident. Some former patients who have been released from incarceration or are pregnant and are being readmitted because they have a history of addiction might have lost their tolerance. Loss of tolerance should be considered for any patient who has abstained from opioids for more than 5 days. In general, the safety principle ìstart low and go slowî applies for early medication dosages in an outpatient OTP. The amount of opioid abuse estimated by patients usually gives only a rough idea of their tolerance and should not be used as a dosing guide for induction, nor should initial dosages be determined by previous treatment episodes or patient estimates of dollars spent per day on opioids. Patients transferred from other treatment programs should start with medication dosages identical to those prescribed at their previous OTPs.

[T]he safety principle ìstart low and go slowî applies for early medication dosages in an outpatient OTP.

Dosage adjustments in the first week of treatment should be based on how patients feel at the peak period for their medication (e.g., 2 to 4 hours after a dose of methadone is administered), not on how long the effects of a medication last. As stores of medication accumulate in body tissues (see below), the effects begin to last longer.

Steady state. Initial dosing should be followed by dosage increases over subsequent days until withdrawal symptoms are suppressed at the peak of action for the medication. Methadone, LAAM, and buprenorphine are stored in body tissues, including the liver, from which their slow release keeps blood levels of medication steady between doses. It is important for physicians, staff members, and patients to understand that doses of medication are eliminated more quickly from the bloodstream and medication effects wear off sooner than might be expected until sufficient levels are attained in tissues. During induction, even without dosage increases, each successive dose adds to what is present already in tissues until steady state is reached. Steady state refers to the condition in which the level of medication in a patientís blood remains fairly steady because that drugís rate of intake equals the rate of its breakdown and excretion.

Steady state is based on multiples of the elimination half-life. Approximately four to five half-life times are needed to establish a steady state for most drugs. For example, because methadone has a half-life of 24 to 36 hours, its steady stateóthe time at which a relatively constant blood level should remain present in the bodyóis achieved in 5 to 7.5 days after dosage change for most patients. However, individuals may differ significantly in how long it takes to achieve steady state.

Patients should stay on a given dosage for a reasonable period before deciding how it will ìhold.î During induction, patients should be instructed to judge their doses by how they feel during the peak period (the point of maximum concentration of medication in the blood [for methadone, 2 to 4 hours after taking a dose]), rather than during the trough period (the low point of medication concentration in blood just before the next dose [for methadone, approximately 24 hours after ingestion]). Patients who wake up sick during the first few days of opioid pharmacotherapy might become convinced that

they need a dose increase, when in fact they need more time for tissue stores to reach steady state. In contrast, patients who wake up sick after the first week of treatmentówhen tissue stores have reached steady-state levelsómight indeed need higher doses.

In closely monitored settings such as inpatient programs, multiple split doses can be administered per day based on patientsí symptoms at peak blood levels. Outpatient programs are limited in this approach because patients can be monitored only when they are at the OTP site. (Split dosing is discussed further below.) Because buprenorphineís safety profile makes overdose less of a concern, some providers opt to give even new patients receiving buprenorphine some take-home medication for multiple dosing during induction (CSAT 2004***a***).

Induction with methadone and LAAM

Because methadone overdose deaths have occurred in the first few days of treatment (Caplehorn and Drummer 1999; Zador and Sunjic 2000), it is important to adjust methadone dosage carefully until stabilization and tolerance are established. Federal regulations require that methadone initially be given daily under observation for either 6 or 7 days per week. (A take-home dose is allowed for all patients when the OTP is closed on Sunday.) LAAM must continue to be given under observation and administered no more than every 2 to 3 days.

Initial dosing. For a patient actively abusing opioids, a typical first dose of methadone is 20 to 30 mg (Joseph et al. 2000) and is limited by regulations to no more than 30 mg. If withdrawal symptoms persist after 2 to 4 hours, the initial dose can be supplemented with another 5 to 10 mg (Joseph et al. 2000). The total first-day dose of methadone allowed by Federal regulations is 40 mg unless a program physician documents in the patient record that 40 mg was insufficient to suppress opioid withdrawal symptoms (42 CFR, Part 8 ß 12(h)(3)(ii)).

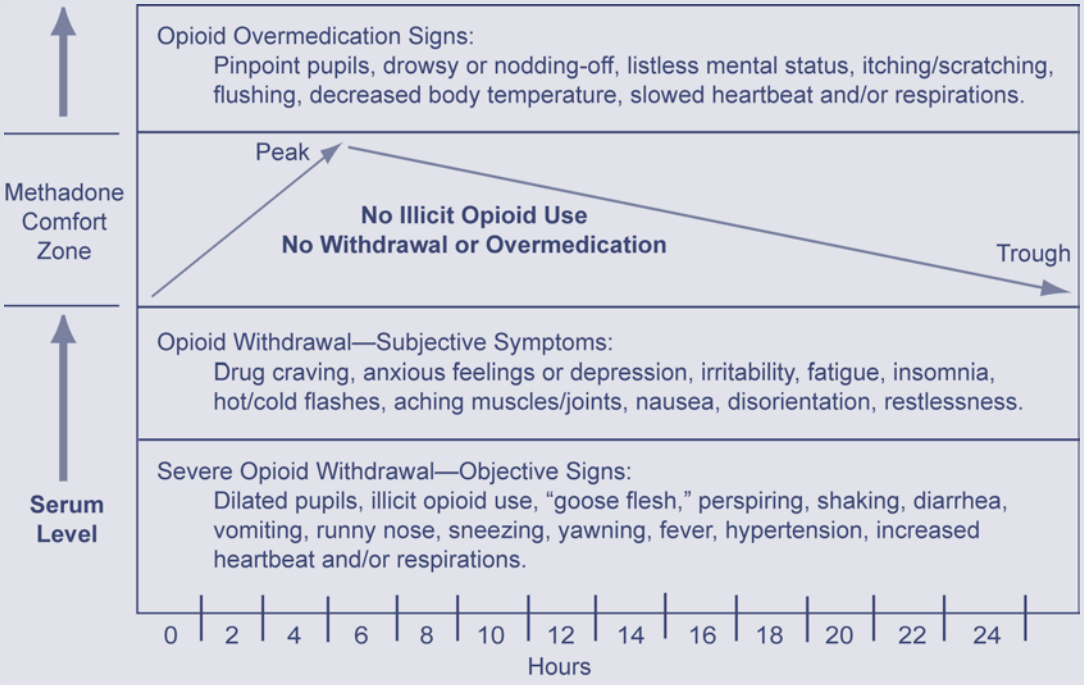
Since 2001, LAAM has carried a restriction that precludes its use as an initial medication for pharmacotherapy because of concerns about its cardiovascular effects. Although direct induction with LAAM can be accomplished with an initial dose of 20 to 40 mg every 48 hours, LAAM has been used almost exclusively in cases involving transfer of patients from methadone maintenance. LAAM must never be given on 2 consecutive days because its extended duration of action can result in toxic blood levels leading to fatal overdose.

Variations in individual response and optimal dosing. Most differences in patient response to methadone can be explained by variations in individual rates of absorption, digestion, and excretion of the drug, which in turn are caused by such factors as body weight and size, other substance use, diet, co-occurring disorders and medical diseases, and genetic factors. Because variation in response to methadone is considerable, the consensus panel believes that the notion of a uniformly suitable dosage range or an upper dosage limit for all patients is unsupported scientifically. Whereas 60 mg of methadone per day may be adequate for some patients, it has been reported that some patients require much more for optimal effect. Treatment providers should avoid thinking of ìhigh dosageî as being above a certain uniform threshold; however, there are few data on the safety of methadone doses above 120 mg/day. For example, diversion of very high doses can be associated with significant risk because the tolerance of the person taking the diverted dose may be insufficient to avoid overdose.

The way a person presents at the OTP is often the best indicator for determining optimal dosage. Looking for clinical signs and listening to patient-reported symptoms related to daily doses or changes in dosage can lead to adjustments and more favorable outcomes (Leavitt et al. 2000). Exhibit 5-1 illustrates the use of signs and symptoms to determine optimal methadone dosages. Generally, the disappearance of opioid withdrawal symptoms indicates adequate dosing and serum methadone levels (SMLs) within the therapeutic comfort zone.

Exhibit 5-1

Using Signs and Symptoms To Determine Optimal Methadone Levels



Adapted from Leavitt et al. (2000), modified with permission from ***Mount Sinai Journal of Medicine***.

Research indicates that patients diagnosed with mental disorders or hepatitis C along with substance addiction may need increases of 50 percent or more in methadone dosage to achieve stabilization (Leavitt et al. 2000; Maxwell and Shinderman 2002).

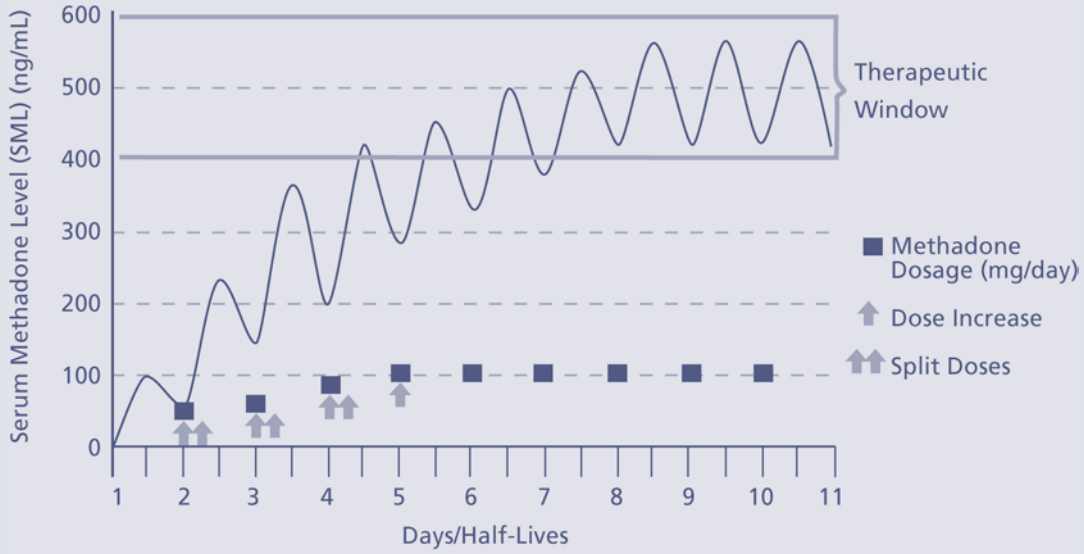
Exhibit 5-2 illustrates how blood levels of methadone rise with repeated dosing until steady state is reached. It is important to understand that steady state is achieved after a dosage ***change***. In Exhibit 5-2, because the last change (to 100 mg) occurred on day 5, steady state was not achieved until approximately day 10.

Induction with buprenorphine

Because buprenorphine has lower abuse potential than methadone or LAAM and is less likely to produce respiratory depression if diverted or misused, qualified practitioners can prescribe buprenorphine without the control structure of an OTP when they meet Drug Addiction Treatment Act of 2000 requirements. No stated requirement exists for observed dosing with buprenorphine, although guidelines strongly recommend dosage monitoring early in treatment (CSAT 2004***a***).

Exhibit 5-2

Induction SimulationóModerate to High Tolerance



Adapted from Payte 2002, with permission.

Initial dosing. Awaiting signs of withdrawal before administering the first dose is especially important for buprenorphine induction because, as explained in chapter 3, buprenorphine can precipitate withdrawal in some circumstances (Johnson and Strain 1999). Precipitated withdrawal usually is more sudden and can be more severe and uncomfortable than naturally occurring withdrawal. The typical first dose of buprenorphine is 4 mg. If withdrawal symptoms persist after 2 to 4 hours, the initial dose can be supplemented with up to 4 mg for a maximum dose of 8 mg of buprenorphine on the first day (Johnson et al. 2003***b***).

Three national evaluations of the buprenorphine-naloxone combination tablet found that direct induction with buprenorphine alone was effective for most people who were opioid addicted. However, buprenorphine tablets without naloxone (sometimes called monotherapy tablets) are recommended during the first 2 days of induction for patients attempting to transfer from a longer acting opioid such as sustained-release morphine or methadone (Amass et al. 2000, 2001) because most of these patients will experience withdrawal effects from the naloxone in the combination tablets. When patientsí tissue levels of a full agonist are a factor and the buprenorphine-naloxone tablet is administered, it may be difficult to determine whether precipitated withdrawal is caused by the partial agonist buprenorphine or small amounts of absorbed naloxone.

For most patients who are appropriate candidates for induction with the combination tablet, the initial target dose after induction should be 12 to 16 mg of buprenorphine in

a 4-to-1 ratio to naloxone (i.e., 12/3 to 16/4 mg [buprenorphine/naloxone]). Bringing patients to this target dosage may be achieved over the first 3 days of treatment by doubling the dose each successive day after initial administration. An initial dose of 4/1 mg (buprenorphine/naloxone) is recommended, followed in 2 to 4 hours with an additional 4/1 mg if indicated. The dosage should be increased on subsequent days to the target dosage (ranging from 12/3 to 16/4 mg per day). During dose induction, patients may need to visit their OTP or physicianís office daily for dose adjustments and clinical monitoring. Further information and guidelines for buprenorphine induction and use can be found in TIP 40, ***Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*** (CSAT 2004***a***).

Induction with naltrexone

The standard procedure for induction to naltrexone therapy is first to make certain that there is an absence of physiological dependence on opioids. This often is done by using a Narcan challenge after a 7- to 10-day period during which opioids are not used. Then the patient is given 25 mg of naltrexone initially, followed by 50 mg the next day if no withdrawal symptoms occur after the first 25 mg dose. Thereafter, the patient is given 50 mg per day or up to 350 mg per week in three doses during the week. The first dose usually is smaller to minimize naltrexoneís side effects, such as nausea and vomiting, and to ensure that patients have been abstinent from opioids for the requisite time (Stine et al. 2003).

Stabilization

The terms ìsteady stateî and ìstabilizationî should be differentiated. Steady state is achieved when a treatment medication is eliminated from the blood at the exact rate that more is added. In contrast, a patient is stabilized when he or she no longer exhibits drug-seeking behavior or craving. The correct (steady-state) medication dosage contributes to a patientís stabilization, but it is only one of several factors, as discussed elsewhere in this TIP. The stabilization stage of opioid pharmacotherapy focuses on finding the right dosage for each patient. The potential for undermedication or overmedication can be avoided by a flexible approach to dosing, which sometimes requires higher dosages of treatment medication than expected, and by taking into account patient-reported symptoms (Leavitt et al. 2000).

Dosage determination

It is critical to successful patient management in MAT to determine a medication dosage that will minimize withdrawal symptoms and craving and decrease or eliminate opioid abuse. Dosage requirements for methadone, LAAM, and buprenorphine must be determined on an individual basis. There is no single recommended dosage or even a fixed range of dosages for all patients. For many patients, the therapeutic dosage range of methadone may be in the neighborhood of 80 to 120 mg per day (Joseph et al. 2000), but it can be much higher, and occasionally it is much lower.

The desired responses to medication that usually reflect optimal dosage include (Joseph et al. 2000)

- Prevention of opioid withdrawal for 24 hours or longer, including both early subjective symptoms and objective signs typical of abstinence
- Elimination of drug hunger or craving
- Blockade of euphoric effects of self-administered opioids (This is not a true blockade like that achieved by naltrexone but reflects cross-tolerance for other opioids, attenuating or eliminating desired sensations when illicit or prescription opioids are self-administered in usual ìstreet doses.î The increasing purity of heroin and availability of highly potent prescription opioids have made it increasingly difficult to achieve complete blockade in patients through cross-tolerance; consequently, some patients require dosages considerably greater than 120 mg per day to achieve this effect.)

- Tolerance for the sedative effects of treatment medication, creating a state in which patients can function normally without impairment of perception or physical or emotional response
- Tolerance for most analgesic effects produced by treatment medication (see "Pain Management" in chapter 10).

Unfortunately, no exact way exists to determine optimal dosage for each patient. However, the consensus panel recommends that OTPs avoid exclusive reliance on drug test results and preconceived notions of correct dosage; instead, OTPs should determine dosage based primarily on patient response. Even when a medication dosage is controlled for body weight (Leavitt et al. 2000), patient responses, such as absence of withdrawal symptoms without oversedation and remission from illicit-opioid use, are the best indicators of appropriate dosage. In addition, the extent of other drug use and alcohol consumption should be considered when determining dosage adequacy. Finally, a patient's complaints (or lack thereof) are also important indicators of dosage adequacy. A patient can experience opioid craving or withdrawal but manage to abstain from illicit opioids.

Methadone. Strong evidence supports the use of daily methadone doses in the range of 80 mg or more for most patients (Strain et al. 1999), but considerable variability exists in patient responses. Some do well on dosages below 80 to 120 mg per day, and others require significantly higher dosages (Joseph et al. 2000). OTPs should exercise additional caution with higher dosages, guarding against diversion of take-home methadone to individuals who are opioid intolerant because higher dosages can be lethal for such individuals.

Buprenorphine. Buprenorphine dosage should be determined in a manner similar to that used for methadone or LAAM. The recommended dosage of buprenorphine to begin stabilization is 12 to 16 mg per day for most patients, with increases provided thereafter as applicable (Johnson et al. 2003***b***). As reviewed by Johnson and colleagues (2003***b***), if patients continue to show evidence of opioid abuse or withdrawal, the dosage should be increased using the same types of guidelines as for methadone. For example, if the goal is to suppress opioid withdrawal symptoms, then dose increases can be less frequent (e.g., weekly or biweekly) because the desired therapeutic response likely will become detectable more slowly.

Most patients are likely to remain stable on 12 to 24 mg per day, although some might need dosages of up to 32 mg per day. Increasing the buprenorphine dosage to 24 mg per day or higher has been shown to prolong the duration of its effects and usually is necessary if patients are to be dosed every other day, which is an option with buprenorphine; however, such an increase usually does not increase buprenorphine's opioid agonist effects to the same degree because of its partial agonist properties (Johnson et al. 2003***b***). Because buprenorphine is a partial agonist, patients who continue to abuse opioids after sufficient exposure to buprenorphine treatment and ancillary psychosocial services or who experience continued symptoms of withdrawal at optimal daily doses of buprenorphine (12 to 32 mg) should be considered for therapy with methadone or LAAM (CSAT 2004***a***; Johnson et al. 2003***b***).

Dosage requirements for methadone, LAAM, and buprenorphine must be determined on an individual basis.

As with all medications used for MAT, when buprenorphine dosage changes are contemplated, the intensity and frequency of other available psychosocial services (see chapter 8) affect patients' ability to refrain from opioid abuse (Bickel et al. 1997) and should be considered.

LAAM. Most patients who begin LAAM are being transferred from methadone and should have been screened for cardiac risk. Equivalency dosing tables for methadone and LAAM are available in the ORLAAM® package insert (Roxane Laboratories, Inc., 2001), and transfer can be done easily. Because of the long-acting nature of LAAM, a patientís reaction should be monitored closely during the first 2 weeks of treatment and adjustments in dosage made accordingly.

Patients may request transfer from methadone to LAAM for various reasons: (1) to avoid the hardship of methadoneís daily observed dosing, (2) to provide negative drug test results at work (LAAM is less likely to show up on screening tests), (3) because they are not doing well on methadone (Borg et al. 2002), (4) because LAAM can be less sedating, and (5) because the patients are rapid metabolizers of methadone and would benefit from LAAM because it is longer acting.

LAAM can be given every other day if an OTP is open all week or three times per week (i.e., two 48-hour doses and one 72-hour dose) if that is more convenient. Although some patients take the same dose on Monday, Wednesday, and Friday, most benefit from an increase on Friday (i.e., 10 to 40 percent more than the Monday and Wednesday doses) with or without an additional small dose of methadone to be taken home and used on Sunday. For stable patients, the best option is a regular LAAM dose on Friday and a full methadone dose (80 percent of the LAAM dose) as a take-home dose for Sunday. The efficacy of LAAM dosing is determined clinically and by patient history and examination; an affordable means to determine blood levels of LAAM and its metabolites is unavailable at this writing.

Naltrexone. Naltrexone can be administered either daily (usually at a dosage of 50 mg per day) or thrice weekly. For the latter, the usual practice is to give 100 mg on Monday and Wednesday and 150 mg on Friday (Stine et al. 2003).

Studies of the importance of dosing

Much evidence shows a positive correlation between medication dosage during MAT and treatment response (e.g., Strain et al. 1999). Higher dosages in some studies probably produced greater cross-tolerance. Cross-tolerance occurs when medication diminishes or prevents the euphoric effects of heroin or other short-acting opioids so that patients who continue to abuse opioids no longer feel ìhigh.î The medication dosage needed for this result depends on how long and how recently a patient has abused heroin or other opioids and how much he or she has used, along with individual differences in the level of brain receptor adaptation induced by chronic opioid use.

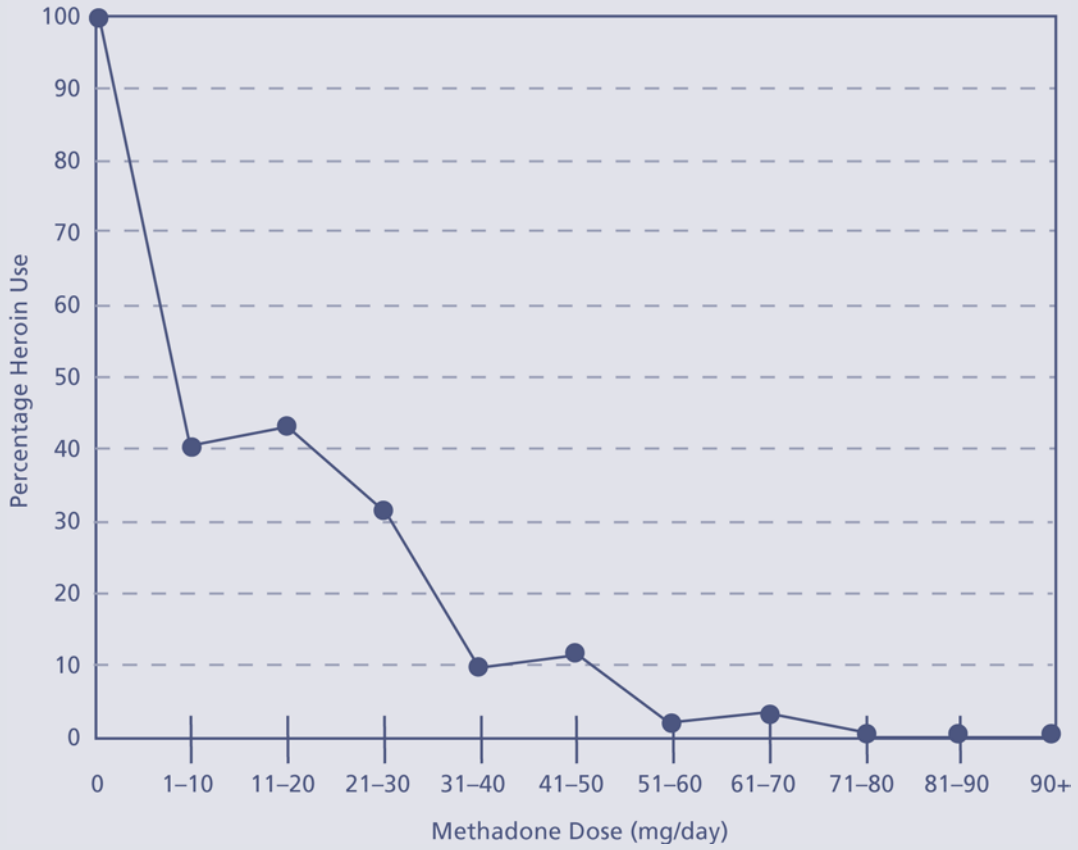
An Australian study connected the importance of dosage with patient retention in MAT (Caplehorn and Bell 1991). The importance of retention for successful treatment outcomes is discussed further in chapter 8. In addition to the benefits of eliminating illicit opioids (see below), reductions in the threats of HIV and hepatitis B and C make adequate dosing and treatment retention high priorities and justify additional studies on the safety and efficacy of methadone doses exceeding 120 mg.

In their classic study, Ball and Ross (1991) clearly demonstrated an inverse relationship between frequency of recent heroin use and methadone dosage. The data in Exhibit 5-3 are based on their study of 407 patients who received methadone maintenance treatment. These data support the premise that lower methadone dosages are less effective than higher or adequate dosages in facilitating abstinence from heroin among patients in MAT. The low end of the effective range has been accepted widely as about 60 mg for most patients (reviewed in Faggiano et al. 2003).

Another study (Maxwell and Shinderman 2002) monitored 144 patients who were not doing well at 100 mg of methadone per day and reported excellent results after raising dosages based on clinical signs and symptoms. Patients receiving

Exhibit 5-3

Heroin Use in Preceding 30 Days
(407 Methadone-Maintained Patients by Current Methadone Dose)



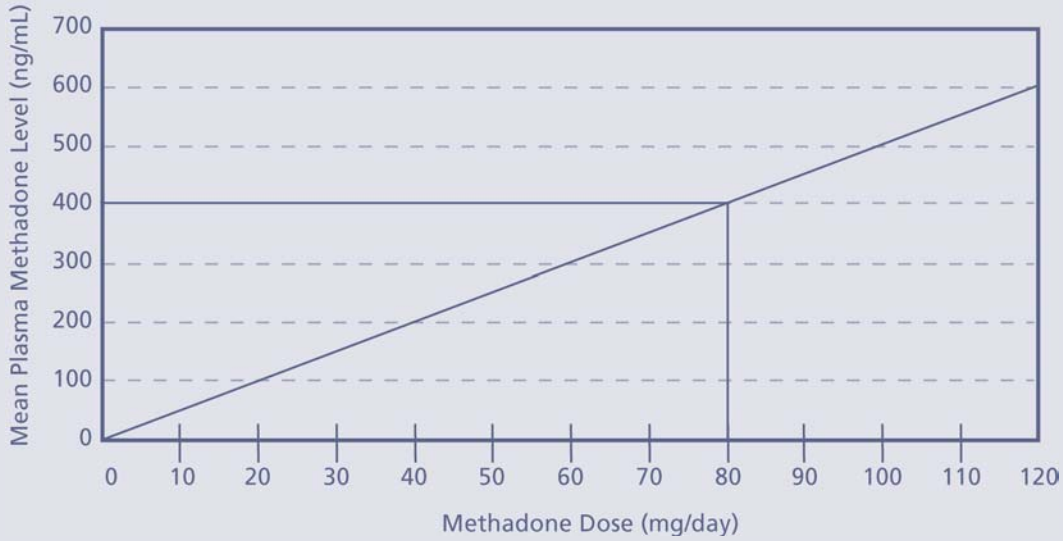
Adapted from Ball and Ross, ***The Effectiveness of Methadone Maintenance Treatment: Patients, Programs, Services, and Outcome***, Appendix B, p. 248, with permission from Springer-Verlag © 1991.

more than 200 mg per day (mean 284.9 mg per day) had improved responses with no apparent increase in adverse events. However, additional controlled research is needed to determine the safety of very high doses of methadone or other medications used in MAT.

With the increased availability of blood testing in OTPs, measurements of blood concentrations of methadone at peak and trough are used more commonly as aids to determine individual methadone dosage requirements. A study in England (Wolff et al. 1991) showed a positive correlation between methadone dosages and concentrations in serum (Exhibit 5-4). Moreover, mean SMLs near or above 400 ng/mL are gaining increasing consensus as ideal levels for treatment effectiveness (Payte et al. 2003). Although mean SMLs of 400 ng/mL

Exhibit 5-4

Methadone Dose/Mean Plasma Levels



Adapted from Wolff et al. (1991) by permission of the AACC.

generally are considered to be sufficient to block the effects of illicit opioids and prevent withdrawal symptoms, some patients may require higher SMLs for stabilization. More research is needed to ***u***nderstand better the relationship between methadone blood levels and cessation of opioid abuse. SML results should continue to be considered along with patient symptoms. For example, a patient with an SML below 400 ng/mL with no symptoms of discomfort would not require a dosage increase, whereas a patient with an SML of 600 ng/mL but with persisting withdrawal symptoms would.

Okruhlica and colleagues (2002) investigated 69 patients receiving methadone dosages of 10 to 270 mg per day and found a significant positive relationship between dosage and mean SMLs, although, at each dosage level, patientsí resulting SMLs differed widely. Some had relatively low (subtherapeutic) SMLs, even at daily doses considerably above 100 mg, which would be expected to affect treatment negatively (Leavitt et al. 2000). Given these and similar data, it is incorrect to conclude that a particular methadone dosage causes a specific SML; many other factors are likely to affect SMLs for individual patients. However, measuring SMLs can be useful to determine why a relatively high methadone dosage does not appear to benefit a patient. In such cases, a blood test may show that a patientís SML remains low and that he or she requires a higher dose.

In their review, Leavitt and colleagues (2000) noted a broad range of SMLs among patients in MAT. They suggested that individual differences in metabolic enzyme activity and other factors may lead to higher or lower serum

levels of the (***R***)-methadone enantiomer, explaining some of the variation in dosage ranges needed for clinical effectiveness. In one study of the clinical uses of methadone blood level measurements, it was suggested that the peak level should be no more than twice the trough level and that, if it is more, the patient should be considered a ìfast metabolizerî and be administered split dosing. When split dosing is used, patients receive two or three doses per day to achieve the targeted peak-to-trough ratio in blood level measurements and to avoid withdrawal symptoms for 24 hours (Payte et al. 2003). Exhibit 5-5 shows 24-hour SML curves at both inadequate and adequate dosages. These curves include peak SMLs at roughly 4 hours after dose ingestion (0 hour) and trough SMLs at 24 hours after ingestion. Data were derived by averaging a series by Inturrisi and Verebely (1972) and another one by Kreek (1973). Exhibit 5-6 shows an example of plasma levels in a fast metabolizer, illustrating that when a dayís dose is split into two (lower curve), the peak SML achieved after each of the two split doses is lower than the peak achieved after a single daily dose (upper curve), and the trough SML reached just before the next split dose is higher than the trough level reached just before the next single dose.

The consensus panel recommends that a maintenance dosage of methadone not be predetermined or limited by policy if that policy does not allow adjustments for individual patients.

Other common dosing issues

Signs and symptoms associated with lesser degrees of withdrawal and acute opioid overdose are well known, but patient changes associated with overmedicating and undermedicating are less dramatic and often more subjective.

Exhibit 5-5

Blood Plasma Levels Over 4 and 24 Hours With an Adequate and Inadequate Methadone Dose

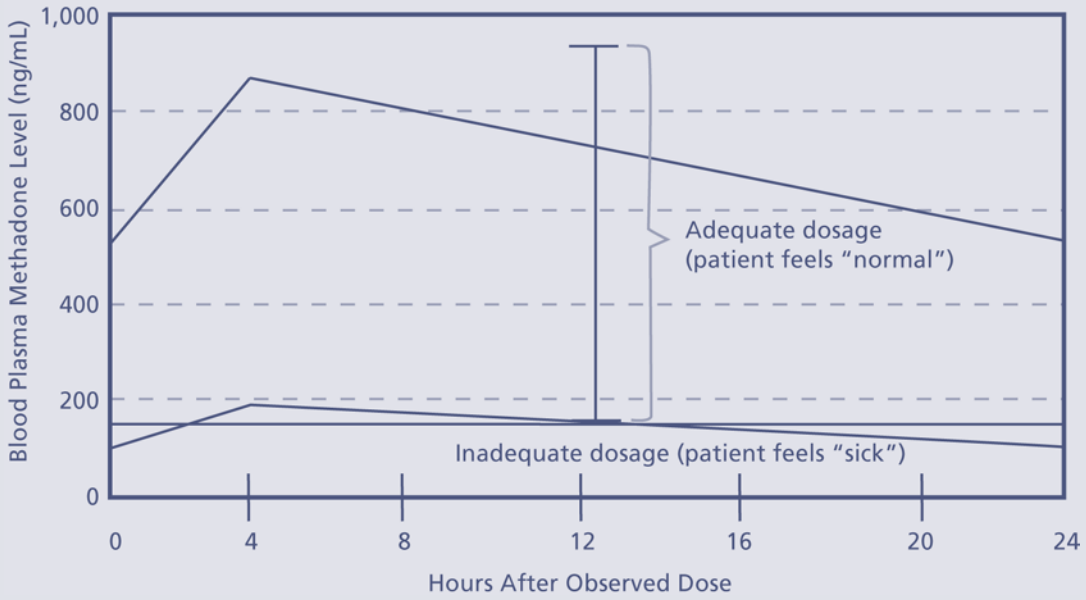
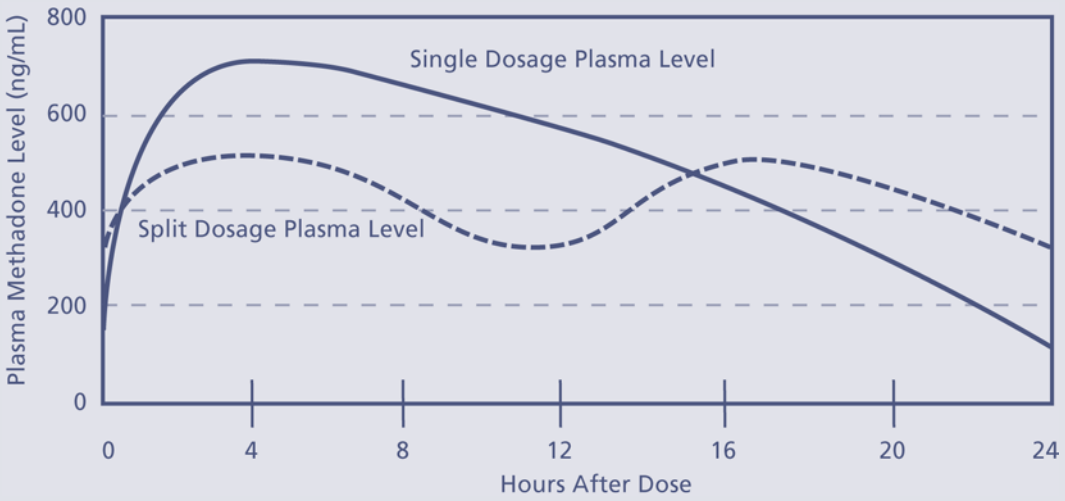


Exhibit 5-6

SMLs After Single and Split Methadone Dosing in a Fast Metabolizer



Certain medical factors may cause a patientís dosage requirements to change, including (but not limited to) starting, stopping, or changing the dosage of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; significant increase or decrease in weight; or aging (elderly patients are sometimes more sensitive to drugs such as opioids). Patient complaints of opioid craving, withdrawal symptoms, medication side effects, or intoxication always should be investigated and never should be dismissed.

Overmedication. Mildly to moderately overmedicated patients might show ìnoddingî and closing of the eyes or might fall asleep at inappropriate times. These patients might scratch their faces continuously, especially their noses. In some cases, sedation might occur but be unapparent, and some overmedicated patients might feel mildly stimulated. Nausea also can occur, particularly in newer patients. Patients should be told when overmedication is suspected, and their dosage should be reduced. Patients also might report feeling high or ìloadedî and ask for a reduced dosage. Such a reduction can be helpful for patients committed to abstinence rather than ongoing medication maintenance because they may find physical reminders of intoxication discouraging, frightening, or relapse triggering.

Vomited doses. Patients who report that they have vomited their medication pose special problems. The consensus panel recommends that only doses lost to witnessed emesis be replaced. Emesis 30 minutes after dosing can be handled by reassuring patients that the full dose has been absorbed. Emesis at 15 to 30 minutes after dosing can be handled by replacing half the dose, and the whole dose should be replaced if emesis occurs within 15 minutes of dosing. If vomiting persists, it is important to remember that only a portion of the gut is emptied with forceful emesis; therefore, the risk of accumulated toxicity increases with repeated dose replacements. Causes of emesisó including pregnancyóshould be explored.

Ingestion of smaller amounts of medication over a few minutes can be helpful and prudent, as can the occasional use of antiemetic medicines.

"Triggered" withdrawal. Environmental cues, including people, places, things, and feelings associated with drug taking, can be associated strongly with opioid craving and withdrawal. Such reactions may be identical to opioid withdrawal symptoms and can stimulate drug craving and relapse long after opioid use has stopped and physical dependence has been controlled (Self and Nestler 1998). Environmental changes and other stressors can cause patients to perceive that a dose on which they were stabilized is no longer adequate and to experience increased drug craving. Events that increase the availability of substances of abuse, such as another person who uses drugs moving into a patientís home or new sources of illicit drugs, can intensify craving. When their discomfort resumes after a period of abstinence, patients might feel that they are weak willed. They need reassurance that this reaction is a condition of their brain chemistry, not a weakness of will. In animal models, withdrawal symptoms have been conditioned to appear with environmental cues after months of abstinence from opioids (Self and Nestler 1998). The consensus panel believes that increased medication dosages are appropriate in such cases, although efforts also should focus on resolving the troublesome situations such as developing ways to avoid people, places, and things that trigger opioid craving or relapse. Conversely, diminished triggers and reduced drug availability can diminish drug craving and might indicate the possibility of decreasing medication dosage if a patient prefers.

Contingent use of dosage. The consensus panel believes that any manipulation of dosage as either a positive or a negative consequence of behavior is inappropriate and has no place in MAT. The only type of contingency contracting related to medication that should be supported in MAT is that associated with take-home medication. Take-home medication is controlled by Federal regulations, and access is based on several factors, including drug abstinence, OTP attendance, length of time in treatment, and overall functioning. An increase in medication dosage should not be a reward for positive behavior change, although not everyone in the MAT field shares this viewpoint. For example, extensive work has demonstrated the effectiveness of using increased dosage (as well as extra take-home doses) as an incentive to decrease substance abuse and increase treatment program attendance (e.g., Stitzer et al. 1986, 1993; see also Petry 2000). Although the consensus panel acknowledges important behavioral aspects of addiction and the value of contingency management as an aid to behavioral change, using medication dosage as a reward or punishment is considered inappropriate.

Maintenance Pharmacotherapy

The maintenance stage of opioid pharmacotherapy begins when a patient is responding optimally to medication treatment and routine dosage adjustments are no longer needed. Patients at this stage have stopped abusing opioids and other substances and have resumed productive lifestyles away from the people, places, and things associated with their addictions. These patients typically receive scheduled take-home medication privileges. Patients who continue to abuse substances, do not seek employment, or remain connected to their drug-using social networks have not reached this stage. Along with continued observed medication treatment, these latter patients are candidates for intensified counseling and other services to help them reach the maintenance stage.

During the maintenance stage, many patients remain on the same dosage of treatment medication for many months, whereas others require frequent or occasional adjustments. Periods of increased stress, strenuous physical labor, negative environmental factors, greater drug availability, pregnancy, or increased drug hunger can reawaken the need for increased dosages over short or extended periods. Serious emotional crises may require long-term or temporary dosage adjustments. Although the counseling relationship and patient interview

are paramount, drug test reports and medication blood levels are useful for dosage determination and adjustment during and after transition from stabilization to the maintenance stage.

Medically Supervised Withdrawal

When stable patients in the maintenance stage ask for dosage reductions, it is important to explore their reasons. They might believe that they can get by on less medication, or they might be responding to external pressures. Patients often perceive that those on lower dosages are ìbetter patients.î These situations require physicians or other staff members to educate patients and their significant others about the importance of adequate dosage and how individual differences in absorption, body weight, metabolism, and tolerance can affect the dosage necessary to achieve stability (Leavitt et al. 2000).

Voluntary Tapering and Dosage Reduction

For various reasons, some patients attempt reduction or cessation of maintenance medication. Some studies indicate high relapse rates, often 80 percent or more, for this group, including patients judged to be rehabilitated before tapering (e.g., Magura and Rosenblum 2001). However, the likelihood of successful dose tapering also depends on individual factors such as motivation and family support. The possibility of relapse should be explained to patients who want to dose taper, especially those who are not stable on their current dosage, as part of the informed-consent process. Patients who choose tapering should be monitored closely and taught relapse prevention strategies. They and their families should be aware of risk factors for relapse during and after tapering. If relapse occurs or is likely, additional therapeutic measures can be taken, including rapid resumption of MAT when appropriate (American Society of Addiction Medicine 1997).

Ideally, withdrawal should be attempted when it is desired strongly by a stable patient who has a record of abstinence and has adjusted positively on MAT. However, sometimes dose tapering is necessary for administrative reasons, such as a response to extreme antisocial behavior, noncompliance with minimal program standards, or a move to a location where MAT is unavailable. In such cases, providers should refer patients to other programs that are more reasonable and practical in terms of the patientsí overall situation (e.g., motivation, resource availability, ability to pay).

In a review of research on withdrawal from MAT, Magura and Rosenblum (2001) noted that many treatment providers lacked effective ways to improve outcomes for patients who undertook planned withdrawal and that opioid craving remained prevalent in this group, even after successful physiological withdrawal. They concluded, therefore, that planned withdrawal from opioid pharmacotherapy should be undertaken conservatively.

Relapse prevention techniques should be incorporated into counseling and other support services both before and during dosage reduction. Such structured techniques can be useful safeguards in preventing and preparing for relapse. Use of mutual-help techniques (see chapter 8) is recommended highly, especially during dosage reduction.

Although most data about outcomes after tapering from opioid medication come from studies of methadone maintenance, the consensus panel believes that success rates are likely to be similar for patients who taper from buprenorphine or LAAM, and similar cautions and monitoring processes should be in place.

Methadone dosage reduction

The techniques and rates of graded methadone reduction vary widely among patients. One common practice is to reduce daily doses in roughly 5- to 10-percent increments with 1 to 2 weeks between reductions, adjusting as needed for patient conditions. Because reductions

become smaller but intervals remain about the same, many months may be spent in such graded reductions. The rate of withdrawal can be increased or decreased based on individual patient response. A slow withdrawal gives patients and staff time to stop the tapering or resume maintenance if tapering is not working and relapse seems likely.

Regardless of the rate of withdrawal from methadone, a point usually is reached at which steady-state occupancy of opiate receptors is no longer complete and discomfort, often with drug hunger and craving, emerges. This point may occur at any dosage but is more common with methadone when the dosage is below 40 mg per day. Highly motivated patients with good support systems can continue withdrawal despite these symptoms. Some patients appear to have specific thresholds at which further dosage reductions become difficult.

Physicians and other staff members should be alert to the possibility of patients attempting dose tapering by substituting other psychoactive substances, such as alcohol, cocaine, sedatives-hypnotics, or other nonopioid substances for their maintenance medication.

Some patients might request blind dosage reduction, that is, withdrawal from medication without their awareness of dose reductions at each step. Blind dosage reduction is appropriate only if requested by a patient. It should be discussed and agreed on before it is implemented. It is inappropriate, clinically and ethically, to withdraw a patient from maintenance medication without his or her knowledge and consent. The consensus panel recommends that OTP staff always disclose dosing information unless patients have given specific informed consent and have requested that providers not tell them their exact dosages.

Withdrawal and termination from LAAM maintenance

Few studies have addressed medically supervised withdrawal from LAAM. Because LAAM is longer acting than methadone, withdrawal should be expected to have a delayed onset and protracted course, although symptoms might be less intense than with other opioids. Patients tend to dislike longer periods of withdrawal, regardless of symptom intensity. Special counseling might be needed to address this aspect of withdrawal from LAAM.

Patients who choose tapering should be monitored closely and taught relapse prevention strategies.

For patients on LAAM who wish to be medication free, dosage can be reduced gradually at a rate determined by their response. Patients who prefer less protracted withdrawal can be converted to and then tapered from methadone. As with tapering from methadone (Moolchan and Hoffman 1994), tapering from LAAM should take into account a patientís level of stability, past functioning without medication, and fear of withdrawal.

Medically Supervised Withdrawal After Detoxification

For patients who neither qualify for nor desire opioid maintenance treatment, methadone or buprenorphine may be used to control withdrawal from illicit opioids or from abuse of prescription opioids (detoxification) and then can be tapered gradually (medically supervised withdrawal). Regulations specify two kinds of detoxification with methadone: short-term treatment of less than 30 days and long-term treatment of 30 to 180 days. These regulations specify that patients who fail two detoxification attempts in 12 months must be evaluated for a different treatment (42 CFR, Part 8 ß 12(e)(4)).

Dosing decisions in medically supervised withdrawal are related to the intended steepness of tapering. Patients undergoing short-term withdrawal may never achieve steady state, and tapering from methadone may be too steep if it begins at a dose greater than about 40 mg. In long-term withdrawal, stabilization of dosage at a therapeutic range is followed by more gradual reduction (see Exhibit 5-7).

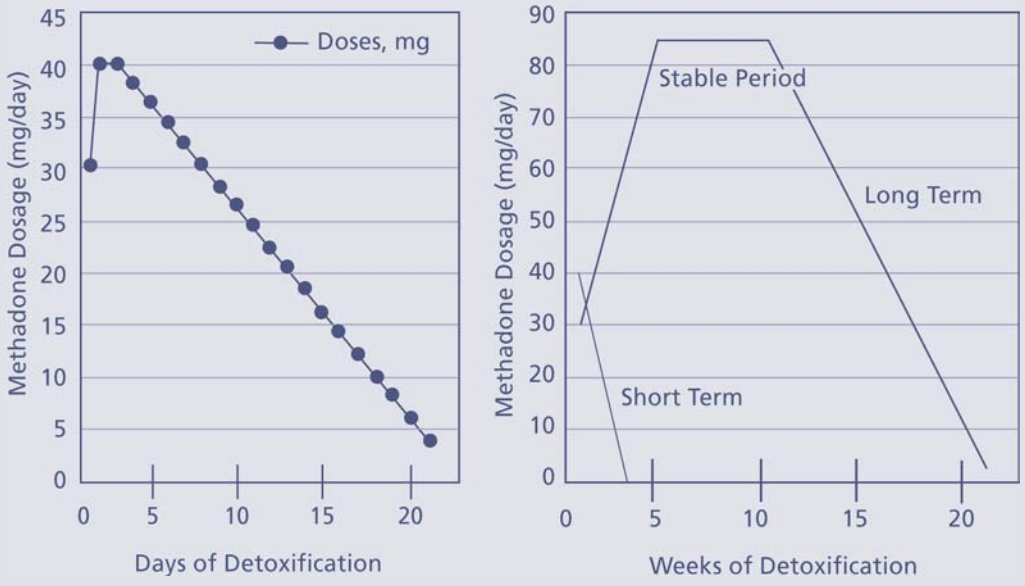
Involuntary Tapering or Dosage Reduction

When patients violate program rules or no longer meet treatment criteria, involuntary tapering might be indicated although it should be avoided if possible (see chapter 8). For example, if many days of dosing are missed and repeated attempts to help a patient comply with daily dosing requirements have failed, maintenance pharmacotherapy no longer may be possible. Treatment decisions should be made in the patientís best interest. If patient progress is unsatisfactory at a particular level of care, the physician should explore the possibility of increasing that patientís care while maintaining him or her on methadone. Involuntary tapering and discontinuation of maintenance medication may be necessary if a patient is unwilling to comply with treatment or tapering or discontinuation of medication appears to be in the patientís best interest.

If a patient is intoxicated repeatedly with alcohol or sedative drugs, the addition of an opioid medication is unsafe, and any dose should be withheld, reduced, or tapered. Disruptive or violent behavior or threats to staff and other patients might be reasons for dismissal without

Exhibit 5-7

Types of Detoxification From Illicit Opioids



tapering or for immediate transfer to another facility where a patient may be treated under safer conditions.

Administrative tapering for nonpayment of fees may be part of the structure to which patients agree on admission. It should be noted that, in addiction treatment, a patientís sudden lack of funds is a marker of possible relapse.

LAAM

When involuntary withdrawal from LAAM is unavoidable, patients can be transferred to methadone before withdrawal because clinical experience with methadone withdrawal is more extensive.

Incarceration

When patients know that they must serve time in jail or prison, planned withdrawal is the best course of action. At this writing, few correctional institutions offer methadone maintenance to nonpregnant inmates (National Drug Court Institute 2002). Many jails do not provide methadone for detoxification. When a patient in MAT is arrested, program staff should make every effort to communicate with the criminal justice authorities involved and to recommend that the patient be withdrawn gradually from medication. Regardless of which opioid medication is used, maintenance or medically supervised withdrawal is preferable to sudden discontinuation of the medication. The consensus panel recommends that opioid pharmacotherapy be made available during incarceration for patients who are already in MAT when incarcerated.

Take-Home Medications

Take-home medication refers to unsupervised doses. Any OTP patient may receive a single take-home dose for a day when the OTP is closed for business, including Sundays and State and Federal holidays. Beyond this, decisions on dispensing take-home medication are determined by the medical director in accordance with eight criteria for take-home medication specified in Federal regulations (42 CFR, Part 8 ß 12(i)):

1. Absence of recent drug and alcohol abuse
2. Regular OTP attendance
3. Absence of behavioral problems at the OTP
4. Absence of recent criminal activity
5. Stable home environment and social relationships
6. Acceptable length of time in comprehensive maintenance treatment
7. Assurance of safe storage of take-home medication
8. Determination that rehabilitative benefits of decreased OTP attendance outweigh the potential risk of diversion.

Once these clinical criteria are met, maximum take-home doses must be further restricted based on length of time in treatment as follows:

- ï First 90 days (months 1 through 3): one take-home dose per week
- ï Second 90 days (months 4 through 6): two take-home doses per week
- ï Third 90 days (months 7 through 9): three take-home doses per week
- ï Fourth 90 days (months 10 through 12): 6 daysí supply of take-home doses per week
- ï After 1 year of continuous treatment: 2 weeksí supply of take-home medication
- ï After 2 years of continuous treatment: 1 monthís supply of take-home medication, but monthly OTP visits are still required.

Additional restrictions are imposed in some States. No take-home doses are permitted for patients in short-term detoxification or interim maintenance treatment.

Specific Clinical Considerations in Take-Home Status

Demands of a concurrent medical disorder

The existence and severity of a concurrent medical disorder (see chapter 10) are additional considerations in determining whether take-home medication is appropriate. For patients with concurrent diseases causing impaired ambulation, reduced OTP attendance might be required to aid recovery and prevent complications. In these cases, OTPs should consider seeking medical exceptions for patients who would not otherwise be permitted to receive take-home doses of medication. These patient exceptions should be requested on Substance Abuse and Mental Health Services Administration (SAMHSA) form SMA-168, Exception Request and Record of Justification. Form SMA-168 is available at dpt.samhsa.gov/Exception168Final.htm.

No take-home doses are permitted for patients in short-term detoxification or interim maintenance treatment.

When a new medication treatmentósuch as rifampin, highly active antiretroviral therapy (HAART), or phenytoinóthat is known to interact with an opioid treatment medication is introduced, a MAT patient might need a dosage adjustment (see chapter 3 for further discussion of medications that interact with opioid treatment medications). Take-home medication should be avoided until a patient is stable on these new medications and the risks of an undesirable outcome have diminished. In these instances, more frequent observations are important to monitor concurrent disease, to avoid methadone-related complications of a concurrent medical disorder, and to ensure that the pharmacological benefits of administering methadone are maintained during the course and treatment of the concurrent disease.

Enhancement of rehabilitative potential

Another important issue in take-home medication involves reviewing whether it is likely to help rehabilitate a patient. Take-home medication may enable patients to engage in employment, education, childcare, or other important endeavors.

Emergency circumstances

During emergency situations or unforeseen circumstances such as personal or family crises; bereavement; or medical, family, or employment hardships, the need may arise for unscheduled take-home medication. An OTP can facilitate emergency or hardship access to medication for a patient by submitting SAMHSA form SMA-168. The OTPís policies should explain who can request exceptions and how it is done. Courtesy dosing at a distant OTP usually can be arranged if unstabilized patients are traveling.

Positive drug tests, diversion control, and take-home medications

The consensus panel believes that take-home medications are inadvisable for patients who continue to abuse illicit drugs or misuse prescription medications, as evidenced by drug testing or other assessment information, and for those whose drug tests do not reflect medication ingestion. Under the disinhibiting effects of other substances, patients might be unable to safeguard or adequately store their take-home doses. They should be encouraged to keep their medication in a locked cabinet away from food or other medicines and out of the reach of children. Some programs require

patients to bring a locked container to the OTP when they pick up their take-home medication to hold it while in transit. This policy should be considered carefully because most such containers are large and visible, which might serve more to advertise that a patient is carrying medication than to promote safety.

Methadone is stable and does not need refrigeration when in diskette or tablet form. However, when methadone diskettes are reconstituted or liquid methadone oral concentrate is used and diluted with juice or some other sugar-based liquid, the mixture may not remain stable beyond a few days without refrigeration. Manufacturer instructions call for adding a minimum of 30 mL or 1 fluid ounce of liquid per dose when reconstituting methadone.

Although methadone has a significant street value, a National Institutes of Health consensus statement refers to it as ìa medication that is not often diverted to individuals for recreational or casual use but rather to individuals with opiate dependence who lack access to [methadone maintenance treatment] programsî (National Institutes of Health 1997***b***, p. 20). Nevertheless, reported deaths attributed to methadone have increased significantly in some States. According to data from the Drug Abuse Warning Network, more than 10,000 emergency room visits related to methadone were reported in 2001 compared with more than 5,000 in 1999 (Crane 2003). This increase has occurred in the context of overall increases in abuse of prescription opioids, in particular hydrocodone and oxycodone. Local reports indicate that most diverted methadone comes from medical prescriptions because it has gained acceptance as an excellent chronic pain treatment (Belluck 2003). Although the slow onset of methadone makes it less attractive than prescription opioids to potential abusers, it also makes methadone more dangerous because respiratory depression can become significant hours after ingestion. To guard against the possibility of methadone-related respiratory depression, the consensus panel recommends the following diversion control policies for take-home medication:

- Require patients to return all empty dose bottles on their next OTP visit after take-home dosing. Staff members who accept these bottles should inspect them to ensure that they are coming from the indicated patient during the appropriate period.
- Institute procedures for responding to patients who frequently fail to return or have unverified reasons for failing to return empty take-home bottles. Staff should consider discontinuing take-home medication for these patients.
- Stay open 7 days a week for dispensing. In this way, take-home doses can be provided only to stable patients with a record of adherence to treatment, rather than to all patients regardless of their status with the program.

Behavior, social stability, and take-home medications

Patients appearing intoxicated; demonstrating aggressive, seriously impaired, or disordered behavior; or engaging in ongoing criminal behavior are poor candidates for take-home medication. Their home environments also are keys to the safety and storage of medication. Where social relationships are unstable, a significant risk exists that methadone take-home doses will be secured inadequately from diversion or accidental use (e.g., by children). If patients with take-home privileges develop altered mental competency, such as in dementia, frequent loss of consciousness, or delusional states, then take-home privileges should be reevaluated.

Monitoring Patients Who Receive Take-Home Medications

Monitoring should ensure that patients with take-home medication privileges are free of illicit drug use and consume their medication as directed. This goal can be met through random drug testing and periodic interdisciplinary assessment of continuing eligibility. OTPs

should consider carefully whether to use pill counts or callbacks of dispensed take-home doses to verify adherence to program rules. In a pill count or callback, the patient receives an unannounced phone call and must show up at the OTP within a reasonable period (e.g., 24 to 36 hours) with all MAT medications. The number of pills remaining must correspond to the number expected based on prescribed ingestion. A physician should review periodically the status of every patient provided with take-home medication. When these strategies are followed, programs should state their policies clearly to patients. Callbacks should be used selectively, not be applied across the board, and focus on high-risk patients who have given OTP staff members reason to be concerned.

Issues for review

The rationale for providing take-home medication should be reviewed regularly and documented to determine whether initial justifications continue to apply. For example, if employment was a reason for take-home medication, the patientís continued employment should be verified. If a concurrent medical disorder was the basis, a medical reassessment is necessary to determine whether the clinical status of the concurrent medical disease still warrants reduced OTP attendance.

Reviewing the original rationale for take-home medication is a necessary but insufficient condition for increased patient monitoring. The monitoring process also should include an assessment of whether medical, psychological, or social reasons exist to rescind these privileges.

Treatment interruptions

Many circumstances, such as work-related travel, illness, funerals, planned vacations, and emergencies, might require patients to miss OTP visits. Some unstable patients might miss days because of chaotic social situations. OTPs should have policies to address treatment interruptions.

Disability or illness. When disability or illness prevents patients from coming to the OTP, authorized staff may use home delivery and observed-dosing procedures to ensure treatment continuity. OTPs should evaluate the need for continuity of other support services, as well as medication, in these circumstances.

Hospitalization. OTPs are responsible for ensuring continuity of treatment when patients are hospitalized for medical or psychiatric problems (see chapters 10 and 12). The best practice is for OTP staff to educate and stay in touch with a patientís hospital clinicians about MAT. For example, hospital staff might be unaware that certain drugs, such as partial agonists or mixed agonists and antagonists for pain management, should be avoided for patients receiving LAAM or methadone for opioid addiction (pain management is discussed in chapter 10). It usually is helpful to provide psychiatric consultation to medical or surgical staff members, especially for patients with co-occurring disorders. Written patient consent is necessary for this kind of program-to-hospital communication; however, if a medical emergency poses a threat to a patientís health, the OTP should use the medical emergency exception for treatment when it lacks patient consent. A publication by the Center for Substance Abuse Treatment (CSAT 2004***b***) provides a description of the confidentiality regulationsí medical emergency exception.

Hospitalization, particularly of unconscious patients, raises the issue of using identification (ID) cards. Patients can get OTP-specific Medic Alert ID Cards from Advocates for Recovery Through Medicine (www.methadonetoday.org/armhelp.htm; telephone 615-354-1320), which can include a patientís name, OTP contact information, and a list of contraindicated medications. Some large urban OTPs provide patients with a photographic ID card to gain admittance to the OTP. Their experience has been that some patients use their OTP cards as generic photographic IDs in lieu of a driverís license; for example, they use them to cash checks, despite the fact that the cards identify them as being in treatment. Smart cards containing a complete medical history are already in use in the United States, Israel, and the

Netherlands and may be useful in OTPs. These cards contain electronically encoded information needed to identify and monitor a patient without outwardly identifying the cardholder as a patient.

Missed doses. When doses are missed, it is critical to evaluate patientsí presenting condition. Concerns should include whether a patient has been using illicit drugs or taking other medications, has lost tolerance for previous doses (i.e., whether a previously tolerated dosage is still safe to administer), or is intoxicated.

One dose missed. For patients who miss one scheduled dose and come to the OTP the next dayófor example, 3 to 4 days after the last LAAM or 2 days after the last methadone doseóthe dosage can remain unchanged, and dosing should resume on schedule. For patients on LAAM who miss a dose and come to the OTP 2 days later (i.e., 4 to 5 days after their last LAAM dose), the scheduled dose still is usually well tolerated.

More than 5 days missed. For patients who are out of treatment for a significant time and might have lost tolerance, dosage reduction or reinduction is advisable. Thereafter, increases of 5 to 10 mg per dose up to the previous level can be ordered because it is unlikely that the dosage needed to maintain stability will change in 1 week. Patients might have to be reminded about steady state and that they may not feel back to normal until tissue stores have built up as well.

Office-Based Opioid Therapy

OTPs should consider assisting with transfer arrangements for long-term methadone-maintained patients who prefer to use a physician in the community for ongoing care. Various forms of this treatment have been studied in the United States and found to be safe and efficacious (King et al. 2002; Schwartz et al. 1999).

Patient selection for this treatment option should focus on a history of negative drug tests, a required length of stability in treatment (at least 1 year), social stability, and minimal need for psychosocial services. Methadone can be ordered by private physicians, through an affiliation or other arrangement with an OTP, and patients can obtain their medication at specially registered pharmacies under a SAMHSA-approved protocol. Under this arrangement, patients on extended take-home-dosing schedules (up to 1 month) no longer must ingest their doses under observation. Outcomes have been uniformly positive, with few relapses and little or no diversion reported (King et al. 2002; Schwartz et al. 1999). Patient satisfaction has been found to be significantly better compared with OTP dosing (Fiellin et al. 2001) but not significantly different from a comparable OTP-based monthly medical maintenance and take-home schedule (King et al. 2002).

6 PatientñTreatment Matching: Types of Services and Levels of Care

In This ChapterÖ

This chapter describes a multidimensional, clinically driven strategy for matching patients in medication-assisted treatment for opioid addiction (MAT) with the types of treatment services and levels of care that optimize treatment outcomes, primarily within or in conjunction with opioid treatment programs (OTPs). Level of care refers to the intensity of a treatment (in terms of frequency, type of serviceóindividual, group, familyóand medication) and the type of setting needed for treatment delivery. For information on criteria and methods to determine levels of care in substance abuse treatment, see the American Society of Addiction Medicine (ASAM) patient placement criteria (Mee-Lee et al. 2001***b***). As explained by Mee Lee and colleagues (2001***b***), the ASAM model conceptualizes opioid pharmacotherapy as a service that can be provided at any level of care, although it is delivered most often in an outpatient setting (i.e., ASAM level I).

The chapter also provides information on developing a treatment plan with short- and long-range goals for each patient. In some cases, patientñtreatment matching and treatment planning involve changes that can move a patient out of comprehensive MAT to a setting that better meets the patientís needs. Because this TIP is primarily about outpatient MAT in OTPs, other settings and programs are discussed only briefly.

In general, patientñtreatment matching involves individualizing, to the extent possible, the choice and application of treatment resources to each patientís needs. The chapter explains recommended elements of a patientñtreatment-matching process, including ways to accommodate special populations with distinct needs and orientations that affect their responses to specific treatments and settings.

Patients enter OTPs at various points along a continuum of substance abuse and addiction. Many also have co-occurring medical and mental health conditions that can be lifelong. Because of the complexity of patientsí circumstances and needs and the range of services required to address these needs, MAT includes not only opioid pharmacotherapy but also other forms of treatment in a comprehensive treatment program

designed to address multiple disorders and needs (see chapter 8).

The consensus panel believes that OTPs not already offering comprehensive MAT services and those lacking resources to adjust levels of care to patient needs either should augment basic opioid pharmacotherapy with services that meet the mental health, medical, and social needs of patients who are opioid addictedóat the level of care each patient needsóor should provide referrals to programs that provide such services.

Steps in PatientñTreatment Matching

Patient Assessment

Patientñtreatment matching begins with a thorough assessment to determine each patientís service needs (see chapter 4); then these needs are matched to appropriate levels of care and types of services. Assessment should include the extent, nature, and duration of patientsí opioid and other substance use and their treatment histories, as well as their medical, psychiatric, and psychosocial needs and functional status. A comprehensive assessment should include a patientís gender, culture, ethnicity, language, motivation to comply with treatment, and recovery support outside the OTP.

Type and Intensity of Treatment Services Needed

Psychosocial treatment services

In a comprehensive MAT setting, patients often have access to a variety of psychosocial services, including individual, family, and group counseling, as well as case management (see chapter 8). Some programs may provide psychosocial services to patients in other settings. Both residential and outpatient programs may offer intensive individual and group counseling or counseling on a periodic or as-needed basis (De Leon 1994; Margolis and Zweben 1998). Ideally, service intensity should depend on the level of care required to help patients achieve and maintain successful treatment outcomes. Most patients in the acute phase of treatment need to see a counselor daily for counseling or case management, just to become stabilized, whereas others, who may be highly functioning with less severe addiction-related psychosocial problems, require fewer counseling services.

Mutual-help programs

Although not a form of treatment, mutual-help programs (e.g., 12-Step programs, Secular Organization for Sobriety groups, Women for Sobriety groups) offer effective reinforcement and motivation for individuals during and after discontinuation of active treatment. Such programs provide social support from others who are in recovery from addiction (Washton 1988). Many patients in MAT participate in mutual-help groups. However, patients with opioid addiction who are maintained on treatment medication can feel out of place in some group settings where continued opioid pharmacotherapy may be misunderstood. Researchers have described a variety of specialized groups and inventive strategies for mutual-help programs that meet the support needs of patients in MAT (Zweben 1991). Chapter 8 presents some of these strategies.

Matching Treatment Service Needs to Settings

After the types and intensities of services that patients need are defined, the next crucial step in patientñtreatment matching is to identify the most appropriate available setting or settings for these services. MAT has been offered primarily in a dedicated outpatient OTP. However, as the importance of treating patientsí varied medical, psychological, social, and behavioral needs as part of addiction recovery has become evident, more varied programs and settings have emerged.

Throughout this TIP, the consensus panel recommends that OTPs lacking the resources to accommodate all their patientsí needs develop cooperative relationships with and refer patients to other treatment providers as appropriate. However, OTPs should coordinate these services. Based on its assessments of patients, the treatment team should collaborate with patients to determine the most appropriate treatment services, intensities of services, and settings needed to meet patient needs. This collaboration should continue throughout MAT, and patient progress should be the basis for adjustments in treatment services and intensities.

Patientsí service needs may change throughout MAT. For example, one patient may need referral to an inpatient program for detoxification from alcohol or benzodiazepines and then return to the OTP setting. Another may need the environment of a residential treatment program while continuing MAT. Therefore, treatment matching in some cases can lead to multiple settings for an individualís treatment. In most cases, the originating OTP should provide case management and liaison for all treatment services.

Types of settings and programs offering opioid addiction treatment services

The following are examples of treatment programs and settings that offer some or all of the comprehensive services recommended in MAT.

Outpatient OTPs. Outpatient OTPs ideally treat patients who are opioid addicted during all phases of treatment and at most levels of care. In reality, many OTPs have capacity or resource limitations or payment requirements that cause them to refer at least some patients to other specialized treatment providers and settings, such as those described below, for services that match patient needs. Either on site or through other care providers, OTPs offer a wide spectrum of treatment services and levels of care for diverse patients.

Appropriate patients for treatment in outpatient OTPs are those who meet Federal and State requirements for opioid addiction treatment (e.g., 42 Code of Federal Regulations, Part 8), those who have done poorly in other types of programs (e.g., medically supervised withdrawal or residential treatment programs), and those who require opioid pharmacotherapy for long-term stabilization.

OTPs in hospital-based outpatient settings may provide a more enhanced continuum of care than freestanding OTPs because access to medical and psychosocial services is readily available. This availability, in turn, increases the likelihood that patients in MAT will engage in and adhere to other medical and psychosocial treatment regimens.

> [S]ervice intensity should depend on the level of care required to help patients achieve and maintain successful treatment outcomes.

Hospital-based MAT programs are appropriate for some patients who also are medically ill and require coordinated services or care by special teams. In addition, because hospitals can provide a one-stop-shopping model of care by incorporating some primary care services with MAT, some patients with histories of poor treatment compliance may be more likely to adhere to medical treatment. For example, one report from a 16-month prospective study of nearly 500 persons in a hospital-based outpatient methadone program found that 81 percent also used onsite primary care services (Selwyn et al. 1993). At this writing, the number of hospital-based programs offering MAT is limited in the United States.

Residential treatment programs. Residential treatment programs offer cooperative living

arrangements for patients in recovery, but they vary in their willingness or ability to accept MAT patients (Margolis and Zweben 1998). A residential treatment setting is indicated for patients who require residential placement to support treatment and ensure their physical or psychological safety and who are unlikely to continue MAT otherwise. Such patients generally exhibit high relapse potential, evidenced by an inability to control substance use despite active participation in less intensive outpatient programs (Margolis and Zweben 1998). On completion of treatment in these settings, patients should return to an outpatient setting to continue MAT.

The success of mobile treatment units…highlights the importance of program accessibility as a factor affecting… positive treatment outcomes.

If a patient in an OTP is referred to a residential program that does not offer or allow onsite opioid pharmacotherapy (i.e., when other residential options are unavailable) or methadone or buprenorphine dispensing or administration, some programs allow resident patients to travel to the OTP for medication. Some States allow exceptions to regulations governing OTP attendance and take-home medications so that concurrent treatment is possible.

Mobile treatment units. The success of mobile treatment unitsóthat is, mobile vansóin such cities as Baltimore, Boston, San Francisco, and Seattle (Greenfield et al. 1996; Schmoke 1995) highlights the importance of program accessibility as a factor affecting length of stay in treatment and positive treatment outcomes (Greenfield et al. 1996). Mobile substance abuse treatment programs either offer comprehensive maintenance services (with medication, collection of samples for drug testing, and counseling provided in one or several mobile units) or work in conjunction with fixed-site outpatient programs that offer medical care and counseling and other psychosocial services, while medication is delivered via the mobile units.

Appropriate patients for treatment in mobile treatment units are those in locations where fixed-site programs are unavailable, those with ambulatory disabilities, and those initially stabilized in an OTP and then transferred to a mobile unit for continued treatment. Mobile units not staffed on weekends are appropriate only for patients who meet State and Federal regulations for weekend take-home medications.

Office-based opioid treatment settings. After achieving biomedical and psychosocial stabilization in an OTP, some patients might be eligible for referral to less intensive physicianís office-based opioid treatment (OBOT) for medical maintenance. In these settings, patients receive the same level of monitoring and intervention as patients receiving other types of health care. When available, OBOT programs offer several advantages (Fiellin and OíConnor 2002), including

- Less intensive service requirements for stable patients (e.g., less restrictive environments, focus on maintenance with stable doses of opioid medication, provision of only those psychosocial services needed to prevent relapse)
- Minimized stigma associated with addiction treatment
- Increased opportunity for new treatment admissions to OTPs
- Expansion of treatment to geographic areas where there are no OTPs or there are waiting lists for admission to OTPs.

Criminal justice settings. At this writing, relatively few jails or prisons offer comprehensive MAT or selected MAT services, but these numbers are likely to increase (for information about substance abuse treatment in criminal

justice settings, see TIP 44, ***Substance Abuse Treatment for Adults in the Criminal Justice System*** [CSAT 2005***a***]). As a result, MAT services are often interrupted or discontinued when patients are incarcerated. Rikers Island, New York Cityís central jail facility, is an example of a model program that provides comprehensive MAT for this patient group (Magura et al. 1993). Patients who receive MAT there are guaranteed a slot at a community-based program in New York City after their incarceration. Other corrections facilities provide rapid medically supervised withdrawal from maintenance medication to patients. When this withdrawal is the only option, OTPs should work with criminal justice institutions to ensure that appropriate dose-tapering procedures are followed. Patients released from a criminal justice setting should be offered referral to an OTP when referral is desirable and feasible.

Other treatment settings. Numerous other settings and specialized programs offer some services and levels of care needed by patients who are opioid addicted. Any of these programs can be sources of referral by OTPs or can function as satellite OTPs to ensure that patients receive services and levels of care they need.

Choice of Medications

The consensus panel recommends that OTPs offer a variety of treatment medications. Chapters 3 and 5 provide more details about the pharmacology and appropriate use of methadone, levo-alpha acetyl methadol, buprenorphine, and naltrexone.

Patients With Special Needs

Effective treatment for opioid addiction should address the unique needs of each patient (OíConnor and Fiellin 2000; Rowan-Szal et al. 2000***a***). Culturally competent and creative treatment planning, implementation, and referrals should address the distinct needs of patients from different backgrounds. More staff training and research are required on the unique constellations of treatment needs for various populations served by OTPs. Findings for particular groups are summarized below. Other treatment groupings may be identified, for example, high-profile persons for whom unique treatment schedules and settings may be needed to protect confidentiality (CSAT forthcoming ***e***).

Patients With Serious Medical Disorders

If a serious medical condition is discovered during medical evaluation or patient assessment, the patient should receive appropriate medical treatment either on site or by referral to a medical center. Chapter 10 describes medical conditions commonly encountered among patients in MAT and provides treatment recommendations. Most OTPs offer only basic medical services. OTPs should develop and maintain referral networks for patients who present for MAT and have other medical conditions. Moreover, OTP staff should coordinate referrals and follow up as needed to ensure compliance with medical treatments and to act as consultants about MAT and medication interactions.

Patients With Serious Co-Occurring Disorders

Many studies have focused on the co-occurrence of substance use and mental disorders (see chapter 12). The existence of co-occurring disorders should not prevent patientsí admission to an OTP; however, diagnosis of these disorders is critical to match patients with appropriate services and settings. Therefore, OTPs should include professional staff trained to screen for the presence of co-occurring disorders, develop appropriate referrals to services (e.g., psychopharmacology or psychotherapy) for these disorders, and provide coordination of care (CSAT 2005***b***). Most staff members can be trained to recognize and flag major symptoms of co-occurring disorders. The OTP should maintain communication and followup with referral resources.

Patients With Housing, Family, or Social Problems

The following psychosocial problems should be addressed during or directly after admission to increase the likelihood that patients will engage successfully in treatment:

- Lack of stable housing
- Broken ties with family members; nonexistent or dysfunctional family relationships
- Poor social skills and lack of a supportive social network
- Unemployment; lack of employable skills.

Once these needs are identified during assessment, referrals can be made. Although some OTPs have social workers on site to manage the assessment and referral processes, most OTPs rely on counselors to assume this role. Case management duties should include arrangements for provision of psychosocial care when indicated. Family members need education about MAT, including information on how to support a partner or loved one in recovery, self-care of family members, signs and symptoms of active addiction, and support and assistance from family members willing to participate in family counseling. Programs can offer monthly classes to patients, their families, and the community, which can reduce the stigma connected with MAT.

Patients With Disabilities

OTPs should try to provide access for patients with physical disabilities. Treatment interventions for these patients usually include vocational rehabilitation, physical therapy, and social services that help procure prosthetic limbs, wheelchairs, and other assistive devices (CSAT 1998*c*). Alternative approaches in MAT, specifically those that reduce OTP visits, include take-home dosing and requests for medical exceptions through visiting-nurse services to provide equal access to treatment for persons with disabilities (see chapter 10).

Mobile medication units and office-based or home-nursing services may offer viable treatment options for patients with disabilities (Fiellin and OíConnor 2002; Greenfield et al. 1996). OTP staff should address these challenges with patients so that barriers to treatment are overcome.

The consensus panel recommends that OTPs engage in discussions with their Federal and State agencies to develop solutions for treating patients with disabilities. Such discussions should balance the medical needs of these patients and the safety issues involved in providing take-home medications for patients with disabilities who continue to engage in substance abuse or create a risk of medication diversion.

Adolescents and Young Adults

Adolescents and young adults present a unique challenge for MAT. Often, ethnic background, peer affiliations, and aspects of the ìyouth cultureî require staff training and special expectations from both staff and patients. Differences in routes of administration for heroin or prescription opioids and in treatment needs between adolescents or young adults and older adults who are opioid addicted might be attributable in part to generational characteristics and life experiences. For example, older adults typically present for treatment after years (sometimes decades) of chronic substance abuse accompanied by loss of family, health, and employment and deterioration in other psychosocial domains. Youth who are opioid addicted tend to present after only a few years of addiction and with different attitudes toward addiction and the recovery process and distinct treatment needs. These youth may be more difficult to evaluate, because, as a result of other modes of administration (i.e., intranasally and by smoking), they do not exhibit some physical markers of opioid use (e.g., track marks).

Treatment for adolescents and young adults should integrate knowledge of their specific developmental and psychosocial concerns and needs. Some needs are related to identity formation and peer group preoccupation (e.g., the strong desire to be viewed as fearless or to feel invincible), legal complications regarding

consent for treatment (see CSAT 2004***b***), and, often, factors leading them to run away from their homes. TIP 32, ***Treatment of Adolescents With Substance Use Disorders*** (CSAT 1999***d***), provides background information.

Other risk factors for this group include possible sexual and physical abuse, young age at first sexual experience, incidents of trading sex for drugs (Astemborski et al. 1994; Fullilove et al. 1990), and co-occurring disorders (Fuller et al. 2002; Hawkins et al. 1992). These risk factors also can contribute to increased risk for HIV infection (Doherty et al. 2000; Fuller et al. 2001) and other sexually transmitted diseases (STDs).

The interaction of developmental and psychosocial factors affects the ability of adolescents and young adults to engage in MAT and therefore complicates the recovery process. OTPs should provide psychosocial services that address the unique needs of this age group, especially those needs that affect their substance use and recovery, or they should establish referrals and links to youth-oriented psychosocial counseling services.

Buprenorphine may be a particularly satisfactory treatment for some adolescents. Because buprenorphine can be administered in an OBOT setting, it should become more widely available and offer more privacy and less stigma for young patients (see CSAT 2004***a***).

Women

Pregnancy

The special needs of women who are opioid addicted and pregnant should be assessed thoroughly through a comprehensive medical evaluation, as discussed in chapter 13. Treatment matching for pregnant patients in MAT should provide optimal, comprehensive, and intensive services related to pregnancy and birth including prenatal care, maternal nutrition, and psychosocial rehabilitation, along with MAT. The integration of a womenís overall health initiative into MAT improves an OTPís capacity to meet the special needs of these patients, to address potential biomedical and obstetrical complications, and to avoid adverse effects of substance use on the fetus (Finnegan and Kandall 1992). Chapter 13 offers a detailed overview of MAT for pregnant women (also see CSAT forthcoming ***f***).

OTPs are required by regulation or accreditation standards to test for pregnancy, but the provision of prenatal care and ancillary services for pregnant women varies depending on the treatment setting. Hospital-based programs may be better suited for pregnant women in some cases because hospitals offer easy access to referrals and links to specialty care (on or off site).

Case management …should include arrangements for… psychosocial care when indicated.

Sexual or physical abuse

Patientsí risks of ongoing abuse in their current relationships should be addressed, and appropriate plans or referrals made. Co-occurring disorders such as posttraumatic stress disorder can occur among both women and men who have experienced sexual or physical abuse. The best treatment settings to address womenís needs in these cases include OTPs with onsite care provided by psychiatrists, psychologists, licensed social workers, or mental health professionals with special training in this area. In lieu of onsite services, OTPs should establish referral links to programs offering such services. Many social service agencies, as well as agencies responsible for domestic violence, offer training and support to OTP staff. TIP 36, ***Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues*** (CSAT 2000***d***), provides further details.

Complex medical problems

The complex medical problems commonly diagnosed in women in MAT include gynecological infections, amenorrhea, hypertension, and pneumonia (Brown et al. 1992). It is optimal to provide primary care services on site; hospital-based programs and OTPs with formalized medical referral systems are best equipped to deliver such services. Chapter 10 of this TIP and the forthcoming TIP ***Substance Abuse Treatment: Addressing the Specific Needs of Women*** (CSAT forthcoming ***f***) provide additional information.

Parents

Because many patients in MAT are parents, the lack of adequate childcare services is often a barrier to OTP attendance and successful treatment. One solution is supervised onsite childcare services, which also may provide opportunities to observe how patients relate to their children. Problems in parenting skills can be addressed in treatment planning and through parenting groups for patients with children. However, onsite childcare services are available in few programs because of limited resources and licensing and insurance requirements. These obstacles might cause missed appointments or lack of privacy and concentration for parents who must bring their children to treatment and counseling sessions. Insufficient treatment may result.

Most patients can be maintained on their MAT dosage while taking short-acting opioids for pain relief…

The consensus panel recommends that OTPs seek opportunities and funding for onsite childcare where appropriate and feasible to help patients with children engage successfully in psychosocial services. Where childcare is unavailable, program staff should offer referrals to community daycare agencies.

In most States, OTPs are mandated reporters of child abuse and neglect. When children are at imminent risk of harm or appear neglected, OTPs are required to notify local childrenís protective services (CPS) agencies so that an investigation can be conducted. This requirement can create conflict between an OTP and a patient, and the OTP should try to address this issue in a supportive way. Programs and treatment providers should not discriminate against patients because they have entered into pretreatment agreements or have difficulties with CPS agencies (see chapter 13).

Lesbian, Gay, and Bisexual Patients

Just as important as sensitivity to cultural differences based on race or ethnicity is providing a treatment climate that is available and sensitive to lesbian, gay, or bisexual (LGB) patients by openly acknowledging their heterogeneity and variations in sexual orientation and treating these individuals with dignity and respect (CSAT 2001***b***; Lombardi and van Servellen 2000). OTP staff should be prepared to assist LGB patients in coping with problems related to their sexual orientation and the need for HIV/AIDS and STD risk avoidance. Providers should help patients obtain appropriate medical care and secure their safety if, for example, they are threatened. OTPs also should acknowledge the unique social support structures of LGB patients, which can provide a way to counteract isolation and separation from community, peers, and immediate and extended family members (Hughes and Eliason 2002; also see CSAT 2001***b***). Finally, the consensus panel recommends that OTPs identify and refer LGB patients to community counseling, support, and spiritual and religious organizations that are sensitive to these groups and address any sexual- or gender-orientation concerns these patients have that could affect treatment.

Aging Patients

MAT treatment planners should consider the stressors common to the aging patient, such as loss of family, retirement, loneliness, and boredom, which can contribute to high risk of self-overmedication and addiction to alcohol and medications. The consensus panel recommends that OTPs focus on the following areas when working with elderly patients:

- Monitoring the increased risk for dangerous drug interactions; elderly patients often are prescribed multiple medications.
- Differentiating between co-occurring disorders and symptoms and disorders associated with aging (including dementia) (Lawson 1989).
- Differentiating between depression and dementia.
- Screening for and treating physical and sexual abuse (see chapter 4).
- Developing referral sources that meet the needs of elderly patients. Relationships with skilled nursing facilities and nursing homes are particularly important (Lawson 1989).
- Training staff to be sensitive to the elderly patient population.
- Providing psychosocial treatment for age-associated stressors and medical screening and referral for common medical conditions affected by the aging process (see CSAT 1998***b***).
- Assessing and adjusting dosage levels of medication for the slowed metabolism of many elderly patients.

Patients With Pain

Patients in MAT often are undertreated or denied medication for acute or chronic pain management (Compton and Athanasos 2003). Health care workers may misperceive pain medication requests by patients in MAT as drug-seeking behavior, in part because of patientsí higher tolerance for opioids and, usually, their need for higher doses. Many physicians who treat pain do not have the necessary education to treat pain in this population (Prater et al. 2002). MAT providers should evaluate patient treatment needs for pain management and assist patients directly in obtaining optimal pain treatment. Medical providers in MAT should work collaboratively with primary care providers and pain and palliative-care clinicians to ensure establishment of appropriate pain interventions for patients in MAT. Providers need education about maintaining current opioid levels while adding sufficient immediate-release treatment agents to manage acute or chronic pain. More frequent dosing and short-term increased demand for pain treatment medication should be expected. Referrals to specialty pain clinics often provide patients a full spectrum of pain care, including pharmacological and psychological or behavioral treatments to alleviate pain symptoms. These services most often are accessible through hospital-based programs or referral linkages. Most patients can be maintained on their MAT dosage while taking short-acting opioids for pain relief; however, individualized pain treatment is usually necessary.

Treatment Planning

After patientsí individual needs are assessed and the best available treatment services and most appropriate levels of care are determined, a treatment plan should be developed with the patient, as required by accreditation guidelines (CSAT 1999***b***).

Developing a Treatment Plan

Treatment planning for MAT should involve a multidisciplinary team, including physicians, counselors, nurses, case managers, social workers, and patients. Based on a thorough patient history and assessment, a treatment plan should be realistic and tailored to each patientís needs, strengths, goals, and objectives. Good treatment plans contain both short- and long-term goals and specify the actions needed to reach each goal. Treatment plans should indicate which goals and objectives require referral to and followup with outside

resources and which are provided by the OTP itself. Treatment plans should contain specific, measurable treatment objectives that can be evaluated for degree of accomplishment.

Role of the counselor in plan formulation

Counselors should ensure that treatment plans incorporate strategies to develop therapeutic relationships with patients, based on respect for patientsí autonomy and dignity, while motivating patients to become willing partners in the change process (CSAT 1999***a***). This role, which places great responsibility on the counselor, usually incorporates cognitive behavioral approaches in which providers strive to enhance patient motivation for change by focusing on patient strengths and respecting patient decisions (CSAT 1999***a***). To engage patients in the process of treatment planning, counselors should encourage the inclusion of motivational enhancement strategies that highlight appropriate, realistic treatment goals (Di Clemente 1991). Research has shown that confrontational counseling or the use of negative contingencies often predicts treatment failure (Miller and Rollnick 2002).

Role of the patient in plan formulation

A patient in MAT should be an integral member of the treatment team with his or her needs and expectations considered respectfully and incorporated into the treatment plan. Patients who agree with the treatment rationale or therapeutic approach tend to experience increased determination to improve (Hubble et al. 1999). A patientís participation in treatment planning can enhance motivation to adhere to change strategies, leading to positive treatment outcomes such as higher rates of abstinence and better social adjustment (CSAT 1999***a***). When possible, the treatment plan should be written in a patientís own words to describe his or her unique strengths, needs, abilities, and preferences as well as his or her challenges and problems. The plan also should contain mutually approved goals that reflect awareness of and sensitivity to a patientís informed choices, cultural background, age, and medical status or disability.

Other factors in plan formulation

Treatment plans should incorporate an assessment of linguistic and cultural factors that might affect treatment and recovery either positively or negatively (U.S. Department of Health and Human Services 2001). Treatment providers should work collaboratively with patients to identify health-related cultural beliefs, values, and practices and to decide how to address these factors in the treatment plan (U.S. Department of Health and Human Services 2001).

Motivation for treatment

Patient motivational strategies should be incorporated throughout the treatment plan. As part of this process, the treatment team can benefit from an understanding of stages of change and their effects on patient progress. Prochaska and colleagues (1982, 1986, 1992), who formulated a useful model that explains how people change, observed five stages of readiness for change during addiction treatment: contemplation, determination, action, maintenance, and relapse. An earlier stage (precontemplation) also plays a role. Patients and treatment providers ideally should develop recommended treatment options in the plan based on each patientís readiness for treatment, which can be determined by identifying the patientís stage-of-change readiness. The stages-of-change model and corresponding counseling responsibilities are described in TIP 35, ***Enhancing Motivation for Change in Substance Abuse Treatment*** (CSAT 1999***a***).

Elements of a Treatment Plan

Because some patients require assistance in many functional areas, treatment plans should address measurable, achievable goals relevant to the patientís current situation. Short-term goals, such as vocational rehabilitation

assessment or computer training, can evolve from a long-term goal, such as full-time employment. However, treatment plans should be simple and not so comprehensive that they overpower a patient with the tasks that must be achieved. Although both short- and long-term goals should be considered, the patientís involvement in defining measurable, achievable goals is important. Treatment plans should be modified periodically when progress can be assessed. Most OTPs have forms to use for treatment planning, many of which were developed to meet regulatory and accreditation requirements, specifying goals, actions, responsible parties, and measurable outcomes. The panel urges that these forms not be overly complex or overwhelming to the patient. Patients should receive a copy of the plan. Exhibit 6-1 provides a case study and an example of a treatment plan.

Exhibit 6-1

Case Study: PatientñTreatment Planning in MAT

Patient is a 30-year-old Hispanic mother of two children who has been divorced for 3 years. She dropped out of high school at age 15 when she became pregnant. As a single mother on public assistance, she first began using heroin intranasally at age 17 and began injecting 1 year later.

Patient was born in Puerto Rico, and her family came to the United States when she was 10 years old. She is the youngest of five children. Her father was an unemployed painter and alcoholic who physically abused her mother. He died in Puerto Rico from cirrhosis of the liver. Patientís relationship with her mother always has been strained. Her mother has had numerous relationships that the patient resented. Patient stated that, as the youngest child, she feels that she never received enough attention or love from her mother.

To support her lifestyle, which includes alcohol, cocaine, and heroin use, patient earned money through prostitution, which led to selling drugs, theft, and other criminal activities. Patient married after giving birth to her second child. Patient has an arrest history and a pending case for selling cocaine. After a divorce, patient lived with her mother. An anonymous call was made to CPS reporting her chronic drug abuse and criminal history. As a result, her children were placed in foster care. After the patientís arrest and the removal of her children, patientís mother asked her to move out of the house; she then lived with whomever she could.

Patient has enrolled in an OTP, motivated by her desire to regain custody of her children. She considers cessation of her cocaine habit secondary to cessation of her heroin abuse. She initially stated that she wanted to change her life, including having her own permanent housing, and she wanted to stop prostituting. Although stabilized on methadone, she continued to use cocaine on a regular basis during her first 6 months in treatment. While in the program, she tested positive for HIV infection. She was assessed as having severe depression, with suicidal ideation, and escalation of cocaine abuse.

Although attempts have been made to motivate patient to stop cocaine use, these attempts have been unsuccessful.

Patientís treatment plan might include the following short- and long-term goals:

(continued on following page)

Short-term goals

1. Address imminent danger of suicide by developing a service plan in conjunction with mental health provider.

- Objective: To rule out suicide; to overcome patientís depression and assess need for medication.
- Action: Have patient sign a consent form for a psychiatric evaluation and communication between provider and OTP staff; set up appointment with psychiatrist; obtain evaluation, diagnosis, and treatment recommendations from the psychiatrist.
- Target date: Immediately for suicidal ideation; within 1 month for ongoing mental health needs.
- Responsible persons: Patient, counselor or caseworker, and psychiatrist.
- Measurable outcome: Patient is stable and no longer at high risk; medication needs are assessed.
- Long-term goal: Stable mental health status with ongoing treatment plan.

2. Obtain housing for patient, with long-term goal of stable permanent housing.

- Objective: To refer to a shelter.
- Action: Make appointment to apply for housing assistance program.
- Target date: Immediately.
- Responsible persons: Patient, counselor or caseworker, and housing staff.
- Measurable outcome: Copy of lease, patient self-report, or both.
- Long-term goal: Access to stable housing.

3. Obtain HIV counseling.

- Objective: To provide support and education about HIV status.
- Action: Provide education, resources, and counseling about safe sex and spread of HIV.
- Target date: 4 to 6 months.
- Responsible persons: Medical staff, counselor, and patient.
- Measurable outcome: Patient has obtained and integrated accurate information; myths are dispelled; patient reports readiness to explore treatment options.
- Long-term goal: Initiation of antiretroviral treatment.

4. Address cocaine abuse.

- Objective: To educate the patient on the psychological and physiological effects of cocaine abuse; to develop a recovery intervention.

- Action: Assess level of use and readiness for change; develop plan with patient to address use (e.g., motivational groups, Cocaine Anonymous, skill-building interventions, drug testing).
- Target date: 2 to 4 months.
- Responsible persons: Patient, counselor, group leader, and medical staff members.
- Measurable outcome: Patient decreases cocaine use, based on self-report, observable behavior, drug testing, and attendance to counseling plan.

Long-term goals

1. Manage or eliminate depression.

- Objective: To stabilize depression; to increase self-esteem and motivation to work on treatment goals.
- Action: Provide regular psychiatric treatment on site or by referral; communicate with providers.
- Target date: 6 months.
- Responsible persons: Patient, counselor, and psychiatric providers.
- Measurable outcomes: Patient regularly attends to psychiatric treatment plan, adherence to medication regimen if prescribed, elimination of or reduction in depression (as assessed by patient report, depression assessment tools, observed behavior).

2. Regain custody of children once in stable housing situation.

- Objective: To reconcile the patient with her family; to maintain a stable living situation.
- Action: Assist patient in obtaining public assistance to ensure stable, safe, appropriate environment for children; access legal assistance for custody issues; obtain permission to communicate with CPS; assist patient in remaining abstinent from substance use.
- Target date: 1 year.
- Responsible persons: Patient, counselor or caseworkers, internal or external social services worker, and lawyer.
- Measurable outcomes: Patient self-report, family and CPS agency reports, rent receipts, progress toward obtaining custody of children.

3. Continue HIV medical care.

- Objective: To obtain ongoing HIV education and treatment.
- Action: Provide access and communication with HIV and primary care providers; provide referral to support group meetings for individuals who are HIV positive.
- Target date: Ongoing.
- Responsible persons: Patient, health care providers, counselor and caseworkers, and group counselor or facilitator.
- Measurable outcomes: Patient self-report, health care providersí report, laboratory reports, and group leader reports about adherence to health care needs.

The Multidisciplinary Team Approach

The complexities of treatment planning for patients who receive MAT require a multidisciplinary treatment team, the composition of which varies with OTP resources and the population being treated. The consensus panel recommends that the treatment team consist of the following:

- A physician trained in addiction psychiatry, who provides leadership, health care, and medical stabilization; conducts detailed evaluations of the patient; monitors medications; and provides needed substance abuse interventions when indicated
- Nonphysician medical staff members (e.g., registered nurse, nurse practitioner, physicianís assistant), who administer medications, assist in medical evaluations, maintain records, and facilitate referrals for medical and psychiatric treatments
- A pharmacist or pharmacy assistant, who dispenses (and sometimes administers) medications, orders controlled substances, maintains records, and consults with program staff on all aspects of patient care, particularly drug interactions
- Nonmedical professional staff members (e.g., case coordinator, social worker, psychologist, vocational and educational specialist), who provide a range of psychosocial services, including counseling and case management, psychotherapy and family therapy, psychological testing and evaluation, health education, and vocational skills assessment and training
- A certified or licensed addiction specialist or drug counselor
- Nontreatment and administrative staff members (e.g., office manager, clerical staff, receptionist, secretary), who often provide information to treatment teams and whose responsibilities include operational management, billing, receipt of payments, review of records, observation of patient interactions, and telephone coverage
- Security personnel, who ensure the safety and well-being of patients and staff on site.

More information on the multidisciplinary team approach is presented in chapter 14.

7 Phases of Treatment

In This Chapter…

The consensus panel recommends that medication-assisted treatment for opioid addiction (MAT) as provided in opioid treatment programs (OTPs) be conceptualized in terms of phases of treatment so that interventions are matched to levels of patient progress and intended outcomes. The sequential treatment phases described in this chapter apply primarily to comprehensive maintenance treatment, rather than other treatment options such as detoxification or medically supervised withdrawal. When MAT is organized in phases, patients and staff better understand that it is an outcome-oriented treatment approach comprising successive, integrated interventions, with each phase built on another and directly related to patient progress. Such a model helps staff understand the complex dynamics of MAT and the potential sticking points and helps counselors organize interventions based on patient needs.

The model described in this chapter comprises either five or six patient-centered phases for planning and providing MAT services and evaluating treatment outcomes in an OTP, including the (1) acute, (2) rehabilitative, (3) supportive-care, (4) medical maintenance, (5) tapering (optional), and (6) continuing-care phases.

Rationale for a Phased-Treatment Approach and Duration

Research on the effectiveness of organizing MAT into phases is limited, partly because MAT is a relatively long-term process, often with no fixed endpoint and with a variety of possible approaches, and partly because patients often leave and then return to MAT, which makes systematic studies difficult. Although research is limited, the consensus panel believes that the notion of phased progression is implicit in treatment and underlies most of a patientís time in MAT. Many OTPs operate according to an informal phased-treatment model, and others use phases at least to develop treatment plans.

Hoffman and Moolchan (1994) recognized the value of treatment phases in OTPs and described a highly structured model. This chapter builds on, adapts, and extends their model as part of an overall strategy for matching patients with treatments. The phases described below are suggested as guidelinesóa way of organizing treatment and looking at progress on a care continuumóand as an adjunct to the levels of care specified by the American Society of Addiction Medicine in its patient placement criteria (Mee-Lee et al. 2001***a***) and referred to by accreditation agencies.

> [T]reatment phases should not be viewed as fixed steps with specific timeframes and boundaries…

The model is not one directional; at any point, patients can encounter setbacks that require a return to an earlier treatment phase. Therefore, the chapter includes strategies for addressing setbacks and recommendations for handling transitions between phases, discharge, and readmission. In terms of medication, the model includes two distinct tracks, one of continuing medication maintenance and the other of medication tapering (medically supervised withdrawal). The implications of both tracks are discussed. Although most patients would prefer to be medication free, this goal is difficult for many people who are opioid addicted. Maintaining abstinence from illicit opioids and other substances of abuse, even if that requires ongoing MAT, should be the primary objective.

Variations Within Treatment Phases

The phase model assumes that, although many patients need long-term MAT, the types and intensity of services they need vary throughout treatment and should be determined by individual circumstances. For many patients, MAT is the entry point for diagnosis and treatment of, or referral for, other health care and psychosocial needs. In general, most patients need more intensive treatment services at entry, more diversified services during stabilization, and fewer, less intensive services after benchmarks of recovery begin to be met (McLellan et al. 1993; Moolchan and Hoffman 1994).

The consensus panel emphasizes that treatment phases should not be viewed as fixed steps with specific timeframes and boundaries but regarded as a dynamic continuum that allows patients to progress according to individual capacity. Some patients progress rapidly and some gradually. Some progress through only some phases, and some return to previous phases. Treatment outcomes should be evaluated not only on how many phases have been completed or whether a patient has had to return to an earlier phase but also on the degree to which the patientís needs, goals, and expectations have been met. As described in chapter 4, assessment of patient readiness for a particular phase and assessment of individual needs should be ongoing.

Duration of Treatment Within and Across Phases

Decisions concerning treatment duration (time spent in each phase of treatment) should be made jointly by OTP physicians, other members of the treatment team, and patients. Decisions should be based on accumulated data and medical experience, as well as patient participation in treatment, rather than on regulatory or general administrative policy.

Phases of MAT

Acute Phase

Patients admitted for detoxification

Although the phases of treatment model is structured for patients admitted for comprehensive

maintenance treatment, some patients may be admitted specifically for detoxification from opioids (see 42 Code of Federal Regulations [CFR], Part 8 ß 12(e)(4)). These patients usually do not wish to be admitted for or do not meet Federal or State criteria for maintenance treatment. Patients admitted for detoxification may be treated for up to 180 days in an OTP. The goals of detoxification are consistent with those of the acute treatment phase as described below, except that detoxification has specific timeframes and MAT endpoints. Detoxification focuses primarily on stabilization with medication (traditionally using methadone but buprenorphine-naloxone tablets are now available), tapering from this medication, and referral for continuing care, usually outside the OTP. During this process, patientsí basic living needs and their other substance use, co-occurring, and medical disorders are identified and addressed. Patients also may be educated about the high-risk health concerns and problems associated with continued substance use. They usually are referred to community resources for ongoing medical and mental health care.

Patients admitted for detoxification should have access to maintenance treatment if their tapering from treatment medication is unsuccessful or they change their minds and wish to be admitted for comprehensive MAT. If these patients meet Federal and State admission criteria, their medically supervised withdrawal from treatment medication should end, their medication should be restabilized at a dosage that eliminates withdrawal and craving, and their treatment plans should be revised for long-term treatment.

Patients admitted for comprehensive maintenance treatment

The acute phase is the initial period, ranging from days to months, during which treatment focuses on eliminating use of illicit opioids and abuse of other psychoactive substances while lessening the intensity of the co-occurring disorders and medical, social, legal, family, and other problems associated with addiction. The consensus panel believes that front-loading highly intensive services during the acute phase, especially for patients with serious co-occurring disorders or social or medical problems, engages patients in treatment and conveys that the OTP is concerned about all the issues connected to patientsí addiction. Exhibit 7-1 summarizes the main treatment considerations, strategies, and indicators of progress during the acute phase.

Goals of the acute phase

A major goal during the acute phase is to eliminate use of illicit opioids for at least 24 hours, as well as inappropriate use of other psychoactive substances. This process involves

- Initially prescribing a medication dosage that minimizes sedation and other undesirable side effects
- Assessing the safety and adequacy of each dose after administration
- Rapidly but safely increasing dosage to suppress withdrawal symptoms and cravings and discourage patients from self-medicating with illicit drugs or alcohol or by abusing prescription medications
- Providing or referring patients for services to lessen the intensity of co-occurring disorders and medical, social, legal, family, and other problems associated with opioid addiction
- Helping patients identify high-risk situations for drug and alcohol use and develop alternative strategies for coping with cravings or compulsions to abuse substances.

Chapter 5 details the procedures for determining medication dosage.

Indications that patients have reached the goals of the acute phase can include

- Elimination of symptoms of withdrawal, discomfort, or craving for opioids and stabilization

Exhibit 7-1

Acute Phase of MAT

Treatment Issue	Strategies To Address Issue	Indications for Transition to Rehabilitative Phase
Alcohol and drug use	ï Schedule weekly drug and alcohol testing ï Educate about effects of alcohol and drugs; discourage their consumption ï Ensure ongoing patient dialog with staff ï Intensify treatment when necessary ï Meet with program physician to ensure adequate dosage of treatment medication	ï Elimination of opioid-withdrawal symptoms, including craving ï Sense of well-being ï Ability to avoid situations that might trigger or perpetuate substance use ï Acknowledgment of addiction as a problem and motivation to effect lifestyle changes
Medical concerns ï Infectious diseases (e.g., HIV/AIDS, hepatitis, tuberculosis [TB]) ï Sickle cell disease ï Surgical needs, such as skin or lung abscesses	ï Refer patients immediately to medical providers ï Vaccinate as appropriate (e.g., for hepatitis A and B)	ï Resolution of acute medical crises ï Established, ongoing care for chronic medical conditions
Co-occurring disorders ï Psychotic, anxiety, mood, or personality disorders	ï Identify acute co-occurring disorders that may need immediate intervention ï Identify chronic disorders that need ongoing therapy	ï Resolution of acute mental crises ï Established, ongoing care for chronic disorders
Basic living concerns ï Legal and financial concerns ï Threats to personal safety ï Inadequate housing ï Lack of transportation ï Childcare needs ï Pregnancy ï Advocacy	ï Assess needs ï Refer patient to appropriate services ï Work cooperatively with criminal justice system ï Explore transportation options ï Link to legal advocate, caseworker, or social worker ï Identify financial resources ï Provide ongoing case management	ï Satisfaction of basic food, clothing, shelter, and safety needs ï Stabilization of living situation ï Stabilization of financial assistance ï Resolution of transportation and childcare needs

Exhibit 7-1

Acute Phase of MAT (continued)

Treatment Issue	Strategies To Address Issue	Indications for Transition to Rehabilitative Phase
Therapeutic relationship ï Establishing trust and feeling of support ï Addressing myths about MAT	ï Advocate adequate dosage ï Remain consistent, flexible, and available; minimize waiting times ï Provide incentives and emphasize benefits of treatment ï Dispel myths about MAT ï Educate patient about goals of MAT ï Build support system ï Build trust	ï Regular attendance at counseling sessions ï Positive interaction with treatment providers ï Focus on treatment goals
Motivation and readiness for change ï Ambivalent attitudes about substance use ï Avoidance of counseling (noncompliance) ï Negative relationships with staff ï Inadequate dosage ï Negative attitude about treatment ï Involuntary discharge	ï Ensure adequate dosage ï Address ambivalence ï Empower patient ï Emphasize treatment benefits ï Emphasize importance of making a fresh start	ï Commitment to treatment process ï Acknowledgment of addiction as a problem ï Lifestyle changes and addressing addiction-related issues

- Expressed feelings of comfort and wellness throughout the day
- Abstinence from illicit opioids and from abuse of opioids normally obtained by prescription, as evidenced by drug tests
- Engagement with treatment staff in assessment of medical, mental health, and psychosocial issues
- Satisfaction of basic needs for food, shelter, and safety.

Alcohol, opioid, and other drug abuse

During the acute phase, OTP staff members should pay attention both to patientsí continuing opioid abuse and to their use of other addictive and psychoactive substances. Patients should receive information about how other drugs, nicotine, and alcohol interact with treatment medications and why medication must be reduced or withheld when intoxication is evident. When substance abuse continues during the acute phase, the treatment team should review patientsí presenting problems and revise plans to address them, including changes in dosage, increased drug testing, or other intensified interventions. Chapter 11 discusses treatment options to address multiple substance use.

In addition, the consensus panel believes that frequent contact with knowledgeable and caring staff members who can motivate patients to become engaged in program activities, especially in the acute phase, facilitates the elimination of opioid abuse. Engaging the patient by scheduling extra individual or group counseling sessions provides additional support and communicates staff concern for the patient. Intensified treatment in the OTP is an effective response and provides improved outcomes when compared with more infrequent counseling sessions (Woody 2003).

Co-occurring disorders

Many people entering OTPs have mental disorders. Persistent, independent co-occurring disorders (i.e., mental disorders that arise from causes other than substance use and need ongoing therapy) and substance-induced co-occurring disorders (i.e., mental disorders directly related to substance use and addiction that probably will improve as the addiction is controlled) should be identified during initial assessment and the acute phase of treatment so that appropriate treatment or referral can be arranged. Patients should be monitored closely for symptoms that interfere with treatment because immediate intervention might prevent patient dropout. Such disorders can be disruptive at the start of MAT and require immediate treatment. The course of recovery from substance-induced co-occurring disorders usually follows that of the substance use disorder itself, and these co-occurring disorders typically do not require ongoing treatment after the acute phase. Some patients may require focused, short-term pharmacotherapy, psychotherapy, or both. However, many patients may have co-occurring disorders requiring a thorough psychiatric evaluation and long-term treatment to improve their quality of life. (See chapters 4 and 12 for more information on assessing these conditions and chapter 12 for more information on psychiatric diagnosis and treatment in MAT.)

Medical and dental problems

Patients often present with longstanding, neglected medical problems. These problems might require hospitalization or extensive treatment and could incur substantial costs for people often lacking financial resources. In addition, many patients in MAT have neglected their dental health (Titsas and Ferguson 2002). Once opioid abuse is stopped, these patients often experience pain because the analgesic effects of the opioids have been removed. Such conditions must be recognized, assessed, and treated, either within an OTP or via referral. (See chapter 10 for discussion of the diagnosis and treatment of medical problems for patients in MAT.)

Legal problems

Most correctional systems do not allow MAT. The consensus panel believes that sudden, severe opioid withdrawal caused by precipitous incarceration can endanger health, especially that of patients already experiencing comorbid medical illness, and can increase the risk of suicide in individuals with co-occurring disorders. Therefore, it is critical to address patientsí legal problems and any ongoing criminal activity as soon as possible, preferably in the acute phase. On behalf of those on probation or parole or referred by drug courts, program staff members should work cooperatively with

criminal justice agencies, educating them about MAT and, with patientsí informed consent (see CSAT 2004***b***), reporting patient progress and incorporating continuing addiction treatment into the probation or parole plan. OTPs should work with local prisons and jails to provide as much support and consultation as possible. When medical care is provided in jails or prisons by contracted health agencies, OTPs should establish contacts directly with these medical providers to improve the care of incarcerated patients in MAT. (See TIP 44, ***Substance Abuse Treatment for Adults in the Criminal Justice System*** [CSAT 2005***a***].)

Basic needs

The consensus panel recommends that patientsí basic needs such as food, clothing, housing, and safety be determined during the acute phase, if possible, as discussed in chapter 4, and that referrals be made to appropriate agencies to address these needs.

Patientsí living situations should be relatively stable and secure so that treatment can move beyond the acute phase. Before they transition to the rehabilitative phase, patients should begin to develop the coping skills needed to remove themselves from situations of inevitable substance use. A patientís inability to gain this control may necessitate revision of the treatment plan to assist the patient in moving past the acute phase. The process often includes meeting directly with the patient to assess motivation and adequacy of dosage and to define treatment goals clearly.

Therapeutic relationships

Positive reinforcement of a patientís treatment engagement and compliance, especially in the acute phase, is important to elicit a commitment to therapy. Chapter 8 addresses the importance of the therapeutic bond between patients and treatment providers and reviews practical techniques to address common problems in counseling.

Furthermore, participation in peer support services and mutual-help groups (provided that these groups support MAT) can be helpful to patients. OTPs can provide information about appropriate meetings and peer support.

The consensus panel recommends that patients be introduced to key OTP staff members as early as possible during the acute phase to foster an atmosphere of safety, trust, and familiarity. Patients consistently report that a strong therapeutic relationship is one of the most critical factors influencing treatment outcomes and that therapistsí warmth, positive regard, and acceptance are major elements in relationship development (Metcalf et al. 1996). Treatment providers should minimize waiting times during scheduled appointments to demonstrate that they value patientsí time. In addition, when providers remain flexible and available during the acute phase, they contribute to patientsí sense of security. Knowing how to reach staff in an emergency can foster patientsí trust in treatment providers.

Patients…report that a strong therapeutic relationship is one of the most critical factors influencing treatment outcomes…

Motivation and patient readiness

As discussed in chapter 4, patient motivation to engage in treatment is a predictor of retention and should be reassessed continually. Counselors should explore and address patientsí negative treatment experiences. It might help to acknowledge the weaknesses of past staff efforts and to focus on future actions to move treatment forward. Counseling and motivational enhancement are discussed in detail in chapter 8.

The level of patient engagement during the acute phase is critical. Research has shown that patient motivation, staff engagement, and the trust developed during orientation and the acute phase are linked more closely to treatment outcomes than patientsí initial reasons for entering an OTP (Kwiatkowski et al. 2000; Marlowe et al. 2001).

Transition to the rehabilitative phase

The panel recommends the following criteria for transition from the acute to the rehabilitative phase:

- Amelioration of signs of opioid withdrawal
- Reduction in physical drug craving
- Elimination of illicit-opioid use and reduction in other substance use, including abuse of prescription drugs and alcohol
- Completion of medical and mental health assessment
- Development of a treatment plan to address psychosocial issues such as education, vocational goals, and involvement with criminal justice and child welfare or other social service agencies as needed
- Satisfaction of basic needs for food, clothing, shelter, and safety.

Rehabilitative Phase

The primary goal of the rehabilitative phase of treatment is to empower patients to cope with their major life problemsódrug or alcohol abuse, medical problems, co-occurring disorders, vocational and educational needs, family problems, and legal issuesóso that they can pursue longer term goals such as education, employment, and family reconciliation. Stabilization of dosage for opioid treatment medication should be complete, although adjustments might be needed later, and patients should be comfortable at the established dosage for at least 24 hours before the rehabilitative phase can proceed. Exhibit 7-2 summarizes the treatment issues addressed during the rehabilitative phase, strategies for addressing them, and indicators for subsequent transition to the supportive-care phase.

As stated for the acute phase, during the rehabilitation phase treatment, providers should continue to assist or provide referrals for patients who need help with legal, educational, employment, medical, and financial problems that threaten treatment retention (Condelli 1993).

Throughout this phase, efforts should increase to promote participation in constructive activities such as full- or part-time employment, education, vocational training, child rearing, homemaking, and volunteer work. As patients attend to other life domains, requirements for frequent OTP attendance or group participation should not become barriers to employment, education, or other constructive activities or medical regimens. Consequently, program policies in areas such as take-home medications and dosing hours should be more flexible in the rehabilitative phase, especially when patients must travel long distances to their OTP or receive medication at restricted hours.

The consensus panel recommends that information about outside support groups, including faith-based, community, and 12-Step groups, be reviewed with patients in the rehabilitative phase and that patients be urged to participate in such groups, assuming that these groups support MAT. As discussed in chapter 14, OTPs also should cultivate direct relationships with organizations that might lend support for patient recovery. Faith-based organizations can provide spiritual assistance, a sense of belonging, and emotional support, as well as opportunities for patients to contribute to their communities, and in the process can educate community members about MAT.

Relapse triggers or cues such as boredom, certain locations, specific individuals, family problems, pain, or symptoms of co-occurring disorders might recur during the rehabilitative phase and trigger the use of illicit drugs or abuse of prescription drugs or alcohol. Helping

Exhibit 7-2

Rehabilitative Phase of MAT

Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
Alcohol and drug use ï Continued opioid use ï Continued abuse of other substances (e.g., alcohol, cocaine, nicotine)	ï Begin behavioral contracting ï Start short-term inpatient treatment ï Introduce disulfiram for alcohol abuse ï Provide pharmacotherapy and cessation groups for tobacco use ï Intensify treatment services ï Introduce positive incentives: take-home medication, recognition of progress ï Adjust dosage as necessary to prevent continued opioid use ï Encourage participation in support groups and family therapy	ï Ability to identify and manage relapse triggers ï Repertoire of coping skills ï Demonstrated changes in life circumstances to prevent relapse ï Discontinuation of opioid and other drug use ï Absence of problem alcohol use ï Smoking cessation plan
Medical concerns ï Chronic diseases (e.g., diabetes, hypertension, seizure disorders, cardiovascular disease) ï Infectious diseases (e.g., HIV/AIDS, TB, hepatitis B and C, sexually transmitted diseases) ï Susceptibility to vaccine-preventable diseases ï Dental problems, nicotine dependence ï Womenís health issues (e.g., pregnancy, family planning services)	ï Ensure onsite primary care or link to other services ï Provide integrated treatment approach ï Provide routine TB testing as appropriate ï Provide education on diet, exercise, smoking cessation ï Provide vaccinations as indicated ï Adjust other medications that interfere with treatment medication or adjust dosage of treatment medication ï Assess need and refer patient for pain management	ï Compliance with treatment for chronic diseases ï Improved overall health status ï Improved dental health and hygiene ï Regular prenatal care ï Stable medical and mental health status

(continued on following page)

Exhibit 7-2

Rehabilitative Phase of MAT (continued)

Treatment Issue	Strategies To Address Issue	Indications for Transition to Supportive-Care Phase
Co-occurring disorders ï Psychotic, anxiety, mood, posttraumatic stress, or personality disorders	ï Evaluate status ï Teach coping skills ï Ensure early identification and referral for co-occurring disorders ï Refer for psychotropic medication or psychotherapy as indicated	ï Stable mental status and compliance with psychiatric care
Vocational and educational needs ï Unemployment/ underemployment ï Low reading skills ï Illiteracy ï Learning disabilities	ï Identify education deficiencies ï Provide onsite general equivalency diploma (GED) counseling or referral ï Provide literacy and vocational training with community involvement ï Provide training on budgeting of personal finances ï Provide employment opportunities or referral to a job developer	ï Stable source of income ï Active employment search ï Involvement in productive activity: school, employment, volunteer work
Family issues ï Absence of family support system ï Emergence of family problems (e.g., traumatic family history, divorce, other problem situations)	ï Involve community or faith-based, fellowship, recreation, or other peer group ï Increase involvement in family life (in absence of family dysfunction that impedes progress) ï Provide for well-child care	ï Social support system in place ï Absence of major conflict within support system ï Increased responsibility for dependents
Legal problems ï Criminal charges ï Custody battles ï Ongoing illegal activities	ï Provide access to legal counsel ï Encourage patient to take responsibility for legal problems ï Identify obstacles to eliminating illegal activities and replace them with constructive activities	ï Resolution of, or ongoing efforts to solve, legal problems ï Absence of illegal activities

patients develop skills to cope with triggers should be emphasized in this phase (Sandberg and Marlatt 1991) and might involve individual, group, or family counseling or participation in groups focused on relapse prevention. (For a discussion of relapse prevention, see chapter 8.)

Many factors that receive emphasis in the acute phase should continue to be addressed in the rehabilitative phase:

- Continued alcohol and prescription drug abuse and use of illicit drugs
- Ongoing health concerns
- Acute and chronic pain management
- Employment, formal education, and other income-related areas
- Family relationships and other social supports
- Legal problems
- Co-occurring disorders
- Financial problems.

Continued alcohol and prescription drug abuse and use of illicit drugs

The consensus panel recommends that elimination of alcohol abuse, illicit-drug use, and inappropriate use of other substances be required to complete the rehabilitative phase. Evidence of heavy alcohol use might warrant that a patient return to the acute phase. If a patient is using medications, particularly drugs of potential abuse prescribed by a nonprogram physician, the patient should be counseled to advise his or her OTP physician of these prescriptions and should sign an informed consent statement permitting OTP staff and the outside physician to discuss these prescriptions. If drug use is illicit or unapproved by the OTP physician, then group, family, and individual counseling should continue, and the patient should remain in the rehabilitative phase. Patients who continue to use illicit drugs or demonstrate alcohol use problems are not eligible for take-home medication. Take-home medication should not be considered until these patients have demonstrated a period of abstinence. Patients also should receive information on the risks of smoking, both for their own recovery and for the health of those around them. (See chapter 11 for techniques to treat continued substance use during MAT and chapter 8 for counseling and behavior modification strategies.)

The frequency of drug testing during the rehabilitative phase and all subsequent phases should depend on a patientís progress in treatment. The consensus panel recommends that, once a patient is progressing well and has consistently negative drug tests, the frequency of random testing be decreased to once or twice per month. The criteria for this should be part of the treatment plan. (See chapter 9 for a detailed discussion of drug testing.)

Ongoing health concerns

As patients advance in the rehabilitative phase, they should attend to other medical problems, and OTP staff should help them navigate the medical- and dental-care systems, while educating practitioners about MAT. Onsite primary health care is optimal and has been instituted successfully in many OTPs and can result in better outcomes for patients (Weisner et al. 2001), although it requires careful coordination of activities and staff (Herman and Gourevitch 1997). When lack of resources precludes onsite medical services in an OTP, referral arrangements with other service providers should be in place.

The consensus panel recommends a more integrated approach to patient health in the rehabilitative phase. A patientís health needs should be diagnosed and treated immediately. Education about topics with longer term benefits, such as nutrition, exercise, personal hygiene, sleep, and smoking cessation, can be started. Eventually, patients should demonstrate adherence to medical regimens for their chronic conditions and address any acute conditions before they are considered for transition from the rehabilitative phase to subsequent treatment phases.

Acute and chronic pain management

Patients in OTPs are at high risk of undertreatment for pain (Jamison et al. 2000; Rosenblum et al. 2003; Scimeca et al. 2000). Chapter 10 provides recommendations for pain management. Because acute pain treatment usually involves opioid medications, programs should work with patients to recognize the risk of relapse and provide supports to prevent it (Jamison et al. 2000).

Employment, formal education, and other income-related issues

The consensus panel believes that some of the most difficult obstacles to a stable life for MAT patients include unemployment and inadequate funds to live comfortably and safely. Most such limitations should be addressed during the rehabilitative phase. (See chapter 8 for detailed discussion.)

Individuals who need access to high-quality social services should be identified during the rehabilitative phase for educational, literacy, and vocational programs that will equip them with the skills needed to function independently. Chapters 6 and 8 discuss such assistance. TIP 38, ***Integrating Substance Abuse Treatment and Vocational Services*** (CSAT 2000***c***), provides more information on this topic.

Ideally, OTPs should provide onsite GED counseling and assistance or make referrals to local adult education programs that are sensitive to the needs of patients in MAT. Efforts can be made to encourage business, industry, and government leaders to create income-generating enterprises that provide patients with job skills and opportunities for entry into the job market and to preclude employment discrimination for patients.

Patients in MAT face unique employment challenges, especially as employers increasingly impose preemployment drug testing and patients must wrestle with whether to disclose their status. The panel recommends that vocational training provided in an OTP include basic education about drug testing, including the fact that methadone may be detected. Patients should be advised to answer all job application questions honestly and should be counseled on ways to manage disclosure of their treatment status. Patients with disabilities should be educated about the basics of the Americans with Disabilities Act and any local antidiscrimination legislation and enforcement.

By the end of the rehabilitative phase, patients should be employed, actively seeking employment, or involved in a productive activity such as school, child rearing, or regular volunteer work. They should have a stable source of legal income, whether from employment, disability benefits, or other legitimate sources, ensuring that they can avoid drug dealing or other criminal activities to obtain money.

Family relationships and other social supports

Broken trust, disappointment, anger, and conflict with family members and acquaintances are realities that patients should face during the rehabilitative phase. Many need to reconcile with their families, reunite with or regain custody of their children, and handle other family issues. Some patients have had little or no family contact during the period of their opioid addiction. Counselors need to help patients improve their social supports and relationships and begin to rebuild and heal severely damaged family relationships. Chapter 8 expands on these goals for patients in MAT.

Transition from the rehabilitative phase should require that patients have a social support system in place that is free of major conflicts and that they assume increased responsibility for their dependents (e.g., by reliably providing child support).

Legal problems

The stress associated with patientsí legal problems can precipitate relapse to illicit drug

use or abuse of alcohol or prescription drugs. Counselors should probe patientsí legal circumstances, such as child custody obligations, and patients should be encouraged to take responsibility for their actions; however, counselors should help patients remain in treatment while resolving pending legal problems. During the rehabilitative phase, counselors should help patients overcome guilt, fear, or uncertainty stemming from their legal problems. In addition, OTP staff should ensure that patients have access to adequate legal counsel, for instance, through a public defender. All major legal problems should be in the process of resolution before patients move beyond the rehabilitative phase. Drug courtsí referrals of patients can result in reporting requirements and specialized protocols (see CSAT 2005***a***).

Co-occurring disorders

The consensus panel recommends that, before patients move beyond the rehabilitative phase, co-occurring disorders be alleviated or stabilized. Although symptoms might continue to arise, patients should have adequate coping skills to avoid relapse to opioid abuse. Chapter 12 provides specific information about co-occurring disorders in MAT.

Supportive-Care Phase

After meeting the criteria for transition from the rehabilitative phase, patients should progress to the supportive-care phase, in which they continue opioid pharmacotherapy, participate in counseling, receive medical care, and resume primary responsibility for their lives. During this phase, patients should begin to receive take-home medication for longer periods and be permitted to make fewer OTP visits. Depending on regulations (State regulations often are more stringent than Federal), these patients might visit their OTP as infrequently as every other week. Often, supportive care provided in an OTP can be augmented by supportive activities through mutual-help, community, faith-based, peer, and acculturation groups.

Exhibit 7-3 summarizes the treatment issues that should be addressed during the supportive-care phase, strategies for addressing them, and indicators for the subsequent transition from the supportive-care phase to medical maintenance or tapering.

Patients should have discontinued alcohol and prescription drug abuse and all illicit-drug use, as well as any involvement in criminal activities, before entering the supportive-care phase. Heavy or problem substance use should result in patientsí return to the acute phase. Patients in supportive care should be employed, actively seeking employment, or involved in other productive activities, and they should have legal, stable incomes. Even though all treatment plans and patientsí progress should be assessed individually, if any requirements largely are unmet, counselors should consider returning these patients to the rehabilitative phase to address areas of renewed concern rather than advancing them to the medical maintenance or tapering phase.

After patients in supportive care are abstinent from illicit drugs or are no longer abusing prescription drugs (as confirmed by treatment observation and negative drug tests) for a specified period, they should be considered for transition to either the medical maintenance or the tapering phase. Opinions vary on the length of time patients should be free from illicit-drug use and abuse of prescription drugs before being allowed to move to the next phase. However, to receive the maximum 30-day supply of take-home medication, a patient must be demonstrably free from illicit substances for at least 2 years of continuous treatment (42 CFR, Part 8 ß 12(i)(3)(vi)). The consensus panel believes that

Heavy or problem substance use should result in patientsí return to the acute phase.

Exhibit 7-3

Supportive-Care Phase of MAT

Treatment Issue	Strategies To Address Issue	Indications for Transition to Next Phase
Alcohol and drug use	ï Monitor use ï Increase frequency of drug screening	ï Discontinued drug use and no problems with alcohol use
Medical and mental health concerns	ï Monitor compliance with medical/psychiatric regimens ï Maintain communication with patientsí health care and mental health care providers	ï Stability
Vocational and educational needs	ï Monitor vocational status and progress toward educational goals ï Assist in addressing workplace problems	ï Stable source of income
Family issues	ï Monitor family stability and relationships ï Refer for family therapy as needed	ï Stability
Legal issues	ï Monitor ongoing legal issues ï Provide needed support	ï Resolution

a period of treatment compliance lasting between 2 and 3 years usually is appropriate. However, the length of time a patient remains in supportive care should be based entirely on his or her needs and progress, not on an imposed timetable. Patientsí progress in coping with their life domains should be assessed at least quarterly to determine whether patients are eligible and ready for transition from supportive care to either the medical maintenance or tapering phase.

In some cases, patients who stop opioid abuse and demonstrate compliance with program rules do not make progress in other life domains. Although such patients might do well in MAT, they still need the ongoing support and pharmacotherapy provided by the OTP and, in the opinion of the consensus panel, should be deemed ineligible or inappropriate candidates for either medical maintenance or tapering. Instead, these patients should continue to receive take-home medication for brief periods (e.g., 1 to several days) along with other services as needed.

The criteria for transitioning to the next phase of treatment depend on whether the patient is entering the medical maintenance phase or the tapering and readjustment phase.

Medical Maintenance Phase

In the medical maintenance phase, stabilized patients who continue to require medication to remain stable are allowed longer term (up to 30-day) supplies of take-home medication and further reductions in the frequency of treatment visits, generally without the suite of services included in comprehensive MAT. Medical

maintenance with methadone can be administered through an OTP or through the office of a qualified physician who operates under Substance Abuse and Mental Health Services Administration (SAMHSA) approval as a ìmedication unitî (42 CFR, Part 8 ß 11(h)) and is linked formally to an OTP. Federal regulations (42 CFR, Part 8 ß 12(i)(3)(vi); 42 CFR, Part 8 ß 11(h)) permit various levels of take-home medication for unsupervised use, with the amount linked to the length of time that patients have been abstinent from illicit opioids or have stopped abusing prescription opioids and to other specified conditions. Some State regulations (e.g., New York) further restrict the amount of take-home opioid treatment medication and supersede Federal regulations.

The consensus panel recommends the following criteria to determine a patientís eligibility for the medical maintenance phase of treatment:

- 2 years of continuous treatment
- Abstinence from illicit drugs and from abuse of prescription drugs for the period indicated by Federal and State regulations (at least 2 years for a full 30-day maintenance dosage)
- No alcohol use problem
- Stable living conditions in an environment free of substance use
- Stable and legal source of income
- Involvement in productive activities (e.g., employment, school, volunteer work)
- No criminal or legal involvement for at least 3 years and no current parole or probation status
- Adequate social support system and absence of significant unstabilized co-occurring disorders.

During the medical maintenance phase, OTPs may play various roles in patientsí primary medical and mental health care. OTPs that provide only limited health care services should integrate their services with those of other health care providers (see chapters 10 and 12 about related medical problems and co-occurring disorders, respectively). Exhibit 7-4 summarizes treatment issues and strategies in the medical maintenance phase of MAT and provides indicators for transition to physicianís office-based opioid treatment (OBOT) or the tapering or continuing-care phases.

In addition, evaluation of life domains including substance use, co-occurring medical and mental problems, vocational and educational needs, family circumstances, and legal issues should continue during the medical maintenance phase, regardless of the setting. Although patients in medical maintenance may not require psychological services, they may need occasional dosage adjustments based on their use of other prescription medication or on such factors as a change in metabolism of methadone (see chapter 5).

The consensus panel recommends random drug testing and callbacks of medication during the medical maintenance phase to make sure that patients are adhering to their medication schedules (see chapter 9). Patients in medical maintenance should be monitored for risk of relapse. Positive drug test results should be addressed without delay, and patients should be returned to the rehabilitative phase when appropriate.

The consensus panel recommends that, as part of the diversion control plan required for all OTPs by SAMHSA (see chapters 5 and 14), evidence of medication diversion by a patient in medical maintenance result in reclassification of that patient to the most appropriate previous phase of treatment and in adjustment of treatment, other services, and privileges. Reinstatement into medical maintenance should occur only after the phase-regressed patient is observed over a reasonable period (at least 3 to 6 months) and has demonstrated required progress.

Considerations for OBOT with methadone

OBOT may be considered for patients receiving methadone in MAT in an OTP who have demonstrated stability in all domains for at

Exhibit 7-4

Medical Maintenance Phase of MAT

Treatment Issue	Strategies To Address Issue	Indications for Transition to OBOT or Tapering or Continuing-Care Phases
Alcohol and drug use	ï Monitor use ï Perform drug testing	ï Continuous stability for 2 years
Medical and mental health concerns	ï Monitor compliance ï Maintain communication	ï Stability
Vocational and educational needs	ï Monitor progress ï Remain available to address workplace problems	ï Stability
Family issues	ï Monitor family stability ï Refer to family therapy as needed	ï Stability
Legal issues	ï Monitor ongoing legal issues ï Provide support as needed	ï Stability

least 2 consecutive years of treatment. If a patient in medical maintenance who is receiving treatment through OBOT relapses (to opioid, other drug, or alcohol abuse) or needs the structure of an OTP for psychosocial reasons, the treating physician is responsible for referring the patient back to an OTP. There are some exceptions in which patients, early in treatment, can be transferred from an OTP to OBOT with methadone (e.g., when travel to an OTP is impossible or there are medical reasons), but these exceptions must be preapproved by SAMHSA (see chapter 5).

Coordination of care is critical in the OBOT model so that patients get the full range of services needed to remain abstinent. Treatment issues listed in Exhibits 7-1, 7-2, and 7-3 also are applicable to patients who receive OBOT. Regardless of the opioid treatment medication used, treatment of opioid addiction requires a comprehensive and individualized treatment approach that includes medication and counseling services. Even for patients who are rehabilitated and stable enough to qualify for medical maintenance, medication alone often is inadequate to treat their opioid addiction (Joseph et al. 2000).

Tapering and Readjustment Phase

ì Taperingî and ìmedically supervised withdrawalî are terms commonly used to describe the gradual reduction and elimination of maintenance medication during opioid addiction treatment. (The term ìdetoxificationî in this TIP refers to tapering from illicit drugs, from inappropriate use of prescription drugs, or from alcohol abuse, not to tapering from treatment medication, to avoid the implication that treatment medications are toxic.) Studies show that most patients who are opioid addicted try

to taper from treatment medication one or more times after reaching and maintaining stability. With proper support systems and skills, many patients succeed in remaining abstinent from opioids without treatment medication for years or even life, but studies have shown that some relapse to opioid abuse (Condelli and Dunteman 1993; Hubbard et al. 1989; Kreek 1987). Chapter 5 describes procedures and other key considerations in tapering. In the phased model presented here, tapering is considered an optional branch.

It is important that any decision to taper from opioid treatment medication be made without coercion and include careful consideration of a patientís wishes and preferences, level of motivation, length of addiction, results of previous attempts at tapering, family involvement and stability, and disengagement from activities with others who use substances. A patient considering dose tapering should understand that the chance of relapse to drug use remains (Magura and Rosenblum 2001) and some level of discomfort exists even if the dose is reduced slowly over months (Moolchan and Hoffman 1994). Patients should be assured that they temporarily can halt the reductions or return to a previous methadone dosage if tapering causes problems.

As medication is being tapered, intensified services should be provided, including counseling and monitoring of patientsí behavioral and emotional conditions. Patients considered for medication tapering should demonstrate sufficient motivation to undertake this process, including acceptance of the need for increased counseling. Tapering from medication can be difficult, and patients should understand the advantages and disadvantages of both tapering from and continuing on medication maintenance as they decide which path is best for them. Exhibit 7-5 presents treatment issues during the tapering phase, strategies to address these issues, and indicators for return to a previous phase.

Reasons for tapering

Sometimes decisions to taper are motivated by the hardships of OTP attendance and other requirements or by the stigma often associated with MAT. The consensus panel urges OTPs to identify such situational motives and ensure that patients who choose medically supervised withdrawal from MAT are motivated instead by legitimate concerns about health and relapse.

Patients and treatment providers might fail to realize or understand that continuing or long-term MAT is the best choice for some patients. OTP staff members consciously or inadvertently might convey that tapering is more desirable or expected than continuing opioid pharmacotherapy, through such practices as celebrating patientsí tapering but not the accomplishments of others who successfully continue in MAT. The consensus panel believes that a basic grounding in MAT pharmacology, the biology of addiction, and the endorphin system helps patients and treatment providers understand that both successful tapering from and continued compliance with medical maintenance treatment are legitimate goals and commendable accomplishments.

Relapse after tapering

The risk of relapse during and after tapering is significant because of the physical and emotional stress of attempting to discontinue medication (Magura and Rosenblum 2001). The consensus panel recommends that patients be encouraged to discuss any difficulties they experience with tapering and readjustment so that appropriate action can be taken to avoid relapse. Patients should be persuaded to return to a previous phase if the need is indicated at any time during tapering. Patients also should be told that they can taper at their own rate, that successful tapering sometimes takes many months, and that they can stop tapering or increase their dosage at any time without a sense of failure. Patients should be educated about how to reenter MAT if they believe that relapse is imminent.

Exhibit 7-5

Tapering Phase of MAT

Treatment Issue	Strategies To Address Issue	Indications for Return to a Previous Treatment Phase
Alcohol and drug use	ï Monitor use ï Increase drug testing ï Increase counseling support	ï Relapse or concern about relapse to opioid use ï Positive drug test for an illicit substance
Medical and mental health concerns	ï Monitor compliance ï Maintain communication with health care providers ï Continue education	ï Unstable health issues
Vocational and educational needs	ï Monitor progress ï Be available to address workplace problems	ï Instability ï Loss of employment
Family issues	ï Monitor family stability ï Refer to family therapy as needed	ï Instability ï Death or loss of loved one ï Unstable housing
Legal issues	ï Monitor ongoing legal issues ï Provide support as needed	ï New criminal involvement

Readjustment

Many patients who complete tapering from opioid medication continue to need support and assistance, especially during the first 3 to 12 months, to readjust to a lifestyle that is free of both maintenance medication and substances of abuse. During this period, treatment providers should focus on reinforcing patientsí coping and relapse prevention skills. Patientsí primary goals should be to increase self-sufficiency and maintain balanced, stable, and productive lifestyles. Participation in 12-Step or other mutual-help groups is recommended as reliance on the OTP is gradually reduced. Motivated patients might be helped by continued naltrexone therapy (see chapter 3), which blocks opioid effects for 2 to 3 days in appropriate doses. Care must be taken to initiate naltrexone well after tapering is completed to avoid precipitating withdrawal symptoms. Other patients might benefit from continued counseling to strengthen relapse prevention skills. Some patients might find the support of continued drug testing helpful after tapering. Other recommended strategies include problemsolving counseling approaches, reinforcement of positive behaviors and attitudes, an open-door policy to maximize availability of counselors and providers, steps to strengthen patientsí own support systems, and development of a relapse prevention plan, including how to return to MAT if necessary.

Reversion to MAT

The consensus panel recommends that all patients attempting tapering be counseled that a return to medication and a previous phase does not represent failure but simply that medical maintenance is more appropriate for some patients in general and for others at particular times in their lives.

Indicators for transition

Successful discontinuation of medication is a key indicator for transition from the tapering phase to the continuing-care phase. Another key indicator is a positive self-image as someone who feels and functions well without medication. Adoption of a socially productive lifestyle without involvement with substances of abuse also is critical to completing this phase and to continued recovery. The absence of signs and symptoms of abuse or dependence, as defined by the ***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision,*** (DSM-IV-TR) (American Psychiatric Association 2000) indicates successful completion of tapering.

Continuing-Care Phase

Continuing care is the phase that follows successful tapering and readjustment. Treatment at this stage comprises ongoing medical followup by a primary care physician, occasional check-ins with an OTP counselor, and participation in recovery groups. Ongoing treatment, although less intense, often is necessary because the chronic nature of opioid addiction can mean continuous potential for relapse to opioid abuse for some patients.

Patients in continuing care should have a socially productive lifestyle, no involvement with drugs or problem involvement with alcohol, and improved coping skills demonstrated over at least 1 year. Significant co-occurring disorders should be well under control. People in this phase should continue to participate regularly in mutual-help groups, but regular attendance at an OTP should be unnecessary, except to return to a more intensive level of treatment if necessary for continuation of recovery.

The panel recommends that appointments with the OTP continue to be scheduled every 1 to 3 months, although many programs prefer that patients in continuing care maintain at least monthly contact. Although many programs curtail this contact after 6 to 12 months, others maintain ongoing contact with patients to assist them in maintaining their medication-free lifestyle. Some patients might not need continuing-care services after tapering, preferring instead a complete break from the OTP. Others might need more extensive continuing care, perhaps including referral to a non-MAT outpatient program that more closely fits their needs.

Transition Between Treatment Phases in MAT

Characteristics of the recommended treatment phases are not immutable, and the criteria for transition between phases are not intended to be rigidly interpreted or enforced. The treatment system should be flexible enough to allow for transition according to a patientís progress and circumstances. The program should modify treatment based on the best interests of patients, rather than infractions of program rules.

Occasional relapses to drug use might not require that a patient return to the acute phase but instead that he or she receive intensified counseling, lose take-home privileges, or receive a dosage adjustment. If a patient is in the medical maintenance phase or the tapering and readjustment phase, a relapse often requires a rapid response and change of phase. In these cases, the patient might be reclassified into the rehabilitative phase. After providing evidence that problems are under control, the patient might be able to return to the supportive-care or medical maintenance phase.

Readmission to the OTP

The consensus panel emphasizes that patients almost always should be encouraged to remain in treatment at some level and that pharmacotherapy should be reinstituted unreservedly for most previously discharged patients if and when relapse occurs or seems likely. Feelings of shame, disappointment, and relapse-related guilt, especially for rehabilitated patients who have close relationships with staff members, should not be allowed to inhibit patients from seeking reentry to treatment. The consensus panel recommends that all patients be informed at entry to the OTP that subsequent reentry is common and can be accomplished more quickly than initial intake because regulations waive documentation of past addiction for returning patients (42 CFR, Part 8 ß 12(e)(3)). All obstacles to reentry should be minimized.

8 Approaches to Providing Comprehensive Care and Maximizing Patient Retention

In This ChapterÖ

A core group of basic- and extended-care services is essential to the effectiveness of medication-assisted treatment for opioid addiction (MAT) in opioid treatment programs (OTPs). Numerous studies support the belief that psychosocial interventions contribute to treatment retention and compliance by addressing the social and behavioral problems and co-occurring disorders affecting patients in MAT (e.g., Brooner and Kidorf 2002; Joe et al. 2001). The consensus panel agrees that a well-planned and well-supported comprehensive treatment program increases patient retention in MAT and the likelihood of positive treatment outcomes.

Core Services

Basic-Care Services

The minimum required services for MAT are outlined in Federal regulations (42 Code of Federal Regulations [CFR], Part 8), but individual program requirements vary according to State standards, accreditation requirements, and local factors. The consensus panel recommends that OTPs offer at least the following services:

- Comprehensive psychosocial assessment (see chapter 4)
- Initial and yearly medical assessment (physical examination and laboratory testing [see chapter 10])
- Medication dispensing (see chapter 5)
- Drug tests (see chapter 9)
- Identification of co-occurring disorders and neuropsychological problems (see chapter 12)
- Counseling to stop substance abuse and manage drug craving and urges
- Evaluation of and interventions to address family problems
- HIV and hepatitis C virus (HCV) testing, education, counseling, and referral for care
- Referral for additional services as needed.

Extended-Care Services

Many patients in MAT have other problems affecting their recovery, including medical, social, family, vocational, and legal problems and co-occurring disorders. Assessing and addressing these problems are important to facilitate recovery from addiction. Various strategies have been developed, including psychosocial and biomedical interventions and peer-support approaches.

Managing an OTP To Meet Service Needs

Substances of abuse

Increasingly since the 1980s, patients have entered OTPs with other addictions, particularly to alcohol, cocaine, marijuana, nicotine, or other sedatives and stimulants. In addition, adolescent and young adult patients often smoke or snort rather than inject heroin, and more patients are addicted to opioid analgesics, such as oxycodone, taken orally (see chapter 11). To manage these developments, OTPs should evaluate and modify their core substance abuse treatment services continuously, based on the changing needs of their patient populations.

Medical needs

People addicted to opioids are at greater risk for sexually transmitted diseases (STDs), pneumonia, and other debilitating conditions that require intensive medical services. Infected injection sites, cellulitis, and abscesses are increasingly common. Bacterial endocarditis remains a concern. Long-term tobacco use contributes to other diseases. Chapter 10 details the medical problems of todayís patients in MAT and the treatment approaches recommended in OTPs.

Staffing needs

Program administrators need to develop comprehensive patient population profiles for planning, staffing, and resource allocation. Managers should provide an appropriate mix of staff for specific patient characteristics and needs and should determine the range of services that can be provided with available funds. Unfunded services should be covered by referral to affiliated agencies. Positive, sustained outcomes are more attainable in a therapeutic environment with readily available, supportive, qualified caregivers. It is difficult to provide high-quality care and facilitate favorable treatment outcomes in a chaotic OTP environment with unqualified or overburdened staff and managers and unreasonable caseloads.

Offsite treatment options

The consensus panel urges OTPs to provide as many basic- and extended-care services as possible on site. OTPs that lack the resources to provide or sponsor the comprehensive list of services recommended in this TIP should engage in active case management while working with other agencies and specialized service providers and educating these collaborators about MAT. Accreditation requirements increasingly are motivating OTPs to pursue these collaborations.

Retaining Patients in MAT

Importance of Retention

Studies of patients who left MAT prematurely have determined that length of retention was the most important indicator of treatment outcomes (e.g., Simpson, D.D., et al. 1997***b***). Patients who stayed in treatment a year or longer abused substances less and were more likely to engage in constructive activities and avoid criminal involvement than those who left treatment earlier, although all patients benefited from treatment, for instance, through less exposure to and transmission of infectious diseases (Hartel and Schoenbaum 1998). Their communities benefited as well.

Improving Patient Retention

Factors affecting patient retention

Patient characteristics, behavior, and other factors unrelated to treatment have been found to contribute relatively little to retention in MAT. One comprehensive study found that retention was determined almost entirely by what happened during treatment, not before, although two factors, older age and less involvement with the criminal justice system, predicted longer retention (Magura et al. 1998, 1999). Another factor found to affect retention was motivation or readiness for treatment (Joe et al. 1998).

In other studies, how patients entered OTPs, whether voluntarily or by a court referral, did not affect treatment retention (Brooner et al. 1998; Fallon 2001). Rhoades and colleagues (1998) reported that patients who previously received methadone were more likely to remain in MAT than first-time patients. Some patients require several attempts at treatment before becoming stabilized for extended periods (Koester et al. 1999). OTPs should not consider patientsí prior failures indicative of future compliance or retention or use these failures as reasons to reject those seeking readmission. Some patients may need longer periods of adjustment to MAT before making a long-term commitment.

Recommended steps to improve patient retention

Individualize medication dosages. Adequate, individualized medication dosages are probably the most important factor in patient retention (Joseph et al. 2000) because they contribute to patient comfort and satisfaction by reducing withdrawal symptoms and craving and enabling more attention to other concerns (reviewed in Leavitt et al. 2000; Strain et al. 1999). (See chapter 5 for further discussion of prescribing practices in MAT.)

Clarify program goals and treatment plans. Treatment providers should explain program goals and treatment plans to every patient. Inconsistent messages adversely affect patient retention, particularly when these messages are about the advisability of remaining in MAT versus tapering from medication (Magura and Rosenblum 2001). Goals related to medication should be individualized and respectful of patientís wishes and goals, but they should incorporate knowledge and research about retention in MAT. Treatment planners should realize that, regardless of OTP recommendations, some patients want to taper from maintenance medication more quickly than seems advisable. Staff should work with these patients to achieve their goals in a reasonable timeframe.

> [R]etention was determined almost entirely by what happened during treatment, not before…

OTP practices and communication with patients should conform to best treatment practices. Setting maximum lengths of stay for all patients or emphasizing low-dose medication goals can discourage retention and produce poor outcomes (Magura and Rosenblum 2001). Rigid operating practices (e.g., requiring extensive travel, inconvenient hours, long waits, frequent pickups) may lower retention and disrupt treatment. Patients have cited other factors that discourage retention, such as staff insensitivity, lack of treatment skills and knowledge, and limited contact.

Simplify the entry process. Shortening intake results in better program retention (see chapter 4).

Attend to patients' financial needs. Patientsí inability to pay may limit both treatment entry and retention, especially in States where MAT

is not covered by Medicaid, State funds, or private insurance. One study found that randomly offering prospective patients either cost-free treatment or moderate fee rates significantly increased treatment entry and retention for the cost-free patients (Kwiatkowski et al. 2000). OTP staff members should work proactively with patients to apply for benefits covering treatment costs, investigate health insurance and work with existing insurers, and develop hardship payment plans.

Staff members should express confidence in MAT when communicating with patients.

Reduce the attendance burden. Attendance requirements can exert powerful effects on retention. Rhoades and colleagues (1998) found that patients who were required to visit an OTP less frequently were less likely to drop out of treatment and no more likely to use other drugs than patients on a daily attendance schedule.

Provide useful treatment services as early as possible. Patients were more likely to stay in treatment when they were motivated strongly and engaged earlier in useful activities (Simpson, D.D., et al. 1997***b***). In the critical first 90 days of treatment, higher service intensities, especially for practical services that helped patients achieve basic goals, have been associated with higher retention. Examples include attentive case management, psychiatric services, introduction to peer groups, and assistance with insurance, transportation, and housing (Grella and Wugalter 1997).

Enhance staff–patient interactions. Good staff attitudes and interactions with patients have been associated with higher retention. In one study, patientsí frequent contact with staff members and the involvement and visibility of OTP administrators increased patient retention (Magura et al. 1999). Some treatment providers have found that patients are more likely to remain in treatment when they are involved in its planning and management. Increased interaction with staff increases communication and information flow, limits problems, and contributes to patientsí sense of well-being. Unfortunately, funding constraints often reduce communication training for staff and opportunities to improve patient-to-staff ratios.

Improve staff knowledge and attitudes about MAT. OTP staff members should understand MAT and appreciate the wealth of science supporting it, and they should be aware of recommended treatment practices so that they can interact effectively and constructively with patients. However, Bell (2000) pointed to studies showing that staff training, favorable patient-to-staff ratios, and better facilities did not eliminate opioid abuse, and he concluded that staff attitudes contributed more directly to outcomes. Staff members should express confidence in MAT when communicating with patients. Attitudes critical of extended pharmacotherapy have been found to be common (even dominant) among many counselors (Kang et al. 1997) and evoke frequent patient complaints.

Counseling and Case Management, Behavioral Treatments, and Psychotherapy

Counseling and Case Management

Patient counseling in individual, family, or group sessions offers a venue for many treatment approaches and educational interventions. It provides support for a substance-free lifestyle and abstinence from substances of abuse. Studies have found that OTPs providing regular, structured, substance abuse-focused counseling had better outcomes than OTPs providing little or no counseling (Kidorf et al.

1999; Magura et al. 1999). Others have concluded that good counseling rapport was related to improved abstinence and reductions in criminality (e.g., Joe et al. 2001).

The consensus panel recommends that counseling in MAT focus on

- Providing support and guidance, especially to eliminate substance use
- Monitoring other problematic behaviors
- Helping patients comply with OTP rules
- Identifying problems that need extended services and referring patients for these services
- Identifying and removing barriers to full treatment participation and retention
- Providing motivational enhancement for positive changes in lifestyle.

The standard components of substance abuse counseling should include

- Assistance in locating and joining mutual-help groups or peer support groups such as Narcotics Anonymous (NA) or Methadone Anonymous (MA)
- Education about addiction and the effects of substances of abuse
- Education about relapse prevention strategies
- Identification of unexpected problems needing attention, such as sudden homelessness
- Assistance in complying with program rules and regulations
- Information about stress- and time-management techniques
- Assistance in developing a healthy lifestyle involving exercise, good nutrition, smoking cessation, and avoidance of risky sexual practices
- Assistance in joining socially constructive groups such as community organizations and faith-based groups
- Continuing education on health issues (particularly HIV/AIDS and hepatitis).

Counseling sessions to relieve patientsí anxiety about MAT and reassure them about its efficacy are of paramount importance during the first weeks of treatment. Usually, individual sessions during the acute phase (see chapter 7) are more intensive than those that follow, although individual needs should dictate the frequency and duration of counseling.

Individual counseling

As MAT progresses, patients should continue meeting with counselors in individual sessions, once per month to several times per week depending on need, the phase of treatment, and State regulations. In some States, Medicaid regulations and contracts require or limit counseling frequency. MAT counselors should continue to identify patientsí needs and refer them to or arrange for other services (e.g., housing, medical and psychiatric care, legal services).

A typical individual counseling session, as envisioned by the consensus panel, might include any of the following activities:

- Reviewing how a patient feels, is coping with cravings, or is changing his or her lifestyle
- Reviewing drug test results and what they mean
- Identifying emergencies and deciding how to address them
- Reviewing the treatment plan
- Identifying measurable goals and reasonable timeframes
- Reviewing progress in achieving goals, including abstinence and related behaviors
- Discussing dosage and take-home medications
- Discussing legal concerns, such as reporting to probation officers and complying with the terms of probation or parole
- Discussing family concerns
- Providing liaison services (e.g., with physicians, courts, social service agencies)
- Addressing routine issues (e.g., transportation, childcare).

Medical staff should educate counselors about patientsí medical problems so that counselors can help patients understand the importance of keeping appointments for and complying with

medical treatment. Counselors should convey observations to medical staff about patientsí conditions and information about other aspects of patientsí lives that might clarify health problems. Although counselors are not expected to understand medical treatments, pathophysiology, or pharmacotherapy in the same way as medical professionals do, they should have general knowledge of common medical conditions affecting patients in MAT and their treatmentsóespecially how treatments for these conditions can interact with addiction treatment medications. Counselors can help patients cope with hepatitis C and adhere to its treatment regimens. Many patients have been exposed to HCV infection (see chapter 10), and effective treatment requires motivation and support from the entire treatment team.

Group counseling

Group counseling has some advantages over individual counseling and therapy (see TIP 41, ***Substance Abuse Treatment: Group Therapy*** [CSAT 2005***c***]). It can reduce patientsí sense of isolation and help them cope with addiction and other life problems by providing feedback from peers, social skill training and practice, structure, discipline, and encouragement. Through peer interaction, patients contribute to one anotherís recovery. Trained individuals should lead these groups. Some State agencies offer courses in group process and dynamics.

The following types of groups are used commonly in MAT:

- Psychoeducational groups
- Skill development groups, such as relapse prevention, stress management, and substance use cessation groups, which help patients learn skills to attain and maintain abstinence
- Cognitive behavioral groups, in which patients learn to alter pervasive thoughts and actions
- Interpersonal-process groups, which delve into developmental issues contributing to addiction or interfering with recovery
- Support groups, which buoy members and provide a forum to share pragmatic information about maintaining abstinence and managing a day-to-day substance-free lifestyle.

In some OTPs, group membership is linked to the phase of a patientís treatment. Some groups keep the same membership but stay together for a short time; others are longer term and have a rolling membershipóthat is, frequent membership changes, with new members entering when they are ready. Neither type of group needs a predetermined end point or set timeframe. Using a manual with a structured curriculum enables counselors and other staff members to lead some groups (Exhibit 8-1). Manuals increase flexibility in resource-limited OTPs and the likelihood that groups cover standard information. Manuals for group counseling in MAT are less common than for general substance abuse counseling. However, the consensus panel believes that the principles used for non-MAT groups can be adapted easily to groups in MAT.

Some patients resist group counseling and avoid sessions. Offering smaller groups might ease their concerns while therapists explore the reasons for their resistance (e.g., fear of talking in groups or confidentiality concerns). In general, an OTP should consider a groupís patient mix. Some patients with co-occurring disorders do better in groups with members who have similar conditions. However, some patients with severe co-occurring disorders cannot participate in groups, and some have problems that require individual counseling.

A patientís gender or sexual orientation can be important in choosing individual or group counseling. Some women are uncomfortable in male-dominated groups and do better in women-only groups. Others feel embarrassed about personal subjects related to their addiction. Gay men, lesbians, and bisexuals might feel isolated in predominantly heterosexual groups. In such cases, the consensus panel recommends individual, women-only, or sexual-orientation-specific groups.

Exhibit 8-1

Resource Materials for Psychoeducational, Skill-Building, and Group Counseling Sessions

- ***Anger Management for Substance Abuse and Mental Health Clients: A Cognitive Behavioral Therapy Manual*** (Reilly and Shopshire 2002)
- ***Anger Management for Substance Abuse and Mental Health Clients: Participant Workbook*** (Reilly et al. 2002)
- ***Cognitive-Behavioral Coping Skills Therapy Manual*** (Kadden et al. 1992)
- ***Cognitive Therapy of Substance Abuse*** (Beck et al. 1993)
- ***A Family Like Yours: Breaking the Patterns of Drug Abuse*** (Sorensen and Bernal 1986)
- National Institute on Drug Abuseís Therapy Manuals for Drug Addiction Series (www.drugabuse.gov)
- ***Recovery Training and Self-Help: Relapse Prevention and Aftercare for Drug Addicts*** (National Institute on Drug Abuse 1993***b***)
- ***Relapse Prevention Workbook for Recovering Alcoholics and Drug-Dependent Persons*** (Daley 2002)
- ***Seeking Safety: A Treatment Manual for PTSD and Substance Abuse*** (Najavits 2002)
- ìSupportive-expressive dynamic psychotherapy of opiate drug dependenceî (Luborsky et al. 1995)
- ***Treatment of Opioid Addiction With Methadone: A Counselorís Manual*** (McCann et al. 1994)

Social services case management

Some researchers have investigated the usefulness of social service-focused case management in addiction treatment settings such as OTPs. McLellan and coworkers (1999) described a system with an active case management component to help patients access services for housing, medical care, and legal and parenting assistance. Six months after the systemís implementation, patients receiving these services showed greater reduction in alcohol use and improvement in medical conditions, family relations, and legal status than patients receiving none of these services. The authors concluded that social service-focused case management was an important and effective adjunct to addiction treatment.

Cognitive and Behavioral Therapies

Other interventions, both in use and under study, include cognitive-enhanced techniques to increase treatment participation, modify behavior, and address patientsí social, emotional, and behavioral problems, as well as any co-occurring disorders. Behavioral treatments such as contingency management (see below),

in which patients enter into agreements that provide positive incentives for treatment compliance, have been especially effective in MAT (see Brooner and Kidorf 2002; Robles et al. 1999).

Behavioral treatments in MAT are derived from principles of cognitive learning and behavioral change developed by psychologists and behavior scientists. The consensus panel believes that substance abuse and addiction involve major learning elements and are influenced by patientsí environments and circumstances. Many elements of cognitive behavioral therapy (CBT)ófor example, emphases on identifying high-risk circumstances that may trigger an event and developing coping responsesóare accepted and incorporated widely into substance abuse education and counseling (Ryan 2002). CBT is associated with increased treatment compliance and improved treatment outcomes.

Node-link mapping

Node-link mapping is a cognitive-enhanced technique that uses flowcharts and other visual aids to diagram relationships between patientsí thoughts, actions, and feelings and their substance use and to increase patient participation in counseling (Czuchry and Dansereau 2003). Studies have found that node-link mapping encouraged communication about topics such as family, job, and substance use (Dees et al. 1997; Pitre et al. 1997) and improved participantsí motivation, self-esteem, and rapport with counselors. Patients with poor attention stamina were found to have greater success in mapping-enhanced counseling than in standard counseling (Czuchry and Dansereau 2003). Less educated patients exposed to mapping-enhanced counseling also had better 12-month followups than those in standard counseling (Pitre et al. 1996). According to Dansereau and colleagues, ìThe use of node-link mapping appears to reduce cultural, racial, and class barriers by providing a visual supplement and a common language that enhances counselorñ client interchangesî (Dansereau et al. 1996, p. 363).

Community reinforcement approach

The community reinforcement approach (CRA), originally developed to treat alcoholism, is another effective model for MAT. This multicomponent treatment facilitates change in a patientís daily environment. CRA counselors work with patients to identify aspects of their lives that reinforce abstinence and to understand how these reinforcers can serve as alternatives to substance use. CRA has been found to reduce opioid use and produce other positive outcomes either with or without voucher-based incentives (Abbott et al. 2003; Higgins and Abbott 2001).

Contingency management

Contingency management reinforces desired behavior with immediate incentives (Griffith et al. 2000). Its efficacy has been demonstrated in several well-designed studies (e.g., Rawson et al. 2002; Robles et al. 1999). Incentives were found to increase such desirable outcomes in MAT as negative drug tests, attendance at counseling and medical appointments, working, and volunteering. This approach is useful for treatment planning because it sets concrete goals and emphasizes positive behavioral changes. Exhibit 8-2 summarizes this strategy in MAT.

The consensus panel emphasizes that effective contingencies usually involve positive reinforcement. Positive contingencies or rewards are more effective than negative, punishing contingencies or threats (Gruber et al. 2000). Negative consequences tend to drive patients from treatment. In one study, a balance of positive and negative reinforcements, as part of a well-constructed contingency management plan, helped patients reduce their drug use (Crowley 1999). Tangible rewards, such as take-home medication privileges, should be paired with social reinforcements, such as praise from the counselor or other patients, to optimize their value.

Exhibit 8-2

Strategy for Contingency Management in MAT

- Pick a target behavior that can be measured easily (e.g., stopping opioid abuse).
- Select a reward that can be given as soon as the desired behavior (e.g., three consecutive negative drug test results) is documented. The reward should be nonmonetary (e.g., nonrefundable movie passes, take-home medication privileges).
- Specify the link between targeted behavior and the reward. For example, a negative drug test result might earn one take-home medication dose (other treatment and program variables must be taken into account, including Federal and State regulations).
- Put the contract in writing, specifying its duration and any changes over time in contingencies (e.g., after 3 substance-free weeks, the patient can receive take-home privileges).

A popular, effective reward in OTPs is the medication take-home privilege (Chutuape et al. 1998). Other incentives may include special scheduling for medication administration, meal vouchers, gift certificates, entertainment tickets, or toys for patientsí children. Designing such programs requires significant effort, yet the rewards can add an important dimension to MAT. Kidorf and colleagues (1997, 1998, 1999) demonstrated the effectiveness of behavior-contingent incentives in OTPs. They used take-home medication privileges to increase the involvement of significant others and improve patientsí job acquisition. They also used behavior-contingent treatment availability to improve drug test results and counseling attendance.

To be most effective, behavior contingencies should be defined clearly and implemented consistently. Contingencies may be individualized based on each patientís targeted areas of behavioral change or implemented on a uniform, programwide basis. Tailoring behavioral contingencies to patientsí needs has been found to work better (Silverman et al. 1999). Piane (2000) effectively combined contingency incentives with systematic desensitization for patients whose anxiety blocked the benefits of contingency incentives alone. When combined with progressive muscle relaxation and desensitization, contingency management had a demonstrated record of effectiveness, whereas systematic desensitization alone was less effective in eliminating opioid use but reduced fear of withdrawal and general anxiety (Piane 2000).

Brooner and Kidorf (2002) described a program of motivational stepped-care levels in which clear contingencies were matched with treatment responses. Patients who responded poorly were moved to a more intensive level of care. Those who responded well received less intensive care. The authors concluded that this approach increased treatment participation and that a stepped-care system was effective and cost sensitive. In another study comparing contingency vouchers (which had monetary value and were exchangeable for goods and services) with methadone dosage increases, both incentives increased negative drug test results, but only contingency vouchers increased durations of drug abstinence (Preston et al. 2000). Dosage increases should be based on evidence of withdrawal symptoms and other medical assessments, not good behavior.

The consensus panel emphasizes that, when contingency management is used to control use of short-acting drugs, objective measures should provide the basis for withholding incentives. Testing frequency (both randomly and, when feasible, regularly at least once per week) must be adequate to detect short-acting drugs. (See chapter 9 for a complete discussion of drug testing.)

Motivational enhancement

Motivational enhancement has emerged as a component of counseling in MAT, although the effectiveness of motivational interviewing in MAT needs more investigation. One study (Saunders et al. 1995) found that brief motivational intervention improved outcomes in MAT. Patients in this study demonstrated greater commitment to abstinence, reported more positive outcomes and fewer opioid-related problems, and relapsed less quickly or frequently than did the control group. Motivational enhancement interventions influence patients to give up secondary substances of abuse, address health issues, and change their social circumstances. TIP 35, ***Enhancing Motivation for Change in Substance Abuse Treatment*** (CSAT 1999***a***), provides a thorough discussion of motivational therapy. Another valuable guide is ***Motivational Interviewing: Preparing People for Change*** (Miller and Rollnick 2002).

Psychotherapy

Psychotherapy is a form of verbal-expressive therapy in which a trained therapist uses psychological principles to modify or remove problematic thoughts, feelings, and behaviors (Kidorf et al. 1999). Whereas counseling focuses on the here-and-now, decisionmaking, values, self-concept, strengths, and goal setting, psychotherapy focuses on changes in personality, and psychoanalytic psychotherapy attends to the subconscious. Both counseling and psychotherapy can be short term and solution directed, but psychotherapy more often is used to resolve chronic psychological and social problems.

Research has shown that psychotherapeutic interventions enhance the efficacy of MAT ó particularly for patients with co-occurring disorders who show little response to counseling alone (OíBrien et al. 1995; Woody et al. 1995***b***). Patients in MAT who have benefited from psychotherapy include those whose anxiety or depression required more than routine, behavior-oriented counseling. Several authors have described effective psychotherapeutic approaches for these patients (reviewed by Woody [2003]).

Because many patients are unstable during the acute phase of MAT, providers usually delay psychotherapy until later in the acute phase or in the rehabilitative phase, but views differ on when psychotherapy is appropriate. The consensus panel believes that psychotherapy has an important role in MAT but that it usually should be deferred until patients are stabilized. Exhibit 8-3 summarizes consensus panel recommendations for psychotherapy in MAT.

Staff qualifications

Staff members responsible for psychotherapy should have more specialized training than those responsible for drug-focused counseling. Psychotherapists should possess advanced degrees and undergo supervised training. If OTPs lack staff or resources for psychotherapy, patients should be referred elsewhere. OTPs should verify and document the degrees and licensure of those providing psychotherapeutic services.

Group psychotherapy

Group psychotherapy and group counseling with an interpersonal, process, or psychodynamic focus can be effective interventions in MAT. These groups should be flexibly structured and focus on interpersonal-relationship building, self-insight, reflection, and discussion (Vannicelli 1992). Patients should be selected carefully for these groups and should be able to

Exhibit 8-3

Common Strategies for Psychotherapy in MAT

- Devote part of each session to addressing patientsí most recent successes and failures regarding their substance use.
- Adopt a more active therapist role than typically required for co-occurring disorders.
- Strengthen patientsí resolve to stop substance use (help them visualize or recall life without drugs to replace memories of enjoyable drug use).
- Teach patients to recognize warning signs of relapse and develop coping skills.
- Support patientsí rearranging priorities so that they are not preoccupied with substance use. This might involve their acquiring job skills, developing hobbies, or rebuilding relationships.
- Assist patients in managing painful affects. (From a psychodynamic approach, this involves exploring the causes of such feelings.)
- Help patients enhance interpersonal functioning and social supports so that the rewards of friendship and relationships replace those of substance use.
- Use psychotherapy only after a strong therapeutic alliance has developed with the patient or other supportive structures are in place to guard against relapse.

commit to the process. Group treatment can provide a sense that individuals are not alone in addressing problems, even serious ones. Such normalization is often a first step toward feeling less isolated and developing new coping strategies. (For a thorough presentation of group therapy in substance abuse treatment, see TIP 41, ***Substance Abuse Treatment: Group Therapy*** [CSAT 2005***c***].)

Other Topics

Effects of sexual abuse

The consensus panel recommends specialized training for counselors and therapists treating patients who have been sexually abused or referral of these patients to qualified mental health care providers. TIP 36, ***Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues*** (CSAT 2000***d***), includes information about the effects, symptoms, and treatment of sexual abuse for patients during substance abuse treatment.

Counseling for HIV/AIDS and hepatitis C

Counseling about the increased risks of HIV and HCV infection arising from drug injection and risky sexual behavior is essential for patients in MAT. TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** (CSAT 2000***e***), thoroughly examines HIV education, which is mandatory for MAT in some States. Many States require that patients receive specialized HIV counseling before and after they receive HIV antibody tests and require that patients be encouraged to ask questions about HIV. Pretest HIV counseling should be factual and medically based. For patients who test negative for HIV, posttest counseling should address how they can reduce infection risk. Patients with positive HIV test results need

referrals for medical care and counseling about what the tests mean, coping with problems and issues raised by the results, treatment options, participation in clinical trials if available, support groups, and behaviors to prevent infecting others or contracting another HIV strain. Rapid HIV tests have been approved by the Food and Drug Administration and are recommended by the U.S. Public Health Service for point-of-care diagnosis of HIV infection in settings such as OTPs (see chapter 4). If an OTP cannot provide onsite testing and counseling, it should develop referral relationships for outside diagnosis and treatment. The consensus panel recommends onsite counseling whenever possible. (For further discussion, see chapter 10.)

Coping with patients who resist counseling and psychotherapy

Some patients resist counseling, psychotherapy, and other treatments out of fear and distrust. They may perceive that proposed treatments will not meet their needs, or they find staff insensitive or uneducated. Some patients may begin MAT to address other aspects of their lives rather than to stop substance use. Others have been pressured into MAT by the courts. Strategies to engage these patients in treatment are described in chapter 6.

Patient Education and Psychoeducation

Patient education and psychoeducation are useful in comprehensive MAT and can be performed in group or individual sessions. Both types of education may involve presenting information about substance abuse and addiction to patients alone, in groups, or with their families. Psychoeducation addresses the full range of patient needs, including education, personal development, recreation, health, and vocational or relationship needs (Stark and Campbell 1991), while addressing patient attitudes and feelings to ensure that a message is understood and internalized. Psychoeducational models, when used with other treatment approaches, increase a patientís ability to function independently and meet his or her daily needs outside the OTP. Exhibit 8-4 summarizes strategies for psychoeducation in MAT.

Recovery Training and Self-Help: Relapse Prevention and Aftercare for Drug Addicts (National Institute on Drug Abuse 1993***b***) provides educational and public health perspectives and educational discussions adaptable to MAT. A helpful, straightforward handbook for patients is ***About Methadone*** (Lindesmith Center-Drug Policy Foundation 2000).

Common topics in patient educational sessions include

- Physical and psychological effects of opioid and other substance abuse
- Health education information, including medical problems related to addiction, smoking cessation, improving nutritional habits (including special needs of persons with HIV), and exercise, including aerobic and meditative exercises (e.g., yoga)
- Effects of drug use on family and other relations
- Introduction to mutual-help groups such as MA
- Effects and side effects of addiction treatment medications and interactions with other drugs
- Symptoms of co-occurring disorders
- Compulsive behaviors besides substance abuse (e.g., gambling, sexual behaviors)
- Skills to attain and sustain abstinence, such as anger management and coping with cravings
- Developing nonñdrug-related leisure activities
- Stress management and relaxation
- Communication skills and assertiveness training
- Time management
- Parenting skills
- Avoidance of STDs and promotion of responsible sexual behavior

Exhibit 8-4

Strategies for Psychoeducation in MAT

- ï Introduce psychoeducation at the beginning of treatment so that it serves as an orientation to both OTP operational and recovery processes.
- ï Involve family members and selected friends, with a patientís informed consent. Provide guidance in how to support the patientís recovery efforts.
- ï Adapt educational strategies and materials to the patientís culture and family.
- ï Discuss methadone and other treatment medications, and dispel the myths related to their use (e.g., ìmethadone rots the bones,î ìitís impossible to get off methadoneî).
- ï Discuss the implications of continuing substance abuse. Question assumptions about alcohol and drug use, and clarify that such use undermines recovery.
- ï Discuss sexual behaviors that may affect relapse, including exchanging sex for drugs, drug use to function sexually or enhance sex, sexual abstinence, and intimacy or sex while substance free.
- ï Discuss the power of triggers with patients and families. For example, merely discussing heroin can be a trigger for resuming its use.
- ï Incorporate special groups to discuss parenting, childcare, womenís issues, and coping with HIV/AIDS and HCV infection. Use generic names for HIV/AIDS groups (e.g., ìhealth care issuesî group) to avoid stigma.

- ï Vocational planning and employment (sometimes linked with cognitive testing and conducted with vocational agencies).

Benefits of Family Involvement

The consensus panel believes that family involvement in treatment provides strong support for patient recovery and that family members also benefit. The concept of ìfamilyî should be expanded to include members of the patientís social network (as defined by the patient), including significant others, clergy, resource people from the community, and others.

Types of Family Interventions

Family involvement usually takes the form of family counseling or family education. Some OTPs hold short family education sessions about MAT, substance use disorders and their effects on the family, and family dynamics. Holding sessions for several families can be cost effective, supportive, and mutually beneficial. Family counseling usually consists of one or more discussion sessions that provide information and allow participants to express their feelings and concerns. Some OTPs have monthly family nights or informal gatherings for ongoing communications between patient families and counselors. These continuing forums help secure family support for patient treatment and identify acute family problems needing focused therapy.

The consensus panel recommends that, because complex factors affect patientsí families, family therapy should be provided only by trained staff and reserved for families with serious problems with behaviors or attitudes that contribute to patientsí addictions, which, if unchecked, might affect recovery. Because many OTPs do not provide family therapy, referrals to community-based services often are needed, and the consensus panel urges that such connections be established. Family therapy may be more effective for some patients than individual counseling, group therapy, or family psychoeducation (Stanton and Shadish 1997). TIP 39, ***Substance Abuse Treatment and Family Therapy*** (CSAT 2004***c***), provides more information.

Children of Patients in MAT

Many children of patients in MAT have emotional and cognitive problems. They are more vulnerable to physical and sexual abuse and neglect and may exhibit more behavioral problems, substance use, criminal involvement, conduct problems, and other social and intellectual impairments than other children (CSAT 2000***d***; Dawe et al. 2000). Child assessment requires trained personnel and may be unrealistic for some OTPs. OTPs can make referrals to appropriate resources and are encouraged to provide parenting support groups, skill development groups, family therapy, or referral for child and family therapy (Juliana and Goodman 1997).

Counselors should be aware of reporting requirements in their State, and patients should be advised that confidentiality protections do not apply if a patient must be reported to authorities for child abuse or neglect (see CSAT 2004***b***). A counselor who determines that a patient is neglecting or abusing young children is required to report the neglect or abuse. Licensed professional staff members (physicians, psychologists, nurses, social workers) are mandated to report child neglect and abuse. In some States, any person who observes this situation ***is required by law*** (42 CFR, Part 2 ß 22) to report it to local authorities (CSAT 2000***d***).

Few OTPs are equipped to address the needs of children whose family members abuse opioids (Dawe et al. 2000). Nunes and colleagues (1998***b***) recommended that treatment providers ask about the mental health and adjustment of patientsí children and consider routine psychiatric screening and early intervention and treatment for these children. Dawe and colleagues (2000) reported improved parentñchild relations and positive outcomes for children with conduct problems after behavioral training that provided their parents with improved parenting techniques.

Parenting Groups

Many patients entering OTPs are in danger of losing custody of their children or already have lost custody. Some patients in MAT might have separate agreements with childrenís protective services (CPS) agencies about what they must do to keep or regain custody of their children. OTPs should treat these patients with respect and avoid displaying negative feelings about their involvement with CPS agencies. In cases in which child custody is at issue, the consensus panel recommends that, once these patients are stable, treatment focus on concerns about custody, children, and parenting. Parenting groups are one useful approach.

Some parenting groups are educational, addressing topics such as interacting with CPS agencies, resource availability, daycare services, and breast-feeding during MAT. Skill-building groups for parents in MAT often address process issues, such as setting limits, appropriate and consistent discipline, divorce, visitation, noncustodial parenting, and tending to sick children.

Psychodynamic parenting groups take a more intensive approach, exploring topics such as ambivalence about losing child custody, fear of parenting, and coping with anger, shame, or guilt. OTPs should develop parenting groups based on the needs expressed by patients.

Domestic Violence

Men and women in MAT may be victims of domestic violence. It is estimated that at least three-quarters of women in MAT experienced partner violence (El-Bassel et al. 2000, 2001). Counselors should incorporate appropriate assessment procedures, referrals, or treatment responses for violence. They might have to help patients remove themselves from dangerous situations. Counselors should have a broad view of domestic violence that includes female (to male) aggression, same-sex physical and emotional abuse, and issues related to elder abuse. TIP 25, ***Substance Abuse Treatment and Domestic Violence*** (CSAT 1997***b***), provides a detailed discussion of this subject. Because many patients are in domestic violence situations, OTPs should provide general didactic groups or seminars and other resources addressing domestic violence. Treatment resources for victims should be integral parts of treatment strategies.

Integrative Approaches

Integrative approaches to MAT complement and enhance OTP efforts with resources from the community. Peer support, or mutual-help, programs are the most common such resources (Chappel and DuPont 1999). OTPs offering comprehensive treatment should have the flexibility and resources to integrate available, beneficial services from the community.

Peer Support, or Mutual-Help, Programs

The most popular, widely used mutual-help models are 12-Step recovery programs, such as Alcoholics Anonymous (AA), NA, MA, and Cocaine Anonymous (CA), which have been effective in helping people remain abstinent from substances and can be important augmentations to therapy. They are sources for social support, peer identification, relapse prevention, and treatment reinforcement, and they provide role models for successful recovery (Chappel and DuPont 1999). Members of support groups gain strength and security from others who understand and share their concerns and who offer practical strategies for surviving ìone day at a time.î McAuliffe (1990) saw peer support groups as providing the long-term support necessary to reinforce addiction recovery. His program, Recovery Training and

Conflict Between MAT and Some Mutual-Help Programs

Because 12-Step and other mutual-help programs vary widely in attitudes toward medications and some are particularly negative about opioid pharmacotherapy, many patients in MAT feel uncomfortable attending meetings for fear of criticism. If they do attend, some try to hide their participation in MAT (Nurco et al. 1991), and some insist on group acceptance of MAT. Some patients, unable to handle rejection, have chosen not to return, others have chosen prematurely to taper from maintenance medication, and some have used this difficulty as justification to self-medicate. Therefore, a decision to encourage patient participation entails some risk. MA groups emerged largely in response to the discrimination perceived by patients in MAT from other 12-Step programs. MA has chapters in most States. OTPs lacking an MA group are encouraged to start one. For information, contact the National Alliance of Methadone Advocates (212-595-6262 or www.methadone.org).

Self-Help (RTSH), helps people become part of a recovery community. He found that participants in RTSH were less likely than controls to relapse to opioid use, and there were favorable effects on employment and criminal behavior.

More information on the above programs is available on the World Wide Web:

- AA, www.alcoholics-anonymous.org
- NA, www.na.org
- MA, www.methadonetoday.org
- CA, www.ca.org
- RTSH, www.smartrecovery.org.

Decreases in substance abuse among group participants have been associated with attending meetings frequently, obtaining a sponsor, ìworkingî the 12 Steps, and leading meetings (American Psychiatric Association 1995, 1996; Landry 1997). However, 12-Step groups are not for everyone. Some groups do not support MAT, and many advocate an approach that may conflict with a patientís personal beliefs. Patients should not be pressured to attend support groups. Rather, an OTP staff member should explain that participation has helped many patients. Resistance to attendance should be discussed and respected. Every effort should be made to help a patient find an appropriate peer support program. Many creative strategies have evolved to promote mutual-help programs, such as simulated meetings to introduce patients to the language, customs, and rules of groups.

Other Support Groups

Groups also exist for friends and relatives of persons in recovery (e.g., Nar-Anon) and of others who refuse treatment. The following groups offer support and teach participants to curb their destructive behaviors:

- Chemically Dependent Anonymous, www.cdaweb.org
- Cocaine Anonymous, www.ca.org
- Double Trouble in Recovery, www.doubletroubleinrecovery.org
- Dual Disorders Anonymous
- Dual Recovery Anonymous, www.draonline.org
- Families Anonymous, www.familiesanonymous.org
- Women for Sobriety, www.womenforsobriety.org
- Secular Organizations for Sobriety (SOS), www.cfiwest.org/sos
- SMART Recovery Self-Help Network (Self-Management and Recovery Training), www.smartrecovery.org.

Other Approaches

In acupuncture, thin needles are inserted subcutaneously at points on the body for therapeutic purposes. Some believe that acupuncture can relieve pain, anxiety, and withdrawal symptoms related to substance abuse, although little empirical evidence exists. Some patients appear to benefit from acupuncture as an adjunct to MAT. Its use to treat opioid withdrawal was first reported in 1973. Efficacy, in that case, remained unclear, owing in part to study design limitations (Alling et al. 1990). However, a National Institutes of Health consensus statement lists addiction as one condition for which acupuncture treatment might be useful. Although the mechanism of acupuncture is not understood, some researchers have focused on the analgesic effects of opioid peptides released during the procedure (National Institutes of Health 1997***a***).

Other approaches to self-help and peer support that might be integrated with MAT include meditation classes; exercise programs; classes in diet, nutrition, and health; and trauma groups. More research is needed on the benefits of these activities and treatments in MAT.

Relapse Prevention

Because opioid addiction is a chronic relapsing disease, the consensus panel recommends that strategies specifically directed at relapse prevention be an important part of comprehensive

MAT in any OTP. A useful manual is ***Relapse Prevention Workbook*** (Daley 2002). Exhibit 8-5 lists consensus panel recommendations for assisting patients in building their relapse prevention skills.

Education about relapse is a key part of treatment. Educational approaches should teach concrete strategies to avoid drug relapse and should address the goals listed in Exhibit 8-5. Additional topics may include cataloging and avoiding high-risk situations and coping with drug cravings and slips to prevent full-blown relapses. Relapse prevention strategies often distinguish between slips and relapses, with slips defined as milder episodes of use. Of course, no level of opioid use should be condoned, but when a relatively mild and isolated episode occurs, the consensus panel recommends that OTP staff members focus on implementing the best available prevention strategy to ensure that a severe relapse is avoided.

Relapse Prevention Strategies for Multiple Substance Use

Patients who abuse multiple substances may require modified relapse prevention strategies. Patients may use formerly coadministered substances separately, which can increase the chance of sequential lapses leading to full relapse (Kosten 1991). Separate interventions may be necessary for each substance because the associated risks of relapse are different for each. Perceptions of actual relapse risks for the same drug can differ among patients. For example, a patient may associate heroin use with socializing and cocaine use with alleviating depression.

Exhibit 8-5

Patient Goals in Building Relapse Prevention Skills

- Understand relapse as a process, not an event.
- Develop new coping skills for high-risk situations.
- Make lifestyle changes to decrease the need for drugs.
- Increase participation in healthy activities.
- Understand and address social pressures to use substances.
- Develop a supportive relapse prevention network (e.g., with significant others).
- Develop methods of coping with negative emotional states.
- Learn methods of coping with cognitive distortions.
- Develop a plan to interrupt a slip or relapse.
- Recognize relapse warning signs, including internal and external triggers and warning signs.
- Combat memories of drug abuse-associated euphoria.
- Reinforce recollections of negative aspects of drug use.
- Overcome the desire to attempt to regain control over use of illicit drugs or abuse of alcohol or prescription drugs.
- Avoid people, places, and things that might trigger drug use.
- Develop pleasurable and rewarding alternatives to drug use.

Some researchers have noted that an abstinence violation effect may occur when a patient abstains from a substance but then relapses and possibly overuses it. The patientís reaction varies and often is contingent on how much he or she perceives relapse as a personal failure. When a slip or lapse occurs, the patientís self-esteem can be lowered, which he or she may attempt to repair by continuing or increasing substance use. Treatment providers should be alert to this phenomenon and educate patients about it (Marlatt 1985; Marlatt and Gordon 1980).

Recognizing Relapse Warning Signs

Indications of a patientís mistaken beliefs or rationalization might precede relapse and provide intervention points for a therapist. It is critical that a counselor or therapist know these warning signs, including the following (Washton 1988):

- The illusion of feeling cured after a few weeks or months of abstinence
- The belief that one can control his or her substance use and can use substances socially
- Idealized recollections of drug-induced euphoria; remembering the pleasurable effects but selectively forgetting adverse effects
- Overreactions to urges and cravings, leading to beliefs that treatment is ineffective or abstinence is unsustainable
- Denial of vulnerability to and refusal to accept the possibility of relapse, leading to overreaction when relapse occurs (causing patients to drop out of treatment)
- Entry into high-risk situations, denial of risks, and self-testing or self-sabotage.

Extinction Therapy

Behavior therapy using cue exposure treatment (extinction) was designed to reduce drug craving by repeated exposures to an experience that previously triggered drug use (Childress et al. 1992). However, a recent review of cue exposure treatment for relapse prevention concluded that these treatments, although studied for years, were ineffective (Conklin and Tiffany 2002).

Patient Followup Strategies

Patient followup and continuing care have been found to be critical to preventing relapse and ensuring that patients remain abstinent (e.g., Zanis et al. 1996). When relapse occurs, OTPs should facilitate reentry into MAT. Followup and continuing-care services ensure a continuum of support, and the consensus panel recommends that these efforts continue, with necessary funding to sustain them. (See the discussion of the continuing-care phase of treatment in chapter 7.)

Referral to Social Services

Most patients in MAT need vocational, educational, housing, or other social services. One review found that an estimated 50 to 80 percent of patients in publicly funded OTPs were unemployed, yet fewer than 5 percent received employment-related interventions (Zanis and Coviello 2001). In another study, social services other than Temporary Assistance for Needy Families (Public Law 104ñ193) often were less readily available to patients in MAT (Widman et al. 1997). OTPs should be proactive in educating social service providers about patient needs and facilitating these services. Patients in OTPs that provide assistance with social services have shown improved outcomes after treatment (Rowan-Szal et al. 2000***a***).

Involuntary Discharge From MAT

Unfortunately, involuntary discharge from MAT, sometimes called administrative discharge, occurs frequently. The consensus panel believes that these discharges are, in many cases, evidence of program shortcomings. A number of recent changes, including the

Substance Abuse and Mental Health Services Administration (SAMHSA)-administered OTP accreditation system with its emphasis on patient care and rights and requirements for consistent policies and procedures (CSAT 1999***b***, amended 2001 [***Federal Register*** 66:4076]), require OTPs to consider and document the reasons and methods for administrative discharges far more carefully than in the past. Other specific details vary from State to State.

In their review of numerous studies, Magura and Rosenblum (2001) concluded that patients who were discharged from medical maintenance or long-term detoxification treatment had consistently worse outcomes than patients who remained in treatment. Zanis and Woody (1998) found substantial increases in death rates among those involuntarily discharged for continued drug use. The consensus panel strongly recommends that involuntary discharge be avoided if possible, especially when patients would like to remain in and might benefit from MAT. When discharge is unavoidable, it should be handled fairly and humanely, following procedural safeguards that comply with Federal regulations and accreditation guidelines.

Reasons for Administrative Discharge

SAMHSA accreditation guidelines mention ìviolence or threat of violence, dealing drugs, repeated loitering, [and] flagrant noncompliance resulting in an observable, negative impact on the program, staff, and other patientsî as well as ìnonpayment of feesî and ìincarceration or other confinementî as possible causes for administrative discharge (CSAT 1999***b***, pp. 17ñ18).

Patient and employee safety

OTPs are responsible for the safety and security of both patients and employees and for maintaining order in the facilities. Threats of violence should be taken seriously, and interventions should be rapid. Staff should document problem behavior. (For discussion about the ethics of discharging patients, see Appendix D.)

Discharge for continued substance abuse

The consensus panel recommends that patients receive every chance to continue treatment and that treatment last as long as it is effective. Program effectiveness may be determined by comparing a patientís substance use and overall adjustment at admission with his or her current status. The Addiction Severity Index (see chapter 4), an assessment tool used in many substance abuse treatment programs, lends itself to such comparisons. Studies have shown significant improvement in patients even when complete abstinence was not achieved (e.g., Strain et al. 1999); therefore, caution should be used in judging patientsí progress in MAT based solely on drug tests. Treatment for other substance use and addiction should be offered to patients coping with dual addictions (see chapter 11). Patients should understand that the ultimate goals of treatment are abstinence from heroin and other illicit drugs and appropriate use of prescription medications.

When discharge is unavoidable, it should be handled fairly and humanelyÖ

Discharge for nonpayment

An OTP should advise patients to inform the program of impending financial problems as soon as possible. OTPs should focus on helping patients who need financial assistance to pay for their treatment, through changes in their payment pattern or the identification of additional funds through Medicare, Medicaid, the U.S. Department of Veterans Affairs, health plan coverage, and other possible sources. If all of these avenues are exhausted and a patient must be discharged for inability to pay fees, then formal notice should precede discharge. Whenever possible, discharge should include

referral to a program with a sliding fee scale or to an OTP receiving funding support through its State Authority. To ensure that patients are not cut off abruptly from medication, some OTPs seek payment for both the first and last months at admission. However, this may present serious obstacles for many patients, especially those in self-pay OTPs. OTPs should assist patients in seeking short-term loans or allow payments in smaller, more frequent installments if that will solve the problem. In 2003, the American Association for the Treatment of Opioid Dependence released new guidelines for addressing involuntary withdrawal from treatment for nonpayment. These guidelines can be found at www.aatod.org/policy_otp.html.

Discharge for incarceration

Unfortunately, MAT almost always is discontinued when patients are incarcerated. When patients face extended incarceration, OTPs should work with correctional facilities to ensure that appropriate and humane medication-tapering procedures are followed and that medical safeguards are in place. Patients should be informed that, on release, they are eligible for readmission to their OTP without having to demonstrate signs and symptoms of withdrawal. They should be reassessed to determine the appropriate treatment phase (42 CFR, Part 8 ß 12(e)(3); CSAT 1999*b*). In cases of short-term detention, OTPs should determine whether the correctional system is continuing to medicate inmates with prescribed medications and, if it is not, OTPs should consider the practicality of offsite dosing.

Preventing and Finding Alternatives to Administrative Discharge

Communicating program rules clearly

Including program rules in patient orientation and education is the first step to prevent administrative discharge. The consensus panel recommends that all OTPs develop, disseminate, and consistently enforce guidelines for patient behavior. Clear communication and awareness by both patients and staff members are important factors in preventing administrative discharge.

Staff members should identify behavioral problems as they emerge and respond to them promptly. Training in interpersonal techniques to handle aggressive or upset patients in nonprovocative ways should be part of training for all staff. The first responses to a behavioral problem should be to identify it, review the treatment plan, discuss the plan with the patient, and modify or intensify treatment to match the patientís treatment status. Remedial approaches to consider include the following:

- Reevaluate medication dosage, plasma levels, and metabolic responses, and adjust dosage for adequacy and patient comfort
- Assess co-occurring disorders, and provide psychotherapy and pharmacotherapy as needed
- Intensify counseling or add other types of counseling or ancillary services
- Treat medical or other associated problems
- Consider alternative medications
- Provide inpatient detoxification from substances of abuse, while maintaining patients on opioid pharmacotherapy
- Change counselors if indicated
- Reschedule dosing to times when more staff members are available
- Provide family intervention.

Dosing should not be a behavioral tooló patients should not be disciplined by having their medication dosage decreased or withheld, nor should they be rewarded for good conduct by having their dosage increased. Programs are encouraged to develop nonpunitive ways to set limits and contain disruptive behavior. However, in some cases, involuntary discharge becomes necessary.

Finding alternative treatment arrangements

Concerns that patients will discontinue medical treatment for or transmit disease (such as HIV/AIDS or hepatitis C) may lead staff members to ignore noncompliance problems to retain patients in a program. At times, such patients may have to be discharged, and the program should make referrals to a more appropriate level of care or type of treatment (CSAT 2000***e***).

Procedures for Administrative Discharge

Ethical criteria for discharge include review and appeals processes, a suitable dosage protocol for withdrawal from medication, and a readmission procedure that includes a behavioral contract. Exact procedures depend on the reason for discharge. For behavioral problems, the approach should include escalating warnings and specified consequences including referral.

Review and appeals processes

CSAT accreditation guidelines recommend, and accreditation body standards require, due process and documentation during administrative discharge (CSAT 1999***b***, sections XVI and XVII). OTP policies should include written guidelines, including confidentiality guidelines, under which cases of involuntary discharge can be appealed and examined by treatment and administrative staffs. Some States have developed regulations to guide this process. OTPs should have a formal appeal mechanism, and patients should be made aware of their rights. Staff members not directly involved with a disciplinary action should conduct a review of that action. OTPs should develop working relationships so that, when patients break rules and need to be discharged, they can be transferred to other programs.

Reviews and appeals should be handled promptly, with attention to procedural regularity and a patientís extenuating circumstances and point of view. Procedures should be fair and impartial because other patientsí view of the program may be influenced by any perceived lack of fairness.

If a decision to discharge is made, supervised withdrawal of medication should begin after the review process is complete.

If a decision to discharge is made, supervised withdrawal of medication should begin after the review process is completed. Involuntary discharge should be done with the understanding that, if identified preconditions are met, the patient may return to the OTP within a specified time. Obstacles to reentry should be minimized. It is advisable to schedule a date on which the patient may return to talk about whether he or she may reenter the program.

Medically supervised tapering and discontinuation

Whatever the reason for discharge, patients should be made as comfortable as possible during medically supervised withdrawal. Exact schedules require medical determination (see chapter 5), but tapering should be as gradual as possible so that patients can find and enter other facilities.

Members of the consensus panel agree that blind withdrawal (withdrawing a patient from medical maintenance or adjusting dosages without his or her knowledge) is unethical unless requested by the patient to aid in the withdrawal process.

Patient Advocacy

Advocacy by and for patients in MAT and their supporters has emerged as a force on the treatment landscape (Woods 2001). Several national and local advocacy groups with slightly different emphases have been organized, including the National Alliance of Methadone Advocates (www.methadone.org), International Center for Advancement of Addiction Treatment (www.OpiateAddictionRx.info), and Advocates for Recovery through Medicine (www.methadonetoday.org/armhelp.htm). These groups believe that MAT is a lifesaving treatment, stigma must be reduced, and patients should be educated about their treatment and encouraged to participate in it. In general, these advocacy groups are made up of stable, long-term patients.

At the OTP level, advocacy groups focus on patient education and support, assistance with practical aspects of treatment, and public education about the benefits of MAT and constructive roles played by patients in many spheres. OTP-based patient advisory committees are becoming increasingly common. Participation in these organizations helps empower patients and enhance patient skills in social interaction. Other benefits include practice in group interaction and problemsolving. Patients gain a greater understanding of OTP operations and perspectives, educate others, identify problems and misinformation, and provide a channel of communication to OTP administration. Because accreditation agencies are concerned with input from patients, such involvement by patients usually is viewed favorably by these agencies.

9 Drug Testing as a Tool

In This Chapter…

Purposes of Drug Testing in OTPs

Since the inception of medication-assisted treatment for opioid addiction (MAT), drug testing has provided both an objective measure of treatment efficacy and a tool to monitor patient progress. Important changes have occurred in current knowledge about and methods for drug testing in opioid treatment programs (OTPs) since the publication of TIP 1, ***State Methadone Treatment Guidelines*** (CSAT 1993***b***). Testing now is performed extensively to detect substance use and monitor treatment compliance. Analysis of test results provides guidance for OTP accreditation, as well as information for program planning and performance improvement. In addition, other agencies concerned with patient progress (e.g., child welfare and criminal justice agencies) routinely request and use drug test results with patientsí informed consent (see CSAT 2004***b***).

Increasing emphasis on treatment outcomes as evidence of program effectiveness has added significance to drug tests in OTPs. Administrators use drug test results in response to quality assurance requirements. For example, an OTP that prescribes adequate maintenance medication should report relatively few illicit-opioid-positive drug tests. Ball and Ross (1991) found that the most effective programs had less than 10-percent positive tests. However, these findings emerged before the purity of heroin markedly increased in recent years and before the ratio of OTP staff to patients decreased in many programs as a result of funding cuts. These events have been associated with increases in opioid positive urine tests in most OTPs. Given the regional variability in factors affecting addiction, for example, differences in heroin purity and availability or in prescription opioid abuse, the consensus panel recommends that OTPs develop new measures to improve outcomes if they report an average of more than 20-percent positive drug tests for patients with at least 1 to 3 years of MAT. Equally important, OTP drug test results should be nearly 100-percent positive for treatment medication because lower percentages could indicate medication diversion, which requires investigation and a corrective-action plan. (Federal regulations require OTPs to maintain diversion control plans as part of their quality assurance efforts [see chapter 14].)

Drug test results help policymakers and OTP administrators detect and monitor emerging trends in substance abuse that may signal a need to redirect resources. Drug use patterns have changed markedly in recent decades; for example, benzodiazepines, amphetamines, methamphetamine, and cocaine have increased in popularity while barbiturate use has diminished. New substances of abuse or combinations of substances and methods of ingestion present new treatment challenges and funding concerns.

Testing for Treatment Compliance

At a minimum, most specimens from patients maintained on methadone should be tested for methadone and its metabolites (testing for metabolites prevents patients from simply adding methadone to a sample), which can be done efficiently and at reasonable cost. Currently, no precise test measures buprenorphine in a patient specimen, although it can be detected in urine, blood, or hair by gas chromatography/mass spectrometry (GC/MS) (Lisi et al. 1997; Vincent et al. 1999) and, as reported by Cirimele and colleagues (2003), by enzyme-linked immunosorbent assay in urine. Until new, commercially available tests are developed, drug testing of patients receiving buprenorphine primarily should be to detect substances of abuse. No reagent is commercially available at reasonable cost to test any specimen type for levo-alpha acetyl methadol (LAAM), although LAAM can be detected in urine by thin-layer chromatography (TLC) and GC/MS (Moody et al. 1995). Therefore, the consensus panel recommends direct monitoring of patients receiving LAAM (American Association for the Treatment of Opioid Dependence, n.d.), assuming that its availability continues (see chapter 3).

Testing for Substances of Abuse

At a minimum, OTPs should test for opioids, cocaine, and benzodiazepines and consider testing for other drugs (e.g., methamphetamine), depending on local substance use patterns. OTP administrators should decide whether to test routinely for alcohol and marijuana or only as needed. Because of the increased depressive effects of alcohol combined with an opioid such as methadone, it is important for OTPs to avoid providing opioid medication to patients who are intoxicated with alcohol. However, no standard cutoff scores for permissible alcohol levels exist across OTPs. Because urine tests for alcohol are highly variable (Warner 2003), breath and blood tests are more useful in OTPs to determine the presence or degree of acute alcohol intoxication. Because breath tests are much simpler and faster and are less invasive than blood tests, they are the most common alcohol testing method used in OTPs.

Exhibit 9-1 summarizes necessary minimum (or cutoff) concentrations for detection of some illicit and prescription drugs in urine, as well as their reliable detection times for both initial patient testing and confirmation of positive results.

Benefits and Limitations of Drug Tests

The consensus panel cautions that drug test results should not be the only means to detect substance abuse or monitor treatment compliance and that the needs of patients whose test results show no immediate problems should not be overlooked. Too often, overworked counselors and caseworkers scan drug test results to determine services, without investing time to develop the trust and concern inherent in a sound counseling relationship. Training and educating staff members about the benefits and limitations of drug tests should ameliorate this situation. Staff members should understand, for example, that certain prescribed and over-the-counter medications and foods might generate false positive and false negative results for different substances. Some drug-testing laboratories provide training about drug testing for

Exhibit 9-1

Typical Testing and Confirmation Cutoff Concentrations and Detection Times for Various Substances of Abuse

Drug	Initial Testing Cutoff Concentrations (ng/mL*)	Analytes Tested in Confirmation	Confirmation Cutoff Concentrations (ng/mL)	Urine Detection Time (Days)
Amphetamine	1,000	Amphetamine	500	2ñ4
Barbiturates	200	Amobarbital, secobarbital, other barbiturates	200	2ñ4 for short acting; up to 30 for long acting
Benzodiaze-pines	200	Oxazepam, diazepam, others	200	Up to 30 for long acting
Cocaine	300	Benzoylecgonine	150	1ñ3 for sporadic use; up to 12 for chronic use
Codeine	300	Codeine, morphine	300, 300	1ñ3
Heroin	300	Morphine, 6-acetylmorphine	300, 10	1ñ3
Marijuana	100, 50, 20	Tetra-hydro-cannabinol (THC)	15	1ñ3 for casual use; up to 30 for chronic use
Methadone	300	Methadone	300	2ñ4
Metham-phetamine	1,000	Methamphetamine, amphetamine	500, 200	2ñ4
Phencyclidine	25	Phencyclidine	25	2ñ7 for casual use; up to 30 for chronic use

*ng/mL: nanograms per milliliter.

Adapted from Cone 1997.

OTP staff. Frank discussions of the issues involved for patients and for the OTP help staff members understand the importance of using test reports appropriately.

Urine drug testing remains the most common method of drug testing in OTPs. The Substance Abuse and Mental Health Services Administration (SAMHSA) has notified OTPs that they may use oral-fluid testing to satisfy the drug-testing requirements in 42 Code of Federal Regulation (CFR), Part 8, if a programís medical director deems this method adequate

(Clark 2003). As other drug-testing methods are developed and attain Federal and State approval, OTPs should consider using them as well.

Alternatives to urine and oral-fluid testing have benefits and limitations. Some investigators (e.g., George and Braithwaite 1999; Moolchan et al. 2001) have maintained that concentrations of methadone in blood plasma are the ìgold standardî to assess treatment compliance in patients maintained on methadone. However, blood testing is impractical, costly, and difficult, and the same investigators recognized that urine drug testing is likely to be the dominant method in OTPs for the foreseeable future.

[U]rine drug testing is dominant in OTPs because obtaining specimens is relatively easy and testing is affordable.

Some investigators evaluating optimal approaches to assessing MAT compliance and determining continued substance use have found patients forthcoming about their drug use and not particularly motivated to avoid detection. Two studies evaluated patientsí self-reports of drug use and concluded that they are at least as reliable as urine drug tests (Zanis et al. 1994) and sometimes more sensitive (Howard et al. 1995). Both studies suggested that a combination of self-reporting and urine testing is more useful than either alone. Another study (Katz and Fanciullo 2002) has challenged these findings.

Urine Drug Testing

Despite its limitations, urine drug testing is dominant in OTPs because obtaining specimens is relatively easy (Moolchan et al. 2001) and testing is affordable. In addition, the technique is well studied, has been in use for a long time, and has well-established cutoff levels and other laboratory guidelines (Cone and Preston 2002). According to one survey (Jones et al. 1994), most patients accept urine testing in an OTP although many do not like it. Concerns usually relate to the specimen collection process or the sensitivity and specificity of results, as well as the possibility of tampering, the need to preserve patient privacy and dignity, risks of collection to staff, and the possibility that substance interactions may confound results.

A patientís physical condition can affect test sensitivity and specificity. Urine testing is not feasible for patients with renal failure (e.g., those on dialysis) or other bladder control impairments. George and Braithwaite (1999) found that variations in metabolism and excretion could affect urine concentrations of methadone or its metabolites. Moolchan and colleagues (2001) noted that renal methadone clearance varies for subjects with certain medical conditions (e.g., renal disease) and those taking other prescribed or illicit drugs. As a result, urine drug tests for patients on relatively low methadone dosages may be methadone negative even though subjects have ingested medication as prescribed (i.e., a false negative result). Furthermore, individuals with paruresis (îshy bladder syndromeî) have a social anxiety disorder that may leave them unable to urinate under observation (Labbate 1996ñ 1997; Vythilingum et al. 2002).

Just as some patients metabolize methadone or other treatment medications at different rates and some medications affect the metabolism of others (see chapter 3), certain medications, for example, HIV medications, change the metabolism of addiction medications and can affect drug test results. OTP staff members should remain current on these interactions as more data become available (see De Maria 2003). A Web site that provides up-to-date information on the pharmacokinetics of methadone and HIV medications is at www.hiv-druginteractions.org.

Baker and colleagues (1995) found similar urine drug test results regardless of whether

patients were notified of tests in advance. In that study, some patients stated that unannounced urine tests deterred them from substance use, but 53 percent said it did not. Contrary to assumptions by some providers that substance abuse is more likely over weekends (presumably resulting in more positive drug tests on Mondays), Compton and colleagues (1996) found that urine drug test results did not vary by day of the week.

Oral-Fluid Drug Testing

Oral-fluid drug testing is an alternative to urine drug testing in OTPs that is approved by SAMHSA (Clark 2003; for a recent review of oral-fluid drug testing, see Kintz and Samyn 2002), but only when a qualified offsite laboratory performs the specimen analysis. According to SAMHSAís interim guidance on the use of oral-fluid testing in OTPs, sent to OTPs in July 2003 (Clark 2003), offsite drug testing using oral fluid may be considered adequate for the purpose of 42 CFR, Part 8 ß 12(f)(6). The choice of drug-testing methodology is an informed medical judgment decision. It is SAMHSAís view that there is sufficient information to confirm the adequacy of oral-fluid testing in the OTP setting. CSAT noted that OTPs still must conform to State laws and regulations in this area (Clark 2003).

Many patients in OTPs react more favorably to the use of oral swabs than to observed urine collection. Researchers have confirmed other benefits of oral-fluid testing. Moore and colleagues (2001) reported that it was highly sensitive and specific for methadone and opioids of abuse and that samples could be stored or sent to a laboratory for analysis. Braithwaite and colleagues (1995) noted that oral-fluid testing ensured privacy and was less susceptible to tampering than urine testing and that specimens required little preparation.

Results of oral-fluid testing generally are similar to those obtained by urine drug testing, but differences exist, and OTP staff members should understand these differences. Concentrations of some substances are lower in saliva than in urine. Some drugs remain detectable longer in urine than in saliva. Drug residue in the oral or nasal cavity was found to contaminate saliva specimens (Swotinsky and Smith 1999). The consensus panel recommends oral-fluid testing when drug testing must be observed because it is more respectful and less invasive and observation does not require watching patients void. Oral-fluid collection requires no temperature strips or other devices to ensure that a specimen was just provided.

Blood Drug Testing

OTPs rarely if ever use blood testing routinely; most often, they use this method to monitor plasma methadone levels when necessary. Testing for the presence of methadone in serum, although more costly than urine testing, is the most accurate method currently available to determine whether other prescribed medications influence methadone metabolism or a patient is a rapid metabolizer. Serum testing is more accurate than other methods to address issues related to the effects of metabolism on methadone dosage.

Blood testing has limitations besides cost. Blood offers a smaller drug detection window than oral fluid or urine; most drugs are undetectable in blood after 12 hours (DuPont 1999). Trained personnel must obtain blood specimens. Concerns about blood-borne pathogens make routine blood testing impractical, and, as discussed in chapter 3, some medications and diseases affect methadone levels in plasma.

Sweat Drug Testing

Sweat patches usually are used as an adjunct to other forms of testing. They provide a longer specimen collection period than either urine or blood and may be less susceptible to tampering than urine. Sweat patches are tolerated well by patients and are considered less invasive and less potentially embarrassing. Taylor and colleagues (1998) found that women were more likely than men to prefer a sweat patch to urine testing. The patch has not been found to deter substance use (Taylor et al. 1998). Preston and

colleagues (1999*a*) compared the patch method with urine testing for detection of cocaine and found good concordance between the two methods.

Playing-card-sized, waterproof adhesive patches are available. Each patch is imprinted with a unique number to track its chain of custody. After a patch is worn for about 1 week, a laboratory can extract about 2 mL of sample to be tested. Compared with urine specimens, sweat yields higher proportions of parent drugs, such as cocaine, heroin, or marijuana. Drug use is assessed cumulatively, but uniform cutoff levels have not been established, and external contamination is a possibility (Swotinsky and Smith 1999).

Hair Drug Testing

Hair analysis provides a longer term look at drug use than other methods because hair retains drugs longerófor example, weeks or months, compared with the 2 or 3 days that cocaine or heroin is detectable in urine. Collecting hair specimens also is less invasive than urine or blood sampling. However, drawbacks include expense, possible ethnic bias (Kidwell et al. 2000), and environmental contamination. Studies of hair analysis have been hampered by poor design, small specimen size, and lack of confirmation. More research is needed.

Drug-Testing Components and Methods

Methods and uses of drug tests vary widely among OTPs. Improvements in standards and technology have made a variety of testing and analytical alternatives available. Drug testing is a multistep process that starts with specimen collection. Specimens are analyzed by one of numerous techniques. The results are recorded and interpreted. When an initial test analysis is positive for a substance of abuse or unexpectedly negative for a treatment medication such as methadone, providers should discuss the results with the patient as soon as possible. If the patient insists that a result is inaccurate, an OTP should recheck the existing report via confirmatory analysis or a retest if the laboratory still has the specimen in question. Preferably, a different analytical method with higher sensitivity is used for confirmation or retesting. A confirmed analysis should be viewed as only one basis for modifying a patientís treatment plan.

The consensus panel recommends that programs incorporate Federal and State regulatory requirements and their own treatment needs into written policies and procedures for drug testing and integrate these policies and procedures into treatment planning and practices. OTP administrators should consider the factors discussed below in establishing and maintaining drug-testing procedures that ensure the integrity and utility of results, as well as compliance with regulations.

Specimen Collection

Setting and approach

The consensus panel emphasizes that specimen collection and testing should be performed in a therapeutic, humane environment and results should be used to help guide patient care, modify treatment plans, and confirm clinical impressions. Specimen collection methods should protect patientsí dignity and privacy while minimizing opportunities for falsification. The bathrooms used for urine collection should be cleaned frequently and supplied with soap and other toilet articles. Collection procedures should be in writing (see ìDevelopment of Written Proceduresî below). Patients should be informed during admission and early treatment about how drug-testing specimens are collected and patientsí responsibility to provide specimens when asked. Patients should receive a copy of OTP policies on and procedures for drug testing, including whether and when direct observation is indicated.

Most OTPs assign a staff member to greet patients and determine whether a urine specimen is required before patients can receive medication. This determination may be based on staff judgment or a random list generated by computer or by OTP managers. In most cases, urine specimens should be obtained randomly based on patientsí OTP visit schedules.

When indicated, a patient is sent to the bathroom to provide a urine specimen in a labeled container. Most programs monitor the bathroom to ensure that only one patient uses it at a time and that patients leave parcels outside the bathroom. The person receiving the urine specimen checks the container to determine whether it is a valid specimen. The specimen then is packaged and sent to a laboratory for testing.

To ensure patient confidentiality, programs should store specimens and related documents and material so that only authorized personnel can access and read them. Handling specimens also raises questions about staff safety (Braithwaite et al. 1995) and the reliability of the chain of custody for samples (Moran et al. 1995). Universal safety precautions for handling urine specimens should be followed; for example, staff members collecting specimens need to wear gloves.

Direct observation versus other methods

Collecting urine specimens, especially when collection is supervised, can be embarrassing for both subjects and supervisors and raises concerns about patientsí privacy rights (Moran et al. 1995). Some patients and treatment providers perceive direct observation of urination as a violation of trust and respect (Moolchan et al. 2001). In addition, patients with paruresis should not be penalized; instead, treatment providers should consider unobserved urine testing, oral-fluid testing, or another drug-testing method.

The consensus panel recommends that OTP staff members use their clinical judgment regarding the need for direct observation of urine collection. Temperature strips, adulterant checks, and other methods should be used when possible to ensure test validity. Moran and colleagues (1995) determined that unsupervised urine collection with a temperature indicator and a minimum 50-mL specimen was practical and reliable and ensured individual privacy and dignity. Many OTPs do use direct observation (Calsyn et al. 1991), but some use one-way mirrors and even video cameras to ensure reliable sample collection.

OTPs that use observed collection have many options, including random observation, observation to ensure treatment compliance before a schedule change, or observation because of suspected drug use. Some OTPs use direct observation only during initial stabilization. Oral-fluid testing is another option. Each OTP should decide whether, when, and how it uses direct observation in specimen collection and should include guidance for direct observation in its written policies and procedures. Some States mandate urine drug testing and direct observation of specimen collection. For programs that elect unobserved collection, other effective options for sample validation exist, such as temperature strips and ambient-temperature ìgunsî (see below).

> [S]pecimen collection and testing should be performed in a therapeutic, humane environment…

Analytical Methods Used in Drug Testing

Knowledge gained from testing enhances the treatment process and ameliorates some regulatory concerns and issues facing OTPs. However, it is important for practitioners and

State and Federal regulators to understand the limits of the drug testing and analytical methods used in most OTPs (Moolchan et al. 2001; Verebey et al. 1998).

Because of the volume and cost of urine testing, most OTPs use TLC or enzyme immunoassay (EIA) to analyze test specimens. The Enzyme Multiplied Immunoassay Technique (EMIT) is the EIA method used most often in this country because its costs are lower, it allows for short analysis time, it can be automated for large-scale samples, and it can be used on site by small programs (Hawks 1986; Manno 1986).

Immunoassays use antibodies with specific surface sites to which drugs or metabolites bind. For urine drug testing, either of two immunoassay typesóradioimmunoassay (RIA) or EIAó can be used. RIA uses radioactive markers and requires an incubation period and centrifugation of the sample. EIA uses an enzyme as its marker. Currently, no commercially available EIA tests exist for LAAM, buprenorphine, or the buprenorphine-naloxone combination tablet.

EIA permits detection of extremely small quantities of substances but lacks specificity to determine which drug in a class is present (Saxon et al. 1990). For example, EIA can detect opioids but cannot distinguish between morphine (the metabolite of heroin excreted in urine), codeine, and other opioids, including

Exhibit 9-2

Common Immunoassays

Immunoassay	Brand Name(s)	Manufacturer(s)	Comments
EIA	EMIT, CEDIA	Syva, Boehringer Mannheim/ Microgenics	Used widely; inexpensive; equipment available for automated, high-volume rapid analysis; sensitive to some adulterants
Fluorescence polarization	Adx, TDx	Abbott Diagnostics	Resistant to several adulterants; reasonably good quantitative estimates of concentrations; slower and more expensive than EIA and KIMS
Kinetic interaction of microparticles (KIMS)	OnTrak, TesTcup, OnLine	Roche Diagnostics	Equipment available for automated, high-volume rapid analysis; used by some large laboratories
Colloidal metal (CMI)	Triage	Biosite Diagnostics	Used in onsite testing
RIA	Abuscreen	Roche Diagnostics	Labor intensive; resistant to several adulterants; not used widely

Adapted from Swotinsky and Smith 1999, with permission of Medical Review Officer Certification Council.

those from poppy seeds used in baked goods. EIA does not distinguish oxycodone (e.g., Percodan®, OxyContin®). In areas where these drugs are abused, OTPs should take additional steps and use other methods to test for oxycodone. Exhibit 9-2 describes several widely available immunoassays.

Chromatographic analyses use flows of liquid or gas to separate molecules and isolate any drugs or drug metabolites in specimens. TLC, one of the oldest of these methods, is inexpensive but less accurate than EIA, and its accuracy depends on the skill of the laboratory technician (Hawks 1986). TLC can distinguish between drugs in a class (a limitation of EIA), but it also can produce false negative reports because it requires relatively large amounts of drugs in specimens before these drugs can be detected. Programs working with laboratories that use TLC should be aware that low doses of addiction treatment medication occasionally yield negative reports. When methadone is used in treatment, periodic assays for its primary metabolite, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), are advised. Unlike methadone, EDDP is pH independent when excreted, so the absence of EDDP from urine may be a more accurate sign of tampering, substitution, or diversion. GC/MS is a sensitive method that can be used to confirm results from EMIT or TLC.

Development of Written Procedures

Procedures for drug testing in an OTP should be described clearly in a written document such as that shown for urine specimen collection in Exhibit 9-3. Similar policies can be developed for oral-fluid testing. Each OTP should develop policies and procedures for drug testing based on its mission, service philosophy, and practices.

Exhibit 9-3

Sample OTP Guidelines for Monitoring Urine Drug Test Specimen Collection

It is the policy of the [name of program] to monitor the use of drugs by collecting random, observed, and/or temperature-monitored urine samples at a frequency determined by clinical staff in accordance with Federal and State regulations.

Purpose

Urine samples are collected and tested to assist in stabilizing a patient on the proper dosage of methadone or buprenorphine. Drug test results may suggest that a patientís dosage needs adjustment or that a more intensive level of care is needed. Positive drug tests alone do not confirm that a patient is not engaged in treatment or is not in compliance. The entire clinical picture must be considered. Drug tests are not used to punish patients or as the sole reason to discharge them from treatment. Patients must be assured that the results are ***confidential*** and will be released only with their permission or pursuant to a court order (21 CFR, Part 2).

(continued on following page)

Exhibit 9-3

Sample OTP Guidelines for Monitoring Urine Drug Test Specimen Collection (continued)

General Information and Desired Outcome

In accordance with program policy and State and Federal regulations, each new patient is asked to provide one random urine sample per week for the first 6 months and samples less frequently thereafter, based on treatment progress. No patient is monitored less than once a month.

Urine samples are collected randomly. A patient is not told when he or she will be asked to provide a urine sample so that a more accurate assessment of drug abuse patterns can be made.

The urine is tested for several drugs of abuse and for the presence of treatment medication. Testing for EDDP, a methadone metabolite, is a more sensitive measure of the presence of ingested methadone than testing for the parent compound (methadone) alone. This type of testing helps distinguish ingested methadone from methadone that has been added to a urine specimen as an adulterant.

Patients may refuse to provide valid urine specimens for many reasons but are encouraged to provide them. If a patient refuses to provide a specimen, then urine is collected on the next dosing appointment. If a patient fails to provide a valid specimen at the next appointment, a review of take-home dosages and progress in treatment takes place and may result in more frequent required clinic visits. When patients refuse to provide samples, the counseling, nursing, and medical staffs are notified and consulted.

Procedure

The following guidelines for observing or temperature-monitoring urine specimens help increase the validity of each sample.

- If a urine specimen is collected with a temperature higher than 99.8F, the patientís temperature is taken (if the patientís temperature is elevated, the temperature of the urine specimen also may be elevated).
- Before a patient enters a bathroom stall, he or she is asked to leave coat, outer garments, purse, and bags outside the bathroom to prevent falsification of the sample. A patient is asked to wash and dry his or her hands before and after giving samples to prevent urine contamination. Bacterial overgrowth invalidates a urine specimen. To the extent possible, staff members ensure that patients do not conceal falsified urine specimens on their persons.

Exhibit 9-3

Sample OTP Guidelines for Monitoring Urine Drug Test Specimen Collection (continued)

- If collection of a urine sample is observed directly (versus temperature monitored), the following steps are performed to ensure an accurate specimen:
  - The patient is observed to ensure that he or she does not add water to the urine from the toilet or sink to dilute it. (Where health department regulations permit, hot water in the bathroom should be turned off.)
  - ***Female:*** A female observer accompanies a female patient into the restroom. The patient is asked to void into a urine container and not to flush the toilet. A wide-mouth collection container may be used and the contents then transferred to a smaller container. The staff member observes collection of the specimen directly. The collection site observer also flushes the toilet.
  - ***Male:*** A male observer accompanies a male patient into the restroom. The client uses a urinal and is asked to void into a urine container. This is observed directly.
- The patient provides 50 cc of urine.
- The sample is checked for color, temperature (90.5–99.8F/32.5–37.7C), and any contamination. The temperature is checked 30 seconds after the specimen is provided.
- After a sample is obtained, a staff member verifies the urine temperature and checks the container for pinholes before placing it in a plastic envelope.
- If the urine sample is not sent immediately to the laboratory, it is stored properly in a refrigerator that is used exclusively for laboratory samples.
- Proper security of urine specimens is maintained to prevent loss or switching of urine. Specimens are placed in a locked refrigerator in a locked room.

If a patient is unable to provide a urine specimen, he or she is asked to drink plenty of water. Special considerations are given to patients with health problems that interfere with urination, including renal failure, neurological disorders, and paruresis. Any patient who still is unable to provide a urine sample must be prepared to give the sample on the following day.

If a patient refuses to provide a sample, he or she must be referred to a counselor. After a clinical review, the treatment plan and the frequency of clinic visits may be modified.

Source: Adapted from the University of New Mexico Hospitals, Addictions and Substance Abuse Programs.

Other Considerations in Drug-Testing Procedures

Frequency of Testing

Given concerns about the cost and reliability of drug tests, some OTPs limit testing and others assume that results are unreliable in many cases. Decisions about how to use drug testing require thought and balance. In addition to conforming to Federal and State regulations, the frequency of testing should be appropriate for each patient and should allow for a caring and rapid response to possible relapse. Drug tests should be performed with sufficient frequency and randomness to assist in making informed decisions about take-home privileges and responses to treatment.

For patients who continue to abuse drugs or test negative for treatment medication, the consensus panel recommends that OTPs institute more frequent, random tests. Increased testing provides greater protection to patients vulnerable to relapse because only short periods pass before a therapeutic intervention can be initiated. However, as emphasized throughout this chapter, programs should avoid making treatment decisions affecting patientsí lives that are based solely on drug test reports.

SAMHSA requires eight drug tests per year for patients in maintenance treatment (42 CFR, Part 8 ß 12(f)(6)). In the opinion of the consensus panel, this is a minimal requirement. The actual frequency of testing should be based on a patientís progress in treatment, and more testing should be performed earlier in treatment than later, when most patients are stabilized. Most OTPs develop policies and procedures on testing frequency that meet or exceed Federal requirements and accreditation standards to assist staff in planning treatment, assessing patient progress, and granting take-home privileges.

Some States require more frequent testing than that required by SAMHSA. Some also require that specific drug-testing methodologies or decision matrices be followed. OTPs must adhere to the more stringent of either the Federal or State regulations. In States with no specific requirements, Federal regulations are the only applicable standard, but, as previously noted, these requirements should be considered minimal and regulatory.

The consensus panel recommends at least one drug test at admission to an OTP. Onsite testing kits are available so that admission can continue while test results are pending (see ìOnsite Test Analysisî below), although some States may disallow these kits. For patients in short-term detoxification, one initial drug test is required, whereas patients receiving longer term MAT are required to have initial and monthly random tests.

Laboratory Selection

The laboratory selected by an OTP to analyze patient specimens must comply with Health Insurance Portability and Accountability Act regulations (CSAT 2004***b***) and the Clinical Laboratory Improvement Amendments (CLIA) (see discussion below). OTPs should understand a laboratoryís analytical methods and know whether and how often the laboratory confirms positive findings, how long specimens are retained for testing, and when results are made available to OTPs. A laboratory should collaborate with an OTP regarding custody of specimens, confidentiality and reporting of results, turnaround times for results, and specimen retention for retesting. Programs also should understand a laboratoryís minimum cutoff levels for determining and reporting positive results.

In a review of requirements for efficient, reliable urine testing for substances of abuse, Braithwaite and colleagues (1995) emphasized the importance of quality control in laboratories. They listed aspects of high-quality assessment, including performing analyses according to manufacturerís instructions, evaluating control samples for every analysis, participating in external quality assessment, adequately

training and supervising staff, and carefully reporting results. They also recommended that laboratories analyze at least 20 to 30 specimens per week from each OTP, have a scientist with expertise in drug addiction and drug testing on staff, and report results confidentially within 2 to 3 days of specimen receipt.

Onsite Test Analysis

Onsite (also known as near-patient or point-of-care) drug test analysis can provide rapid results but may have limitations such as increased cost or reduced accuracy. Some State regulations disallow onsite test analysis. In an extensive review, D. Simpson and colleagues (1997) found that immediately available drug test results improved patient cooperation and program management. In their review of available commercial analytical methods, they found that all were rapid, reliable, and useful but required confirmation of positive results, and some lacked sensitivity, specificity, or both. A more recent review by George and Braithwaite (2002, p. 1639) concluded that onsite analytical devices for drugs of abuse were ìan expensive and potentially inaccurate means to monitor patient treatment and drug abuse states.î

Onsite analysis of test specimens also requires that staff be trained in calibration of the testing device and interpretation of results. OTPs need ongoing quality assessment procedures. Analyses performed outside a laboratory setting require special facilities to ensure safety. Onsite specimen analysis also raises questions about the chain of custody, provision, stability, and storage of samples (Simpson, D., et al. 1997). However, the U.S. Department of Health and Human Services is developing guidelines for onsite analytical methods in workplace drug-testing programs, which suggests that this approach will become more common (Cone and Preston 2002). The use of onsite specimen analysis for decisionmaking may subject OTPs to the requirements of CLIAóFederal guidelines for any entity doing laboratory analysis of specimens from humansóand require these OTPs to obtain approval from their State health departments. If an OTP falls under CLIA requirements, it must register or seek a waiver to continue its own laboratory analysis of test specimens.

Exhibit 9-4 provides a list of commercial resources, manufacturers, and contact information for onsite analytical methods.

Interpreting and Using Drug Test Results

Test results should be documented in patient records along with appropriate justifications for subsequent treatment decisions, particularly in unusual situations such as when take-home medications are continued despite test results that are consistently positive for substances. OTPs should confirm positive results whenever possible, bearing in mind the factors that can confound results (e.g., using over-the-counter medications, eating foods containing poppy seeds).

> [P]rograms should avoid making treatment decisions affecting patientsí lives that are based solely on drug test reports.

OTP directors should ensure that results are not used to force patients out of treatment and that no treatment decisions are based on a single test result. Patients should be informed of positive results for substances of abuse or negative results for treatment medication as soon as possible and should have an opportunity to discuss these results with OTP staff. A patient who refutes test results should be taken seriously, particularly when results are inconsistent with the treatment profile and progress of that patient.

OTPs should use drug test results clinicallyó not punitivelyófor guidance, treatment planning, and dosage determination. OTPs should

Exhibit 9-4

Examples of Onsite Analytical Methods for Drug Tests

Test	Manufacturer	Contact
Abuscreen OnTrak	Roche Diagnostics, Somerville, New Jersey	www.roche-diagnostics.com
OnTrak TesTcup		
Triage	Biosite, Inc., San Diego, California	www.biosite.com
Triage Screening Cassette		
E-Z SCREEN	American Biomedica, Ancramdale, New York	www.americanbiomedica.com
Bionike One Step	Bionike Laboratories, South San Francisco, California	
AcuSign	Drug Test Resources International, Boca Raton, Florida	drugtest4u@aol.com
Verdict	MedTox, St. Paul, Minnesota	www.medtox.com
Micro Line	Casco Standards, Yarmouth, Maine	www.microgenics.com

retest (using more sensitive analytical methods if necessary) when results indicate continuing problems; monitor carefully the chain of custody for specimens; document results, patient responses, and action plans in the case record; respond rapidly to relapse indications; and ensure that positive results for substance abuse or negative results for treatment medication trigger treatment, relapse prevention counseling, HIV counseling, and other intensified interventions. Continued use of heroin or other opioids (and possibly other substances) should generate a review of a patientís addiction medication dosages.

Responding to Unfavorable Drug Test Results

Patients who continue to abuse substances while receiving addiction treatment medication create concern among OTP staff members for their progress in treatment, negative perceptions of OTPs, and community concerns that may lead to regulatory actions by SAMHSA, accrediting bodies, or the U.S. Drug Enforcement Administration.

Most OTPs must review a significant number of unfavorable drug test results. Again, the consensus panel emphasizes that results should be used to explore different treatment interventions and treatment plans that will reduce and eliminate substance use and improve treatment compliance. Reports indicating substance abuse

should signal the need for a medical review of medication dosage and for intensification of counseling and education aimed at preventing HIV and hepatitis transmission. Also, because of regulatory concern about medication diversion, reports indicating absence of treatment medication should be evaluated carefully. Because dose, pH, and urine concentration can limit detection of treatment medications, staff members should consider all these areas in conducting their medical reviews and deciding on a plan of action.

When patients deny substance use despite a positive laboratory result, a careful history of their prescribed or over-the-counter drug use should be obtained and discussed with a pathologist or chemist to determine whether these drugs might produce false positive results or otherwise confound tests. Whenever possible, a questionable test should be redone (if the specimen is available) and the result confirmed by another method. If this is impossible, confirmatory analysis should be performed for all subsequent tests. More accurate testing methods such as RIA or GC/MS can be used to verify laboratory reports. Specimens can be collected under direct observation, and a chain of custody can be maintained to assure a patient that every effort is being made to prevent errors and respond to his or her denial.

Confirmations of positive drug test results generally are conducted in a laboratory rather than at the OTP. D. Simpson and colleagues (1997) emphasized the need to confirm unexpected negative as well as positive results with additional analyses. Their exhaustive review concluded that TLC is a simple, inexpensive way to confirm the absence of methadone in a urine drug test, but gas chromatography is the best choice for rapid, reliable results. GC/MS usually is reserved for confirmation in cases with legal implications. High-performance liquid chromatography is an improving technology with an increasing role in testing for and confirming the presence of methadone and its metabolites, as well as other drugs.

Patient Falsification of Test Results

False negatives can occur as a result of patient falsification of drug test results or laboratory error. Braithwaite and colleagues (1995) summarized some ways in which patients tamper with or obscure the results of urine drug tests, including substituting urine from another person, diluting urine specimens, or adding other substances (such as bleach or salt) to samples.

Strategies to minimize sample falsification should be balanced by sound treatment ethics and the overall goals of the programórecovery and rehabilitation. Common strategies include

- Turning off hot water in bathrooms to prevent patients from heating specimens brought from elsewhere (although not feasible in States where other regulations prohibit this step)
- Using bathrooms within eyesight of staff to preclude use by more than one person at a time and feeling specimen containers for warmth as soon as received (freshly voided specimens should be near body temperature [37C])
- Using temperature and adulterant strips or collection devices that include temperature strips
- Using a temperature ìgunî (infrared thermometer [visit www.coleparmer.com]) to measure the temperature of urine specimens
- Using direct observation by staff of specimen collection.

The consensus panel believes that falsification is reduced when patients understand that urine test results are not used punitively to lower doses of addiction treatment medication. Continued use of drugs requires counseling, casework, medical review, and other interventions, not punishment. In the past, some OTPs reduced medication dosages as a direct result of positive drug tests although this has proved ineffective and sets up an adversarial relationship between patients and the OTP. When it is clear that interventions for substance abuse

are ineffective, moving patients to a higher level of care, rather than discharging them, is warranted.

Patients should be encouraged to discuss their substance use with OTP physicians, caseworkers, or counselors and to trust them with this information. Ideally, once trust has developed, drug test results will confirm what already has been revealed in individual or group sessions. Nevertheless, some patients fear loss of take-home privileges or remain in denial about their drug use and do not disclose their noncompliance willingly; drug test results are necessary to alert OTPs to these patientsí noncompliance.

Reliability, Validity, and Accuracy of Drug Test Results

Another critical concern is the reliability of drug testing, which varies by methodology (Blanke 1986; Verebey et al. 1998). Accuracy also depends on the choice of laboratory, use of proper equipment and methods, quality control, and adherence to high-quality standards by all involved. As in all laboratory testing, human errors, confounding results, a poorly controlled chain of custody for samples, and other problems lower test reliability.

In the opinion of the panel, urine drug testing is reliable and valid. A number of studies have examined the validity and accuracy of various urine drug-testing analytical methods. Studies generally report that urine analysis by EIA techniques is at least 70 percent as accurate as that for RIA or GC/MS (Caplan and Cone 1997).

On the basis of cost, the consensus panel believes that EIA and TLC usually are adequate analytical methods in OTP drug testing. When results are contested or confusing, confirmation analyses should be performed. For example, when EIA indicates the presence of illicit drugs but the patient denies any drug use or has progressed well in treatment, confirmatory GC/MS can be useful. Confirmatory analysis offsets the limitations of single tests.

False Positive and False Negative Drug-Testing Results

Numerous medications and substances can produce false positive results in urine drug tests (see Graham et al. 2003, p. 338). Some researchers have compared quantitative versus qualitative testing, that is, testing to measure the amount and frequency of substance use versus testing to identify the presence or absence of a substance. Wolff and colleagues (1999) noted that false positive results can arise from incorrect identification of a drug or misinterpretation of a finding. Cone and Preston (2002) pointed out that EIA analysis lacks the specificity to distinguish among opioids, and Narcessian and Yoon (1997) reported a case in which consumption of a poppy seed bagel resulted in a positive urine EIA for morphine. Although EIA can produce some false positive results, TLC may be less sensitive than EIA, causing more false negative results (Verebey et al. 1998). In addition, laboratory and clerical errors and other problems cause inaccuracies. To check for any of the above problems, unexpected results should be discussed with the laboratory before they are conveyed to the patient.

Cone and Preston (2002) also addressed the pitfalls of qualitative testing, such as the increased possibility that with frequent testing a single drug use episode might trigger multiple positive test results (and result in consequences for the patient). In a comparative study, Preston and colleagues (1997) found that quantitative urine drug testing provided more information about patterns and frequency of cocaine use during treatment than qualitative testing. McCarthy (1994) similarly argued that quantifying the amount and frequency of drug use (including methadone) is more useful for treatment assessment and decisionmaking than qualitative analysis that simply identifies the presence or absence of a drug.

Responses to Test Results

Staff members should discuss drug test results with patients using a therapeutic, constructive approach. For example, staff members might express concern to patients over any tests that are positive for illicit drugs and seek additional information to explain these results. If a patient receives medication from a physician outside the OTP, staff should request informed consent to contact the physician and coordinate treatment, ask the patient to bring in prescription bottles, and record these prescriptions in patient records. OTP physicians should review prescriptions to determine whether and for how long their use is appropriate, particularly when medications have abuse potential.

Ultimately, if a positive drug test represents continuing drug use or a relapse after a period of abstinence, the counselor and patient should explore strategies to eliminate future use. Medication dosage and triggers to substance use should be examined, motivation for abstinence should be explored, and the patient should be taught skills to manage triggers and cravings. If drug tests continue to be positive, the medication dosage, amount of counseling, and number of OTP visits should be evaluated and may need adjustment. Furthermore, the patient might need the support provided by increasing counseling sessions and drug tests. These changes should be reflected in an updated treatment plan.

Medication Diversion

Since methadone treatment gained prominence in the late 1960s, concerns have existed about the diversion of medication from legitimate treatment use through theft, robbery, or patients or staff selling or giving away medication. SAMHSA-approved accrediting bodies pay particular attention to drug test results and whether an OTP appropriately monitors and follows up with patients who receive take-home medications (see chapter 5). The accrediting bodies require all OTPs to develop and implement a diversion control plan as part of their quality assurance program and to integrate the plan into both patient and staff orientations. The diversion control plan must contain specific measures to reduce the possibility of diversion and assign specific implementation responsibility to medical and administrative staff (see chapter 14).

Decisions About Take-Home Medication

Although drug test reports are a key factor in take-home medication decisions, OTPs should consider and document other considerations, such as employment and medical problems. Current Federal regulations (42 CFR, Part 8) outline eight criteria that the medical director of the OTP must consider when granting take-home privileges (see chapter 5). The physician also is required to reevaluate the appropriateness of take-home medications at least every 3 months.

When results are contested or confusing, confirmation analyses should be performed.

Sometimes privileges are revoked simply to prevent possible medication diversion, without a concomitant programmatic response to address an unfavorable drug test report. When this occurs without discussion or explanation, OTPs create barriers between themselves and patients and appear to function more as monitoring and surveillance units than as treatment programs. If patients who are receiving take-home medications have positive drug test results, OTPs should consider such steps as a review of medication dosage and an increase if indicated, revision of the patient treatment plan, or an increase in the level of care, in addition to cessation or reduction in take-home doses.

10 Associated Medical Problems in Patients Who Are Opioid Addicted

In This ChapterÖ

This chapter identifies medical problems commonly encountered in people addicted to opioids, discusses their treatment in opioid treatment programs (OTPs), and notes important considerations in deciding which medical services will be provided in an OTP and which can best be performed as a referred service. The chapter also covers medical screening and diagnostic services that are required by Federal and State regulations or Substance Abuse and Mental Health Services Administration accreditation guidelines. As such they should be available in or through OTPs.

Some medical problems are more prevalent and often more severe in people addicted to opioids than in the general population. Many are infections, including some that can be acutely life threatening, such as cellulitis, wound botulism, necrotizing fasciitis, and endocarditis. Diseases that are transmissible pose serious public health threats and are life threatening, such as HIV/AIDS, hepatitis, syphilis, and tuberculosis (TB).

Many patients in medication-assisted treatment for opioid addiction (MAT) have chronic diseases such as diabetes, asthma, or hypertension, as well as conditions such as severe dental problems or seizure disorders, which may have been neglected or poorly managed for years. Some patients have chronic obstructive pulmonary disease (COPD), hypertension, coronary artery disease, or other illnesses related to long-term heavy tobacco use. Management of chronic pain for patients in MAT is particularly challenging because of the role of opioids in pain treatment. In addition, opioid intoxication may result in head trauma or other bodily injury. Criminal activity may produce severe physical injuries such as gunshot wounds. The general approach in OTPs for these and other medical problems is to remain alert and knowledgeable, facilitate preventive measures, and provide ongoing medical care and emergency treatment to the extent possible.

Integrated Versus Referral Services

Given that many OTPs lack resources to treat acute and chronic medical problems associated with addiction, applicants with these medical issues may sometimes be denied treatment admission for addiction because an OTP cannot manage their other medical needs. Even when people with difficult medical problems are admitted to an OTP, unavailable or fragmented medical and psychiatric services may cause these patients to leave MAT prematurely, relapse to substance use, or resort increasingly to inpatient, emergency, or other expensive services because proactive care is lacking.

The consensus panel believes that many medical problems associated with opioid addiction should be treated either within the OTP or through liaisons with outside specialists and programs. One randomized, controlled trial in a large health maintenance organization showed that integrating addiction treatment and medical care was cost effective and improved patient outcomes (Weisner et al. 2001). Integrating medical and addiction treatments is both a challenge and an opportunity to match strategies for more cost-effective interventions. Medical services for at least the most common problems (such as soft-tissue infections, hepatitis, HIV infection, hypertension, diabetes, and COPD) should be provided at the OTP with expansion to other medical services as resources permit. Several studies have shown the public health benefits of this arrangement (e.g., Batki et al. 2002; Umbricht-Schneiter et al. 1994).

> OTPs [should] establish sound links with medical providers and programs skilled in treating problems that go beyond the direct services of the OTPs.

The consensus panel recommends that each OTP clearly define the medical services it offers on site versus by referral. Safety, practicality, and efficacy are important considerations in these decisions. For example, patients needing treatment for acute conditions such as bacterial endocarditis, those needing treatment for severe liver disease, or those requiring obstetric and gynecologic services generally are referred to primary or specialty care providers because most OTPs lack the resources to provide those services. The panel recommends that OTPs establish sound links with medical providers and programs skilled in treating problems that go beyond the direct services of the OTPs.

It is important for patients to understand an OTPís policies regarding services provided on site versus by referral. For example, an OTP might offer testing for infectious diseases but refer patients for treatment of these diseases. Such distinctions, as well as whether and how staff members will follow up to ensure that patients comply with offsite treatment, should be clear. Referral services should be part of a patientís opioid addiction treatment plan. The consensus panel recommends that primary care responsibility be established either on site or through a community provider because specialists are more likely to accept patients if their primary care responsibility has been assigned. OTPs also should inform local hospitals about their services and willingness to provide medical information (e.g., dosage information for addiction treatment medications, assuming a patientís informed consent) when a patient in MAT is admitted to a hospital for medical treatment.

In many cases, patients need help to understand their testing and treatment experiences at other sites, and they may feel uncomfortable asking offsite providers questions. OTP staff should be ready to help patients understand

procedures and care received off site and what these experiences mean for their overall care.

Routine Testing and Followup for Medical Problems

Because medical problems associated with opioid abuse sometimes emerge or are resolved during MAT, OTPs should establish protocols for both assessment of acute problems and periodic reassessments. The consensus panel recommends periodic (every 6 to 12 months) testing for hepatitis A, B, and C; syphilis and other sexually transmitted diseases (STDs); TB; HIV infection; hypertension; and diabetes. Liver and kidney functions also should be evaluated routinely. With the exception of HIV testing, these tests can be performed during routine evaluation. HIV testing requires a patientís written permission, along with counseling before and after the test (see TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** [CSAT 2000***e***]). Some OTPs repeat physical examinations annually, and others do so every 2 years. The consensus panel believes that physical examinations of patients in MAT should be performed at least annually. Tuberculin skin tests should be performed every 6 to 12 months, depending on the epidemiology of the region and recommendations from public health authorities.

Acute, Life-Threatening Infections

OTP medical staff, in particular those performing intake assessments, should recognize most potentially life-threatening infections related to opioid abuse. Some of these conditions can mimic opioid or intoxication withdrawal. In many cases, patients may be unaware of the severity of their conditions or may attribute their symptoms to withdrawal. Because patients are focused on avoiding withdrawal, their descriptions of their histories may be unhelpful. The most common of these life-threatening conditions are discussed below.

Endocarditis

Endocarditis is an infection, usually bacterial, of the inner lining of the heart and its valves. A diagnosis of possible endocarditis should be considered in any patient with recent injection marks and fever or a newly appearing heart murmur. A history of previously treated endocarditis might produce persistent heart murmur. Patients who have survived endocarditis by having a valve replacement are at increased risk of recurrent endocarditis. Fever in patients with a heart murmur always merits careful clinical investigation.

Soft-Tissue Infections

Soft-tissue infections, such as abscesses and cellulitis, involve inflammation of skin and subcutaneous tissue, including muscle. Contaminated injection sites often swell and become tender. When swelling and tenderness persist, infection is likely. A fluctuant abscess might need incision and drainage. Depending on its severity, cellulitis may require treatment with intravenous antibiotics. Patients with abscesses or cellulitis might not have fever.

Necrotizing Fasciitis

Necrotizing fasciitis, sometimes called flesh-eating infection, usually is caused by introduction of the bacterium ***Streptococcus pyogenes*** into subcutaneous tissue via a contaminated needle. It is uncommon, and cases caused by other bacteria also have been reported (Noone et al. 2002). The infection spreads along tissue planes and can cause death from overwhelming sepsis within days without much evidence of inflammation. Some patients may lose large areas of skin, subcutaneous tissue, and even muscle, requiring grafting. Case fatality rates from 20 to more than 50 percent have been reported (Mulla 2004). This infection should be considered when pain at an injection site is more severe than expected from the redness or

warmth at the site. Edema (fluid accumulation and swelling), fever, hypotension, and high white blood cell counts are additional clues. Treatment includes extensive debridement (cutting away of infected tissue) and intravenous antibiotics. Earlier ingestion of antibiotics, especially if these antibiotics were unprescribed, may result in partial treatment of necrotizing fasciitis and modify its diagnosis and course (Smolyakov et al. 2002).

Wound Botulism

Botulism is caused by the neurotoxin of ***Clostridium botulinum***, a bacterium usually found in contaminated food. Botulism causes loss of muscle tone, including respiratory muscle weakness, making it life threatening. The presenting symptoms and signsódifficulty swallowing (dysphagia), difficulty speaking (dysphonia), blurred vision, and impaired body movements (descending paralysis)ómay mimic signs of intoxication (Anderson et al. 1997). An epidemic of botulism poisoning among people who injected drugs occurred in the 1990s in several areas, particularly California (Werner et al. 2000). Several cases in people who injected drugs have been reported in Europe and Great Britain (Jensen et al. 1998; McGarrity 2002).

Infectious Diseases

Some infectious diseases that are prevalent among patients in MAT, including TB, viral hepatitis, HIV infection, and STDs, are monitored closely by the Centers for Disease Control and Prevention (CDC), which provides recommendations about testing, evaluation, classification, and treatment and publishes surveillance data. This information changes periodically, and the most recent data can be obtained from CDCís Web site (www.cdc.gov) and its publications.

The incidence of reported cases of TB and syphilis in the general population in the United States peaked in 1992. Groups identified to be at high risk included individuals who were homeless, incarcerated, or infected with HIV, as well as some immigrant groups. Intensive public health efforts decreased reported cases of syphilis from the 1990s through 2000, but reported cases increased 2.1 percent in 2001 (Centers for Disease Control and Prevention 2003***c***). Reported TB cases continued to decrease during the same period (Centers for Disease Control and Prevention 2002***b***).

TB

Public health statutes in all States require that the U.S. Public Health Service be notified of all cases of known or suspected active TB. State and Federal laws mandate appropriate followup and treatment of anyone whose TB might have been acquired from known exposure to an individual with active TB.

Frequency and types of testing

The consensus panel recommends that patients in MAT be screened for TB every 12 months unless local epidemiology and transmission patterns and the recommendations of local health authorities indicate that more frequent testing is needed. High-risk groups, for example, patients still injecting drugs and health care workers who must treat them, should be screened more frequently (e.g., every 6 months). New staff members should be screened for TB, and all staff members should be retested regularly, depending on local prevalence. Patients should receive a purified protein derivative (PPD) skin test for TB both on admission and annually, unless local health authorities indicate that more frequent testing is needed or patients are known to be PPD positive. In addition, treatment providers should look for and question patients about other symptoms of active TB, such as persistent cough, fever, night sweats, weight loss, and fatigue. OTPs should use the Mantoux test, which injects five tuberculin units of PPD intradermally. Patients who are HIV positive are considered PPD positive if an induration of 5 mm or more appears. Those who are HIV negative are considered PPD positive if an

induration of 10 mm or more appears. The standard classification system for TB is shown in Exhibit 10-1.

Positive PPD. The PPD skin test detects the immune response when a patient has been infected with TB. However, patients who have received a Bacillus Calmette-Guerin (usually called BCG) vaccination will have a positive PPD, and a chest x ray is indicated. Infections need not be active to be detected. Earlier infections controlled by the immune system are inactive, but they cause positive test results. In these cases, patients do not have symptoms of TB, and chest x rays show no evidence of active TB. These patients are considered to have class 2 TB and should receive prophylaxis with isoniazid to prevent later activation of infection (Centers for Disease Control and Prevention 2002***b***). Patients with class 2 TB do not transmit the disease. Those who have a history of exposure (e.g., when a family member has TB) but remain uninfected (i.e., their skin tests are negative) are considered to have class 1 TB and sometimes are treated prophylactically.

The consensus panel recommends following CDC guidelines on frequency of chest x rays for patients in MAT who are PPD positive. The medical staff should facilitate referrals for such patients to be evaluated at appropriate facilities (e.g., county TB clinics, affiliated or local hospitals, patientsí private physicians) and should ensure necessary followup.

Exhibit 10-1

Classification of TB

Class	Type	Description
0	No TB exposure	No history of exposure; negative skin test for TB
1	TB exposure; no evidence of infection	History of exposure; negative skin test for TB
2	TB infection; no disease	Positive skin test for TB; no clinical, bacteriologic, or radiographic evidence of active TB
3	TB infection; clinically active	***Mycobacterium tuberculosis***-positive culture (if done); clinical, bacteriologic, or radiographic evidence of active TB
4	TB infection; not clinically active now; clinically active in past	History of TB episodes or Abnormal but stable radiographic findings; negative bacteriologic studies (if done); positive skin test for TB and No clinical or radiographic evidence of active disease
5	TB suspected	Diagnosis pending

Source: Centers for Disease Control and Prevention 2000, p. 15.

Negative PPD. A negative PPD means one of three things: there is no TB infection (class 0), the infection is in the incubation period, or the patient is unable to respond to the skin test (i.e., is anergic) (see Exhibit 10-1). Because many patients who are immunocompromised and HIV infected are immunologically anergic, chest x rays are considered a routine part of their HIV care.

Prevention of TB in MAT

Adequate room ventilation is important for TB prevention (Centers for Disease Control and Prevention 2000). Special attention should be paid to waiting rooms, corridors, and offices. Patients with active TB who are coughing in an unventilated room are most likely to spread the disease and should receive masks or special precautions should be taken to prevent transmission pending medical evaluation. OTP staff should be educated about this risk. Patients diagnosed with active TB are quarantined in a hospital when treatment begins and generally are not released until their sputum tests revert to negative. Undiagnosed cases of TB increase the exposure risk in communities; therefore, aggressive evaluation and screening are crucial.

> [T]reatment providers should look for and question patients about… symptoms of active TB…

Treatment of TB during MAT

Isoniazid is used with vitamin B6 for prophylaxis to prevent active TB. Isoniazid is combined with other medications when patients have active TB (Centers for Disease Control and Prevention 2000). In either case, OTP staff members should monitor medication compliance actively to prevent the emergence of multidrug-resistant TB. Some patients may benefit from receiving their TB medication under direct observation along with their addiction treatment medication (Batki et al. 2002; Gourevitch et al. 1996). However, directly observed treatment for eligible patients should be optional. Addiction treatment medications should not be withheld to ensure adherence to TB medications.

Isoniazid is effective in TB prevention but can cause liver toxicity (Centers for Disease Control and Prevention 2000). In view of the high prevalence of liver disease and hepatitis among patients in MAT, liver enzymes should be monitored during isoniazid therapy. A significant increase (i.e., doubling or more) in one or more liver enzymes (alanine aminotransferase or serum pyruvic transaminase, aspartate aminotransferase, or lactate dehydrogenase) suggests liver toxicity and warrants a thorough medical evaluation.

If rifampin is used to treat TB in patients receiving MAT, their addiction treatment medications should be adjusted carefully because rifampin accelerates clearance of methadone and other drugs metabolized by the liver (see chapter 3). Rifabutin can be used as an alternative in patients receiving methadone. The methadone dose may need to be increased, split, or both.

STDs

Syphilis

The consensus panel recommends that all patients admitted to OTPs be tested at intake for syphilis with one of the serologic blood tests described by CDC (Centers for Disease Control and Prevention 2002***c***), including the rapid plasma reagent or the Venereal Disease Reference Laboratory test. Because false positive results are common with nontreponemal serologic tests in people who inject drugs, all positive tests should be confirmed with a treponemal antigen test such as fluorescent treponemal antibody absorption or ***Treponema pallidum*** particle agglutination. Patients with a confirmed positive serologic test for syphilis

need to receive treatment either on site or by referral to a local clinic, hospital, physicianís office, or health department. Treatment of syphilis is particularly important because syphilis has been shown to facilitate sexual transmission of HIV.

Chlamydia and gonococcus infections

Genital chlamydia and gonococcus infections often go undetected and may facilitate the sexual transmission of HIV. One cross-sectional study found that 7.9 percent of all adults between ages 18 and 35 had untreated gonococcal or chlamydial infections (Turner et al. 2002). Although testing for sexually transmitted genital infections is recommended in OTPs, it often is ignored because it requires a full pelvic and genital examination. Increased availability of urine testing for STDs might enhance access to their treatment in patients receiving MAT. Additional information is available in TIP 6, ***Screening for Infectious Diseases Among Substance Abusers*** (CSAT 1993***a***).

Hepatitis

Hepatitis A

Hepatitis A is an important viral liver infection that affects people who abuse drugs at higher rates than rates found in the general population. Hepatitis A can cause serious morbidity and mortality in patients already infected with hepatitis B virus (HBV) or hepatitis C virus (HCV). OTPs should screen for hepatitis A virus (HAV) and provide vaccination services or referral to such services for individuals who are unexposed.

Hepatitis B

Fifty to seventy percent of people who begin injecting drugs contract hepatitis B within 5 years, accounting for 17 percent of all new cases in 2000 (Centers for Disease Control and Prevention 2003***d***). This prevalence is particularly disturbing because vaccination can prevent HBV infection. In people with chronic HBV infection, both active and carrier states are marked by persistent surface antigen expression. A chronic carrier is someone who remains positive for serum hepatitis B surface antigen for 6 months or more. Recovery is marked by the disappearance of surface antigen, which is replaced by surface antibody. Core antibody (antibody to HBV core proteins) is present whenever patients are infected with HBV, regardless of outcome. If patients are not exposed to HBV, tests for the core antibody will be negative, but these patients remain susceptible to infection if exposed.

Testing is important to identify individuals with acute hepatitis B, those in chronic HBV carrier states, and those who are untreated but symptomatic for chronic active hepatitis B, as well as those unprotected from HBV infection who can be immunized (Centers for Disease Control and Prevention 2002***c***). All patients in MAT should be tested on admission via blood tests for both anti-HBV core antibody and HBV surface antigen. If patients are positive for the surface antigen, further medical evaluation and counseling about avoiding transmission to others is important. Medical evaluation, including liver function testing, needs to be done on site or by referral.

Patients who are negative for core antibody and surface antigen should be advised of their susceptibility to HBV infection and vaccinated at the OTP if possible, although cost is a factor in most OTPs. Patients who are positive for HBV surface antibody either have been infected or were vaccinated and probably are protected.

All staff members risk exposure to HBV infection, especially those who do physical examinations or handle urine or blood specimens, and they should receive hepatitis B vaccine, according to Occupational Safety and Health Administration standards for blood-borne pathogens (29 Code of Federal Regulations [CFR], Part 1910 ß 1200).

Hepatitis C

An estimated 70 to 90 percent of people who inject drugs have serologic evidence of

exposure to HCV (National Institutes of Health 2002), which indicates that OTPs will treat some patients with chronic HCV infection. The most appropriate intervention depends on HCV stereotype liver disease, alcohol consumption, and HIV status.

Testing for HCV. The consensus panel recommends that patients be tested by enzyme immunoassay for exposure to HCV. Testing should be simple and accessible on site. When HCV antibody test results are negative, it is important to educate patients about HCVís high transmissibility. The main method of transmission in this group is injection drug use (National Institutes of Health 2002). Hepatitis C is transmitted more than hepatitis A or B or HIV/AIDS. In one study, most subjects became infected with HCV within the first 2 years of injection drug use (Thomas et al. 1995). Hepatitis C also can be acquired through sexual transmission. However, this is much less efficient than the parenteral route. Sexual transmission of HCV occurs more frequently in HIV-infected individuals than in other individuals.

Determination of HCV disease activity. A positive HCV antibody test indicates patient exposure to HCV. Further evaluation should determine whether HCV infection has self-resolved (cleared) or is chronic. Approximately 15 to 25 percent of patients exposed to HCV clear their infections. To determine whether HCV infection still is present, a test for HCV ribonucleic acid is required. This test uses polymerase chain reaction and is costly, presenting a significant barrier for patients without health insurance. Detection of liver enzymes is a cheaper test but is insufficient to detect the virus. Twenty-five to fifty percent of people with HCV infection have normal liver enzymes (Inglesby et al. 1999). Patients with chronic hepatitis C infection may have few or no symptoms, so they have little incentive to incur further expense and visit their physicians.

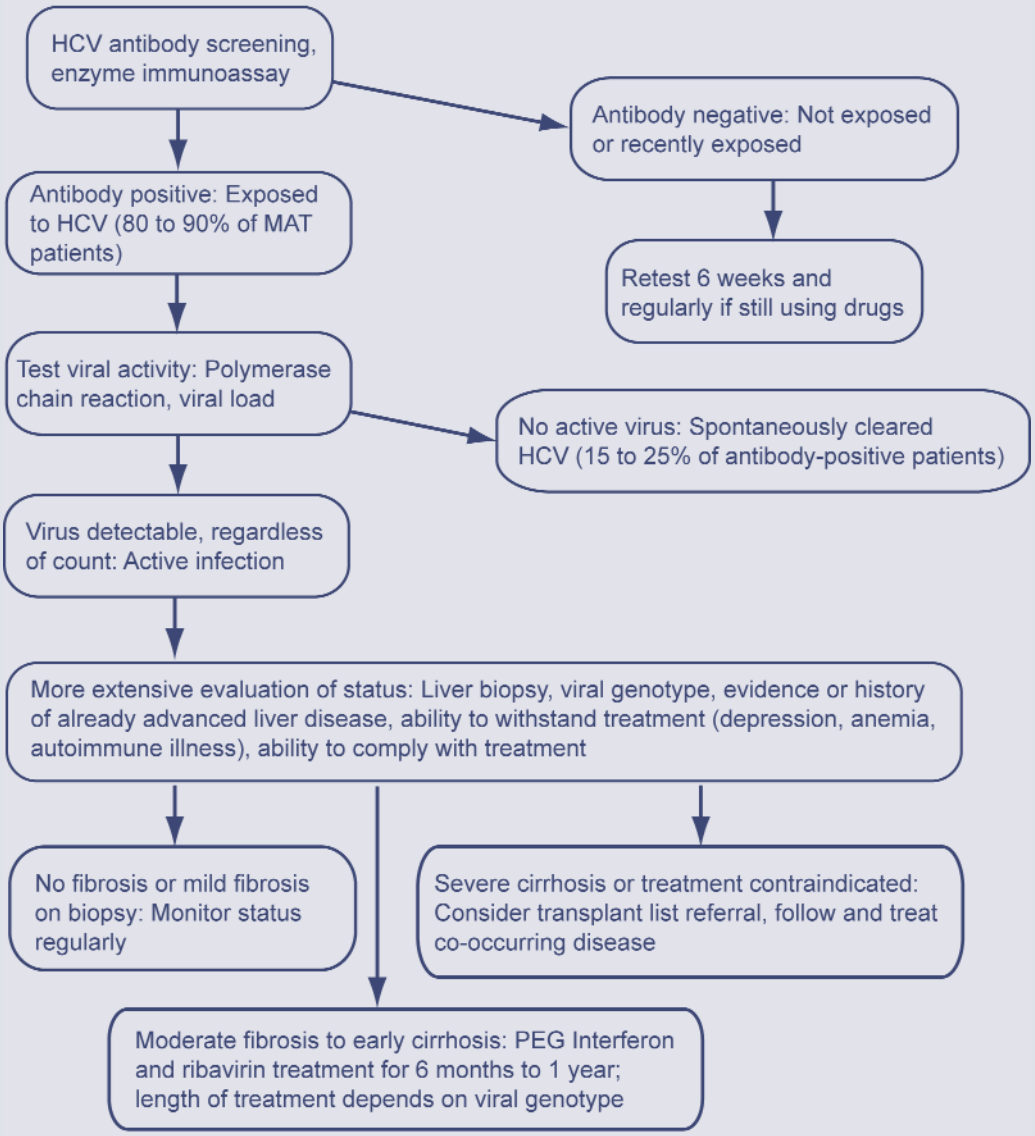
The consensus panel recommends that OTPs provide patients who are HCV positive with advice on minimizing their risk of liver damage, as well as encouragement to be evaluated further. These patients should know that alcohol ingestion significantly worsens hepatitis C (Regev and Jeffers 1999). They also should be tested and receive vaccinations for HAV and HBV infections if they have not been vaccinated. Because acute hepatitis A can be severe among HCV-infected patients, hepatitis A vaccination is recommended for all persons who are HCV infected. Many standard ìhepatitis panelî blood tests include a test for HAV antibody. In addition, patients who are HCV-antibody positive should avoid high doses of acetaminophen because it can cause liver damage, and their HCV antibody status should be communicated to any physician prescribing medication so that liver-toxic drugs are avoided (Thomas et al. 2000).

In contrast to HIV, the viral load of HCV does not correlate with its liver disease severity. For patients who have quantitative HCV, a complete evaluation of liver disease includes determination of liver enzymes and a liver biopsy (Saadeh et al. 2001). Virus genotyping is important if pharmacotherapy is considered because the results indicate the optimal length of treatment. Treatment decisions are not based on patientsí symptoms but on HCV genotype, level of liver disease, co-occurring illnesses, and willingness to undergo treatment. A decision flowchart for evaluating patients for HCV exposure is given in Exhibit 10-2.

Treatment of hepatitis C. The decision to treat patients in MAT for chronic hepatitis C infection is complex because it must include many factors, such as presence of co-occurring disorders, motivation to adhere to a 6- to 12-month weekly injection schedule, and medication side effects. Results of HCV genotyping (another expensive blood test) and a liver biopsy also must be considered. Counselors in OTPs can support patients who are deciding whether to undergo hepatitis C treatment. Patients with HCV infection who do not need treatment (minimal liver disease) may be concerned about liver disease progression. They should be informed that liver disease progresses to cirrhosis in 10 to 15 percent of cases and that its

Exhibit 10-2

Hepatitis C Evaluation Flowchart



progression is more likely with alcohol consumption. Co-infection with HIV or other types of hepatitis also may be associated with higher risks of disease progression (National Institutes of Health 2002).

The duration of hepatitis C treatment depends on the virus genotype. Most patients are infected with genotype 1 virus and require approximately a year of treatment, consisting of polyethylene glycol (PEG) interferon-alpha combined with ribavirin. In genotype-2 and

genotype-3 patients, 6 months of treatment usually is sufficient. The most effective interferon at this writing is pegylated interferon alpha-1 or alpha-2a. Treatment combines one interferon injection per week with ribavirin taken twice daily in capsule form for up to 1 year depending on viral subtype. Side effects include flulike symptoms and depression. Ribavirin also can have numerous adverse effects, most notably anemia and neutropenia. Therefore, co-occurring disorders and anemia should be evaluated carefully before initiating hepatitis C treatment. Pretreatment with antidepressants can be helpful to control treatment-induced depression. Some selective serotonin reuptake inhibitors can increase plasma levels of methadone or levo-alpha acetyl methadol (LAAM) (see chapter 3); therefore, patients receiving these medications should be observed for sedation or other effects of overmedication.

Treatment effectiveness is measured by absence of detectable HCV after the treatment course and at 24 weeks after completion of treatment…

Many treatment providers are reluctant to treat patients who are opioid addicted for HCV infection, but their concerns are unsupported by evidence (Edlin et al. 2001). Sylvestre (Sylvestre 2002***a***, 2002***b***) and Sylvestre and Clements (2002) reported excellent treatment results for HCV in patients on methadone maintenance, using a model that included pretreatment with antidepressants when necessary and weekly group support meetings, a key element in treatment success. Success in treatment did not require abstinence, although patients who used illicit drugs daily did not respond well (Sylvestre 2002***b***; Sylvestre and Clements 2002). Patients required moderate increases in methadone during treatment, perhaps related to the discomfort of side effects (Sylvestre 2002***a***). Support groups met twice per week, led by both a counselor and a peer; educated patients about HCV; and provided a forum to share fears, crises, problems, and successes (Sylvestre 2003). A National Institutes of Health consensus statement (National Institutes of Health 2002) also encouraged hepatitis C treatment for patients who inject drugs:

> Many patients with chronic hepatitis C have been ineligible for trials because of injection drug use, significant alcohol use, age, and a number of comorbid medical and neuropsychiatric conditions. Efforts should be made to increase the availability of the best current treatments to these patients.

Treatment effectiveness is measured by absence of detectable HCV after the treatment course and at 24 weeks after completion of treatment (sustained virologic response [SVR]). In one study, combination treatment with pegylated interferon and ribavirin produced an SVR in more than 40 percent of patients (Manns et al. 2001). Most patients (75 percent or more) had genotype 1 HCV infection, which is associated with worse response (Manns et al. 2001). In studies of all patients receiving these treatments (i.e., not just patients who abused substances), pegylated interferon and ribavirin produced higher response rates for HCV genotypes 2 and 3 after only 6 months of treatment, whereas regular interferon was less effective (Manns et al. 2001). From approximately 50 (Lau et al. 1998) to more than 90 percent (Fontaine et al. 2000) of patients with an SVR in these studies remained virus free. Treatment had partial benefits for those who did not clear the virus, such as reduced liver disease (Baffis et al. 1999; Poynard et al. 2000).

Treatment choices are complex for patients who have not responded to hepatitis C infection treatment, have dropped out of treatment, or have been judged too ill or behaviorally disturbed for treatment. There is no consensus

on whether treatment reinstatement might be beneficial or medical maintenance should be continued for partial responders.

Liver transplant. Transplantation is a last recourse for patients with hepatitis C infection with end-stage liver disease. The consensus panel recommends that MAT providers become familiar with the policies of regional transplant centers and their acceptance requirements. Success in obtaining a transplant may depend on timeliness of action by a patientís extended treatment team. Patients receiving methadone, LAAM, or buprenorphine for opioid addiction may be barred from transplant programs or accepted only if they taper from their maintenance medication before transplantation (Koch and Banys 2001). OTP medical staff members can serve as advocates for patients needing transplants. A common concern is that patients will be unable to comply with complicated care after their transplant. On the contrary, limited reports on transplantation in patients receiving MAT have shown excellent compliance with aftercare, although their outcomes were not compared with patients with no history of substance use (Kanchana et al. 2002; Koch and Banys 2002).

HIV/AIDS

Since the early 1990s, the prevalence of HIV infection has increased substantially in most of the United States among people who inject drugs (Hartel and Schoenbaum 1998). A 1998 survey by the American Methadone Treatment Association (now the American Association for the Treatment of Opioid Dependence) reported that approximately 25 to 30 percent of patients receiving methadone treatment in the United States were infected with HIV (Gourevitch and Friedland 2000). In practical terms, these statistics mean that OTPs should be prepared to care for many patients who are HIV positive or have AIDS.

Relatively early in the AIDS epidemic, it was shown that rates of needle use and conversion to HIV seropositivity decreased in patients receiving methadone maintenance compared with untreated groups and that these rates continued to decrease with time in treatment (e.g., Ball et al. 1988; Novick et al. 1990). These lifesaving benefits of MAT have contributed significantly to the respect MAT is accorded within the medical community.

TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** (CSAT 2000***e***), provides information on the natural history or course of HIV/AIDS and treatment for HIV/AIDS. A publication from the Center for Substance Abuse Treatment (CSAT 2004***b***) provides information on confidentiality issues related to substance abuse treatment programs.

Testing for HIV infection

The U.S. Public Health Service and many State health departments recommend that HIV counseling and testing be routinely offered in drug or alcohol prevention and treatment programs, especially where most patients have injected drugs and therefore are at increased risk (Centers for Disease Control and Prevention 2001***a***). ìRoutinely offeredî means providing these services to all patients after informing them that the test can be done either on site or through referral. CDC also recommends that pretest counseling be required for all patients (Centers for Disease Control and Prevention 2001***a***) and that HIV testing be recommended strongly and viewed as a routine procedure. Individuals should be informed that they may decline this testing without losing health care or other services. Counseling and testing also should be made available to patientsí acquaintances who might have been exposed to HIV.

The consensus panel further recommends that HIV counseling and testing be provided by the OTP at no cost. Either a trained employee or someone from an outside agency can provide counseling and testing services. Some States may have certification requirements. Many State health departments, as well as CDC, provide training or training materials for HIV counseling and testing. Standard tests include enzyme immunoassay for antibodies to HIV-1 and HIV-2 and confirmation by Western blot

analysis (Centers for Disease Control and Prevention 2001***a***). Several other tests are approved by the U.S. Food and Drug Administration (FDA), including tests using urine and saliva and rapid tests that give results in 10 to 60 minutes (see chapter 4). These newer tests are for HIV-1 only, and positive tests are reconfirmed by Western blot. OraQuick also tests for HIV-2. Although HIV-2 is rare in the United States, testing for it still is recommended for blood bank donations and in special populations, such as immigrants from West Africa. There also is an FDA-approved home collection kit that allows a sample to be sent from home for testing (Branson 1998; Centers for Disease Control and Prevention 2001***a***). TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** (CSAT 2000***e***), provides additional information about patients infected with HIV.

Prevention of HIV infection

Universal precautions to prevent the spread of HIV through contaminated bodily fluids (Centers for Disease Control 1988***a***) should be followed in any OTP. The consensus panel recommends that staff members be educated about how HIV is transmitted both to avoid exposure and to reduce generally unfounded fears of contamination during daily interactions with patients such as counseling or shaking hands. Prevention should include a factual understanding of the highly charged, often panic-laden beliefs surrounding AIDS.

The panel believes that having an AIDS coordinator on staff as the resident expert, community liaison and educator, and patient resource is optimal in areas with high HIV prevalence. Education about HIV should be part of the intake process for all patients and should include a description of the modes of transmission (stressing sexual as well as needle-sharing transmission), assessment of risk status, guidelines for prevention, and the importance of HIV testing in prevention and intervention.

HIV medications and methadone

Gourevitch and Friedland (2000) summarized interactions between methadone and commonly used HIV medications. Some medications, such as fluconazole, increase methadone levels, and others, such as nevirapine, efavirenz, and ritonavir, lower them. These authors pointed out that decisions about raising or lowering methadone dosages for patients in MAT who are HIV positive should be based on observation during the first month of any treatment change because some patients react differently than indicated by published information (Gourevitch and Friedland 2000). If necessary, peak and trough blood levels can be drawn and split dosing provided accordingly.

Neurologic complications of AIDS and its treatment

Pain from neuropathy is difficult to control with opioids alone, and some patients do better with gabapentin or antidepressants instead of, or in addition to, an increased methadone dosage or the addition of another opioid for breakthrough pain (see ìPain Managementî below). Patients with AIDS-related dementia or loss of balance may become erratic and difficult to monitor in an OTP. For them, a referral for neuropsychological evaluation may be helpful to identify any cognitive deficits and effective ways to provide supportive care. As dementia worsens, patients with take-home privileges may lose methadone bottles or mistakenly take more than one daily dose. Patients who fall or are unsteady might be assumed erroneously to be intoxicated. Close cooperation between OTP staff and providers treating these patients for AIDS is key to managing patients with neurologic complications of AIDS.

Referral for treatment

Most OTPs offer no onsite treatment for HIV because of its complexity and their limited resources. Referral usually should be made for medical assessment of patients who are HIV positive. A standard assessment may include a

baseline CD4 T-cell count, viral load, and tuberculin skin test, along with updated immunizations. Based on the results, physicians should discuss the potential utility of antiviral therapy (Krambeer et al. 2001). Depending on the availability of medical services, referrals can be made to private physicians, infectious disease specialists, HIV early-intervention treatment programs, hospital-based clinics, or community health centers. TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** (CSAT 2000***e***), provides suggestions regarding medical-care referrals.

Benefits of early intervention

The benefits of early intervention to control HIV and opportunistic infections should be stated clearly to patients. Patients and treatment staff, including drug counselors, should discuss the importance of notifying patientsí sex and needle-sharing partners, and staff members should offer help in this. Encouragement to continue in MAT or another form of addiction treatment is extremely important because addiction treatment participation may foster adherence to HIV treatment and lead to reductions in the spread of HIV.

Patients With Disabilities

OTPs increasingly must address the needs of disabled patients. TIP 29, ***Substance Use Disorder Treatment for People With Physical and Cognitive Disabilities*** (CSAT 1998***c***), discusses the requirements of the Americans with Disabilities Act of 1990. Many patients with AIDS have disabilities such as visual impairment, or they lack the strength to visit an OTP. Other patients may have hearing impairments or other disabilities, some since birth and some caused by trauma or other events. In one study, prevalence of illicit drug use was higher for persons with disabilities than for others. The types of drugs used varied with age (Gilson et al. 1996).

Home Dosing for Patients With Disabilities in MAT

Home dosing is an important option for patients whose disabilities preclude daily OTP visits. However, some patients are ineligible. For example, those with AIDS or other medical problems that affect neurological functioning may be unable to manage their medication without supervision. Others who are medically compromised and continue to abuse substances usually are ineligible for take-home dosing. These patients pose major challenges for OTPs, and treating them requires creative planning.

> Patients in methadone maintenance… have high levels of tolerance for the analgesic effects of opioids.

Solutions vary from program to program and in different areas. For patients with disabilities who do not meet take-home eligibility criteria, home dosing sometimes can be negotiated under the emergency dosing provisions of Federal or State regulations. For example, some OTPs identify a responsible family member or significant support person to assist with dosing. With patient permission, these individuals can be educated about addiction treatment medications and made responsible for picking them up from the OTP, ensuring safe storage (e.g., locked boxes, limited key access), and administering them daily to these patients. For patients who cannot identify such people, OTPs might negotiate medication support through the Visiting Nurses Association or comparable programs that can assist in this process.

Some OTPs deliver medication directly to disabled patientsí homes, but such arrangements may be impractical when patients live far from their OTPs, and delivery often is expensive.

Switching from methadone to LAAM might ease the accessibility problem somewhat, but, as indicated elsewhere in this TIP, the future availability of LAAM is doubtful. Buprenorphine, with its longer duration of action, also might be considered.

Home dosing is an important option for patients whose disabilities preclude daily OTP visits.

Regardless of the strategy, meeting the needs of homebound patients is a challenge. Home dosing can be time consuming and expensive, and it introduces safety and security problems. Consideration should be given to negotiating with pharmacies or interested physicians who can work directly with OTPs to provide home dosing in geographically remote areas. The consensus panel encourages OTP administrators to engage in discussions with their State agencies, the U.S. Drug Enforcement Administration (DEA), FDA, and other Federal and local agencies to develop creative solutions.

Pain Management

Patients in MAT have been shown to have high rates of acute and chronic pain (Rosenblum et al. 2003). Medical treatment providers, accrediting bodies, and the popular press have focused considerable attention on the need for adequate pain treatment, particularly to relieve chronic, nonmalignant pain or pain at the end of life, including palliative care with large doses of opioids. Pain in MAT patients can sometimes be managed with nonopioid medications, as well as nonpharmacologic approaches, but often the pain is severe and refractory to nonopioid analgesics or nonpharmacologic treatments.

Increased attention to pain control has made even physicians who are not addiction specialists more familiar with the use of methadone in pain treatment, and they also are more likely to understand that methadone should be continued if patients receiving MAT are hospitalized. Reluctance to provide adequate pain treatment to patients in MAT usually is based on the mistaken belief that a maintenance dose of opioid addiction treatment medication also relieves acute pain. In fact, long-term opioid pharmacotherapy produces substantial tolerance for the analgesic effects of opioid treatment medications; therefore, a usual maintenance dose affords little or no pain relief.

Patients receiving methadone maintenance treatment were shown to be hyperalgesic, meaning that they experienced pain more severely than those not receiving methadone (Doverty et al. 2001***b***). Patients in methadone maintenance also were shown to have high levels of tolerance for the analgesic effects of opioids, suggesting that conventional doses of morphine may be ineffective in managing episodes of acute pain in this patient group (Doverty et al. 2001***a***).

Another common concern is that opioid-containing analgesics aggravate addiction disorders. In fact, relapse to illicit opioid use has occurred when opioid analgesics are given to people in recovery. Such patients generally should not be given the drugs they abused previously, and patients with current or past opioid addiction should be monitored more closely than those without these problems. Relapse occurs most often when practitioners are unaware of their patientsí opioid addiction history.

Occasionally some patients do not meet ***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*** (DSM-IV-TR) (American Psychiatric Association 2000), criteria for addiction, but they believe they are addicted to pain medication because they are dependent physically as a result of chronic use of these medications. A patient or physician who lacks education about MAT might interpret physical dependence alone (i.e., not psychological addiction) or drug

seeking for poorly managed chronic pain as addiction. Ideally, such patients should be referred to pain management specialists. However, the consensus panel recommends that they also be accepted for MAT. Disadvantages of this approach are that regulations and requirements for observed dosing may be onerous and that these patients receive treatment where most patients are opioid addicted, which might not be therapeutic for patients not addicted in the usual sense. If these patients are treated in OTPs, the new regulatory framework allows for up to 1 month of take-home medication, provided evidence of stability and absence of unprescribed drug use exist (see chapter 5). This option could reduce markedly the burdens imposed by the earlier, more rigid regulatory framework of OTPs. In smaller communities with no OTPs, such patients might be ostracized from pharmacies or from primary care offices for insisting on proper pain control. Effort should be made to find physicians who will help them manage their pain. Some physicians are willing to accept patients after they have been stabilized by the OTP.

Types of Pain

Examples of conditions, either foreseeable or unplanned, that produce ***acute pain*** include traumatic injury, dental procedures, and labor and delivery. A dying patient with lung cancer probably has ***chronic malignant pain***. Patients with arthritis or disc disease might have ***chronic nonmalignant pain***. In addition, patients in MAT might have withdrawal-related pain, usually as aches in bones and joints along with other withdrawal signs and symptoms. Various types of pain are not mutually exclusive. For example, withdrawal, anxiety, and depression make chronic pain worse, and patients with chronic pain may have acute exacerbations of their pain. The most therapeutic intervention for pain depends on its type, community resources, patient preferences, and the extent of services available.

Acute pain

Patients occasionally require medical, surgical, and dental procedures that must be performed away from the OTP. In their guidelines for treating pain in patients receiving methadone, Scimeca and colleagues noted that these patients often required large doses of opioids at relatively short intervals for pain control because they had developed tolerance for opioids. One recommended approach to pain management for this group was to prescribe adequate doses of an alternative mu opioid agonist, such as morphine, hydromorphone, or oxycodone, while maintaining the maintenance dose of methadone or LAAM (Scimeca et al. 2000). Partial agonists such as buprenorphine, butorphanol tartrate, and nalbuphine should be avoided because they can cause opioid withdrawal in patients receiving MAT (Rao and Schottenfeld 1999). Whenever possible, pain management should be discussed with care providers before surgery or dental procedures.

Several principles provide the basis for managing acute pain in hospitalized patients also receiving opioid addiction pharmacotherapy (Compton and McCaffery 1999; Savage 1998; Scimeca et al. 2000):

- Methadone should be continued at the same daily dose, whether by oral or intramuscular routes, although it can be divided. For example, 50 percent of the usual dose can be given before surgery and 50 percent after. If methadone must be given parenterally, the injected dose should be 50 percent of the oral dose, because it is absorbed twice as efficiently by injection.
- LAAM patients can be treated temporarily with equivalent daily methadone doses (usually the 48-hour LAAM dose divided by 1.2), taking into account the timing of the last LAAM dose and its longer acting effects.
- Buprenorphine treatment may have to be suspended temporarily because it can attenuate or block the effects of opioids.
- Hospital physicians should be aware that methadone can be prescribed by any physician with a DEA registration for treating

nonaddiction problems and that maintenance treatment can be continued without a special registration throughout hospitalization, provided that a patient is being treated in a certified and accredited program. For example, when a patient in MAT is admitted for treatment of any disorder other than addiction, Federal regulations indicate that a hospital physician may continue to prescribe maintenance doses of methadone (21 CFR, Part 1306 ß 07(c)).

- ï Pain management should be discussed with affected patients, and they should receive assurances that they will be afforded adequate relief.
- ï Patientsí levels of pain should be monitored and, if increases are evident, pain should be treated promptly. Doses of short-acting opioids might have to be administered in addition to maintenance treatment, which is preferable to increased methadone doses for patients in MAT with acute pain. The doses of opioid analgesic required to interrupt pain in these patients can be larger and more frequent than for persons not in MAT because of the higher tolerance of patients in MAT. A patientís previous drug of abuse should not be prescribed for pain treatment. Patient-controlled analgesia can be successful to treat postoperative pain in patients who are opioid addicted, although the increments used should be monitored to minimize the reinforcing properties of the medications (Savage 1998).
- ï Partial agonist or agonist antagonist drugs such as pentazocine, butorphanol tartrate, nalbuphine hydrochloride, and buprenorphine should be avoided in methadone-maintained patients because these agents can precipitate withdrawal symptoms.
- ï Changeover to nonopioid agents should occur as soon as practical.
- ï Take-home opioids should be monitored for appropriate use and amounts limited. Patients should be seen at shorter intervals for refills, and prescriptions should specify a fixed schedule rather than ìas needed.î The actual time of day should be specified, rather than ìtwice dailyî (or ìb.i.d.î) or ìthree times dailyî (ìt.i.d.î) (Savage 1998). Increasing the drug testing frequency also may be advisable to verify that only prescribed medications are taken.
- ï Hospital physicians should communicate clearly with OTPs about discharge dates and times and the amounts of final methadone doses given in the hospital, to allow maintenance pharmacotherapy to be resumed effectively without interruption and to avoid overmedication.

Chronic pain

Patients who complain of chronic pain first need a thorough examination to determine and treat the cause of the pain. Some patients may need referral to specialists for testing and treatment. Several options should be tried before a patient receives opioids for pain. Nonopioid pain treatments may be tried, including medications, for example, nonsteroidal anti-inflammatory drugs (which are not without risksógastrointestinal bleeding is a well-known side effect of chronic use), COX-2 inhibitors, or other pharmacotherapies and physical therapy or surgery. Exhibit 10-3 lists nonpharmacologic approaches to managing chronic, nonmalignant pain. Unfortunately, many pain centers that provide these treatments hesitate to accept patients taking opioid treatment medications.

Special consideration is needed to provide opioid therapy for patients in MAT who have chronic, intractable, nonmalignant pain. Studies of patients receiving methadone have found that 37 to 60 percent have chronic pain (Jamison et al. 2000; Rosenblum et al. 2003). Use of opioids to treat chronic pain in this group is controversial because of potential side effects and hyperalgesia (Compton et al. 2001). However, withdrawal of patients with chronic pain from maintenance opioids is rarely appropriate and often results in failure to treat both the addiction and the pain disorder. A pain management expert and an addiction specialist should coordinate treatment of patients in MAT, following an extended team approach.

Exhibit 10-3

Nonpharmacologic Approaches to Managing Chronic Nonmalignant Pain

Physical Interventions	Psychological Interventions
Cold and heat	Deep relaxation
Ultrasound	Biofeedback
Counterstimulation (TENS*)	Guided imagery
Massage and manipulation	Cognitive behavioral therapy
Stretching and strengthening	Mood disorder treatment
Orthotics, splints, and braces	Posttraumatic stress disorder treatment
Positioning aids (pillows, supports)	Family/relationship therapy

* Transcutaneous electrical nerve stimulation.

Source: Adapted with permission from Savage 1998.

Some OTPs restrict take-home dosing for patients also receiving opioids for pain. The consensus panel believes that such policies are unfair and counterproductive. When a patient in MAT uses opioid pain medications only as prescribed, informs his pain treatment physician of his or her addiction history and participation in MAT, and refrains from abusing substances, long-term use of opioid pain medication should not disqualify the patient from take-home dosing in MAT. Drug testing can be useful in evaluating the degree to which such patients are complying with treatment regimens although it is not foolproof; urine drug tests, for example, identify only the presence or absence of substances, not the amount taken (see chapter 9).

Adjustment of Methadone Schedule

The methadone-dosing schedule to treat pain is three or four times daily or every 6 to 8 hours. Some patients in MAT with chronic pain might benefit from having their daily methadone dosage split for better pain control, which necessitates a take-home schedule for the remaining daily doses. When possible, program guidelines should require that an OTP staff member witness the first dose of the day.

Additional Opioids

Some patients with chronic pain have variable levels of pain or bursts of acute pain as well. For them, prescribing additional doses (or ìrescueî doses) of opioid analgesics to manage breakthrough pain may be indicated as part of a comprehensive approach. If so, the amount of rescue medication should be calculated prospectively based on a patientís history (Savage 1999). The rescue medication should be monitored, and unannounced drug testing may be indicated to prevent abuse or diversion. A primary care physician or a pain specialist can prescribe rescue medication. If a patient needs frequent rescue medication, then his or her substance abuse treatment medication probably should be increased in lieu of prescribing increasingly higher doses of short-acting opioids. Certain types of pain respond well to anticonvulsant adjuvant medications

such as carbamazepine or phenytoin, both of which are potent CYP450 3A inducers that can lead to a sharp reduction in serum methadone levels. Gabapentin, which also is effective in neuropathic pain, does not alter CYP450 3A isoenzymes and therefore does not change methadone levels.

Hospitalization of Patients in MAT

During a medical crisis requiring hospitalization of a patient in MAT, it is important that the OTP physician communicate with the attending physician and other members of the patientís hospital health care team. The hospital team should be informed of the patientís methadone dosage, the date on which methadone was last administered, and the patientís medical, co-occurring, or social problems.

During hospitalization, it is extremely important for the treating physician to understand that a patient in MAT probably will require larger doses of medication for anesthesia and that adequate pain relief might require the patient to receive a normal methadone dose (or its equivalent) plus additional medication, as described earlier in this chapter. Communicating these facts to the hospital team ensures appropriate care. Failure to provide sufficient baseline opioid medication in accordance with previous daily use plus additional medication for anesthesia can lead to inadequate pain relief, even with additional opioids.

In addition, the hospital team should be advised to institute appropriate controls to prevent a patient from obtaining and using illicit substances or abusing prescription drugs while in the hospital. These controls are especially important for unstable patients in the acute phase of MAT. Such controls include limiting visitors, preventing a patientís wandering through the hospital, and conducting regular drug tests. It usually is helpful to provide psychiatric consultation to medical or surgical staff treating patients in MAT, especially for patients with co-occurring disorders.

Some patients in MAT are hospitalized frequently. For example, a patient on dialysis might require repeated shunt revisions, a patient with chronic lung disease might have pneumonia several times a year, or a patient with cirrhosis might have episodes of variceal bleeding. In such cases, OTP staff members who dispense medications may be in a position to monitor patients to facilitate early treatment.

General Medical Conditions and MAT

As patients become engaged in MAT, they are more likely to take better care of themselves, modify their lifestyles, and participate in the medical followup needed to manage common chronic illnesses. In general, their medical care for other conditions should be identical to that given patients not in MAT. Primary care for common medical conditions such as diabetes, hypertension, and COPD can be provided easily in an OTP by nurse practitioners and other staff members working in collaboration with primary care physicians or internists. In some cases, medications for these medical conditions might need adjustment because of interactions with opioid addiction treatment medications (see chapter 3).

General advice on diet, exercise, smoking prevention, and stress management should be integrated into MAT, especially if nurse practitioners or physicianís assistants are on staff. A comprehensive approach addressing all aspects of patient health facilitates treatment of neglected medical problems. Age- and risk-appropriate medical screening, such as mammograms, sigmoidoscopy, prostate checks, or exercise stress tests, should be discussed with patients during regular examinations. The counseling staff can use printed educational material or videotapes to present this information. Some programs have developed health-related educational videotapes that are played in the waiting room so patients can receive information during daily OTP visits.

11 Treatment of Multiple Substance Use

In This Chapter…

Concurrent opioid and other substance use is a serious problem in opioid treatment programs (OTPs). Patients in medication-assisted treatment for opioid addiction (MAT) commonly use alcohol, amphetamines, benzodiazepines and other prescription sedatives, cocaine, and marijuana (THC [delta-9-tetrahydrocannabinol]). Patterns of use range from occasional low doses to regular high doses that meet dependence criteria. Central nervous system (CNS) depressants such as alcohol, benzodiazepines, and barbiturates are especially dangerous when used with opioids.

Except for naltrexone, which is used to treat alcohol dependence, the treatment medications used in MAT do not address nonopioid substance use directly, although patients stabilized on adequate treatment medication are less likely to abuse other substances than patients who are undermedicated. Because multiple substance use during MAT may complicate treatment greatly, the consensus panel recommends that staff members be trained to recognize the pharmacologic and psychosocial effects of both opioid and nonopioid substances of abuse. OTPs should have treatment options available to address multiple substance use either directly or by referral.

An essential purpose of preliminary assessment is to determine whether new patients are abusing or are dependent on substances other than opioids (see chapter 4). If one of these problems is identified, OTPs should adjust treatment plans and the types of services provided accordingly. OTPs should not exclude patients automatically from MAT who test positive for illicit drugs other than opioids. Treatment providers should treat patients for their concurrent substance abuse aggressively or refer them appropriately. Providers should try to understand and address the underlying causes of concurrent substance use.

Prevalence of Multiple Substance Use in MAT

Patients Entering OTPs Who Abuse Other Substances

The Treatment Episode Data Set (TEDS) summarizes data on admissions to substance abuse treatment programs in the United States. According to TEDS, 42.7 percent of patients entering substance abuse treatment in OTPs in 2000 reported using only heroin (Substance Abuse and Mental Health Services Administration 2002***d***). Exhibit 11-1 presents TEDS data on heroin and other substances used by people admitted to OTPs in 2000. Proportions of patients using additional drugs

Exhibit 11-1

Reported Use of Other Substances by Patients Admitted to OTPs

	Primary Substance of Abuse	
	Heroin	**Other Opioids**
Total number of admissions	243,523	25,839
Average number of substances used (per admission)	1.8	1.8
Substance Used in Addition to Primary Substance	**Percent**	**Percent**
None	42.7	44.4
Alcohol	23.3	24.4
Marijuana/hashish	12.1	14.2
Nonsmoked cocaine	22.2	7.2
Smoked cocaine	12.1	5.4
Methamphetamine/amphetamine	2.8	3.2
Other stimulants	0.2	0.3
Heroin	NA	7.8
Other opioids	4.3	1.3
Hallucinogens	0.3	0.4
Tranquilizers	3.0	10.2
Sedatives	0.7	4.0
Phencyclidine	0.2	0.1
Inhalants	<0.5	0.1
Other	0.7	1.5

Percentages sum to more than 100 because 1 patient could report more than 1 additional substance.
NA, not applicable.

Source: Substance Abuse and Mental Health Services Administration 2002***d***.

and the types of drugs used varied by locality, depending primarily on drug availability. Although not shown in Exhibit 11-1, rates of cigarette smoking in this population reportedly range from 85 to 92 percent (Clarke, J.G., et al. 2001; Clemmey et al. 1997).

Exhibit 11-2 summarizes results of a large-scale study of co-dependence in 716 patients admitted to OTPs in Baltimore, Maryland, over a 5-year period (1989 to 1994). Patients with co-occurring disorders had higher rates of substance co-dependence than patients without co-occurring disorders. Rates were substantially higher for lifetime co-dependence, even among patients not co-dependent during the study (Brooner et al. 1997).

Emergency Room Admissions and Fatalities Involving Concurrent Opioid and Other Substance Use

The Drug Abuse Warning Network tracks data from hospital emergency departments and other institutions that report admissions for substance use and drug-related deaths. In 2001, 93,064 nonfatal admissions mentioned heroin use. Of these, 5 percent mentioned concurrent alcohol use only, 25 percent mentioned concurrent use of another drug but not alcohol, and 15 percent mentioned concurrent use of alcohol and another drug or other drugs as well as heroin (Substance Abuse and Mental Health Services Administration n.d.***a***). Nearly 90 percent of heroin-related deaths may involve concurrent use of other substances (Substance Abuse and Mental Health Services Administration 2002***b***).

Common Drug Combinations Used by Patients in MAT

Exhibit 11-3 summarizes reasons patients in MAT give for using particular combinations of substances, based on the consensus panelís experience. A common reason is that patients have become dependent on the substance along

Exhibit 11-2

Current Substance Use Disorders in Patients Dependent on Another Substance While Addicted to Opioids and Admitted to OTPs, With and Without Co-Occurring Disorders (N=716)

Substance	With Co-Occurring Disorders (%)	Without Co-Occurring Disorders (%)
Cocaine	48.5	32.7
Marijuana	16.8	15.7
Alcohol	31.5	18.6
Sedatives	21.8	12.5

Percentages sum to more than 100 because 1 patient could report more than 1 additional substance.

Adapted from Brooner et al. 1997.

with their opioid addiction. Another common reason is the need to self-medicate withdrawal symptoms or uncomfortable affects (e.g., anxiety, depression, anger, loneliness) related to nonñsubstance-induced mental disorders or difficult life situations. Patientsí initial substance use experiences and continued attraction to drugs may indicate enhancementñ avoidance reactions. That is, substances may be used to enhance an experience (e.g., use of alcohol as a social lubricant or cocaine to heighten sexual pleasure) or to avoid or neutralize strong feelings (e.g., incest survivorsí substance use before sex to numb their feelings or adolescentsí substance use before sex to avoid accepting responsibility for their actions). Some patients develop unique drug regimens that vary throughout the day, for example, using stimulants in the morning, anxiolytics in the afternoon, and hypnotics at night.

Effects of Other Substance Use

Alcohol

The acute effects of alcohol are well known, including sedation, as well as impairment of judgment, coordination, psychomotor activity, reaction time, and night vision. Overdose deaths can occur when alcohol is used alone in high doses or in lower doses with opioid treatment medication or sedatives (Hardman et al.

Exhibit 11-3

Drug Combinations and Common Reasons for Use

Combination	Reasons
Heroin plus alcohol	Enhance a high; create euphoria or sedation
Heroin followed by alcohol	Medicate opioid withdrawal; medicate cocaine overstimulation (e.g., anxiety, paranoia)
Heroin plus cocaine (ìspeedballî)	Enhance or alter cocaine euphoria
Heroin followed by cocaine	Medicate opioid withdrawal
Cocaine plus alcohol	Enhance high; reduce cocaine overstimulation (e.g., anxiety, paranoia)
Cocaine followed by heroin	Reduce cocaine overstimulation (e.g., anxiety, paranoia); modulate the cocaine crash
Methadone plus alcohol	Create a high; sedate
Methadone plus cocaine	Reduce cocaine overstimulation (e.g., anxiety, paranoia); moderate the cocaine ìcrashî
Methadone plus benzodiazepines	Create a high; sedate
Any opioid plus any nonbenzodiazepine sedative	Create a high; sedate
Any opioid followed by any nonbenzodiazepine sedative	Medicate opioid withdrawal
Any opioid plus amphetamine	Create a high

1996). The effects of concomitant alcohol and methadone, levo-alpha acetyl methadol (LAAM), or buprenorphine use are additive and more sedating than either alcohol or treatment medication alone. Alcohol abuse can aggravate liver damage from hepatitis C, which is common among patients in MAT. Alcohol-related factors are a major cause of death among patients in MAT, both during and after treatment, and of administrative discharges from OTPs (Appel et al. 2000). On average, patients in MAT who are alcohol dependent have more medical and mental disorders, greater criminality, and poorer social and family functioning and peer relations than patients who are not alcohol dependent (Chatham et al. 1995***b***).

Alcohol abuse among patients in MAT can affect treatment compliance (Bickel and Amass 1993) and outcomes adversely. Continuous use may induce enzyme activity that increases the metabolism of treatment medication, reducing medication plasma levels and resulting in symptoms of undermedication that further complicate treatment.

Research is limited or conflicting on alcohol disorder treatment for patients in MAT. Many studies comparing alcohol use before OTP admission and after 1 year have found little or no improvement (e.g., Fairbank et al. 1993; Hubbard et al. 1997). However, one study found that short-term MAT reduced alcohol consumption significantly in patients who did not meet alcohol-dependence criteria (Caputo et al. 2002), and a 10-year study found that less than 6 percent of patients in MAT reported alcohol problems in the previous 6 months (Appel et al. 2001).

Lubrano and colleagues (2002) found an association between inadequate methadone doses and increased cravings for both heroin and alcohol. Others noted that continued alcohol consumption among patients dependent on alcohol was associated with smaller increases in methadone doses during MAT (El-Bassel et al. 1993). Stastny and Potter (1991) found that many patients in MAT who abused alcohol also abused benzodiazepines.

Treatment for alcohol dependence involves a comprehensive approach combining detoxification if needed, counseling, medications such as disulfiram, and participation in mutual-help groups (Fuller and Hiller-Sturmhofel 1999). Many groups do not support use of maintenance medication. Other interventions have met with limited success. A pilot study provided intensive education for staff members at OTPs in which 220 patients receiving methadone also were treated for alcohol dependence. Eighty percent of these patients complied with treatment requirements and completed treatment (Kipnis et al. 2001).

Benzodiazepines

Benzodiazepines such as diazepam (Valium®) and clonazepam (Klonopin®) have antianxiety and sedative effects. They are schedule IV drugs, signifying relatively low abuse liability. However, people with other addiction disorders are more likely to abuse benzodiazepines than are members of the general population (Ross and Darke 2000). In an early study, patients receiving opioid treatment medication who also abused benzodiazepines typically took the latter within 1 hour of the former and reported that benzodiazepines increased the effects of the medication (Stitzer et al. 1981). These effects likely result from an interaction in which each drug potentiates the sedative aspects of the otheróknown on the street as ìboosting.î When used in prescribed doses, benzodiazepines are not dangerous for patients in MAT, except when they cause patients to seek other drugs with sedative effects. High-dose benzodiazepines can cause serious problems, including severe intoxication and higher risk of injuries or fatal overdoses. These risks are potentiated when high doses of benzodiazepines are mixed with methadone or other drugs that produce sedation and respiratory depression, even among patients in MAT who have developed tolerance for the respiratory-depressant effects of opioids.

In the experience of the consensus panel, patient use of benzodiazepines negatively affects attendance at treatment sessions and

progress in MAT. Regular benzodiazepine use for 3 months or more may be associated with physiologic dependence, even when benzodiazepines are taken in prescribed doses. Patients who are abusing or dependent on benzodiazepines usually need detoxification and more intensive treatment interventions to remain safely in MAT.

Nonbenzodiazepine Sedatives

Nonbenzodiazepine sedatives such as intermediate- or short-acting barbiturates or glutethimide are more likely than benzodiazepines to produce lethal overdose because people who abuse them develop tolerance for their sedative and euphoric effects but not for their respiratory-depressant effects. Therefore, as these people increase their dosages to get high, they suddenly can overdose to respiratory depression. People who are opioid addicted and abuse nonbenzodiazepine sedatives usually need inpatient detoxification before starting MAT or may do better with referral to a long-term, residential program such as a therapeutic community. Nonbenzodiazepine sedatives induce cytochrome P450 3A, an enzyme involved in methadone, LAAM, and buprenorphine metabolism (see chapter 3), and can make stabilization difficult.

The consensus panel recommends that OTPs withhold treatment medication for patients who appear intoxicated with a sedative-type drug until intoxication has cleared and patients are either detoxified from sedatives or confirmed not to be sedative dependent. Nonbenzodiazepine sedative and barbiturate abuse is rare in most areas. These medications are less widely abused than in the past, because benzodiazepines are less dangerous and easier to obtain in many areas.

Cocaine and Other Stimulants

Stimulant abuse, especially cocaine, is another serious problem in many OTPs (see Exhibit 11-1). Adverse effects of these substances include cardiovascular effects (hypertension, stroke, arrhythmias, myocardial infarction), respiratory effects (perforation of nasal septum, bronchial irritation) if inhaled or smoked, or mental effects (anxiety, depression, anger, paranoia, psychotic symptoms). Patients in MAT who abuse stimulants may be disruptive if the stimulants have severe mental effects, and these patients may have problems with mood swings and compliance with group or individual therapy. TIP 33, ***Treatment for Stimulant Use Disorders*** (CSAT 1999***c***), provides more information.

Another concern for patients in MAT who use cocaine is concurrent alcohol use. The combination of alcohol and cocaine is popular because it can create a more intense high and less intense feelings of inebriation than either substance alone. Individuals also use alcohol to temper discomfort when they come down from a cocaine-induced high. Patients in MAT who abuse both alcohol and cocaine are significantly more difficult to engage and retain in treatment than patients who do not abuse all three substances (Rowan-Szal et al. 2000***b***). In addition, cocaethylene, a psychoactive derivative of cocaine formed exclusively during the combined administration of cocaine and alcohol, can increase the cardiotoxic effects of either substance alone. The combination of alcohol and cocaine tends to have exponential effects on heart rate and may increase violent thoughts and tendencies (Pennings et al. 2002). The mixture of opioids, cocaine, and alcohol can be lethal and has been identified as a leading cause of accidental overdose (Coffin et al. 2003).

Tennant and Shannon (1995) found that cocaine use appeared to lower the methadone concentration in blood. In addition, some patients reduced their cocaine use when their methadone dosages were increased. Borg and colleagues (1999) found that adequate doses of methadone seemed to reduce cocaine use even though methadone does not target cocaine directly. More focused treatments and research on these interactions are needed.

Traditionally, disulfiram has been used to treat alcohol dependence (chapter 3). Because cocaine often is used with alcohol, Petrakis and

colleagues (2000) evaluated disulfiram treatment for cocaine dependence, with and without alcohol abuse, for patients in MAT. Patients who were treated with disulfiram significantly decreased the quantity and frequency of their cocaine use, whereas those treated with a placebo did not. Related studies found that the positive effects of disulfiram on cocaine use among patients in substance abuse treatment remained evident after 1 year (Carroll et al. 2000) and that disulfiram also was promising for patients treated with buprenorphine (George et al. 2000). More research on the benefits of disulfiram therapy for cocaine dependence during MAT is needed.

Marijuana

In general, THC use is not as prevalent as cocaine or amphetamine use among patients in MAT (see Exhibit 11-2). Some studies have concluded that THC use in MAT does not affect MAT outcomes adversely. For example, Epstein and Preston (2003) found that THC was not associated with either poor treatment retention or problem use of other substances such as cocaine. One study (Wasserman et al. 1998) showed that, for patients committed to opioid abstinence and doing well, positive tests for THC could predict relapse, but this finding has not been replicated (Epstein and Preston 2003).

OTPs vary in whether they require THC-free drug tests before patients can qualify for or continue take-home medication privileges. The consensus panel recommends that OTPs address patient THC use because, as with other substances of abuse, THC increases the probability that patients will engage in activities that put them at higher risk of relapse to opioid use, other health problems, other related illicit activities, and legal problems.

Patients in MAT sometimes use THC to self-medicate for anxiety or insomnia. Approaches to address THC use in these patients include increased counseling, treatment of their anxiety disorders with standard psychotropic medications and psychotherapy, and requirements that drug tests be free of THC before patients can qualify for take-home medication. Unlike people addicted to nonopioid substances, patients in MAT who are opioid addicted rarely seek treatment for THC dependence. Therefore, it has received less attention in OTPs than in other substance abuse treatment programs.

Nicotine

Tobaccoñsmoking-related illnesses are a major cause of morbidity and mortality among patients in MAT as they are in the general population. For example, 40 percent of deaths over 15 years in one physicianís office-based MAT program were related to cigarette smoking, which was more than deaths from HIV/AIDS, hepatitis C, and violence combined (Salsitz et al. 2000). Frosch and colleagues (2000) found that patients in MAT who smoked heavily were more likely to abuse cocaine and opioids than were patients who did not smoke heavily, suggesting an association between nicotine and other substance use. In other research, patients receiving methadone who reduced their tobacco use also reduced cocaine use, although cocaine was not addressed directly in treatment (Shoptaw et al. 1996).

> [S]moking interventions neither detract from nor interfere with addiction recovery…

Many OTPs avoid addressing nicotine dependence because it may create additional stress for patients. Research has shown that smoking interventions neither detract from nor interfere with addiction recovery and that patients who attempt nicotine cessation are at the same risk for relapse as other patients (Ellingstad et al. 1999; Hughes 1995). Furthermore, many patients in MAT want to stop smoking (Clemmey et al. 1997).

The consensus panel believes that OTPs should address nicotine dependence routinely. In addition, because effective medications are available, tobacco cessation should be a regular part of patientsí treatment plans. The forthcoming TIP ***Detoxification and Substance Abuse Treatment*** (CSAT forthcoming ***a***) contains information on medications and other interventions for nicotine cessation.

Management of Multiple Substance Use in MAT

Although some studies have indicated that patients in MAT reduce other substance use significantly when they receive adequate doses of methadone, LAAM, or buprenorphine, none of these medications reliably and consistently stopped nonopioid abuse in studies reported by Borg and colleagues (1999) and by Tennant and Shannon (1995). A major concern is how to determine what level of other substance abuse by patients indicates that MAT is insufficient and other treatments should be tried or that MAT should be stopped, perhaps against patient wishes.

OTPs should have clear policies declaring the desirability of cessation of all substance use.

Some have argued for early treatment discharge if patients continue using multiple substances. In addition, some State regulations set specific timetables for compliance, although the requirement is unsupported by research. Some OTP staff members may feel that patientsí continued use of alcohol and illicit drugs, despite progress in recovery from opioid addiction, reflects negatively on OTP credibility and that these patients are taking the places of people who would benefit more from MAT. Patients who continue using illicit drugs sometimes erode the morale of other patients, who may conclude that treatment compliance and abstinence are optional.

Policies favoring treatment termination for patients who use substances negate a fundamental principleóthat longer retention in treatment is correlated highly with increased treatment success (Hubbard et al. 1997, 2003). In fact, substantial remission from all substance use is a common and positive outcome of MAT, particularly when treatment includes regular drug counseling and other psychosocial services (McLellan et al. 1993). Consensus panel members have found that, if patients with secondary substance use problems remain in MAT and staff members address overall substance abuse patterns for these patients, many patients stop using nonopioid and nonprescribed substances.

Changing staff attitudes can be helpful to both patients and staff. Abuse of other substances along with opioid addiction presents many problems and challenges for treatment providers and patients. Without treatment, a person with these problems may continue criminal activity; remain obsessed with substance use; experience severe financial, vocational, and personal problems; and be at increased risk for overdose death.

Given the importance of retention in MAT for positive outcomes, the consensus panel agrees that a policy of discharge for other substance use is seldom appropriate. Instead of setting standard timetables for discharge, limits should be determined on a case-by-case basis. Patient discharge should be done with great caution for reasons stated elsewhere in this TIP (e.g., chapter 8) and only when staff members have exhausted all reasonable alternatives. When grappling with these difficult problems, providers should keep in mind where patients started, how far they have progressed, the degree to which they are engaged in treatment, whether all available interventions have been

tried, the riskñbenefit ratio of keeping these patients in treatment versus discharging them, and a realistic expectation for patients, given the resources available. If discharge must occur, staff members should work with patients to arrange transfer to another program where a treatment slot is open and they can obtain more benefit.

Other Procedures

A key element in treating multiple substance use in an OTP is the need for intensified services and heightened structure and supervision (see chapter 8). Because few chronic diseases respond to a single care model, OTPs need a variety of techniques for patients who abuse multiple substances. These techniques should incorporate available medical, mental health, and social services. Usually patients who abuse multiple substances require a more intensive level of care for a limited period. Treatment providers also should have referral agreements with inpatient facilities for brief detoxification from nonopioid substances, extended stabilization before reentry into an OTP, or admission to a therapeutic community, residential treatment, or other long-term, more structured and controlled environment. OTPs can enter into agreements with residential treatment programs to allow continued MAT along with treatment for other substance dependence.

A common problem is that some OTP staff members and patients assume that stopping opioid and injection drug use is the sole objective of treatment. Use of cocaine and other substances should cause concern because it undermines patient stability. Nonetheless, use of some substances such as THC may be viewed as less serious unless clear evidence exists of impaired functioning. Many people entering an OTP regard alcohol use as acceptable because it is legal. Changing such attitudes and behaviors requires patience and effort. OTPs should have clear policies declaring the desirability of cessation of all substance use. These policies should clarify any ambiguity about abstinence from nonprescribed medications but encourage therapeutic use of medications that are effective to treat legitimate, diagnosed conditions. OTPs should encourage abstinence from alcohol and nicotine, but it is difficult to require it because these are legal substances. However, OTPs may withhold medication if patients have consumed alcohol shortly before or are intoxicated during treatment and should address alcohol problems.

The consensus panel believes it is helpful, both when patients are admitted to an OTP and throughout treatment, to maintain the position that opioid use is only the most obvious part of patientsí problems and that the role of all intoxicants (both licit and illicit) in patientsí lives and their overall substance-using lifestyle are other important issues. Patients in MAT should recognize that use of any intoxicant undermines their progress.

Dosage Adjustments

During the dosing period (see chapter 5), OTPs should ensure that patientsí dosages suppress withdrawal and produce significant cross-tolerance for opioids of abuse. Patients may be abusing other drugs to self-medicate withdrawal symptoms caused by inadequate dosages or other factors that affect medication metabolism. In this case, raising the dosage or splitting doses may lessen other substance use.

Increased Counseling and Other Psychosocial Services

Numerous studies have shown that regular counseling is associated with a reduction in opioid and other substance use by patients in MAT (Villano et al. 2002; see chapter 8 in this TIP). In a study of patients who abused multiple substances and had co-occurring disorders or criminal histories, those who received more intensive cognitive behavioral treatments reduced their cocaine use more than those in less intensive treatment (Rosenblum et al. 1995). In another study of patients in MAT who received additional cognitive behavioral therapy for cocaine abuse and patients who received standard methadone treatment,

cocaine use declined significantly for both groups (Magura et al. 2002).

Increased Drug Testing

One obstacle to detecting other substance use during MAT is that infrequent drug tests primarily identify only those patients who use substances frequently, for example, daily. Early detection and intervention requires occasional periods of more intensive, random drug testing. OTPs, however, should have objective policies that require combining increased drug testing with more intensive counseling. Testing frequency might be used as a contingency, with more negative tests for illicit drugs resulting in less frequent testing (see chapter 8).

Inpatient Detoxification and Short-Term Stabilization

Use of alcohol or other CNS depressants with opioids may cause depression of respiration, loss of consciousness, life-threatening withdrawal reactions, and increased risk of lethal overdose (Baskin and Morgan 1997). This type of withdrawal is not treatable with methadone (Sporer 1999; White and Irvine 1999). Signs and symptoms of withdrawal from CNS depressants include elevated body temperature, hypertension, rapid pulse, confusion, hallucinations, and intractable seizures. When a patient in MAT abuses a CNS depressant, the depressant should be withdrawn medically from the patientís system, and the opioid treatment medication should be continued with consideration of the need for a dosage increase.

The patient may require inpatient detoxification from CNS depressants and should continue MAT during the inpatient stay. In addition, a history of seizures or toxic psychosis during withdrawal from a sedative-hypnotic or anxiolytic drug or from alcohol is an absolute indication for inpatient detoxification. The forthcoming TIP ***Detoxification and Substance Abuse Treatment*** (CSAT forthcoming ***a***) contains more information on detoxification from substances of abuse.

12 Treatment of Co-Occurring Disorders

In This ChapterÖ

Many people who are opioid addicted have co-occurring mental disorders. However, mental health and addiction treatment systems often are separated. This situation may result in patientsí being treated at one location for addiction and at another for mental disorders. Some mental health care facilities do not accept patients in medication-assisted treatment for opioid addiction (MAT), forcing these patients to choose which disorder to treat. These problems, along with uncertainties about effective interventions for patients with both addiction and mental disorders, have stimulated research in this area. This chapter summarizes current thinking and consensus panel recommendations on screening, diagnosing, and treating these patients in opioid treatment programs (OTPs).

The term ìco-occurring disorderî in this TIP means a mental disorder that coexists with at least one substance use disorder in an individual. The consensus panel acknowledges that other types of disorders also occur with substance use disorders, such as cognitive and medical disorders and physical disabilities. These conditions also require individualized treatment approaches, and, for patients who are opioid addicted, other chapters in this TIP present discussions of treatments for other types of disorders that occur with substance use disorders. Chapter 6 discusses patients with physical disabilities. Chapter 8 discusses patients with cognitive disorders. Chapter 10 discusses patients with other medical disorders.

TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***); ***Report to Congress on the Prevention and Treatment of Co-Occurring Substance Abuse Disorders and Mental Disorders*** (Substance Abuse and Mental Health Services Administration 2002***c***); and ***Strategies for Developing Treatment Programs for People With Co-Occurring Substance Abuse and Mental Disorders*** (Substance Abuse and Mental Health Services Administration 2003***d***) provide additional information on co-occurring disorders in substance abuse treatment. This chapter focuses on co-occurring disorders in patients with opioid addiction.

Patients in MAT who have co-occurring disorders often exhibit behaviors or feelings that interfere with treatment. These symptoms may indicate either underlying co-occurring disorders that would be present regardless of substance use (i.e., independent or primary disorders) or co-occurring disorders caused by substance use (i.e., substance-induced or secondary disorders). Symptoms may also indicate the presence of both independent disorders and self-induced disorders along with substance use disorders. Patients may have identifiable co-occurring disorders on admission to an OTP, or disorders may emerge during MAT.

Unless MAT providers distinguish co-occurring disorders accurately by type and address them appropriately, these disorders likely will complicate patientsí recovery and reduce their quality of life. Numerous studies have indicated that rapid, accurate identification of patientsí co-occurring disorders and immediate interventions with appropriate combinations of psychiatric and substance addiction therapies improve MAT outcomes. The consensus panel for this TIP endorses this view. Many standard treatments for mental disorders can be modified readily for patients with co-occurring disorders in MAT.

Prevalence of Co-Occurring Disorders

Exhibit 12-1 lists the most common co-occurring disorders among patients in MAT, based on representative studies (e.g., Brooner et al. 1997; Mason et al. 1998). They are grouped into Axis I and II disorders, as defined in ***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*** (DSM-IV-TR) (American Psychiatric Association 2000).

Studies comparing patients in MAT with the general population have confirmed higher rates of co-occurring Axis I and II disorders in these patients (e.g., Calsyn et al. 1996; Mason et al. 1998). In a study by Brooner and colleagues (1997), nearly half of patients in MAT had co-occurring disorders during their lifetimes.

Factors Affecting Prevalence of Co-Occurring Disorders

Some factors found to increase the prevalence of co-occurring disorders among people with substance use disorders include older age, lower socioeconomic status, and residence in urban areas (Kessler et al. 1994); homelessness (North et al. 2001); and incarceration (Robins et al. 1991). Certain mental disorders (e.g., antisocial personality disorder [APD], schizophrenia) and some affective and anxiety disorders (phobias, bipolar depression) have been found to be more prevalent among persons with substance use disorders than in the general population (Regier et al. 1990). However, some of these studies did not determine whether symptoms of co-occurring disorders were related to the pharmacological effects of substances or to an underlying nonñsubstance-related disorder. TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***), discusses factors affecting the prevalence of co-occurring disorders.

Gender Differences in Prevalence of Co-Occurring Disorders

Rates of co-occurring disorders have been found to differ between men and women. For example, Ward and colleagues (1998***b***) found that more women than men who were opioid addicted had affective and anxiety disorders, whereas more men than women who were opioid addicted had APD and were dependent on alcohol. A study by Brooner and colleagues (1997) found women were more likely than men to have Axis I diagnoses, particularly major depression; seven times more likely to have borderline personality disorders; only half as likely to be diagnosed with APD; and less likely than men to manifest problems with other

Exhibit 12-1

Common Co-Occurring Disorders in Patients Who Are Opioid Addicted

Axis I Categories (Clinical Disorders and Other Conditions)	Axis II Categories (Personality Disorders and Mental Retardation)
ï **Mood Disorders** Major depressive disorder Dysthymic disorder Bipolar disorder	ï **Personality Disorders** APD Borderline personality disorder Narcissistic personality disorder
ï **Anxiety Disorders** Generalized anxiety disorder Posttraumatic stress disorder (PTSD) Social phobia Obsessive-compulsive disorder Panic disorders ï **Attention Deficit/Hyperactivity Disorder (AD/HD)** ï **Schizophrenia and Other Psychotic Disorders** ï **Cognitive Disorders** ï **Eating Disorders** ï **Impulse Control Disorders: Pathological Gambling** ï **Sleep Disorders**	

substances, including alcohol. Another study indicated that female patients receiving methadone were more likely than male patients to have psychotic and affective disorders (Calsyn et al. 1996). Another study of patients in MAT found that women were more likely than men to have PTSD (Villagomez et al. 1995).

Motivation for Treatment and Co-Occurring Disorders

Some studies have found that co-occurring disorders motivated people who were addicted to seek treatment. Community surveys from both the Epidemiologic Catchment Area study and the National Comorbidity Study found that, among respondents with substance use disorders, those with co-occurring disorders were more likely to obtain treatment (Kessler et al. 1994, 1996; Regier et al. 1990).

Etiology of Co-Occurring Disorders

Mueser and colleagues (1998) identified four common models to explain the relationship between co-occurring and substance use disorders:

- **Primary substance use disorder and secondary co-occurring disorder.** This ìdisease modelî holds that substance use disorders cause most co-occurring disorders in patients. Appropriate treatment, by this theory, focuses on the underlying substance use.
- **Primary co-occurring disorder and secondary substance use disorder.** This ìself-medicationî model, proposed by Khantzian (1985), argues that preexisting mental disorders are a significant cause of substance use disorders. People who are drug addicted choose drugs that lessen painful feelings caused by their mental disorders, for example, opioids or alcohol to alleviate anxiety or cocaine or other stimulants to relieve depression. By extension of this view, adequate treatment of the psychopathology resolves the substance use disorder.
- **Common pathway.** This model holds that shared genetic or environmental factors may cause both substance use and co-occurring disorders. For example, accumulating evidence indicates that childhood conduct disorders that persist to become adult antisocial or borderline personality disorders are significant risk factors for substance abuse (e.g., Compton et al. 2000; Mueser et al. 1999). Other studies (e.g., Ahmed et al. 1999; Nunes et al. 1998*b*) have found that relatives of patients who were opioid addicted had higher rates of major depression, alcoholism, and substance use disorders, indicating that genetic factors increase susceptibility to both addiction and co-occurring disorders.

[A]dmission and ongoing assessment routinely should incorporate screening for co-occurring disorders.

- **Bidirectional model.** This model emphasizes that socioenvironmental and interpersonal factors, such as poverty, social isolation, drug availability, or lack of accountability by adult caregivers, also contribute to both substance use and co-occurring disorders through a complex interaction between environment and genetic susceptibility. The bidirectional model has not been evaluated systematically.

Screening for Co-Occurring Disorders

The consensus panel believes that admission and ongoing assessment routinely should incorporate screening for co-occurring disorders. This screening should yield a simple positive or negative result, depending on whether signs or symptoms of co-occurring disorders exist. A negative result generally should rule out immediate action, and a positive result should trigger detailed assessment by a trained professional (see chapter 4).

To identify patients in MAT with co-occurring disorders, treatment providers must decide

- When and how to screen patients
- How to integrate psychological screening with standard intake assessment
- Which instruments to use for screening and confirming co-occurring disorders
- What qualifications are needed by staff who conduct screenings
- How to classify symptoms and other evidence
- How to determine the most appropriate treatment methodology and level of care.

Specific Screening Procedures

OTPs should establish specific screening procedures for co-occurring disorders and train counselors and intake workers to perform these procedures, including how to recognize the presenting symptoms of the most commonly encountered co-occurring disorders. Few significant differences in symptoms of mental disorders exist between patients who are addicted to opioids and other people who are not; therefore, the symptoms described in

DSM-IV-TR are applicable during admission screening. When possible, screening for co-occurring disorders should be linked with other assessments to avoid duplicate efforts by staff and unnecessary burdens on patientsí time. An OTPís screening procedures for co-occurring disorders should specify

- Questions or instruments to be used
- When and where to conduct screening segments (e.g., address all safety-related questions during initial intake and defer other questions until applicants are no longer intoxicated or in withdrawalóbut wait no longer than a specified period after admission)
- Who conducts screenings
- How to record results
- Cutoff scores or other indicators of positive results for co-occurring disorders
- Exactly how to handle positive results (e.g., whom to inform, how, and when; what constitutes a psychiatric emergency and how to address it)
- How extensively a patientís self-reported information must be corroborated with information from other sources (e.g., family and friends, caseworkers, previous treatment records)
- Which staff members to consult if questions arise about these procedures or the results.

Screening for co-occurring disorders usually entails determining

- An applicantís immediate safety and self-control, including any suicide risk, aggression or violence toward others, or domestic or other abuse or victimization and the ability to care for himself or herself (see ìHandling Emergency Situationsî below).
- Previous diagnosis, treatment, or hospitalization for a mental disorder and, if applicable, why, when, and where, as well as the treatment received and its outcome. Questions about the relationship of mental disorders to substance useófor example, whether a mental disorder was present during abstinence or before the substance use disorderó determine whether a co-occurring disorder is substance induced or independent.
- The applicantís current co-occurring disorder symptomatology based on DSM-IV-TR criteria, including whether any psychotropic medications have been prescribed or are being used (usually included on a screening questionnaire).
- Trauma history (e.g., physical or sexual abuse, living through a natural disaster or war, witnessing death or tragedy). Questions about trauma should be brief and general, without evoking details that might precipitate stress. Several screening instruments for PTSD are described in other TIPs (see the forthcoming TIP ***Substance Abuse and Trauma*** [CSAT forthcoming ***d***]; TIP 25, ***Substance Abuse Treatment and Domestic Violence*** [CSAT 1997***b***]; and the Modified PTSD Symptom Scale: Self-Report in TIP 36, ***Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues*** [CSAT 2000***d***]).
- Any history of mental disorder-related symptoms among immediate relatives and their diagnoses, treatments, or hospitalization.
- Any unusual aspects of an applicantís appearance, behavior, and cognition. If indications of a cognitive impairment are present, a mental status examination should be conducted.

Screening for cognitive impairment

The accuracy of instruments to screen for co-occurring disorders may be compromised if administered to patients with cognitive impairments. A brief preexamination of cognitive functioning during a mental status examination is recommended for individuals who are disoriented with respect to time, place, or person; have memory problems; or have difficulty understanding information in their first language. TIP 29, ***Substance Use Disorder Treatment for People With Physical and Cognitive Disabilities*** (CSAT 1998***c***), contains an 18-item screening instrument for cognitive

impairment and functional limitations. TIP 33, ***Treatment for Stimulant Use Disorders*** (CSAT 1999***c***), lists nine brief screening tools to determine cognitive impairment and reproduces the Repeated Memory Test. Treatment providers who prefer the familiar Mini-Mental State Examination (Folstein et al. 1975) can order either the standard or extended version via the World Wide Web at www.minimental.com.

Screening Tools

Many States require specific screening or assessment instruments, such as the Addiction Severity Index (ASI), to document baseline patient data. Other important considerations in selecting a screening tool for co-occurring disorders include its psychometric properties and cultural appropriateness and, if the test is self-administered, the literacy level required. The consensus panel believes that no instrument in an OTP can identify co-occurring disorders satisfactorily, and many of the most thoroughly tested are not in the public domain. The ASI records symptoms of mental disorders but does not diagnose. More information on the ASI and other screening instruments, including Mental Health Screening Form III, the Mini International Neuropsychiatric Interview (M.I.N.I.), and some proprietary instruments, is in TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***). Other tools focusing on particular disorders or pathologies (e.g., suicide danger, PTSD, AD/HD, depression) can be accessed through the Web sites listed in Appendix 12-A.

Making and Confirming a Psychiatric Diagnosis

After a possible co-occurring disorder is identified during screening, an experienced, licensed mental health clinician (e.g., psychiatrist, psychologist, clinical social worker) should perform additional evaluation to make or confirm a diagnosis. Ideally, this expertise is available at the OTP. When it is not, appropriate consultants and referral resources must be substituted, but procedures to use and reimburse these resources should be well established.

The most widely used systems to classify mental and substance use disorders are provided in DSM-IV-TR and the ***International Classification of Diseases, 10th Edition*** (ICD-10), ***Classification of Mental and Behavioural Disorders: Clinical Descriptions and Diagnostic Guidelines*** (World Health Organization 1992). Both systems present diagnosis criteria accepted by national (DSM-IV-TR) or international (ICD-10) experts.

DSM-IV-TR Criteria

Although many insurance companies require International Classification of Diseases diagnostic codes for reimbursement purposes, clinicians and researchers in the United States traditionally use the DSM classification system. As this system has evolved over several editions, its authors have made important changes in definitions for substance-related disorders. Specifically, the DSM-IV-TR divides these disorders into two types: substance use disorders and substance-induced co-occurring disorders.

Substance use disorders

DSM-IV-TR divides substance use disorders into abuse and dependence with or without physiological features such as tolerance or withdrawal. It also makes distinctions pertaining to early or sustained remission; programs offering agonist, partial agonist, or agonist/antagonist therapy; and treatment while living in a controlled environment (e.g., jail).

Substance-induced co-occurring disorders

Substance-induced co-occurring disorders are associated with intoxication, withdrawal, and the persistent effects of substances of abuse. Substance-induced ***persisting*** disorders are those in which substance-related symptoms continue long after a person stops using a drug (e.g., prolonged flashbacks from hallucinogen use, substance-induced persistent dementia,

substance-induced persistent amnesia). Exhibit 12-2 shows the association between substance-induced co-occurring disorders and substances of abuse. It is noteworthy that different drugs have been associated with different types of co-occurring disorders and that some (such as opioids) have relatively few or no reported psychotoxic effects, whereas others have many.

Structured and Semistructured Interview Formats for Psychiatric Diagnoses

A number of carefully designed and tested instruments are available to determine DSM-IV or ICD-10 diagnoses, although a careful clinical interview usually can serve this purpose. Not all instruments have been updated for DSM-IV-TR diagnoses, but DSM-IV diagnoses are similar. Examples include the

- Structured Clinical Interview for DSM-IV Axis I and II Disorders, Clinical Versions
- Composite International Diagnostic Interview, Core Version 2.1
- Psychiatric Research Interview for Substance Abuse and Mental Health Disorders
- Diagnostic Interview Schedule, Version 4
- Alcohol Use Disorder and Associated Disabilities Interview Schedule.

TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***), discusses these and other screening and assessment instruments and their sources at greater length.

Differential diagnosis

Careful assessment including a family history is critical to determine whether presenting symptoms indicate independent co-occurring disorders or disorders induced by substance use or a general medical or neurological condition. In many cases, people who abuse multiple substances have both an independent co-occurring disorder and various substance-induced symptoms precipitated by intoxication or withdrawal. Substance use can magnify symptoms of independent co-occurring disorders. For example, substance use can heighten the mood swings of bipolar disorder; intensify the hallucinations and paranoid delusions of schizophrenia; or increase the risk of suicide, violence, and impulsive behaviors among individuals with antisocial or borderline personality disorders (American Psychiatric Association 2000).

> [I]ndependent and substance-induced co-occurring disorders differ in their course.

The accuracy of differential diagnosis has treatment implications because independent and substance-induced co-occurring disorders differ in their course. Independent disorders tend to follow a typical course for each diagnosis and require specific, long-term treatment (e.g., pharmacotherapy, psychotherapy). Substance-induced disorders tend to follow the course of the substance use disorder and to dissipate with abstinence, although persistent disorders can deviate from this sequence. Substance-induced symptoms can be disruptive at the start of MAT, but they typically do not require ongoing psychiatric treatment (Woody et al. 1995***a***).

Timing for confirming a diagnosis

Accurate diagnosis of independent co-occurring disorders is difficult during the early phases of MAT because substance-induced symptoms also usually are present. A definitive diagnosis often must wait until a patient is stabilized on treatment medication for a minimum of 5 to 7 days (but preferably 2 to 4 weeks) and any continuing substance use is eliminated. Although several weeks of abstinence may improve the accuracy of diagnoses, symptoms of severe co-occurring disorders (e.g., suicidality, psychotic reaction) need prompt attention and might require more immediate pharmacological

Exhibit 12-2

DSM-IV-TR Classification of Diagnoses Associated With Different Classes of Substances

	Dependence	Abuse	Intoxication	Withdrawal	Intoxication Delirium	Withdrawal Delirium	Dementia	Amnestic Disorder	Psychotic Disorders	Mood Disorders	Anxiety Disorders	Sexual Dysfunctions	Sleep Disorders
Alcohol	X	X	X	X	I	W	P	P	I/W	I/W	I/W	I	I/W
Amphetamines	X	X	X	X	I				I	I/W	I	I	I/W
Caffeine			X								I		I
Cannabis	X	X	X	X	I				I		I		
Cocaine	X	X	X	X	I				I	I/W	I/W	I	I/W
Hallucinogens	X	X	X		I				I*	I	I		
Inhalants	X	X	X		I		P		I	I	I		
Nicotine	X			X									
Opioids	X	X	X	X	I				I	I		I	I/W
Phencyclidine	X	X	X		I				I	I	I		
Sedatives, hypnotics, or anxiolytics	X	X	X	X	I	W	P	P	I/W	I/W	W	I	I/W
Polysubstance	X												
Other	X	X	X	X	I	W	P	P	I/W	I/W	I/W	I	I/W

*Also Hallucinogen Persisting Perception Disorder (flashbacks).
Note: X, I, W, I/W, or P indicates that the category is recognized in DSM-IV-TR. In addition, I indicates that the specifier With Onset During Intoxication may be noted for the category; W indicates that the specifier With Onset During Withdrawal may be noted for the category (except for Withdrawal Delirium); and I/W indicates that either With Onset During Intoxication or With Onset During Withdrawal may be noted for the category. P indicates that the disorder is Persisting.

Source: Reprinted from DSM-IV-TR. Copyright 2000, American Psychiatric Association.

treatment or hospitalization (Woody et al. 1995***a***). OTPs should be aware that even symptoms of less severe co-occurring disorders can prevent a patientís stabilization and should be addressed quickly.

Guidelines for distinguishing nonñsubstance-induced from substance-induced co-occurring disorders

To assist with a differential diagnosis, the following information (Woody et al. 1995***a***) should be collected and reviewed:

- ï Previous history of mental disorders and treatment, focusing on temporal relationship of symptoms to substance use and response to previous treatment
- ï Type, quantity and frequency, and time of last use of illicit substances or prescribed psychotropic drugs (each substance class produces specific physiological and behavioral effects, especially during acute intoxication or withdrawal after prolonged, high-dosage use)
- ï Family history of mental disorders.

DSM-IV-TR (American Psychiatric Association 2000) offers the following procedures to ascertain whether a co-occurring disorder is primary or secondary:

- ï Label the disorder according to predominant symptom pattern and specified criteria (e.g., mood, anxiety, psychotic disorder)
- ï Consider the co-occurring disorder ***primary*** (not substance induced) if
  - ñ Symptoms developed before the substance use disorder
  - ñ Symptoms have persisted during 30 days or more of abstinence (depending on the characteristic withdrawal course for each substance)
  - ñ Symptoms are inconsistent with or exceed those produced by the abused substance at the dosage used (e.g., hallucinations after opioid withdrawal, paranoid delusions after low-dose marijuana use)
  - ñ Substance use or another medical disorder cannot account better for the symptoms
- ï Consider the mental disorder ***secondary*** (substance induced) if
  - ñ Symptoms developed only during periods of active substance use or within 1 month of intoxication or withdrawal
  - ñ Symptoms are consistent with intoxication or withdrawal from substances used
  - ñ Other features (e.g., age at onset) are atypical for primary co-occurring disorder
  - ñ Another co-occurring or medical disorder does not account better for the symptoms.

Prognosis for Patients With Co-Occurring Disorders

Patients with co-occurring disorders generally have been found to have poorer prognoses and to be more difficult to treat than those with diagnoses of either a substance use or mental disorder (Dausey and Desai 2003; Kessler 1995). Research has suggested that persons with co-occurring disorders are at higher risk of suicide, psychiatric hospitalization, legal difficulties and incarceration, homelessness, life-threatening infectious diseases, domestic violence, abuse or neglect of their children, unemployment, and other interpersonal problems (e.g., Dausey and Desai 2003; Room 1998).

Effects of Co-Occurring Disorders on Treatment Outcomes

The conventional view, which has considerable empirical support, is that unidentified, untreated co-occurring disorders impede progress for patients in MAT and lead to difficulties in engaging patients in treatment, establishing a

therapeutic alliance between patients and treatment providers, maintaining adherence to treatment regimens, eliminating substance abuse and other risky behaviors, and preventing premature dropout or early relapse. Conversely, a review by Drake and Brunette (1998) concluded that substance abuse complicates co-occurring disorders, often precipitating relapse to psychopathological symptoms, hospitalization, disruptive behavior, familial problems, residential instability, decreased functional status, HIV infection, or medication noncompliance.

Because research on treatment outcomes for patients with opioid addiction and co-occurring disorders usually examines small groups of subjects and because patients in these groups are not homogeneous, the general applicability of current findings is limited. Many confounding factors exist (Room 1998). Despite these limitations, numerous studies have found that many patients with co-occurring disorders did well when appropriate psychiatric and substance abuse treatments were delivered. The consensus panel recommends more intensive and psychiatrically specific treatment for these patients.

Effects of Symptom Severity

Studies disagree on whether the severity of co-occurring disorder symptoms in patients who are addicted is a useful predictor of treatment outcomes. Early studies found that the severity of co-occurring disorder symptoms, particularly in patients with anxiety or depression, strongly predicted treatment outcomes and that the most severely symptomatic patients had the heaviest substance use and most impaired adjustment, whereas the least symptomatic did best in addiction treatment (McLellan et al. 1993; Rounsaville et al. 1986). However, later studies have found that higher symptom severity, although associated with higher levels of substance use and worse overall adjustment, did not predict treatment response. In one study, drug test results for patients with severe psychopathology improved significantly over time (Belding et al. 1998). In another study, patients in MAT for at least 90 days who had co-occurring disorders and high levels of symptom severity had positive treatment responses (Joe et al. 1995). Patients with more than one co-occurring disorder engaged in treatment more readily than those who were addicted only, and both groups were similar in average incidence of drug use or criminal activity. Patients with depression, anxiety, suicidal ideation, and other pathologies at intake were twice as likely to attend individualóbut not groupócounseling sessions and significantly more likely to discuss psychological problems than those reporting none of these symptoms.

Consequently, caution is advised in predicting a simple, stable correlation between symptom severity of co-occurring disorders and treatment outcomes. However, the consensus panel believes that co-occurring disorders can improve substantially but that outcomes depend heavily on additional treatment being provided for these disorders and that patients with severe symptoms may require longer, more intensive treatment.

Prognosis for Specific Co-Occurring Disorders

Effects of co-occurring APD on progress in MAT

APD has been estimated to affect 24 to 39 percent of people seeking treatment for opioid addiction (Brooner et al. 1997; Darke et al. 1996; King et al. 2001). Some studies have found that people with APD and opioid addiction had more criminal activity, more history of early violent and aggressive behaviors, greater likelihood of engaging in activities that risked HIV transmission, more extensive and severe polydrug abuse, and earlier onset of opioid use than persons who were opioid addicted without APD (Brooner et al. 1997; Darke et al. 1996).

However, agreement is lacking on the significance of a diagnosis of APD in MAT. Some studies have found that patients with

co-occurring APD had less favorable outcomes than those without this disorder, even if the former group received additional psychotherapy (e.g., Alterman et al. 1998; Galen et al. 2000). Others have found that patients with APD in MAT improved to the same extent, on average, as those without APD (e.g., Cacciola et al. 1995; Darke et al. 1996), although the former group had more severe symptoms at both entry and followup. This lack of consistent findings has led some researchers to question the clinical utility, reliability, or validity of DSM-IV-derived APD diagnoses in MAT patients (Alterman et al. 1998; Cacciola et al. 1995). Darke and colleagues (1998) expressed concern that people addicted to opioids might be diagnosed with APD as a reflection of their risk-taking and drug-dealing lifestyles rather than actual existence of their underlying personality disorders.

Patients with APD can improve in MAT, and OTPs should be prepared to manage and limit aggressive, impulsive, or criminal behaviors by patients, regardless of whether the behaviors are related to a DSM-based diagnosis of APD.

Effects of co-occurring PTSD on progress in MAT

Increasing attention has been paid to the high prevalence and negative effects of PTSD on patients in MAT, especially women (Villagomez et al. 1995). Hien and colleagues (2000) found that women with symptoms of PTSD at admission were significantly less likely than those without such symptoms to adhere to treatment requirements, including abstinence from substances during the first 3 months of MAT. In another study, patients with current PTSD symptoms had greater drug abuse severity (Clark et al. 2001). These patients may need special attention paid to depression and suicidal ideation (Villagomez et al. 1995). TIP 36, ***Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues*** (CSAT 2000***d***), and TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***), provide more information on PTSD and substance abuse treatment.

Effects of co-occurring AD/HD on progress in MAT

King and associates (1999) studied 125 people admitted to OTPs over a 1-year period to determine the relationship of AD/HD to current attention problems, other co-occurring and substance use disorders, and other outcome variables. Nineteen percent of patients had a history of AD/HD, and 88 percent with lifetime AD/HD diagnoses had current symptoms of AD/HD. Although patients with AD/HD showed poorer attention during continuous performance testing and more concurrent Axis I and II disorders (e.g., dysthymia, anxiety disorders including social phobia, APD) than those without AD/HD, the AD/HD diagnosis was not a significant predictor of decreased treatment retention, poor treatment compliance, or continuing substance abuse.

> [P]atients with severe symptoms may require longer, more intensive treatment.

Treatment Issues

General Treatment Considerations for Patients With Co-Occurring Disorders

Clearly, co-occurring disorders should not exclude people with opioid addiction from admission to an OTP. The consensus panel believes that the best strategy is to stabilize these patientsí opioid addiction with methadone, buprenorphine, or levo-alpha acetyl methadol (LAAM) while assessing their co-occurring disorder symptoms and choosing the most appropriate treatment course. Although OTP staff members often focus on

the condition that is most severe and threatening, it usually is best to address all of a patientís disorders simultaneously because each can influence the others. TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***), provides information about treatment planning and implementation for this group.

> [C]o-occurring disorders should not exclude people with opioid addiction from admission to an OTP.

The consensus panel believes that the following principles are essential to manage patients with co-occurring disorders in an OTP:

- Treatment of co-occurring disorders should be integrated or closely coordinated with substance abuse treatment when the former is not available on site.
- Staff members, whether primarily from the substance abuse treatment or mental health fields, should be knowledgeable about treatments for both disorders.
- Psychotropic medications should be prescribed only after patients are stabilized on the treatment medication (which in the panelís experience takes an average of 3 to 7 days for buprenorphine and 3 weeks to a month for methadone), unless an independent co-occurring disorder is evident from past records or clinical examination or significant impairment associated with the symptoms of a co-occurring disorder exists.
- All medications used by patients and patientsí adherence to medication regimens should be monitored carefully, for example, via drug testing. Physicians should be careful about prescribing substances with abuse potential, such as benzodiazepines. If such medications are prescribed, the less abusable drugs in a class should be chosen, for example, oxazepam (Serax®) rather than lorazepam, clonazepam, alprazolam or diazepam.
- Patients resistant to being psychiatrically diagnosed should be assured that it is not shameful but is likely to provide a better understanding of their problems and aid in treatment. Educating patients about co-occurring disorders helps.
- Therapy for patients with co-occurring disorders should be more intensive, on average, than for patients without co-occurring disorders. The primary goal is abstinence from substances. Remission of co-occurring disorder symptoms should be an important secondary goal.

Co-Occurring Disorders and Treatment Planning

Because patients in MAT exhibit a wide range of co-occurring disorders, the consensus panel believes that early treatment planning and resource management should include classifying patients, at least tentatively, into categories based on types and severity of co-occurring disorders, although treatment always should be tailored individually.

Patients in acute psychiatric danger

Patients presenting with suicidal or homicidal ideation or threatsówhether resulting from acute intoxication or withdrawal or from an independent co-occurring disorderóor those manifesting psychotic symptoms (e.g., hallucinations, paranoia) that may interfere with their safety and ability to function should be assessed and treated immediately. Although their symptoms may be short lived, admission to a psychiatric unit for brief treatment may be necessary if outpatient care is too risky or problematic. Immediate administration of antipsychotic drugs, benzodiazepines, or other sedatives may be required to establish behavioral control (Minkoff 2000). A physician, physicianís assistant, or nurse practitioner on staff can prescribe medications at the OTP. Otherwise,

referral is warranted. In emergencies, OTPs should send patients to affiliated hospital emergency rooms (see ìHandling Emergency Situationsî below).

Patients with established, severe co-occurring disorders

Patients in MAT who are not in acute danger but have been diagnosed or treated for severe co-occurring disorders (e.g., schizophrenia, bipolar disorder) should receive medication with the lowest abuse potential for their condition. If an OTP is staffed appropriately and prepared to treat patients with severe co-occurring disorders, these patients can be treated on site. Otherwise, they should be referred to an OTP with these qualifications. If there is no such OTP, patients may need to remain in a less optimal OTP but receive psychiatric treatment at another facility. For referrals, effective communication between OTPs and mental health providers is necessary to coordinate treatment.

Patients with less severe, persisting or emerging symptoms of co-occurring disorders

Patients in MAT with nondisabling symptoms of less severe co-occurring disorders (e.g., mood, anxiety, and personality disorders), psychiatric treatment histories, or verified diagnoses and current prescriptions for medications to treat such disorders (regardless of whether they are used) should continue or begin medication, psychotherapy, or both for their co-occurring disorders. These patients should continue in MAT if the OTP is staffed to treat them. Although it is desirable for patients to be stabilized on methadone, buprenorphine, or LAAM before other pharmacotherapy is initiated, newer medications with relatively benign side effects can be initiated sooner (e.g., selective serotonin reuptake inhibitors [SSRIs]) if a primary mental disorder is indicated. Such medications may facilitate engagement in MAT and addiction recovery (Minkoff 2000).

Patients with less severe, presumptively substance-induced co-occurring disorders

The consensus panel recommends that patients in MAT with symptoms of Axis I disorders but no history of primary co-occurring disorders receive no new psychotropic medications until they are stabilized on MAT because their symptoms might remit or significantly diminish after a period of substance abuse treatment (Joe et al. 1995). Exceptions include patients who have acute, substance-induced disorders such as extreme anxiety or paranoia that are likely to be transitory but require temporary sedation or antianxiety medication.

Effects of Co-Occurring Disorders on HIV Risk Behaviors and Comorbidity

King and colleagues (2000) found that patients with co-occurring disorders in MAT were at higher risk for contracting and transmitting HIV than those without these disorders. In another study, patients who were HIV seropositive and had co-occurring disorders were more likely than those without co-occurring disorders to continue using drugs, less likely to be prescribed HIV medications or to adhere to medication regimens, and more likely to develop AIDS (Ferrando et al. 1996). People with co-occurring disorders, particularly depression or dysthymia, were more likely than those without Axis I disorders to continue needle sharing and other high-risk behaviors (Camacho et al. 1996). Patients in MAT who injected drugs and had APD were at higher risk for contracting and spreading HIV (Brooner et al. 1993). To decrease the spread of HIV, it is important to treat both substance use and co-occurring disorders and provide education and support for patients who inject drugs. More information on HIV/AIDS and substance abuse treatment, including the combined treatment of HIV/AIDS, substance abuse, and mental illness, can be found in TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** (CSAT 2000***e***).

Models of Care

Although it is not always feasible to provide more specialized services on site, patient adherence to medical treatment was found to drop dramatically when such services were provided through offsite referral (Batki et al. 2002). Even when referrals are to services near an OTP, noncompliance may have significant consequences for personal, social, and public health.

If a program cannot provide onsite ancillary services, it is important that staff members identify co-occurring disorders early so that they can refer patients to appropriate resources. It is essential to monitor patient progress and compliance with offsite treatment, which can be done by a counselor, case manager, nurse, or physicianís assistant or by assigning one staff member to coordinate and monitor all referrals. Offsite referrals also may be necessary to obtain psychotropic medications and evaluate patientsí reactions to them.

Handling Emergency Situations

A high percentage of patients with co-occurring disorders in MAT have reported suicide attempts or difficulty controlling violent behavior during their lifetimes (Cacciola et al. 2001). Patients who present an acute danger to themselves or others or have psychotic symptoms or disordered thinking that could interfere with their safety or that of others should receive immediate, aggressive intervention on admission and throughout treatment. Staff members should be trained to notice indications of suicidal or homicidal risks. These observations should be documented and communicated to designated staff members who can take necessary action, including appropriate medication, notification of family members and involved agencies (e.g., probation office, childrenís protective services), or transfer of patients to more secure or protective settings. Staff members should understand thoroughly and be prepared to act on an OTPís ìduty to warnî (CSAT 2004***b***) about potentially violent behavior by patients.

Risk factors and predictors for suicidal ideation and threats

People who are opioid addicted have high rates of suicide and attempted suicide, ranging from 8 to 17 percent in some studies with even higher rates among certain groups (Krausz et al. 1996). Substance intoxication or withdrawal can cause or exacerbate suicidal ideation or threats, and the presence of co-occurring disorders further increases the risk. Chapter 4 discusses risk factors for suicide and recommended treatment responses. Risk factors do not predict individual behavior, but a high-risk profile merits immediate and ongoing attention (Chatham et al. 1995***a***; Hall et al. 1999). In one study of suicidality among patients in an OTP, the strongest predictors of suicide risk were psychosocial dysfunction (e.g., depression, social withdrawal, hostility toward friends and family), help-seeking behaviors (e.g., previous treatment episodes, attendance at mutual-help meetings, self-referral), and perceived lack of support from others (Chatham et al. 1995***a***).

At least two studies of patients in MAT who overdosed on opioids concluded that overdoses usually were accidental and not predictive of subsequent suicide attempts. In an early work, Kosten and Rounsaville (1988) found that accidental overdoses were three times more likely than suicidal ones. More recently, Darke and Ross (2001) reported that 92 percent of patients who overdosed characterized the overdose as accidental. In that study, of the 40 percent who acknowledged a previous suicide attempt, only 10 percent deliberately overdosed with heroin compared, for example, with 21 percent who deliberately overdosed with benzodiazepines.

Protocol for identifying and handling suicide and homicide risk

All intake workers, certified addiction counselors, and clinicians should be alert to risk factors for suicide and homicide and should question at-risk patients routinely about suicidal or homicidal thoughts or plans. This is

important for patients who appear withdrawn, depressed, angry, or agitated or are known to have experienced a recent significant loss or other source of stressóespecially if a co-occurring disorder is suspected or diagnosed or if a patient still is intoxicated or withdrawing from a psychoactive substance. Although the consensus panel believes such screening is helpful, the research evidence supporting its effectiveness is limited (Kachur and DiGuiseppi 1996).

To aid in screening and referral for suicidality and homicidality, all programs should have protocols in place that specify

- Who asks what questions or uses what specific tool to identify these types of risk
- How identified risks are documented
- Who is informed about risks and is responsible for taking actions and what resources he or she can use (e.g., medications, referral/transfer, family involvement).

Any patient suspected of suicide or homicide risk should be referred immediately to a mental health clinician for further evaluation. If the OTP has no psychologist, clinical social worker, or psychiatrist on staff, it should have arrangements for rapid consultations. Decisions should be made about using antipsychotic medications, benzodiazepines, or other sedatives to establish behavioral control rapidly (Minkoff 2000). Such medications may be needed to alleviate or control symptoms until other mood stabilizers or antidepressants take hold, which can take several weeks. Medication-assisted treatment of acute suicidality should be on an inpatient basis unless family members or friends are willing to be responsible for administering the drugs regularly, keeping the at-risk patient safe, and monitoring his or her reactions.

Patients identified as being at imminent risk of committing suicide or homicide might need hospitalization for short-term observation. Some key factors in this decision are clearly expressed intent, specific and lethal plans, accessible means, limited social or familial resources, severe symptoms of mental illness or psychosis, command hallucinations, hopelessness, and previous suicide or homicide attempts. If a referral is made, the patient should not be left alone until responsibility for monitoring safety is transferred to the referred facility.

Counseling, Psychotherapy, and Mutual-Help Groups for People With Co-Occurring Disorders in MAT

Chapter 8 discusses counseling, case management, and psychotherapy for patients in MAT. Programs should encourage participation in mutual-help groups that focus on the needs of people with co-occurring disorders. Exhibit 12-3 lists some of the best known of these groups, along with contact information.

Exhibit 12-3

Mutual-Help Groups for People With Co-Occurring Disorders

- Double Trouble in Recovery (www.doubletroubleinrecovery.org)
- Dual Recovery Anonymous (www.draonline.org)
- Dual Disorders Anonymous (847-781-1553 or P.O. Box 681268, Schaumburg, IL 60168)
- Dual Diagnosis Recovery Network (www.dualdiagnosis.org) (active mostly in California)

Psychoeducation for Patients With Co-Occurring Disorders in MAT

Group sessions presenting information about topical issues can help patients with co-occurring disorders and their families. Patients can explore relevant themes by emphasizing positive coping strategies and sharing experiences. Possible topics for psychoeductional groups are presented in Exhibit 12-4.

Pharmacotherapy for Patients With Co-Occurring Disorders in MAT

Several pharmacological treatments for co-occurring disorders are available and should be used when indicated. Most medications are more effective when used with counseling or psychotherapy in comprehensive MAT.

In many ways, an OTP is an optimal setting to initiate and monitor psychiatric pharmacotherapy for co-occurring disorders because patients attend daily (at least in the early stages of treatment) and onsite physicians and other staff can observe their reactions to psychotropic medications as well as to methadone or other addiction treatment medications.

When psychotropic medications are used in an OTP, they should be prescribed

- In a comprehensive program that integrates medical, psychiatric, and social interventions and supports patient compliance with medication dosing schedules.

Exhibit 12-4

Topics for Psychoeducational Groups for People With Co-Occurring Disorders

- Causes, symptoms, and treatment for substance use and co-occurring disorders
- Medical and mental effects of co-occurring disorders
- Psychosocial effects of co-occurring disorders
- The recovery process for co-occurring disorders
- Medications to treat co-occurring disorders, their side effects, and medication management
- Coping with cravings, anger, anxiety, boredom, and depression
- Changing negative or maladaptive thinking
- Developing a sober support system
- Addressing family issues
- Learning to use leisure time constructively
- Spirituality in recovery
- Joining 12-Step and co-occurring disorder recovery mutual-help groups
- Risk factors in ongoing recovery
- Understanding and getting maximum benefits from psychotherapy and counseling

Adapted from Daley 2000.

- In the context of a multidisciplinary-team approach in which regularly scheduled team meetings ensure that all members are aware of the patientís progress in treatment.
- With careful selection of medications because some patients may attempt to get high on any medication prescribed. Some medications (e.g., amitriptyline, tramadol, benzodiazepines) have little abuse potential in other populations but pose a significant risk of abuse in this population (Cicero et al. 1999).

If patients in an OTP are prescribed other medications in addition to addiction treatment medications, the consensus panel recommends the following procedures:

- All prescribed psychotropic medications should be to treat suspected or confirmed co-occurring disorders, not to alleviate normal discomfort (Minkoff 2000).
- Fixed, rather than ìprnî or ìas needed,î doses of psychotropic medications should be prescribed because, especially early in MAT, patients addicted to opioids have difficulty regulating medications of any kind (Minkoff 2000). Whenever possible, given resource availability, potentially abusable medications should be dispensed by OTP staff along with addiction treatment medication.
- Patients receiving psychotropic medications should be educated about each drugís expected benefits, potential disadvantages and limitations, side effects, implications for pregnancy and breast-feeding, length of time before full effects should begin, and potential to cause tolerance and withdrawal. This education can be done individually or in a group, but all information should be communicated both in writing and orally.
- An onsite (full- or part-time) physician or psychiatrist should have regular contact with each patient with a co-occurring disorder to review medication response and compliance. This professional also should supervise counselor interactions with these patients and participate in team meetings to discuss treatment plans.

OTPs should consider a hierarchical approach to treating patients with co-occurring disorders, starting with psychosocial interventions such as increased counseling or psychotherapy (unless the patient has a disorder clearly needing medication). Depending on severity and acuity of symptoms, treatment providers may be able to use nonpharmacological approaches such as psychotherapy, either alone or with psychiatric medications. If these psychosocial approaches are ineffective or of limited benefit, providers should select psychiatric medications with the lowest abuse potential that are likely to be effective. TIP 37, ***Substance Abuse Treatment for Persons With HIV/AIDS*** (CSAT 2000***e***, pp. 83ñ84), provides a summary of abuse potential for psychiatric medications. The psychiatric medications should be, in most instances, adjunctive to other ongoing interventions, not a substitute for them. However, other factors to consider include

- The potential effect of medication side effects on compliance
- Potential negative interactions with addiction treatment medication or other drugs
- Lethality if the drug is used impulsively or intentionally for suicide
- Potential effects on a patientís physical conditionófor example, whether the drug might injure an already damaged liver or increase blood pressure in a hypertensive patient.

Some studies have found that methadone may, by itself, relieve some symptoms of mood and anxiety disorders but not Axis II personality disorders (Calsyn et al. 2000***a***; Musselman and Kell 1995). From a practical viewpoint and assuming sufficient time to observe patients before further intervention, the consensus panel believes that the best approach is careful observation during the first weeks of MAT to determine whether symptoms of co-occurring disorders diminish before psychiatric medications are considered.

Medications for major depression and bipolar disorder

The hierarchical approach described in the previous two paragraphs for treating patients in MAT with co-occurring disorders should be used to determine which patients diagnosed with major depression or bipolar disorder may benefit from antidepressant medication. Exhibit 12-5 summarizes interactions of some

Exhibit 12-5

Interactions of Some Medications for Depression and Bipolar Disorder With Methadone and Recommended Treatment Response in MAT

Medication Type and Examples	Action With Methadone	Recommended Treatment Response
SSRIs fluvoxamine (Luvox®), fluoxetine (Prozac®), sertraline (Zoloft®)	Some SSRIs inhibit metabolism of methadone and increase methadone blood levels (Eap et al. 1997). Fluoxetine and sertraline do not increase methadone levels significantly. Fluvoxamine is the most dangerous SSRI and should be avoided for patients in MAT.	Observe patients carefully for signs of methadone overmedication during the first weeks of treatment with SSRIs. Methadone withdrawal symptoms may occur after discontinuation of fluvoxamine.
Carbamazepine (Tegretol®)	Carbamazepine speeds production of liver enzymes that metabolize methadone and can cause severe opioid withdrawal symptoms (Eap et al. 2002).	Avoid carbamazepine and use alternatives such as valproate (Depakote®). Increase and/or split the methadone dosage to increase its blood levels.
Tricyclics desipramine, nortriptyline, imipramine, doxepin	Methadone impairs the metabolism of tricyclics and can cause increased tricyclic medication blood levels (Maany et al. 1989).	Adjust doses of tricyclic medications as needed; monitor blood levels if clinically indicated.
Monoamine oxidase (MAO) inhibitors	MAO inhibitors may have dangerous interactions with certain foods and substances of abuse (Kleber 1983).	Use extreme caution in prescribing these medications in MAT.
Lithium	None.	Monitor closely because window between therapeutic and toxic dose is narrow.

antidepressant medications with methadone and recommended treatment response. Antidepressants have been used successfully to treat depression in patients in MAT. One example is a study of patients with chronic depression who were treated with the tricyclic imipramine or a placebo. Fifty-seven percent of imipramine-treated patients showed both significant improvement in mood and some decreases in illicit drug use according to self-reports, compared with only 7 percent of placebo patients who reported results (Nunes et al. 1998***a***). However, no significant reductions in substance use were found between the two groups based on drug testing. There is no theoretical reason to presume that tricyclic medications are unique among antidepressants improving mood, and SSRIs are much safer and may be the preferred treatment. Antidepressants also may be helpful for anxiety disorders.

Bipolar disorder in patients in MAT can be treated with antipsychotic or mood-stabilizing medications. Mood stabilizers shown to be effective include lithium, valproate, and carbamazepine (Hellewell 2002). Lamotrigine (Lamictal®) also has been shown to be effective.

Anxiety disorders

Anxiety disorders, including panic disorder, PTSD, and others, can be treated with psychotherapy, pharmacotherapy, or both. These disorders can be treated effectively with antidepressant medications such as the SSRIs, venlafaxine (Effexor®), and the tricyclics. Patients sometimes respond better to one drug class or a specific drug in a class. Therefore, another antidepressant should be considered if patients do not respond to their first one after a 4- to 8-week trial. Some antidepressants also have sedative effects (e.g., mirtazapine [Remeron®], trazodone, and some tricyclic antidepressants), which might be beneficial for patients with insomnia when these drugs are taken before bedtime, or for patients with high levels of anxiety. Nonsedating antidepressants might be especially useful for patients with psychomotor inhibition.

The well-documented abuse potential of benzodiazepines has led to a common belief that they are contraindicated in patients receiving methadone. However, evidence suggests major differences in the abuse liability of benzodiazepines. Those with a slower onset of action such as oxazepam rarely are mentioned as substances of abuse, have a wide margin of safety, and are effective in reducing anxiety, even over extended periods (Sellers et al. 1993). Several case reports have indicated that benzodiazepines, particularly those with low abuse liability, may be used safely for patients with substance use disorders (Adinoff 1992; Sellers et al. 1993). Sellers and colleagues also found a ìserious pattern of nontherapeutic benzodiazepine use . . . among opiate-dependent persons, particularly those in methadone maintenance treatment programsî (1993, p. 72), leading these authors to recommend that ìif benzodiazepine is used [with this group], those with an apparently low abuse potential are generally preferable.î

The consensus panel believes that patients who have a history of benzodiazepine abuse should not be disallowed from receiving previously prescribed benzodiazepines, provided that they are monitored carefully and have stopped the earlier abuse. They may be attempting to reduce symptoms of co-occurring disorders, and, when they receive a prescribed medication with low abuse liability and are monitored for their co-occurring anxiety and substance use disorders, improvement and cessation of other benzodiazepine use may occur naturally. Some drug-testing laboratories can determine specific types of benzodiazepines used. If such a resource is available, testing can determine whether patients are using only their prescribed benzodiazepines or supplementing them with others obtained illicitly. The latter would indicate a need to change patientsí treatment plans.

AD/HD

Stimulants such as methylphenidate (Ritalin®) are the treatment of choice for childhood AD/HD. Stimulant treatment in adulthood also is potentially effective but carries the obvious

risk of abuse by patients in MAT. Use of cocaine could be an attempt to control symptoms of AD/HD (Levin et al. 1998). If AD/HD is severe, treatment providers should consider treatment with medications such as methylphenidate, amphetamine, or atomoxetine (Strattera®) because these medications reduce AD/HD symptoms and address cocaine or other stimulant use. However, they should be monitored carefully because some patients have abused them by injection, and medical complications can result from long-term injection use. Tricyclic antidepressants also are effective for some patients in MAT with co-occurring AD/HD and depression (Higgins 1999), and these drugs carry no addiction liability. Recently, the nonstimulant atomoxetine was approved to treat AD/HD and may prove advantageous for patients in MAT with co-occurring AD/HD. However, because atomoxetine is metabolized by the cytochrome P450 system of liver enzymes, the potential for interaction with methadone exists, and it should be used cautiously until more information is available.

Schizophrenia

Patients in MAT who have schizophrenia often have profound impairment in thinking and behavior and are unlikely to fit in well in many OTPs. Antipsychotic medication, along with psychosocial intervention, is the mainstay of treatment. Newer atypical antipsychotic medications for schizophrenia are preferred over older ìtypicalî agents, which carry a risk of movement disorders such as tardive dyskinesia, a neurological syndrome caused by long-term use of neuroleptic medications (National Institute of Neurological Disorders and Stroke 2001).

Newer antipsychotic medications (clozapine [Clozaril®, olanzapine [Zyprexa®], risperidone [Risperdal®]), quetiapine, ziprasidone [Geodon®], and aripiprazole [Abilify®]) have fewer side effects, are more effective in many cases, and should be considered as the initial treatment for some patients or as a second option for those not responding to more traditional medications. TIP 42, ***Substance Abuse Treatment for Persons With Co-Occurring Disorders*** (CSAT 2005***b***), provides more information.

Collaboration Between Counselors and Physicians

Many counselors have little or no psychiatric background and need training in

- Working with patients who may have co-occurring disorders but who resist evaluation or respond only partially to treatment
- Exploring stereotypes and feelings about what it means to have a co-occurring disorder
- Helping patients keep physician appointments, understand information, and follow physician recommendations
- Supporting patients to try medication if recommended
- Supporting patients to tolerate side effects long enough to determine whether medications help
- Providing guidance about when to contact a physician to report side effects or lack of relief from or worsening symptoms
- Supporting patients to continue taking medication, even when they feel better.

Physicians need training or guidance in

- Providing education to OTP staff about co-occurring disorders and medications
- Recognizing common misunderstandings about and resistances to medication in addiction treatment
- Creating protocols that make good use of counselor ability to provide detailed observations and ongoing feedback on patientsí conditions (Zweben 2003).

Appendix 12-A. Internet Resources for Accessing Psychiatric Instruments

- **Comorbidity and Addictions Center: George Warren Brown School of Social Work** (www.gwbweb.wustl.edu/Users/cac/measurescollection.htm). Lists 175 instruments for measuring aspects of substance use and psychopathology with hyperlinks to descriptions. Information for each measure or scale includes purpose, authors, key references, target populations, variables, administration and scoring options, and time estimates as well as copyright, cost, and ordering information.
- **Medical Outcomes Systems, Inc.** (www.medical-outcomes.com). Contains a description of the Mini International Neuropsychiatric Interview as well as downloadable versions of all M.I.N.I. instruments, including the screen version and standard and expanded (Plus) 5.0.0 editions (January 2002). Although materials are protected by copyright, researchers and clinicians working in nonprofit or publicly owned settings (e.g., universities, teaching hospitals, government institutions) may make copies for clinical or research purposes.
- **National Institute on Alcohol Abuse and Alcoholism** (www.niaaa.nih.gov/publications). Provides access to information first published in ***Assessing Alcohol Problems: A Guide for Clinicians and Researchers*** (Allen and Columbus 1995). The site specifies useful measures for screening, diagnosing, and planning treatment for alcohol-related and other psychoactive substance use disorders, as well as co-occurring disorders. The site also includes information on administration and scoring options, estimated times for administration, key variables, groups on which normative data for the instrument were based, psychometric properties, and ordering costs.
- **University of Adelaide (Australia) Library Guide** (www.library.adelaide.edu.au/guide/med/menthealth/scales.html). Contains a list of psychiatric rating scales and information about where copies and descriptions of these instruments can be obtained, hyperlinks to electronic versions, and references on developmental history and psychometric properties of each instrument.

13 Medication-Assisted Treatment for Opioid Addiction During Pregnancy

In This Chapter...

Little information exists on the prevalence of opioid use by pregnant women, but there is some information about opioid use by pregnant women entering substance abuse treatment programs. Of the 400,000 women admitted to programs in 1999, 4 percent were pregnant when admitted. Opioids were the primary substance of abuse for 19 percent of both pregnant and nonpregnant women who entered these programs (Office of Applied Studies 2002).

Acceptance of Methadone Maintenance as the Standard of Care

Methadone has been accepted since the late 1970s to treat opioid addiction during pregnancy (Kaltenbach et al. 1998; Kandall et al. 1999). In 1998, a National Institutes of Health consensus panel recommended methadone maintenance as the standard of care for pregnant women with opioid addiction (National Institutes of Health Consensus Development Panel 1998). Methadone currently is the only opioid medication approved by the U.S. Food and Drug Administration (FDA) for medication-assisted treatment for opioid addiction (MAT) in pregnant patients. Buprenorphine is classified as a category C drug by FDA (i.e., one lacking adequate, well-controlled studies in pregnant women) and, at this writing, is not FDA approved to treat pregnant women, although several studies have found it safe and effective in this group (e.g., Fischer et al. 2000; Lacroix et al. 2004). Even though it is a category C drug, buprenorphine may be used with pregnant patients in the United States under certain circumstances (see ìUse of Buprenorphine During Pregnancyî later in this chapter).

Effective medical maintenance treatment with methadone has the same benefits for pregnant patients as for patients in general. In addition, methadone substantially reduces fluctuations in maternal serum opioid levels, so it protects a fetus from repeated withdrawal episodes

(Kaltenbach et al. 1998). Comprehensive methadone maintenance treatment that includes prenatal care reduces the risk of obstetrical and fetal complications, in utero growth retardation, and neonatal morbidity and mortality (Finnegan 1991).

Diagnosing Opioid Addiction in Pregnant Patients

In the consensus panelís experience, some women who are opioid addicted do not acknowledge pregnancy readily, or they misinterpret early signs of pregnancy, for example, fatigue, headaches, nausea and vomiting, and cramps, as opioid withdrawal symptoms. Consequently, onset of pregnancy may cause these patients to increase their use of illicit opioids or other substances that do not alleviate their perceived withdrawal symptoms but expose their fetuses to increased serum levels of these substances.

Many women who are opioid addicted confuse the amenorrhea caused by their stressful, unhealthful lifestyles with infertility. They might have been sexually active for years without using contraceptives and becoming pregnant. The consensus panel has noted that, because methadone normalizes endocrine functions, it is not unusual for women in the early phases of MAT to become pregnant unintentionally, especially if they receive no counseling for this possibility.

Procedures for diagnosing opioid and other addictions in pregnant women should incorporate information from their medical and substance use histories, physical examinations, drug test reports, and observed signs or symptoms of withdrawal. Other indications of addiction may include evidence of diseases associated with drug use (e.g., hepatitis, bacterial endocarditis, cellulitis), poor attendance for prenatal care, and unexplained fetal growth abnormalities (e.g., intrauterine growth retardation). Using an opioid antagonist to diagnose addiction in pregnant women is ***absolutely contraindicated*** (Finnegan 1991); inducing even mild withdrawal can cause premature labor or other adverse fetal effects.

Medical and Obstetrical Concerns and Complications

Pregnant women who abuse substances, including alcohol and nicotine, have a greater-than-normal risk of medical complications. These women should be monitored regularly for signs of anemia, poor nutrition, increased blood pressure, hyperglycemia, sexually transmitted diseases (STDs), hepatitis, preeclampsia, and other complications of pregnancy or health problems related to addiction. Good nutrition, including vitamin supplements, should be encouraged. Pregnant women should be educated about the potential adverse effects of substance use on their fetuses, such as fetal alcohol syndrome and premature labor associated with opioid withdrawal or stimulant use. Patient use of prescribed medications other than methadone should be monitored for compliance with usage directions and for adverse effects.

Chronic substance use in pregnancy can cause medical complications (some are listed in Exhibit 13-1), depending on how substances are administered and when or whether problems are identified and treated. Infections account for a high percentage of these complications in pregnant women who are opioid addicted, as they do in all people who abuse opioids (see chapter 10). Infections can be profoundly harmful to both women and their fetuses, particularly if infections remain unrecognized and untreated during gestation. Hepatitis B and C, bacterial endocarditis, septicemia, tetanus, cellulitis, and STDs are especially frequent (Finnegan 1991).

The rate of vertical perinatal transmission of hepatitis B virus (HBV) is high (ranging from 70 to more than 90 percent [Centers for Disease Control 1988***b***; Ranger-Rogez et al. 2002]), especially if a pregnant woman has active infection (determined by a positive

Exhibit 13-1

Common Medical Complications Among Pregnant Women Who Are Opioid Addicted

Anemia	STDs
Bacteremia/septicemia	Chlamydia
Cardiac disease, especially endocarditis	Condyloma acuminatum
Cellulitis	Gonorrhea
Depression and other mental disorders	Herpes
Edema	HIV/AIDS
Gestational diabetes	Syphilis
Hepatitis (acute and chronic)	Tetanus
Hypertension/tachycardia	Tuberculosis
Phlebitis	Urinary tract infections
Pneumonia	Cystitis
Poor dental hygiene	Pyelonephritis
	Urethritis

Adapted from Finnegan 1979.

hepatitis B antigen test) in the third trimester or within 5 weeks postpartum. If a new motherís hepatitis B antigen test is positive, the neonate should receive both hepatitis B vaccine and hepatitis B immune globulin (Kaltenbach et al. 1998). The rate of perinatal transmission of hepatitis C virus (HCV) is lower than that of HBV, as discussed below; however, vaccines exist for hepatitis A virus and HBV but not for HCV. Recommended laboratory tests for pregnant women who are opioid addicted are listed in Exhibit 13-2.

HCV

Pregnant women with a history of injection drug use are at high risk for HCV infection and should be screened for anti-HCV antibody. HCV ribonucleic acid (RNA) testing should be performed if an anti-HCV antibody test is positive. The results facilitate referral for further evaluation, staging, and treatment of liver disease after delivery. Infants whose mothers have hepatitis C should receive HCV RNA testing along with antibody testing for HCV between ages 2 and 6 months and again between 18 and 24 months (Roberts and Yeung 2002).

During pregnancy, HCV can be transmitted vertically from mother to fetus. However, multiple studies have shown low overall HCV vertical transmission risk and greater risk from factors such as HIV co-infection or high HCV viral load (Roberts and Yeung 2002). Vaginal delivery and breast-feeding do not appear to increase the risk of neonatal HCV infection significantly (Dinsmoor 2001; Roberts and Yeung 2002). Available treatments to prevent vertical

Exhibit 13-2

Laboratory Tests for Pregnant Women Who Are Opioid Addicted

ï Complete blood count with differential and platelets ï Chemistry screen (K, Na, Cl, Ca, P, CO_2, creatinine, blood glucose, blood urea nitrogen, total bilirubin, total serum protein albumin) ï Hepatic panel (liver function tests) ï Hepatitis B surface antigen (full panel if positive) ï Hepatitis C antibody ï Rubella titer ï Serology (Venereal Disease Research Laboratory or Rapid Plasma Reagin tests) ï Sickle prep (if appropriate) ï Blood type; Rh and indirect Coombs Varicella (if unsure of history) ï HIV (with counseling)	ï Urine tests Urinalysisóroutine and microscopic Urine culture and sensitivity Urine drug screen ï Tuberculin skin test (Mantoux) ï Alpha-fetoprotein between 15 and 21 weeksí gestation (optimal, 16 to 18 weeks) ï 1-hour, 50 mg glucose challenge test at 24 to 28 weeksí gestation (at initial visit if risk factors) ï Repeat complete blood count and serology at 24 to 28 weeksí gestation ï Group B Strep vaginal-rectal culture at 35 to 37 weeksí gestation

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transmission, however, are limited by the fetal toxicity of the medications currently available for HCV infection.

HIV/AIDS

Pregnant women who are opioid addicted and HIV positive present a unique treatment problem. A limited number of studies with small numbers of patients have examined the relationship of HIV, methadone, and immune function (e.g., Beck et al. 2002; Siddiqui et al. 1993). These studies have not been replicated widely. Therefore, it is difficult to conclude any significant relationship involving HIV, methadone, and immune function until additional studies are completed. Studies on the combined effects of HIV antiretroviral treatment and methadone especially are needed.

During the early 1990s, before effective prevention treatments were available, studies in North America and Europe found mother-to-child or perinatal HIV transmission rates of 16 to 25 percent. However, between 1996 and 2000, after the implementation of new guidelines, studies in the United States found transmission rates of 5 to 6 percent, and more recent studies have found rates below 2 percent when antenatal antiretroviral drugs or zidovudine (AZT) is combined with cesarean section (Centers for

Disease Control and Prevention 2001*b*). Although AZT prophylaxis reduces the risk of perinatal HIV infection, monotherapy often is inadequate to treat a motherís HIV disease. Combination antiretroviral therapy is now the standard of care (Paul et al. 2001).

Studies in the United States and Europe have found that pregnancy has no effect on HIV progression (Burns et al. 1998; Saada et al. 2000). Studies before the availability of antiretroviral therapy showed no increase in prematurity, low birth weight, or intrauterine growth restriction associated with HIV infection. These data are difficult to interpret because of relatively high rates of adverse events in the control groups attributed to other conditions such as substance abuse (Brocklehurst and French 1998; Bucceri et al. 1997). Studies have not found increases in birth defects or fetal malformation related to HIV infection (Brocklehurst and French 1998).

The consensus panel recommends that women who are opioid addicted and HIV infected receive additional counseling and support during the postpartum period to improve their adherence to antiretroviral therapy and to meet the demands of caring for a newborn. Breast-feeding by HIV-infected women has been associated with an increased risk of HIV transmission and should be discouraged (Nduati et al. 2000).

Obstetrical Complications

Obstetrical complications in pregnant women who are opioid addicted are the same as those seen at increased rates in all women who lack prenatal care (see Exhibit 13-3). These complications may be difficult to diagnose in patients who are opioid addicted because they often deny the existence of complications or avoid medical settings. When obstetrical complications are confirmed, standard treatments, including use of medications to arrest preterm labor, can be initiated safely.

Methadone Dosage and Management

The pharmacology of methadone in pregnant women has been evaluated thoroughly. Methadone is distributed widely throughout

Exhibit 13-3

Common Obstetrical Complications Among Women Addicted to Opioids

Abruptio placentae	Postpartum hemorrhage
Chorioamnionitis	Preeclampsia
Intrauterine death	Premature labor/delivery
Intrauterine growth retardation	Premature rupture of membranes
Intrauterine passage of meconium	Septic thrombophlebitis
Low Apgar scores	Spontaneous abortion
Placental insufficiency	

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the body after oral ingestion, with extensive nonspecific tissue binding creating reservoirs that release unchanged methadone back into the blood, contributing to methadoneís long duration of action (Dole and Kreek 1973). Peak plasma levels occur between 2 and 6 hours after a maintenance dose of methadone is ingested, with less than 6 percent of the ingested dose in the total blood volume at this time. Lower sustained plasma concentrations are present during the remainder of a 24-hour period (Stine et al. 2003).

As pregnancy progresses, the same methadone dosage produces lower blood methadone levels, owing to increased fluid volume, a larger tissue reservoir for methadone, and altered opioid metabolism in both the placenta and fetus (Weaver 2003). Women who are methadone maintained often experience symptoms of withdrawal in later stages of pregnancy and require dosage increases to maintain blood levels of methadone and avoid withdrawal symptoms (Jarvis et al. 1999; Kaltenbach et al. 1998). The daily dose can be increased and administered singly or split into twice-daily doses (Kaltenbach et al. 1998).

> [M]ethadone dosages for pregnant women [should] be determined individually to achieve an effective therapeutic level.

Historically, treatment providers have based dosing decisions on the need to avoid or reduce the incidence of neonatal abstinence syndrome (NAS) (Kaltenbach et al. 1998; Kandall et al. 1999) rather than to achieve an effective therapeutic dosage. This low-dose approach, which emerged from several 1970s studies (e.g., Harper et al. 1977; Madden et al. 1977), has been contradicted by more recent studies (e.g., Brown et al. 1998; Kaltenbach and Comfort 1997). The consensus panel knows of no compelling evidence supporting reduced maternal methadone dosages to avoid NAS. On the contrary, higher dosages have been associated with increased weight gain, decreased illegal drug use, and improved compliance with prenatal care by pregnant women in MAT and with increased birth weight and head circumference, prolonged gestation, and improved growth of infants born to women in MAT (De Petrillo and Rice 1995; Hagopian et al. 1996). Moreover, reduced methadone dosages may result in continued substance use and increase risks to both expectant mothers and their fetuses (Archie 1998; Kaltenbach et al. 1998). The consensus panel recommends that methadone dosages for pregnant women be determined individually to achieve an effective therapeutic level.

Induction and Stabilization

Methadone dosages for pregnant women should be based on the same criteria as those for women who are not pregnant. Women who received methadone before pregnancy should be maintained initially at their prepregnancy dosage. However, if pregnant women have not been maintained on methadone, the consensus panel recommends that they either be inducted in an outpatient setting by standard procedures or be admitted to a hospital (for an average stay of 3 days) to evaluate their prenatal health status, document physiologic dependence, and initiate methadone maintenance if possible.

For pregnant women being inducted in an outpatient setting, a widely accepted protocol is to give initial methadone doses of 10 to 20 mg per day, with exact dosage based on a patientís opioid use history. A patient should be asked to return at the end of the day for followup evaluation, and the initial dose may be followed by regular adjustments of 5 to 10 mg based on therapeutic response (Archie 1998). Twice daily observation should continue until the patient is stabilized. If evidence of intoxication or withdrawal emerges, treatment providers should adjust the patientís dosage immediately. Most pregnant women can be stabilized within

48 to 72 hours (Kaltenbach et al. 1998). In outpatient settings, where fetal monitors usually are unavailable, it is crucial that patients record measures of fetal movement at set intervals (Jarvis and Schnoll 1995).

Split Dosing

Split-dosing methadone regimens are accepted widely for pregnant patients, but little empirical investigation has been done of its effects on fetuses or maternal plasma levels (Jarvis et al. 1999). Although split dosing may improve maternal compliance with treatment and decrease cocaine use (De Petrillo and Rice 1995), traveling to an opioid treatment program (OTP) twice a day or, for unstable or newly admitted patients, qualifying for take-home medication doses may be difficult.

Managing Polysubstance Use

A large percentage of pregnant women in MATóup to 88 percent in one studyócontinue to use other substances including alcohol, nicotine, heroin, cocaine, barbiturates, and tranquilizers (Edelin et al. 1988). The risks of other substance use for both maternal and fetal health are well documented (Reid 1996). It is essential that patients be monitored for use of both licit and illicit drugs and alcohol to manage appropriately the perinatal care of both mothers and infants (Kaltenbach et al. 1998).

Polysubstance use is a special concern during pregnancy because of the adverse effects of cross-tolerance, drug interactions, and potentiation (Kaltenbach et al. 1998) and the serious maternal and fetal health risks from continued substance use and lack of adequate prenatal care (Svikis et al. 1997***a***). Chapter 11 provides more information about treatment of multiple substance abuse in MAT; the forthcoming TIP ***Substance Abuse Treatment: Addressing the Specific Needs of Women*** (CSAT forthcoming ***f***) contains additional information on the effects of different substances on pregnant women.

Management of Acute Opioid Overdose in Pregnancy

Opioid overdose in pregnancy threatens both pregnant women and their fetuses. Naloxone, a short-acting, pure opioid antagonist, is the pharmacological treatment of choice for opioid overdose but should be given to pregnant patients only as a last resort (Weaver 2003). Patients should receive naloxone (0.01 mg/kg of body weight) intravenously after an airway is established to ensure adequate respiration. Patients can receive additional naloxone doses every 5 minutes after they regain consciousness. Naloxoneís duration of action is from 30 minutes to 2 hours, depending on the dose and type of substance that was used, whereas that of most opioids is from 6 to 8 hours and that of methadone or other long-acting opioids (e.g., morphine sulfate contin, OxyContin®) is from 12 to 48 hours (or more for levo-alpha acetyl methadol). Therefore, symptoms are likely to recur within 30 minutes to 2 hours of naloxone treatment, and treatment providers should continue administering naloxone intravenously or intramuscularly at intervals until the effects of illicit opioids markedly diminish, which may take 2 to 3 days. Special care is needed to avoid acute opioid withdrawal that can harm a fetus. Treatment providers should titrate the naloxone dose against withdrawal symptoms and use a short-acting opioid to reverse acute withdrawal symptoms (Archie 1998).

Managing Withdrawal From Methadone

Withdrawal from methadone, called medically supervised withdrawal (MSW) or dose tapering, is not recommended for pregnant women. When MSW is considered, however, a thorough assessment is important to determine whether a woman is an appropriate candidate for MSW because the procedure frequently results in relapse to opioid use. Appropriate patients for MSW during pregnancy include those who

- Live where methadone maintenance is unavailable
- Have been stable in MAT and request MSW before delivery
- Refuse to be maintained on methadone
- Plan to undergo MSW through a structured treatment program (Archie 1998; Kaltenbach et al. 1998).

A patient who elects to withdraw from methadone should do so only under supervision by a physician experienced in perinatal addiction treatment, and the patient should receive fetal monitoring. MSW usually is conducted in the second trimester because the danger of miscarriage may increase in the first trimester and the danger of premature delivery or fetal death may increase in the third trimester (Kaltenbach et al. 1998; Ward et al. 1998***a***). However, the consensus panel has found no systematic studies on whether withdrawal should be initiated only during the second trimester. If MSW is undertaken, methadone should be decreased by 1.0 to 2.5 mg per day for inpatients and by 2.5 to 10.0 mg per week for outpatients. Fetal movement should be monitored twice daily in outpatients, and stress tests should be performed at least twice a week; MSW should be discontinued if it causes fetal stress or threatens to cause preterm labor (Archie 1998; Kaltenbach et al. 1998).

Postpartum Treatment of Mothers in MAT

Current treatment practices include continuing methadone after delivery either at dosages similar to those before pregnancy or, for women who began methadone maintenance during pregnancy, at approximately half the dosages they received in the third trimester. However, no empirical data support these approaches, and any decrease should be based on signs of overmedication, withdrawal symptoms, or patient blood plasma levels (Kaltenbach et al. 1998).

Breast-Feeding

Mothers maintained on methadone can breast-feed if they are not HIV positive, are not abusing substances, and do not have a disease or infection in which breast-feeding is contraindicated (Kaltenbach et al. 1993). Hepatitis C is no longer considered a contraindication for breast-feeding.

The American Academy of Pediatrics has a longstanding recommendation (1983) that methadone is compatible with breast-feeding only if mothers receive no more than 20 mg in 24 hours. However, studies have found minimal transmission of methadone in breast milk regardless of maternal dose (Geraghty et al. 1997; Wojnar-Horton et al. 1997). McCarthy and Posey (2000) found only small amounts of methadone in breast milk of women maintained on daily doses up to 180 mg and argued that available scientific evidence does not support dosage limits of 20 mg a day for nursing women.

Effects on Neonatal Outcome

NAS

Infants prenatally exposed to opioids have a high incidence of NAS, characterized by hyperactivity of the central and autonomic nervous systems that is reflected in changes in the gastrointestinal tract and respiratory system. Infants with NAS often suck frantically on their fists or thumbs but may have extreme difficulty feeding because their sucking reflex is uncoordinated (Kaltenbach et al. 1998). Withdrawal symptoms may begin from minutes or hours after birth to 2 weeks later, but most appear within 72 hours. Preterm infants usually have milder symptoms and delayed onset. Many factors influence NAS onset, including the types of substances used by mothers, timing and dosage of methadone before delivery, characteristics of labor, type and amount of anesthesia or analgesic during labor, infant maturity and

nutrition, metabolic rate of the infantís liver, and presence of intrinsic disease in infants. NAS may be mild and transient, delayed in onset or incremental in severity, or biphasic in its course, including acute neonatal withdrawal signs followed by improvement and then onset of subacute withdrawal (Kaltenbach et al. 1998). Although NAS can be more severe or prolonged with methadone than heroin because of methadoneís longer half-life, with appropriate pharmacotherapy, NAS can be treated satisfactorily without any severe neonatal effects.

Onset of NAS may be delayed by other neonatal illnesses. In addition, various other conditions may mimic NAS, such as hypoglycemia, hypocalcemia, sepsis, and neurological illnesses. To rule out such conditions, infants suspected of having NAS should have a complete blood cell count with differential, electrolyte and calcium levels, comprehensive neurological consultation, and head ultrasound if indicated.

An abstinence scoring system should be used to monitor opioid-exposed newborns to assess the onset, progression, and diminution of symptoms (Kaltenbach et al. 1998). The Neonatal Abstinence Score (Finnegan and Kaltenbach 1992) is used widely to estimate NAS severity, determine whether pharmacotherapy is needed, and monitor the optimum response to therapy. All infants of mothers with an opioid use history should be scored every 4 hours. Control is achieved when the average Neonatal Abstinence Score is less than 8, infants exhibit rhythmic feeding and sleep cycles, and infants have optimal weight gains.

If pharmacological management is indicated, infants should be treated with neonatal opioid solution (0.4 mg/mL of morphine-equivalent solution; starting dosage, 0.4 mg/kg/dose given orally in six to eight divided doses [timed with the feeding schedule]). Dosage should be increased by 0.4 mg/kg/dose as needed until control is achieved or a maximum dosage of 2.0 mg/kg/day is reached. If Neonatal Abstinence Scores remain high but daily doses approach the maximum, the infantís symptoms should be reassessed and concurrent pharmacotherapy with phenobarbital considered (American Academy of Pediatrics Committee on Drugs 1998).

When control is achieved, the dosage should be continued for 72 hours before pharmacological weaning begins, in which dosage is decreased 10 percent daily or as tolerated until 0.2 mg/kg/day is reached, when medication may be discontinued. Decisions about dosage decrease rate during pharmacological weaning should be based on Neonatal Abstinence Scores and daily weight and physical exams.

Maternal Methadone Dosage and Extent of NAS

The relationship between maternal methadone dosage and NAS has been difficult to establish, and the consensus panel believes no compelling evidence shows that methadone reduction avoids NAS. Although a number of investigators have reported significant relationships between neonatal withdrawal and maternal methadone dosage (e.g., Malpas et al. 1995; Mayes and Carroll 1996), most have found no such relationship (e.g., Berghella et al. 2003; Brown et al. 1998).

Perinatal Outcomes

Another area of concern is the intrauterine growth of infants born to women maintained on methadone. Early research yielded somewhat inconsistent findings, and not much new has been added since the 1980s. Studies comparing infants born to women addicted to heroin but not receiving methadone with infants born to women receiving methadone found differential effects, with reduced fetal mortality and greater birth weights indicated for

…NAS can be treated satisfactorily without any severe neonatal effects.

infants of women maintained on methadone (Connaughton et al. 1977; Kandall et al. 1977). Some studies comparing infants born to women not using opioids with infants of women in methadone treatment found lower birth weights in the latter group (Chasnoff et al. 1982; Lifschitz et al. 1983), whereas others found no differences in birth weights (Rosen and Johnson 1982; Strauss et al. 1976).

A study by Kaltenbach and Finnegan (1987) with 268 infants found that those exposed to methadone had lower birth weights and smaller head circumferences than those not exposed to drugs. However, the infants exposed to methadone were not small for their gestational age, and there was a positive correlation between head circumference and birth weight in both groups. These data suggested that infants born to women who are opioid addicted and maintained on methadone may have lower birth weights and smaller head circumferences than nonñdrug-exposed comparison infants, but the former are not growth restricted.

Researchers (e.g., Chasnoff et al. 1984; Jeremy and Hans 1985) who used the Brazelton Neonatal Behavioral Assessment Scale (Brazelton 1984) to investigate neurobehavioral characteristics in newborns undergoing opioid withdrawal have found differences consistently in behavior between these infants and infants born to women not opioid addicted. Infants exposed to opioids were more irritable, exhibited more tremors, and had increased muscle tone. Several studies have reported less responsiveness to visual stimuli and reduced alertness among infants exposed to opioids (Strauss et al. 1975).

> [I]nfants born to women who are opioid addicted and maintained on methadone may have lower birth weights and smaller head circumferences…

Important aspects of these behavioral characteristics are their implications for motherñ infant interactions. In the consensus panelís experience, these infants are frequently difficult to nurture, causing poor motherñinfant bonding, which Hoegerman and colleagues (1990) suggested might be the most devastating legacy of perinatal addiction.

Developmental Sequelae

Research on developmental sequelae associated with in utero methadone exposure has found that infants through 2-year-olds function well within the normal developmental range (e.g., Kaltenbach and Finnegan 1986; Rosen and Johnson 1982). Lifschitz and associates (1985) found no significant developmental differences between children of mothers maintained on methadone and children of mothers still using heroin or using no opioids, when sociodemographic, biological, and other health factors were considered. Other data have suggested that maternal drug use is not the most important factor in how opioid-exposed infants and children develop but that family characteristics and functioning play a significant role (Johnson et al. 1987). More information is needed to update or extend these findings from the 1970s and 1980s.

Use of Buprenorphine During Pregnancy

Buprenorphine use for pregnant women has not been approved in the United States, although it may be used with pregnant patients under certain circumstances (see below). It may be a safe and effective treatment for some pregnant women who are opioid addicted, but more research is needed. Several animal studies have been conducted. However, only limited prospective and open-label studies using sublingual buprenorphine tablets in pregnant women have been reported, and these represent the most closely controlled data (e.g.,

Johnson et al. 2001; Lejeune et al. 2002). Several case studies have been reported, mainly in France, of buprenorphine use during pregnancy (e.g., Marquet et al. 1997, 1998). Johnson and colleagues (2003***a***) provided a complete review of these reports. The studies all found that buprenorphine was well accepted by mothers and infants during the early neonatal stage and appeared useful to treat pregnant women who were opioid addicted.

In view of incomplete data and the absence of FDA approval for use of buprenorphine in pregnant patients, the consensus panel recommends that buprenorphine be used only when the prescribing physician believes that the potential benefits justify the risks. For example, patients already maintained and stable on buprenorphine who become pregnant probably should continue on buprenorphine with careful monitoring. Pregnant women who are opioid addicted but cannot tolerate methadone, those for whom program compliance has been difficult, or those who are adamant about avoiding methadone may be good candidates for buprenorphine. In such circumstances, it should be clearly documented in the patientís medical record that she has refused methadone maintenance treatment or that such services are unavailable; that she was informed of the risks of using buprenorphine, a medication that has not been thoroughly studied in pregnancy; and that she understands these risks. When treating pregnant patients, treatment providers should use buprenorphine monotherapy tablets (Subutex®) because no work has been done on the effects of fetal exposure to sublingual naloxone in buprenorphine-naloxone combination tablets (Suboxone®) during pregnancy. Consensus panelists have found that a patient already maintained on buprenorphine-naloxone combination tablets who becomes pregnant can be transferred directly to buprenorphine monotherapy tablets.

A more detailed discussion on buprenorphine use in the treatment and management of pregnant patients and its effects in newborns can be found in TIP 40, ***Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*** (CSAT 2004***a***). For a comprehensive review of buprenorphine use in pregnant patients and its effects on the neonate, see the article by Johnson and colleagues (2003***a***). Current data indicate that buprenorphine probably is safe and effective for some women who are pregnant and opioid addicted, but more research is needed.

Buprenorphine Effects on NAS

Johnson and colleagues (2003***a***) reviewed 21 reports of buprenorphine use during pregnancy, most from Europe, and found that NAS was reported in 62 percent of approximately 309 infants exposed to buprenorphine, with 48 percent requiring treatment and 40 percent confounded by other drug use. Another study of 100 infants of mothers maintained on buprenorphine found NAS in approximately 67 percent (Johnson et al. 2001). Of these, 53 percent required treatment for withdrawal, and approximately 7 percent were admitted to a neonatal intensive care unit. Similar to infants born to women receiving methadone, infants of women receiving comprehensive prenatal care plus buprenorphine had improved birth outcomes compared with those whose mothers received no comprehensive prenatal care.

Buprenorphine-associated NAS generally appears within 12 to 48 hours, peaks at 72 to 96 hours, and lasts 120 to 168 hours, although some reports have indicated buprenorphine-related NAS lasting 6 to 10 weeks. Buprenorphine-associated NAS was found to be less intense than that associated with methadone (Johnson et al. 2003***a***). If controlled randomized trials confirm that newborns of mothers treated with buprenorphine have less NAS than those of mothers treated with methadone, it may be appropriate to switch patients from methadone to buprenorphine during early pregnancy to reduce chances for marked withdrawal syndromes in newborns.

Breast-Feeding During Buprenorphine Treatment

Research has indicated that only small amounts of buprenorphine and buprenorphine-naloxone pass into breast milk, with little or no effect on infants (Johnson et al. 2001; Schindler et al. 2003; CSAT 2004***a***). These data are inconsistent with product labeling, which advises against breast-feeding in mothers treated with buprenorphine or the buprenorphine-naloxone combination. Based on research data, particularly findings that buprenorphine is likely to be poorly absorbed by infants via the oral route, the consensus panel recommends that women maintained on buprenorphine be encouraged to breast-feed because of the benefits to infants and motherñchild interaction. The panel recommends more research, particularly to confirm that infants absorb little buprenorphine during breast-feeding.

Importance of Integrated, Comprehensive Services

Pregnant women who are opioid addicted need comprehensive treatment services, including individual, group, and family therapy to address both the physiological and psychological effects of substance use and psychosocial factors. Psychosocial complications may include disruption of the motherñchild relationship, guilt over the adverse effects of addiction on the family, and family adjustment when a newborn is retained in the hospital. Problems associated with domestic violence, financial support, food, housing, and childcare issues can be overwhelming to women in recovery and should be addressed. AIDS prevention, counseling, testing, and educational services should be available during prenatal and parenting classes. Services should be aimed at eliminating substance use, developing personal resources, improving family and interpersonal relationships, eliminating socially destructive behavior, and helping new parents cope with their environment.

Integrated services, whether on site or through linkages to other community-based agencies, encourage prospective patients to enter a treatment program and continue treatment. Services should be woman centered and directly address traumatic events. The array of services may include

- Special groups to address problems of pregnant women who are opioid addicted
- Available treatments for women addicted to opioids, including pharmacotherapies
- Education and discussion groups on parenting and childcare
- Special groups and services for children and other family members
- Couples counseling
- Case management and assistance in locating safe, affordable housing.

The forthcoming TIP ***Substance Abuse Treatment: Addressing the Specific Needs of Women*** (CSAT forthcoming ***f***) has more detailed information on the psychosocial components of women-centered treatment.

Psychosocial Barriers

Women addicted to opioids typically face financial, social, and psychological difficulties that affect their options and treatment progress. Many have histories of negative experiences with the legal system or childrenís protective services that may cause them to be resistant to or noncompliant with treatment. Guilt and shame coupled with low self-esteem and self-efficacy can produce behaviors difficult for some staff members to tolerate, such as lateness, missed appointments, continued illegal drug use, and demanding or provocative behaviors. For successful treatment, care should be provided in a gender-specific, nonpunitive, nonjudgmental, nurturing manner, with attention to each patientís fears and cultural beliefs (Kaltenbach et al. 1998; Ward et al. 1998***a***).

Contingency Management Treatment Strategies

As discussed in chapter 8, contingency management strategies offering positive reinforcement for behavioral change have been effective in treating a range of substance use disorders. Voucher-based reinforcement therapy (VBRT) has been particularly effective in increasing abstinence from substances and strengthening behaviors such as compliance with treatment plans and participation in vocational training (Kidorf et al. 1998; Petry 2000; Silverman et al. 1996). These and other studies also have suggested that VBRT may help manage poly-substance abuse and improve retention for pregnant women in MAT.

Although few systematic studies have been done with pregnant women who are opioid addicted, available evidence has indicated that positive-contingency rewards for abstinence or treatment attendance can improve pregnancy outcomes (Chang et al. 1992; Jones et al. 2001). Contingency management incentives for this population have ranged from cash (Carroll et al. 1995; Chang et al. 1992) to vouchers exchangeable for goods and services (Jones et al. 2000, 2001; Svikis et al. 1997***b***).

Carroll and colleagues (1995) compared the effectiveness of an enhanced treatment program for pregnant patients that included a contingency management component, in which clients could earn $15 weekly for three consecutive negative drug tests, with an unenhanced treatment program. The group receiving enhanced treatment had better neonatal outcomes, but the two groups did not differ in percentages of positive drug tests. The authors attributed these results primarily to more frequent prenatal care in the contingency management group. However, results of the study were limited by the small sample size (seven women in each group), the inability to discern which components contributed to improved outcomes, and use of a demanding contingency procedure that reinforced continuous abstinence (e.g., three consecutive negative drug tests) but not discrete abstinence (each negative drug test).

Many pregnant women who receive MAT discontinue treatment prematurely, with the highest dropout rates occurring on transfer from residential to outpatient treatment. A related series of controlled, randomized studies (Jones et al. 2000, 2001; Svikis et al. 1997***b***) examined whether brief voucher incentives improved patient participation and decreased substance use during this transition phase. In pregnant women maintained on methadone, low-value incentives did not influence substance use (Jones et al. 2000). However, greater incentives, using an escalating reinforcement procedure, both decreased substance use and increased full-day outpatient treatment attendance (Jones et al. 2001).

Overall, these studies have suggested that contingency management using positive rewards for desired behaviors may be an important adjunct to MAT for pregnant women. It is noteworthy that interventions such as VBRT not only are compatible with MAT but address both continued substance abuse and poor program attendance.

> Integrated services… encourage prospective patients to enter a treatment program and continue treatment.

Nutrition Assessment, Counseling, and Assistance

People with substance use disorders often are poorly nourished. Substances themselves may impair usersí metabolism, interfere with nutrient availability, and affect appetite. However, other lifestyle factors associated with substance use play a significant role, including poverty, poor eating and exercise habits, lack of concern

about nutrition and health, and diets restricted by physiological conditions.

Pregnancy is an opportune time to help women improve their health-related attitudes and behaviors. The consensus panel recommends that all pregnant patients in MAT receive

- An assessment of nutritional status, eating habits, and weight
- Education on appropriate diet and weight to meet optimal targets for the pregnancy
- Counseling to ensure that special nutrition-related medical and psychosocial problems are addressedówith high priority given to stopping or substantially reducing cigarette, alcohol, and other substance use with known adverse effects on fetuses
- Supplemental nutrients when nutritional needs cannot be met by diet changes
- Information about and referral to food assistance programs.

Nutritional Education for Pregnant Patients in MAT

Most pregnant women in MAT can benefit from nutritional guidance that encourages them to have wholesome, well-balanced diets consistent with their ethnic or cultural backgrounds and financial situations. Such guidance helps them understand how diet and substance use affect the fetus, pregnancy, labor and delivery, and breast-feeding.

Some OTPs have trained nurses or other staff members who facilitate a nutrition education program. In addition, the National Center for Nutrition and Dietetics of the American Dietetic Association (800-366-1655 or www.eatright.org) refers inquirers to registered dietitians in the local area who provide individual or group counseling or program information about diet during pregnancy. Another useful resource, ***Pregnancy and Nutrition***, a seven-page pamphlet developed by the National Womenís Health Information Center (www.4women.gov/faq/preg-nutr.htm), covers recommended dietary allowances for pregnant women, diet changes and weight gain, cravings, exercise, dietary supplements, diabetes, morning sickness, and nausea.

OTPs wishing to assess patientsí knowledge about nutrition might be interested in the U.S. Department of Agricultureís 22-page survey forms (www.barc.usda.gov/bhnrc/foodsurvey) to ascertain respondentsí knowledge of nutrition, food composition, labeling requirements, and serving sizes, as well as eating habits and attitudes.

Food Program Assistance for Pregnant Patients in MAT

Pregnant women in MAT who are nutritionally at risk or financially needy may be eligible for supplemental food assistance. Their school-age children also might qualify for school breakfast and lunch programs, as well as summer food programs. OTP counselors should be familiar with the services and requirements of each type of program and make appropriate referrals. Facts about food stamps can be found at www.fns.usda.gov/fns. Information about the Federal Women, Infants, and Children program can be accessed at www.fns.usda.gov/wic or www.nal.usda.gov/wicworks.

14 Administrative Considerations

In This ChapterÖ

This chapter describes policies, procedures, and considerations that make opioid treatment program (OTP) administrators and managers more effective, therefore contributing to improved treatment outcomes. OTPs are complex, dynamic environments, and their staffing and management are challenging. OTP directors influence patient outcomes positively by providing sound leadership and staff management (Magura et al. 1999). Managers are responsible for keeping staff members focused on patient care and improved treatment outcomes. Conflict or misunderstanding about treatment goals can increase the stress of working in an OTP (Bell 1998). Managers should set clear staff guidelines, supply the needed resources, and create a culture that nurtures professional growth and staff retention.

Staffing

> How . . . interactions [between OTP staff and patients] are conducted, and particularly the attitude of staff members, is probably the next most important determinant of treatment effectiveness after an adequate dose of methadone. (Bell 1998, p. 168)

Successful treatment outcomes depend on staff competence, values, and attitudes. To develop a stable group of competent personnel, OTP administrators should recruit qualified, capable, culturally competent people; offer competitive benefit packages; and provide careful supervision and ongoing training. Employees then can increase their understanding of medication-assisted treatment for opioid addiction (MAT).

Qualifications

Licensing, certification, and credentialing

The complexities of treating patients who are opioid addicted demand highly trained caregivers who can provide direct patient care and coordinate access to other services that their OTP cannot provide. To ensure these qualifications, OTPs should hire individuals who are

licensed or credentialed under State regulations and have a record of working effectively with the types of patients served by the OTP. Licensed and credentialed staff members also may be viewed as having more legitimacy by State regulators, community members, and third-party payers.

Staff interpersonal characteristics

In addition to hiring licensed or credentialed staff, administrators should employ people with empathy, sensitivity, and flexibility, particularly regarding patients in MAT. Empathic staff members create a therapeutic milieu (Joe et al. 2001). In addition, staff members should maintain appropriate professional boundaries with patients.

> [A]dministrators should recruit qualified,…culturally competent people; offer competitive benefit packages; and provide careful supervision and ongoing training.

Transference and countertransference. Some patients with addictions project feelings or emotions onto their treatment providers or cast providers in unintended roles, a phenomenon known as transference. Countertransference occurs when treatment providers project their feelings onto patients, which can interfere with treatment and be destructive to therapeutic relationships. OTP supervisors should ensure that staff members avoid countertransference (e.g., displaying anger toward patients or disappointment with them). TIP 36, ***Substance Abuse Treatment for Persons With Child Abuse and Neglect Issues*** (CSAT 2000***d***), contains a detailed discussion of these topics.

Sensitivity to cultural, gender, and age issues. In a review of the literature on culturally relevant health care interventions and their effect on treatment outcomes, Kehoe and colleagues (2003) found that treatment provider knowledge of cross-cultural principles significantly improved outcomes for patients with drug addictions. OTP staff members should be willing to work with people from diverse backgrounds, explore and accept other value systems, and understand how culture and values can relate to patientsí behavior. Support staff should be accepting and understanding of patients from diverse groups because these staff members often are the first people a new patient sees at the OTP and those with whom the patient interacts most. If possible, management should recruit employees who reflect patient demographics and should consider hiring people who are recovering from addiction (see below).

People working with diverse groups should remember that diversity also exists within cultures. It is important to be sensitive to cultural differences but to avoid acting on cultural assumptions. Understanding both a patientís cultural influences and his or her individuality requires taking time to know the patient.

Treatment staff should be sensitive to other factors that can affect recovery, such as patientsí sexual orientations or ages, but should avoid generalizing about patients based on these factors. Correctly identifying such factors requires an effort to see the world through each patientís eyes. Information on cultural competence and diversity is available at Web sites of the National Association of Social Workers (www.socialworkers.org/diversity) and Substance Abuse and Mental Health Services Administration (SAMHSA) (www.samhsa.gov/search/search.html) and in ìCultural Competence for Social Workersî (Center for Substance Abuse Prevention 1995) and the forthcoming TIP ***Improving Cultural Competence in Substance Abuse Treatment*** (CSAT forthcoming ***b***).

Multicultural and multilingual representation. The consensus panel is aware of no published

data demonstrating improved outcomes from ethnic matching of patients and substance abuse treatment providers. Sterling and colleagues (2001) noted the existence of ìequivocal findings of the effect that therapist and patient similarity plays in treatment outcomeî (p. 1015) in substance abuse treatment programs and concluded that more research is needed. However, the panel believes that, when program staff generally reflects the demographics of the population served, patients are more likely to feel comfortable in the OTP. When multicultural representation among staff is limited, OTPs should find ways to communicate acceptance of diverse cultures and groups.

Programs with nonñEnglish-speaking patients should provide information in patientsí first languages by employing staff members or interpreters who can communicate with patients. Federal and State resources are available for programs seeking literature in languages other than English. Community colleges, universities, and other institutions or agencies might assist in translating forms and pamphlets. Information about translation services is available via the Internet (visit www.atanet.org/bin/view.fpl/52076.html).

Flexibility in thinking, behavior, and attitudes. Staff attitudes about MAT and opioid addiction can affect patient outcomes. Administrators should seek staff members who are free of rigid biases, are not judgmental, and do not have punitive attitudes toward patients (Bell 2000).

OTP staff members sometimes hold negative attitudes toward patients (Caplehorn et al. 1997) or MAT (Forman et al. 2001). At least one study has associated such attitudes with lower rates of patient retention and poorer patient outcomes (Caplehorn et al. 1998). OTP managers should be vigilant about monitoring staff attitudes and conduct inservice training to create or sustain appropriate attitudes about patients and MAT.

The verbal expressions used by OTP staff members can reflect how they feel toward patients. Treatment staff members, who might have absorbed societyís antipathy toward people in MAT, sometimes use countertherapeutic language, for example, the phrase ìdirty urineî to describe an unsatisfactory urine drug test (ìpositive testî is less judgmental). Staff should avoid terms suggesting the criminal justice system, such as ìprobationî or ìprobationary,î to refer to the status of patients doing poorly in treatment. ìTerminationî should be avoided in reference to patient discharge. Other preferred expressions in MAT include ìpatientsî not ìclientsî and ìdose taperingî or ìmedically supervised withdrawalî not ìdetoxî in reference to withdrawal from treatment medication. Applying words derived from ìtoxinî to treatment medication suggests that the medication is a toxin; ìdetoxificationî should refer only to withdrawal from substances of abuse.

Inclusion of recovering patients. The consensus panel believes that employing treatment professionals and support staff who are in recovery also adds valuable perspectives to treatment and provides role models for patients. OTP policies on hiring people who are in addiction recovery should be in writing and include procedures for addressing staff members who relapse. State regulations may establish a minimum abstinence period before an OTP can hire someone in recovery. Policies also must comply with Federal and many State laws prohibiting discrimination against people who are addicted (CSAT forthcoming ***b***). Staff members who are in recovery and their colleagues who have no addiction history should be treated similarly.

Staff Retention

Retaining staff is important for several reasons:

- Stability of treatment staff may affect treatment outcomes.
- High staff turnover can undermine relations with the community, funders, and others.
- Investment in recruitment and training is lost when staff members leave.
- Unfilled staff positions result in longer patient waiting lists.

- Reducing staff turnover minimizes disruption to patientsí treatment.
- Accreditation standards place importance on the stability of OTP staff.

Factors that may contribute to high staff turnover include low salaries and benefits, negative stereotypes of MAT and its patients, job stress, excessive counselor workload, unreasonable operating hours, and unsafe OTP locations. Staff members can experience burnout when they work in isolation with difficult patients and inadequate support or feedback. Managers should take concrete steps to retain staff, including the following:

- Establish and maintain clear policies and procedures, and apply them consistently.
- Avoid excessive caseloads. Even the most professional, committed counselor struggles when the caseload is too large. Managers can use a monitoring system that focuses on the number of counseling hours a caseload requires, which can differ dramatically from the number of cases assigned per counselor, depending on the requirements of individual patients.
- Encourage a team approach. Staff members usually feel less isolated and overwhelmed when a team makes treatment decisions. When a lack of cohesion exists, staff members risk burnout, disillusionment, or cynicism. A well-coordinated team also reduces the level of intrastaff disagreements about patient care and decreases the likelihood of ìstaff splitting,î when patients pit staff members against one another.
- Encourage a culture of mutual respect through team cooperation, clear and effective communication, and inclusive, interdepartmental decisionmaking. Managers should hold regular staff meetings. Staff cooperation also can be fostered through training and retreats. The program director or manager should mediate disputes among staff members.
- Establish job descriptions that clearly delineate roles, responsibilities, and lines of communication (Bell 1998), and review them annually with personnel.
- Establish objective performance standards derived from job descriptions, and conduct regular performance evaluations that include feedback based on patient outcomes.
- Establish regular consulting sessions among counselors, their supervisors, and other staff members. Supervisors should be well trained and supported.
- Provide opportunities for professional training, either by onsite training or by permitting staff members to attend offsite training during work hours.
- Encourage professional development by supporting staff certifications.
- Establish personnel policies that demonstrate concern for staff well-being, including flexible work schedules to reduce stress.
- Offer routine praise and recognition for staff contributions and achievements.

The forthcoming TIP ***Substance Abuse: Administrative Issues in Outpatient Treatment*** (CSAT forthcoming ***c***) provides more information on supervision, and Newman (1997) provides information on the therapeutic alliance between patients and treatment providers.

Training

Training should be offered for all staff members, including secretaries, nurses, counselors, supervisors, and managers, to ensure a strong knowledge base so that staff members do their best and to affirm that all staff members are valued members of the treatment team. The importance of training has increased because accreditation standards require OTPs to provide continuing staff education, with many States requiring such education for OTPs to maintain licensure. OTPs should help professional staff members acquire education credits to maintain their licensure by offering onsite training, collaborating with other agencies for reciprocal training, or paying for educational leave or tuition.

At minimum, training should focus on the following areas:

- **Facts about MAT and the health effects of treatment medications.** Educating OTP staff about the health effects of MAT medications and the value of remaining in treatment is essential. Some studies have revealed a high level of misinformation among OTP staff members about the health effects of maintenance medications (e.g., Kang et al. 1997). Other studies have shown that many staff members hold negative attitudes about MAT (e.g., Caplehorn et al. 1997), which negatively affect patient outcomes (Caplehorn et al. 1998). One way to address negative staff attitudes is to include successful patients in training (Bell 2000).
- **Up-to-date information about medications.** Staff should be able to discuss medications with patients. Medical staff members should be able to assess patients and determine, with input from other treatment team members, which medication is most appropriate.
- **Up-to-date information about drugs of abuse.** Training should ensure that staff members are knowledgeable about drug abuse trends in the community.
- **Up-to-date information about communicable diseases.** Training should focus on both diseases commonly experienced by patients in MAT, such as hepatitis C, and emerging diseases in the community, possibly including tuberculosis or HIV/AIDS.
- **Skills training.** Staff members should have access to generic skills training such as crisis management, communications, and problem-solving, as well as new evidence-based MAT treatments. They should have access to training about the populations the OTP serves, including cultural information and information about specific disorders.
- **Patient sensitivity training.** The importance of emphasizing sensitivity to patient needs should be reviewed periodically. No matter how creative and naturally sensitive a staff member may be, factors such as burnout can affect how he or she responds.

A large OTP can tap into its own staff to provide training. A program physician might educate staff members about the etiology of addiction and effects of medications. A psychiatrist might distinguish primary mental disorders from those that are substance related and provide information on psychotropic medications. Therapists and social workers might teach behavior management techniques, parenting, and resource allocation. Nurses might provide training on gender and wellness, as well as the side effects of pharmacologic regimens. Consistent inservice training can help staff members understand the programís mission and the effects of MAT.

The importance of training has increased because accreditation standards require OTPs to provide continuing staff education…

Federal and State agencies and professional associations offer seminars, courses, and workshops. SAMHSAís Addiction Technology Transfer Centers (ATTCs) offer an array of training events and resource materials (www.nattc.org). Some States offer training leading to certification for addiction specialists and counselors. Hospitals and large OTPs sometimes allow staff from smaller programs to attend their sessions. Professional societies, such as the American Society of Addiction Medicine, American Academy of Addiction Psychiatry, and Osteopathic Academy of Addiction Medicine, offer training for medical personnel in various therapeutic techniques. National counseling organizations, such as the Association for Addiction Professionals, and professional nursing societies also offer treatment courses.

OTP administrative, financial, clerical, maintenance, and custodial staff may lack direct treatment responsibilities, but they are very much part of the team. Reception staff members, often the first to speak with patients, play an important role. They should receive an

orientation about MAT to ensure that they understand how the OTP operates so that they develop favorable attitudes about patients. If possible, all staff members should receive annual training in such areas as confidentiality requirements, cultural competence, prevention of workplace violence, and patient rights.

Medication Diversion Control Plans

Federal opioid treatment standards state that an OTP must maintain a current diversion control plan (DCP) that includes measures to reduce the possibility of medication diversion and assigns responsibility for control measures to medical and administrative staff members (42 Code of Federal Regulations [CFR], Part 8 ß 12(c)(2)).

A DCP should address diversion of medication both by patients, who might sell or give their take-home medication to others, and by staff, who might steal medication or spill or otherwise waste it.

Reducing the Possibility of Diversion by Patients

Patients considered for take-home medication must meet Federal criteria. The medical director makes decisions about take-home medications (42 CFR, Part 8 ß 12(i)(2)), and these decisions and their basis must be documented (42 CFR, Part 8 ß 12(i)(3)). Staff should ensure that patients can store medications safely in their homes (42 CFR, Part 8 ß 12(i)(2)(vii)). All take-home medication must be labeled with the OTP ìname, address, and telephone number andÖpackaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containersî(42 CFR, Part 8 ß 12(i)(5)).

> [A]n OTP must maintain a diversion control plan…to reduce the possibility of medication diversion…

Callbacks (see chapter 5) help prevent patient diversion of take-home medication. Callbacks require OTPs to select patients at random to return to the OTP with their remaining take-home medication. A random-callback policy avoids patient complaints of being unfairly ìpicked onî by staff members. Programs also can require patients to undergo drug tests when they bring in their medications. OTPs should document that patients have been informed of their responsibilities regarding callbacks (e.g., how much notice they will receive beforehand) and about the consequences of failure to respond or of discrepancies in medication amounts. The OTP callback policy should be stated clearly in the program DCP.

A no-loitering policy is part of an effective DCP. The policy should be clarified at the beginning of treatment and enforced consistently. Extending OTP hours helps eliminate overcrowding and loitering. The OTP should include routine meetings with community leaders, attendance at neighborhood civic association meetings, and open communications with local law enforcement officials to help resolve community concerns.

Reducing the Possibility of Diversion by Staff Members

OTPs rely on the integrity of employees who handle U.S. Drug Enforcement Administration (DEA)-scheduled substances. Even so, protocols should be in place to reduce the risk that staff will divert medications. All scheduled substances should be accounted for rigorously and inventoried continuously. Receipt and dispensing should be noted in logbooks. Working stocks should be logged and tracked from receipt through dispensing and measured at the beginning and end of each workday. Measurements and daily reconciliations should be monitored by supervisors and checked

periodically by dispensary managers. Any significant discrepancy should prompt an investigation. The dispensary manager, executive director, and medical director should follow up on investigation findings. The security of computerized records and systems also should be ensured to prevent employee theft of medication. Spills and other accidents should be reported immediately. Within the dispensary, employees should open the safe or work with scheduled substances only in the presence of other staff members. In matters of medication dispensing, OTPs must consult and comply with DEA regulations (Drug Enforcement Administration 2000).

The Community Effort

Community Opposition, Stigma, and the Importance of Community Relations

Community resistance to MAT has been chronicled for decades (e.g., Genevie et al. 1988; Joseph et al. 2000; Lewis 1999; Lowinson and Langrod 1975). The consensus panel believes that this resistance has been reduced since TIP 1, ***State Methadone Treatment Guidelines*** (CSAT 1993***b***), was published, particularly through efforts to improve scientific clarity about opioid addiction, to affirm the efficacy and benefits of MAT, and to educate professionals and the public about MAT. The expanding patient advocacy movement effectively may be countering some stereotypes and misunderstandings about MAT. Some treatment providers have overcome community oppositionósometimes called not-in-my-backyard (NIMBY) syndromeóthrough outreach and educational efforts (e.g., Weber and Cowie 1995). Many prevention and treatment programs are becoming increasingly responsive to the needs of cultural and ethnic groups (i.e., more culturally competent). These successes provide models for effective community relations in other settings.

Despite progress, MAT remains stigmatized and controversial in many U.S. communities (Joseph et al. 2000). The association of MAT with substantial improvements in individual health and employment and with reductions in HIV risk and criminal behavior has been validated by research (e.g., Krantz and Mehler 2004; Mueller and Wyman 1997), but MAT remains misunderstood even among some health care professionals.

Sensationalized media coverage and successful NIMBY-type opposition have continued to delay or preempt the siting of new facilities (Lawmakers may restrict 2000; Shepard 2001; Sissenwein 2000; Zoning fight over Michigan 1998). Introducing MAT into communities is difficult without community support. However, the consensus panel believes that, since the early 1990s, the willingness of treatment professionals and patients; government officials; agencies representing health, mental health, addiction treatment, research, and criminal justice; and the general public to learn more about MAT and opioid addiction has increased. Organizations appear more willing to include OTPs in community health planning as well-regarded community services, but this effort remains a work in progress.

Good Community Relations

Good community relations are part of good treatment. When TIP 1 was published in 1993, Federal regulations guiding the operation of OTPs did not mandate efforts to improve community relations or educate the community. Transition in Federal oversight of substance abuse treatment from the U.S. Food and Drug Administration (FDA) to SAMHSA altered the Federal regulatory perspective, as reflected in SAMHSA regulations guiding OTPs (21 CFR, Part 291, and 42 CFR, Part 8 [***Federal Register*** 66:4076ñ4102]). In the panelís view, this change in oversight is bringing OTPs into the medical mainstream, under the purview of SAMHSA, by establishing an OTP accreditation system similar to the requirements of other medical services. Furthermore, the new rules have codified SAMHSAís earlier guidelines for

OTP accreditation (CSAT 1999*b*), which recognize community relations, education, and stigma reduction as necessary operational elements. SAMHSAís approved OTP-accrediting organizationsóincluding at this writing the Commission on Accreditation of Rehabilitation Facilities, Council on Accreditation for Children and Family Services, Joint Commission on Accreditation of Healthcare Organizations, National Commission for Correctional Health Care, State of Missouri Department of Mental Health Division of Alcohol and Drug Abuse, and Washington State Department of Social and Health Services Division of Alcohol and Substance Abuseó require that MAT providers demonstrate effective community relations and stigma-reduction efforts.

OTPs serve both patients and the community. They affect public health, education, and citizensí sense of well-being. Publicly funded OTPs often rely on community support. Moreover, MATís placement within the medical and behavioral spectrum of health care affects relations with the payer community (Edmunds et al. 1997), including government and private insurers and managed care organizations. These connections increase the need for effective outreach to other community services and entities.

Overcoming Negative Community Reactions to OTPs

Joseph and colleagues (2000) reported that most community resistance involves concern about patient loitering, drug sales, and the diversion of methadone (see ìMedication Diversion Control Plansî above). Adding alternative care models and longer acting pharmacotherapies to the services continuum can decrease loitering, illicit transactions, illegal parking, and other activities that increase community concerns. These options enable highly functioning patients who meet specific criteria to receive ongoing medical care and pharmacotherapy with fewer visits to the OTP. In the view of the consensus panel, incorporation of primary medical care, day treatment, and short-stay residential models into treatment options can affect community perceptions positively because patients involved in MAT are less likely to loiter near the OTP.

Facilities for onsite patient activities to limit outside loitering are beneficial. Having adequate onsite staff is equally important in avoiding and resolving community problems. Glezen and Lowery (1999) provide other practical guidelines for addressing community concerns about substance abuse treatment facilities.

Community opposition can be triggered when community groups believe that they have been informed or consulted insufficiently. OTP administrators should meet regularly with community leaders to ensure that all parties are heard. The physical appearance of facilities should be conceived carefully. The OTP should be clean and orderly to distinguish it as a professional, responsible facility. Surrounding property (e.g., entrances, sidewalks, fencing, trash receptacles, signs) and OTP hours should not impede pedestrian or vehicle traffic. The availability of public transportation is important when considering an OTPís location (Glezen and Lowery 1999).

Some communities have found mobile treatment facilities more acceptable than fixed-site OTPs. Mobile services allow more people addicted to opioids to be treated without confronting NIMBY reactions. Pilot studies have confirmed their success (e.g., Gleghorn 2002; Ho 1999).

Whether institution or community based, fixed site or mobile, OTPs should be situated, designed, and operated in accordance with accreditation standards, Federal guidelines, and State and local licensing, approval, and operating requirements. The consensus panel recommends that MAT providers thoroughly know and understand their communities and provide the levels of input and support requested by community leaders, representatives, and constituents to site a facility and develop services that are responsive to community needs.

Community Relations and Education Plan

Each OTP should develop a community relations and education plan that extends from its general mission statement. Staff and patients should be part of a multifaceted, proactive effort to educate community entities affected by OTP operations, including the medical community, neighbors, and agencies and individuals providing support services. Although program activities differ in specificity and scope, a community relations plan should address the following:

- Learning about the community, its structures, and directly affected constituents
- Delineating the community relations mission, goals, protocols, and staff roles
- Initiating and maintaining contact with community liaisons
- Educating and serving the community
- Establishing effective media relations
- Developing policies and procedures to address community concerns about the OTP
- Documenting community contacts and community relations activities.

The forthcoming TIP ***Substance Abuse: Administrative Issues in Outpatient Treatment*** (CSAT forthcoming c) provides additional information on developing a community relations and education plan.

Delineating the community relations, mission, goals, protocols, and staff roles

In the opinion of the consensus panel, community relations and education should be an inherent function of OTP staff. OTPs with sufficient resources might employ or retain a community relations professional to establish links with local leaders, coordinate staff and patient participation in community activities, determine who will represent the OTP at local events and when, and arrange speaking and other community education activities. If funding for dedicated community relations staff is unavailable, the OTP should develop an internal plan for community relations and education. If the OTP is affiliated with a larger institution, it should ensure full cooperation from the parent organizationís community relations department.

Initiating and maintaining contacts with community

Personal contact with community leaders permits open dialog, information sharing, and discussion of community developments, needs, and problems. Members of the consensus panel agree that such communication fosters trust in the OTP. Moreover, personal contact with community representatives

- Encourages leaders to use the OTP as a resource on addiction and related health issues
- Promotes MATís public health benefits
- Highlights the value of the OTP for community members with addiction- and other health-related problems.

Regular contact with key liaisons should include onsite and offsite meetings. Demystification of MAT occurs when treatment is viewed firsthand. Community members who visit OTPs can observe operations and speak with staff and consenting patients, assuming OTP operation is unimpaired and patient confidentiality is maintained.

OTP administrators should meet regularly with community leadersÖ

Educating and serving the community

Information about MAT and the OTP can be presented through various media. Brochures and factsheets can be developed that cover the programís mission, its board membership, the

Highly visible community services demonstrate an OTPís commitment to community improvement and counter negative stereotypes.

types of services offered, and data on patients. Occasional press releases can notify the public about specific services, activities, accomplishments, announcements, improvements, or events. Highlights of an OTPís annual report can be shared with community officials, liaisons, and the general public. A program newsletter highlighting health and addiction issues and containing OTP information and patient and staff articles can be distributed. The Internet has enabled the public to view more information about opioid addiction and MAT. Government and private organizations, professional journals, sponsoring or research institutions, provider coalitions, advocacy organizations, and individual OTPs and patients offer Web sites that discuss MAT options, policies, services, and developments and frequently link to related Internet sites. Some examples are the following:

- American Association for the Treatment of Opioid Dependence, Inc. (AATOD; www.aatod.org)
- National Institute on Drug Abuse (NIDA; www.nida.nih.gov)
- SAMHSA (www.samhsa.gov)
- SAMHSAís National Help Line (www.ncadi.samhsa.gov) and Treatment Improvement Exchange
- White House Office of National Drug Control Policy (www.whitehousedrugpolicy.gov).

Some OTPs have developed speakersí bureaus for local events. Interested, successful patients, patient advisory committees, patient family groups, and OTP alumni can be promoted as potential speakers. Advocacy groups are becoming increasingly instrumental in empowering patients as active participants in public relations, community outreach, and program support initiatives and in local, State, and national community education efforts.

OTPs should take an aggressive, proactive stance in community projects and events, including some not directly tied to MAT. Sponsoring conferences, forums, exhibits, and awareness events establishes an OTP as a leader, resource, and participant in the community. Staff members with community development expertise can support other organizations in advocacy, promotional, and support efforts. OTPs can provide noninvasive medical-screening services (e.g., blood pressure, pulse, and weight checks; nutritional advice) to community members. Hospital-based OTPs and those licensed to provide primary medical services can furnish immunizations to community residents. OTPs can donate surplus office items or other products to organizations or groups. Consenting patients and staff can organize projects such as community cleanups and neighborhood patrols. Highly visible community services demonstrate an OTPís commitment to community improvement and counter negative stereotypes.

OTPs also serve communities by providing addiction treatment for community residents and offering jobs for qualified residents. The panel recommends that efforts be made to recruit and hire responsible, qualified personnel from the local community.

OTP administrators and staff can be active as representatives, speakers, or planners at professional conferences and as members or leaders in professional and community coalitions, including advisory councils. Such affiliations augment community relations efforts through increased professional education and public awareness, providing an opportunity to exchange information with and counter MAT stigmatization among other treatment professionals. These forums also may present

community relations models that can be adapted effectively by OTPs. Staff participation on local planning or development bodies can contribute to community improvement, particularly in social and health services.

OTPs are encouraged to participate in national SAMHSA campaigns, for instance, by supporting National Alcohol and Drug Addiction Recovery Month or sponsoring events to emphasize that addiction recovery is possible and facilitating MAT as compassionate and a sound investment.

Establishing effective media relations

Print, broadcast, and Internet media play critical roles in reporting and educating, as well as influencing public opinion. Local and national media differ widely in their portrayals of opioid addiction, MAT, and people addicted to opioids. These differences reflect a combination of factors including journalistic integrity, reporting style and philosophy, political leanings, regional influences, and business considerations. News accounts and other depictions of MAT often seem limited, misinformed, and negative.

Nevertheless, many noteworthy, responsible features have been produced, providing important, accurate information to the public about the science and policy of opioid addiction and treatment (e.g., Barry 2002; Hammack 2002; Moyers and Moyers 1998). Although treatment providers sometimes are disciplined to resist media exposure in order to protect patient confidentiality and avoid misrepresentation, the consensus panel believes that successful media outreach enhances an OTPís image, improves understanding of a programís mission and methods, and generates supportive public policies. Media outreach can demystify treatment, counteract stigma, and improve fairness of coverage.

OTPs operating in larger institutions can work with institutional public affairs professionals. Administrators should respond to or address members of the local press when necessary, as an outgrowth of providing service to the public. The panel believes that providing quality treatment and operating OTPs responsibly position programs to interact openly and confidently with the media.

The forthcoming TIP ***Substance Abuse: Administrative Issues in Outpatient Treatment*** (CSAT forthcoming ***c***) provides additional details for establishing media relations.

Developing policies and procedures to address and resolve community concerns

The best intentions to educate and serve the community are undermined if they are not followed up to resolve problems and concerns about OTPs. The panel recommends that detailed strategies and procedures be in place to respond to sources of community anxiety and hostility.

It is essential for OTPs to take stepsópossibly including staff or security patrols of the community, visits with local merchants or representatives, and establishment of a community hot lineóto curtail loitering, drug sales, and the diversion of methadone before they prompt community complaints. These patrols should emphasize observation, not intervention. Logs summarizing observations should be maintained. Staff visibility reminds patients of the negative effect of loitering and similar behavior and demonstrates to neighbors that OTPs actively are committed to community safety and improving quality of life.

Patients observed loitering should be counseled, and their treatment plan should be revised to address this behavior. OTPs with loitering problems should investigate day treatment programs to provide increased treatment intensity. Discharge should be considered for patients observed in illegal transactions or medication diversion. Although discharge is counter to the mandates of voluntary treatment, patients who are unconcerned about an OTPís community acceptance might be better

served by a facility equipped to handle their behaviors.

Decisions to discharge patients for loitering should balance consequences for the individual patient and public health against the need to ensure a stable OTP environment and maintain community-based services open to all patients. The panel recommends that loitering policies that culminate in patient discharge should first provide for progressive discipline and intervention and incorporate patient rights to a fair hearing and treatment (see discussion in Appendix D).

Community representatives should have OTP contact information to report problems involving patients. However, OTPs should clarify that they cannot assume a police role; in emergency and criminal matters, the police should be contacted first, not the OTP. Effective liaison with local law enforcement personnel is critical to OTP relations with the community. Although police officers are generally supportive, OTPs should correct any misconceptions police personnel have about OTPs. Patients should be differentiated from people actively using illicit drugs or abusing prescription drugs, and law enforcement personnel should be informed about OTP operations, with the understanding that police and OTPs share a purposeóaddressing substance abuse in the community. Other community problems (e.g., drug sales, unsafe community conditions) identified during staff tours can be reported to law enforcement authorities. Local officers should be encouraged to contact the OTP about problems involving patients. Confidentiality remains paramount, so this relationship should be delineated carefully.

Documenting community contacts and community relations activities

Programs should document their efforts to establish productive community contacts and resolve community concerns. A database should be developed and updated (e.g., the number and nature of community complaints received and the programís response). Communications should be logged, and staff participation in community events should be summarized. Letters and communications substantiating community complaints and the programís followup should be on file. Records should be kept of staff participation in professional and community conferences, articles published in professional journals, and contributions to local news organizations.

Using this information, OTP administrators regularly should evaluate community relations efforts. Such reviews can identify organizations excluded from previous efforts or problems requiring revision of program policies or practices.

OTPs and National Community Education Initiatives

OTPs should be aware of and involved in the national dialog and efforts to promote MAT, improve and disseminate information about opioid addiction, and partner with other national organizations and agencies in public relations and community education efforts. In addition, OTPs should build on and contribute to these national initiatives within their communities.

Numerous resources are available to educate the public about MAT and assist OTPs with public relations. National organizations such as AATOD and the American Society of Addiction Medicine hold national and regional conferences that bring together treatment providers, policymakers, researchers, and advocates to share knowledge and discuss how to advance national drug policy and expand effective treatment models, including strategies to improve public relations and reduce stigma. Focused training sessions also provide critical information, for example, to encourage physicians not associated with OTPs to enter into MAT or explain how to improve their current treatment of patients who are opioid addicted. Other sessions may focus on improving staff attitudes

and the treatment system regarding implementation of accreditation (Parrino 2001).

NIDA has invited professionals, practitioners, policymakers, and the public to sessions focused on merging research with everyday clinical practices in community-based drug treatment programs. For example, one conference, Blending Clinical Practice and ResearchóForging Partnerships To Enhance Drug Addiction Treatment, held in April 2002 (National Institute on Drug Abuse 2002), incorporated a special forum focused on the mediaís role in presenting addiction treatment and research issues in the context of science reporting.

Publications and other information resources, often available without charge or at low cost, highlight stories about the life-changing effects of MAT (e.g., American Methadone Treatment Association, Inc. 2000; CSAT 2000***a***). To educate drug court judges and practitioners, AATOD has produced ***Drug Court Practitioner Fact Sheet*** (Parrino 2002). DEA and AATOD developed the first DEA-specific guidelines for OTPs, ***Narcotic Treatment Programs: Best Practice Guideline*** (Drug Enforcement Administration 2000), which is distributed nationally to MAT providers and addresses the safekeeping of and proper accountability for controlled opioid treatment medications. The Center for Substance Abuse Treatmentís (CSATís) ***Siting Drug and Alcohol Programs: Legal Challenges to the ìNIMBYî Syndrome*** (Weber and Cowie 1995) provides assistance with problems related to siting treatment facilities including OTPs.

In 1999, SAMHSA convened expert panels and hearings to examine critical issues affecting the National Treatment Plan Initiative to improve and extend alcohol and drug treatment to all communities and people in need in the United States (CSAT 2000***b***). This extensive exploration documented widespread stigma and bias and its effect on public support and policy, such as delaying the acknowledgment of addiction as a disease; inhibiting prevention, care, treatment, and research efforts; and diminishing the life opportunities of those stigmatized. ***Changing the ConversationóImproving Substance Abuse Treatment: The National Treatment Plan Initiative*** (CSAT 2000***b***) affirmed the value of mass media public health education campaigns, comprehensive community-based health communications, media advocacy, and the application of commercial marketing technologies to programs to change social attitudes. This publication proposed a unique national approach to reducing stigma that incorporates science-based marketing research, a social marketing plan, facilitation and support of grassroots efforts by the recovery community, and promotion of the dignity of people in treatment.

NIDAís Community Epidemiology Surveillance Networksómultiagency work groups with a public health orientationóstudy the growth and development of drug abuse and related problems in communities nationwide. The primary objectives are to describe drug abuse patterns in defined geographic areas, identify changes in these patterns, detect emerging substances of abuse, and communicate and disseminate information so that appropriate community agencies and organizations can develop prevention and treatment strategies.

OTPs should be…

involved inÖ

efforts to promote MAT, improve and disseminate information about opioid addiction, and partner with other national organizations and agenciesÖ

As government and provider-based organizations mobilize national efforts, patients in and providers of MAT, along with other interested citizens, have been encouraged to unite and organize, educate

health providers and their communities, and actively engage in public relations initiatives and other advocacy efforts that advance knowledge and change attitudes about MAT. CSATís Recovery Community Support Program assists advocacy organizations in promoting their messages (www.samhsa.gov/search/search.html).

Evaluating Program and Staff Performance

Why Program Evaluation and Performance Improvement Are Important

Recent developments lend urgency to the development of good program evaluation and performance improvement procedures in OTPs. Federal regulations (42 CFR, Part 8 ß 12(c)) and guidelines (***Guidelines for the Accreditation of Opioid Treatment Programs*** [CSAT 1999***b***], Section III, Part C) require OTPs to establish performance improvement programs based on ongoing assessment of patient outcomes. SAMHSA-approved accrediting bodies (listed above) require performance improvement objectives in their guidelines. Many Single State Agencies and managed care organizations also require programs to collect and analyze outcome data. OTPs are pressed increasingly to demonstrate their effectiveness and efficiency. Administrators and staff must implement program evaluation processes that help meet these demands. Program evaluation contributes to improved treatment by enabling administrators to base changes in services on evidence of what works.

OTPs are pressed increasingly to demonstrate their effectiveness and efficiency.

Beyond the general information below about program and staff evaluation in an OTP, readers who want to know more about the specific questions to ask and the considerations that should be made during evaluation should refer to ***Demystifying Evaluation: A Manual for Evaluating Your Substance Abuse Treatment ProgramóVolume 1*** (CSAT 1997***a***).

Background

MAT is one of the most frequently studied addiction therapies, but evaluating program performance based on patient outcomes is relatively new to OTPs. Previous regulations (21 CFR, Part 291), which gave regulatory oversight to FDA, stressed process evaluation based on compliance with recommended treatment procedures. Process evaluation does not ask whether a recommended process has worked, only whether it has been followed.

The Institute of Medicine (IOM) was among the first organizations to recommend an outcome evaluation system for OTPs based on ìdirect and valid measures of reduction in opiate and non-opiate drug use and improvement in positive social functionî (Institute of Medicine 1995, p. 228), which could be used by OTPs, regulatory and funding agencies, and researchers. IOM looked to the Methadone Treatment Quality Assurance System (MTQAS)óa NIDA-funded effort lasting from 1989 to 1998óto develop a performance-based reporting and feedback system as the foundation for a formal performance improvement system in OTPs. MTQAS was never fully adopted because most OTPs lacked the ìfocused technical assistanceî (Ducharme and Luckey 2000, p. 87) required to translate feedback into action. Eight States participated in the MTQAS study, but only Massachusetts and North Carolina are using elements of the system at this writing. Many OTPs appear to be on their own in conducting program evaluations that comply with accreditation and State mandates.

Outcome and Process Evaluation

Both performance outcome and process evaluations have value, but they answer different questions and require different approaches. Performance outcome evaluation focuses on results, for example, patient progress. Process evaluation focuses on how results were achievedóthe active ingredients of treatment. The forthcoming TIP ***Substance Abuse: Administrative Issues in Outpatient Treatment*** (CSAT forthcoming ***c***) and ***Demystifying Evaluation: A Manual for Evaluating Your Substance Abuse Treatment Programóvolume 1*** (CSAT 1997***a***) describe and contrast these two types of evaluations.

Outcome evaluation in OTPs

Outcome evaluation in OTPs focuses on patients and their progress during or after participation in MAT. It should focus on progress markers (see chapter 7) and behavioral improvements as guideposts and avoid terms such as ìsuccessî and ìfailure.î Even small improvements may be significant. For example, an outcome evaluation might measure drug use (as quantified by drug testing) in patients who have spent various times in treatment. Such a study can set a baseline and provide a benchmark to evaluate the effects of changes in program practices, for example, prescribing individually appropriate dosages for patients. Researchers measure many variables to assess MAT treatment outcomes, including drug use, criminal activity, medical problems, vocational skills, employment, family relationships, and social activities. The measures selected by an OTP should agree with the target behaviors specified in program goals and objectives. For example, evaluation of a treatment initiative designed to reduce substance use, decrease criminal involvement, and increase job skills should be based on data in those areas. An OTP can measure other outcomes (such as patientsí use of emergency rooms for medical care) to assess whether it has had other effects on patient behaviors or the community.

SAMHSAís accreditation guidelines list the following treatment outcomes as examples of what might be measured by OTPs:

- ìreducing or eliminating the use of illicit opioids, other illicit-drugs, and the problematic use of prescription drugs
- reducing or eliminating associated criminal activities
- reducing behaviors contributing to the spread of infectious diseases
- improving quality of life by restoration of physical and mental health and functional status.î (CSAT 1999***b***, p. 7)

Outcome evaluation also can be focused narrowly; it can assess the results of particular treatment approaches on patient behavior. For example, an OTP might provide patients with bus tokens to defray transportation costs to and from treatment (some cities fund this kind of intervention). After a certain period, the OTP could evaluate whether providing bus tokens improved program attendance. This simple evaluation would require only attendance data. The most reliable evaluation uses a control group for comparison (e.g., a group of patients who must purchase their bus tokens), but this is not always practical or ethical.

Process evaluation

Process evaluation describes what is happening in the treatment program: what kind of treatment, who conducts the sessions, how many and how long the sessions are, and where the sessions occur. A process evaluation documents what actually happens during an intervention, how a new program or initiative is put into operation, who the players are and what steps they take, specific problems and barriers encountered, strategies used to overcome these problems and barriers, and necessary modifications to the original plan. Process evaluation also may describe what is happening within the ìblack boxî of the treatment program. Black box, a commonly used term in this context (Ball and Ross 1991, p. 5), refers to the unknown quality of some treatment programsóthat is, the fact that patients go into a program as

known entities and come out with certain measurable outcomes, but what actually occurs in treatment is not readily apparent. Process evaluation permits others to replicate methods that achieve their goals by evaluating the factors responsible for those achievements. A process evaluation can lead to development of a manual describing the theories and practices of an OTP to guide others. Implementation analysis should document a process fully. It is well suited to documenting an OTPís efforts in community relations, which is required in the accreditation process.

A process evaluation can serve as a management tool for program development if it is used to assess the strengths and weaknesses of a program and suggest ways to improve operations. A process evaluation helps administrators understand how program resources, including both staff and time, are used and can lead to improved resource allocation. Process evaluation is useful for examining whether OTP procedures are congruent with its stated goals. For example, if a goal is to facilitate patientsí use of peer support groups, the OTP could measure how often meetings of such groups are held on site, how often counselors provide patients with lists of local meetings, or whether patients actually receive interventions as intended. For example, an OTP intending to individualize care and match services to patientsí needs may decide to use the Addiction Severity Index (ASI) as a guide to treatment planning because research shows that the ASI indicates effective patientñservice matches (McLellan et al. 1997). A process evaluation might examine the degree to which treatment plans and service delivery were congruent with the needs identified by the ASI. If the program finds a lack of congruence, it can make corrections through training and supervision. The process evaluation also can measure the intensity and duration of services received by patients.

Resources for Program Evaluation and Performance Improvement

CSAT has published a comprehensive, detailed guide to program evaluation that provides a modularized learning approach, including exercises, for designing and conducting evaluations. ***Demystifying Evaluation: A Manual for Evaluating Your Substance Abuse Treatment ProgramóVolume 1*** (CSAT 1997***a***) is available from SAMHSAís National Clearinghouse for Alcohol and Drug Abuse Information at 800-729-6686 or www.ncadi.samhsa.gov.

For OTPs that want to use cost accounting as a form of program evaluation, NIDA has developed a manual based on a cost-procedure-process-outcome analysis model that has been well researched and tested in substance abuse treatment programs. ***Measuring and Improving Costs, Cost-Effectiveness, and Cost-Benefit for Substance Abuse Treatment ProgramsóA Manual*** is available at www.nida.nih.gov/IMPCOST/IMPCOSTIndex.html.

The Institute of Behavioral Research at Texas Christian University has carried out a substantial body of research on treatment process and outcomes (Simpson, D.D., et al. 1997***a***, 2000). The instituteís findings and experience in adapting assessments to field settings have guided development of a set of core instruments that are available at www.ibr.tcu.edu/pubs/datacoll/coresetforms.html. The Web site also contains useful program evaluation forms for gathering OTP data, including the organizationís readiness to change and patient satisfaction with treatment.

United Way of America has developed an Outcome Measurement Resource Network that is available through national.unitedway.org/outcomes.

The Change Book, a guidebook for organizational change in OTPs, is produced and distributed by the National ATTC, which can be reached at 877-652-2882 or www.nattc.org/resPubs/cbResources.html#cb.

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Appendix B: Abbreviations and Acronyms

AA	Alcoholics Anonymous
AAS	American Association of Suicidology
AATOD	American Association for the Treatment of Opioid Dependence (formerly American Methadone Treatment Association [AMTA])
ADA	Americans with Disabilities Act of 1990
AD/HD	attention deficit/hyperactivity disorder
AMA	American Medical Association
APA	American Psychiatric Association
APD	antisocial personality disorder
ASAM	American Society of Addiction Medicine
ASI	Addiction Severity Index
ATTC	Addiction Technology Transfer Center
AZT	zidovudine
CA	Cocaine Anonymous
CALDATA	California Drug and Alcohol Treatment Assessment
CARF	Commission on Accreditation of Rehabilitation Facilities
CBT	cognitive behavioral therapy
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CJS	criminal justice system

CNS	central nervous system
COPD	chronic obstructive pulmonary disease
CPS	childrenís protective services
CRA	community reinforcement approach
CSA	Controlled Substances Act
CSAT	Center for Substance Abuse Treatment
CYP3A4	cytochrome P3A4
CYP450	cytochrome P450
DASIS	Drug and Alcohol Services Information System
DATA	Drug Abuse Treatment Act of 2000
DAWN	Drug Abuse Warning Network
DCP	diversion control plan
DEA	U.S. Drug Enforcement Administration
DHHS	U.S. Department of Health and Human Services
DSM-IV-TR	***Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision***
ECA	Epidemiological Catchment Area
ECG	electrocardiogram
EEG	electroencephalogram
EIA	enzyme immunoassay
EMIT	Enzyme Multiplied Immunoassay Technique
FDA	U.S. Food and Drug Administration
GC/MS	gas chromatography/mass spectrometry
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	human immunodeficiency virus
ICD-10	***International Statistical Classification of Diseases and Related Health Problems, 10th Edition***
IND	investigational new drug
IOM	Institute of Medicine
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
LAAM	levo-alpha acetyl methadol
LGB	lesbian, gay, and bisexual
MA	Methadone Anonymous
MAT	medication-assisted treatment for opioid addiction
MDI	Bayley Mental Development Index
MSW	medically supervised withdrawal
MTQAS	Methadone Treatment Quality Assurance System
NA	Narcotics Anonymous
NAPAN	National Association for the Prevention of Addiction to Narcotics
NAS	neonatal abstinence syndrome
NASADAD	National Association of State Alcohol and Drug Abuse Directors

NCADI	SAMHSAís National Clearinghouse for Alcohol and Drug Abuse Information
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMBY	not in my back yard
NIMH	National Institute of Mental Health
OBOT	office-based opioid treatment
ONDCP	Office of National Drug Control Policy
OTP	opioid treatment program
PCR	polymerase chain reaction
PEG	polyethylene glycol
PPD	purified protein derivative
PTSD	posttraumatic stress disorder
QSOA	Qualified Service Organization Agreement
RIA	radioimmunoassay
RNA	ribonucleic acid
RTSH	Recovery Training and Self-Help
SAMHSA	Substance Abuse and Mental Health Services Administration
SAPT	Substance Abuse Prevention and Treatment (name of block grant)
SMA	State Methadone Authority
SML	serum methadone level
SSA	Single State Agency
SSRI	selective serotonin reuptake inhibitor
STD	sexually transmitted disease
SVR	sustained virologic response
TB	tuberculosis
TC	therapeutic community
THC	tetra-hydrocannabinol
TIP	Treatment Improvement Protocol
TLC	thin layer chromatography
TMA	transcription mediated amplification
VBRT	voucher-based reinforcement therapy

Appendix C: Glossary

-A-

abstinence. Nonuse of alcohol or any illicit drugs, as well as nonabuse of medications normally obtained by prescription or over the counter. Abstinence in this TIP does not refer to nonuse of or withdrawal from maintenance medications (methadone, buprenorphine, LAAM, or naltrexone) when they are used in MAT. Compare ***medically supervised withdrawal.***

accreditation. Process of periodic review of an OTP for conformance with accrediting-body standards. Accrediting bodies and their standards are approved by SAMHSA. See 42 CFR, Part 8 ß 2, for other accreditation-related terms and definitions.

acute phase. Initial and usually the most symptomatic intensive-treatment phase of MAT.

addiction. Combination of the physical dependence on, behavioral manifestations of the use of, and subjective sense of need and craving for a psychoactive substance, leading to compulsive use of the substance either for its positive effects or to avoid negative effects associated with abstinence from that substance. Compare ***dependence.***

administrative discharge. Release or discharge of a patient from an OTP, often against the patientís wishes. See ***involuntary discharge.***

admission. Formal process of enrolling patients in an OTP, carried out by qualified personnel who determine that the patient meets acceptable medical criteria for treatment. Admission can include orientation to the program and an introduction to peer support, patient rights, services, rules, and treatment requirements related to MAT.

agonist. See ***opioid agonist***.

analgesic. A compound that alleviates pain without causing loss of consciousness. ***Opioid analgesics*** are a class of compounds that bind to

specific receptors in the central nervous system to block the perception of pain or affect the emotional response to pain. Such compounds include opium and its derivatives, as well as a number of synthetic compounds. Chronic administration or abuse of opioid analgesics may lead to addiction.

antagonist. See ***opioid antagonist***.

assessment. Process of identifying the precise nature and extent of a patientís substance use disorder and other medical, mental health, and social problems as a basis for treatment planning. Assessment usually begins during program admission and continues throughout treatment. It includes a personal substance abuse history, physical examination, laboratory evaluation, and determination of disease morbidity. Severity of disease often is assessed further in terms of physiologic dependence, organ system damage, and psychosocial morbidity. Assessment also may involve determining patient motivation and readiness for change.

assessment tools. Instruments (e.g., questionnaires) used to capture the range of patient variables affecting treatment planning, methods, and outcomes. Valid assessment tools contain quantifiable indicators to measure patient progress and to track patients through treatment.

Axis I. DSM-IV-TR disorder classification comprising definitions and descriptions of major disorders (i.e., psychotic, mood, and substance use disorders) that may require clinical attention.

-B-

benzodiazepines. Group of medications having a common molecular structure and similar pharmacological activity, including antianxiety, sedative, hypnotic, amnestic, anticonvulsant, and muscle-relaxing effects. Benzodiazepines are among the most widely prescribed medications (e.g., diazepam, chlordiazepoxide, clonazepam, alprazolam, lorazepam).

best-treatment practices. Methods determined, often by a consensus of experts, to be optimal for defined therapeutic situations. Such guidelines usually are based on both an analysis of published research findings and the experience of experts.

blood testing. Identifying evidence of opioid and other psychoactive substance use and measuring the levels of substances or medications in the body by examining patient blood specimens for the presence and concentrations of identifiable drugs and their metabolites.

buprenorphine. Partial opioid agonist approved by FDA for use in detoxification or maintenance treatment of opioid addiction and marketed under the trade names Subutex® and Suboxone® (the latter also containing naloxone).

-C-

certification. Process by which SAMHSA determines that an OTP is qualified to provide opioid addiction treatment under the Federal opioid treatment standards.

civil commitment. Legal process that permits individuals to be confined against their will in psychiatric or other treatment facilities, which usually is justified by determining that a patient is a threat to himself or herself or others. Although statutes permitting involuntary civil commitment may remain in some States, such laws rarely have been used to commit people who abuse substances and are not under criminal justice jurisdiction.

Commission on Accreditation of Rehabilitation Facilities (CARF). One of several SAMHSA-approved accreditation organizations charged with ensuring that OTPs meet the standards set forth in Federal regulations and SAMHSA guidelines. Also known as CARF. . . The Rehabilitation Accreditation Commission.

comprehensive maintenance treatment. Continuous therapy with medication in conjunction with a wide range of medical, psychiatric, and psychosocial services. Compare ***medical maintenance***.

comprehensive treatment assessment. Evaluation made after formal admission to an OTP, in which trained staff members determine the range and severity of a patientís problems and the patientís service needs. These determinations are used to establish short- and long-term treatment goals in the patientís treatment plan.

confidentiality regulations. Rules established by Federal and State agencies to limit disclosure of information about a patientís substance use disorder and treatment (described in 42 CFR, Part 2 ß 16). Programs must notify patients of their rights to confidentiality, provide a written summary of these rights, and establish written procedures regulating access to and use of patient records.

consent to treatment. Form completed with and signed by an applicant for MAT and by designated treatment program staff members, which verifies that the applicant has been informed of and understands program procedures and his or her rights and treatment goals, risks, and performance expectations.

contingency contracting. Use of preestablished, mutually agreed-on privileges (e.g., take-home dosing) or consequences (e.g., loss of privileges) to motivate improvements in treatment outcomes. Many experts agree that negative contingencies in MAT (e.g., reduction in medication) are neither effective nor ethical and should be avoided.

continuing-care phase. Optional phase of MAT in which patients who have completed medically supervised withdrawal from treatment medication and are leading socially productive lives continue to maintain regular contact with their treatment program.

co-occurring disorder. In this TIP, a mental disorder, according to DSM-IV diagnosis, that is present in an individual who is admitted to an OTP.

counseling. In MAT, a treatment service in which a trained counselor and a case manager evaluate both a patientís external circumstances and immediate treatment progress and offer appropriate advice and assistance or referral to other experts and services as needed. A major objective in MAT is to provide skills and support for a substance-free lifestyle and encourage abstinence from alcohol and other psychoactive substances. Compare ***psychotherapy.***

craving. Urgent, seemingly overpowering desire to use a substance, which often is associated with tension, anxiety, or other dysphoric, depressive, or negative affective states.

cross-tolerance. Condition in which repeated administration of a drug results in diminished effects not only for that drug but also for one or more drugs from a similar class to which the individual has not been exposed recently.

cultural competence. Capacity of a service provider or organization to understand and work effectively in accord with the beliefs and practices of persons from a given ethnic/racial/religious/social group or sexual orientation. It includes the holding of knowledge, skills, and attitudes that allow the treatment provider and program to understand the full context of a patientís current and past socioenvironmental situation.

cultural diversity. Differences in backgrounds and beliefs that may affect the way groups of patients in OTPs and individuals within these groups view the world and

their place in it, their substance use, and treatment.

-D-

dependence. State of physical adaptation that is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, and/or decreasing blood level of a substance and/or administration of an antagonist. Compare ***addiction.***

detoxification. In this TIP, treatment for addiction to an illicit substance in which the substance is eliminated gradually from a patientís body while various types and levels of reinforcing treatment are provided to alleviate adverse physical or psychological reactions to the withdrawal process. This TIP avoids the term ìdetoxificationî to designate the process of dose tapering from maintenance medication because that term incorrectly suggests that opioid treatment medications are toxic. Compare ***medically supervised withdrawal***.

diagnosis. Classification of the nature and severity of the substance use, medical, mental health, or other problems present in a patient who is addicted to opioids. DSM-IV-TR and ICD-10 classifications commonly are used to classify substance use and mental disorders.

discharge. Release from or discontinuation of enrollment in treatment when maximum benefit has been achieved or when a patient is deemed no longer suitable for treatment. See ***administrative discharge, involuntary discharge.***

diversion. Sale or other unauthorized distribution of a controlled substance, usually for a purpose other than the prescribed and legitimate treatment of a medical or mental disorder.

diversion control plan. Documented procedures to reduce the possibility that controlled substances are used for other than their legitimate use. Federal opioid treatment standards (42 CFR, Part 8 ß 12(c)(2)) require a diversion control plan in an OTP as part of its quality assurance program.

dosage determination. Process of identifying the amount of medication that will minimize withdrawal symptoms and craving in patients in MAT and eliminate their opioid abuse. Much evidence supports a linear relationship among the amount of medication provided, the timeframe over which it is allowed to act before another dose is administered (dose frequency), and treatment response.

dose tapering. See ***medically supervised withdrawal***.

drug interaction. Action of one drug on the effectiveness or toxicity of another drug.

drug testing. Examination of an individual to determine the presence or absence of illicit or nonprescribed drugs or alcohol or to confirm maintenance levels of treatment medications, usually by a methodology that has been approved by the OTP medical director based on informed medical judgment. OTPs also must conform to State laws and regulations in this area. See ***blood testing, oral-fluid drug testing, urine testing.***

duration of action. Length of time that a treatment medication effectively prevents withdrawal symptoms or craving. Duration of action can be affected by many factors, including drug interactions, certain diseases and medical conditions, patient cross-tolerance, and the relative affinity of a medication for its targeted cell receptor.

-E-

eligibility. See ***treatment eligibility***.

elimination half-life. Time required after administration of a substance (e.g., methadone) for one-half the dose to leave the body. Elimination half-life affects the duration of action of a substance or

medication and can be influenced by patient factors such as absorption rate, variable metabolism and protein binding, changes in urinary pH, concomitant medications, diet, physical condition, age, pregnancy, and even use of vitamins and herbal products.

-H-

half-life. See ***elimination half-life***.

hepatitis C. Viral disease of the liver that is the leading cause of cirrhosis in the United States and a particular concern in MAT because of the high incidence of the disease and spread of the infection among people who inject drugs.

high-risk behavior. Activity that increases the likelihood that a recovering patient in substance abuse treatment will relapse to substance use or contract a substance use-related disorder, such as an infectious disease.

hospital-based treatment. Treatment of opioid addiction and related complications that requires patient residency for some period in a hospital setting or outpatient treatment in a hospital-linked facility to ensure that necessary services and levels of care are available.

-I-

iatrogenic opioid addiction. Addiction resulting from medical use of an opioid (i.e., under physician supervision), usually for pain management.

induction. Initial treatment process of adjusting maintenance medication dosage levels until a patient attains stabilization.

induction stage. The period of opioid pharmacotherapy, usually during the acute phase of treatment, in which steady-state blood levels of a medication are achieved.

intake. Initial screening of applicants for admission to an OTP.

intensity of treatment. Frequency and method of delivery for therapeutic services. In this TIP and in American Society of Addiction Medicine Patient Placement Criteria, intensity of treatment is one component, along with treatment setting, that determines the level of care for a patient. Levels of care are adjusted during MAT based on patient needs and the treatment plan. See, for example, ***intensive inpatient treatment*** and ***intensive outpatient treatment.***

intensive inpatient treatment. Level of care in which addiction professionals and clinicians provide a regimen of around-the-clock evaluation, care, and therapy in an inpatient setting. Involvement of physicians can range from monitoring multidisciplinary staff members to direct management of cases, depending on the severity of patientsí problems.

intensive outpatient treatment. Level of care (possibly including partial hospitalization) in which addiction professionals and clinicians provide therapeutic services to clients who live at home or in special residences. Treatment is delivered in two to five regularly scheduled sessions per week totaling 6 to 24 hours per week. Many treatment services and levels of care are compatible with intensive outpatient treatment, but most programs include structured psychoeducation and group counseling.

interim maintenance treatment. Time-limited pharmacotherapeutic regimen in conjunction with appropriate medical services while a patient awaits transfer to an OTP that provides comprehensive maintenance treatment (42 CFR, Part 8 ß 2).

intervention. The process of providing care to a patient or taking action to modify a symptom, an effect, or a behavior. Also the process of interacting after assessment with a patient who is substance addicted to present a diagnosis and recommend and negotiate a treatment plan. Also frequently used

as a synonym for ***treatment***. Types of intervention can include crisis intervention, brief intervention, and long-term intervention.

involuntary discharge. Formal discontinuation of a patientís enrollment in an OTP without patient consent, usually for reasons related to program operations, safety, or treatment complianceófor example, violence or threats of violence; buying and selling drugs; repeated loitering; flagrant noncompliance with program rules resulting in an observable, negative impact on the program, staff, and other patients; nonpayment of fees; and incarceration or other confinement. See ***administrative discharge***.

-J-

Joint Commission on Accreditation of Healthcare Organizations (JCAHO). One of several SAMHSA-approved accreditation organizations charged with ensuring that OTPs meet the standards set forth in Federal regulations and SAMHSA guidelines.

-L-

LAAM. See ***levo-alpha acetyl methadol***.

level of care. The setting or combination of settings in which the appropriate intensities and types of treatment services can be provided for individual patients.

levo-alpha acetyl methadol (LAAM; trade name ORLAAM). An opioid agonist medication derived from methadone that is effective for up to 72 hours. Reports in 2000 and 2001 of potential arrhythmogenic cardiac effects of LAAM led to tightening of guidelines, including recommendations that LAAM no longer be used for first-line therapy but only for treatment of patients who already have used it successfully or do not show an acceptable response to other addiction treatments. At this writing, LAAMís future availability for opioid pharmacotherapy is doubtful.

-M-

maintenance dosage. Amount of medication that is adequate to achieve desired therapeutic effects for 24 hours or more, with allowance for day-to-day fluctuations.

maintenance medication. Medication used for ongoing treatment of opioid addiction.

maintenance treatment. Dispensing of an opioid addiction medication at stable dosage levels for a period in excess of 21 days in the supervised treatment of an individual for opioid addiction (42 CFR, Part 8 ß 2).

medical maintenance. (1) Phase of MAT and type of treatment by an OTP, medication unit, or physician affiliated with an OTP in which a person who has achieved a stable lifestyle and has remained abstinent from illicit drugs for at least 2 years (longer in some States) receives ongoing pharmacotherapy with methadone, buprenorphine, or LAAM but no longer requires the structure or frequency of psychosocial treatment services provided in an OTP, as determined by the OTP medical director. (2) Medical maintenance also can be provided by physicians using buprenorphine or naltrexone (42 CFR, Part 8 ß 12(i)(3)(vi); 42 CFR, Part 8 ß 11(h)).

medically supervised withdrawal. Dispensing of a maintenance medication in gradually decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of opioid drugs. The purpose of medically supervised withdrawal is to bring a patient maintained on maintenance medication to a medication-free state within a target period.

medication-assisted treatment for opioid addiction (MAT). Type of addiction treatment, usually provided in a certified, licensed OTP or a physicianís office-based treatment setting, that provides

maintenance pharmacotherapy using an opioid agonist, a partial agonist, or an antagonist medication, which may be combined with other comprehensive treatment services, including medical and psychosocial services.

medication unit. Facility established as part of, but geographically separate from, an opioid treatment program, from which certified private practitioners or community pharmacists may dispense or administer opioid agonist medications for observed ingestion (42 CFR, Part 8 ß 11(i)(1)).

methadone. The most frequently used opioid agonist medication. Methadone is a synthetic opioid that binds to mu opiate receptors and produces a range of mu agonist effects similar to those of short-acting opioids such as morphine and heroin.

methadone maintenance treatment. Dispensing of methadone at stable dosage levels for more than 21 days in the supervised treatment of an individual for opioid addiction (42 CFR, Part 8 ß 2).

mobile treatment services. Substance use treatment provided directly to patients from traveling units or vans, ranging from comprehensive maintenance services (with medication and counseling in one or several mobile units) to more limited care, usually medication maintenance therapy, in conjunction with a fixed-site program offering counseling and other psychosocial services.

multiple substance abuse. Concurrent opioid and other substance useóa serious problem in OTPs. Other substances commonly used by people addicted to opioids include alcohol, amphetamines, benzodiazepines (particularly alprazolam and diazepam), other prescription sedatives, cocaine, marijuana, and nicotine. Patterns of use range from periodic low doses to regular high doses that also can meet criteria for addiction. Some drugsóin particular, high-dose barbituratesóused in combination with opioids are immediately life threatening.

mutual-help program. Program offering the benefits of peer support to people who are substance addicted, through attendance at group meetings and other activities. Twelve-Step programs are one type of mutual-help program.

-N-

naloxone. Short-acting opioid antagonist. Because of its higher affinity than that of opioids for mu opiate receptors, naloxone displaces opioids from these receptors and can precipitate withdrawal, but it does not activate the mu receptors, nor does it cause the euphoria and other effects associated with opioid drugs. Naloxone is not FDA approved for long-term therapy for opioid addiction, except in the combination buprenorphine-naloxone tablet. Some programs use naloxone to evaluate an individualís level of opioid dependence. See ***naloxone challenge test.***

naloxone challenge test. Test in which naloxone is administered to verify an applicantís current opioid dependence and eligibility for admission to an OTP. Withdrawal symptoms evoked by naloxoneís antagonist interaction with opioids confirm an individualís current dependence.

naltrexone. Derivative of naloxone and the only opioid antagonist approved for use alone in long-term treatment of people with opioid addiction. Naltrexone is used primarily after medically supervised withdrawal from opioids to prevent drug relapse in selected, well-motivated patients.

narcotic. See ***opioid*** (preferred usage).

not-in-my-backyard (NIMBY) syndrome. Informal name used to label opposition to the placement of OTPs in communities.

-O-

office-based opioid treatment (OBOT). MAT provided in a physicianís office or health care setting other than an OTP (42 CFR, Part 8 ß 11(i)(1)). See ***medication unit***.

opiate receptors. Areas on cell surfaces in the central nervous system that are activated by opioid molecules to produce the effects associated with opioid use, such as euphoria and analgesia. Opiate receptors are activated or blocked by opioid agonist or antagonist medications, respectively, to mediate the effects of opioids on the body. Mu and kappa opiate receptor groups principally are involved in this activity.

opioid. Natural derivative of opium or synthetic psychoactive substance that has effects similar to morphine or is capable of conversion into a drug having such effects. One effect of opioid drugs is their addiction-forming or addiction-sustaining liability.

opioid addiction. Cluster of cognitive, behavioral, and physiological symptoms resulting from continuation of opioid use despite significant related problems. Opioid addiction is characterized by repeated self-administration that usually results in opioid tolerance, withdrawal symptoms, and compulsive drug taking.

opioid addiction treatment. Dispensing of approved medication to prevent withdrawal and craving during the elimination of opioid use by a patient in MAT, with or without a comprehensive range of medical and rehabilitation services or medication prescribed when necessary to alleviate the adverse medical, psychological, or physical effects. This term encompasses medically supervised withdrawal, maintenance treatment, comprehensive maintenance treatment, and, under restricted timeframes, interim maintenance treatment (adapted from 42 CFR, Part 8 ß 2).

opioid agonist. Drug that has an affinity for and stimulates physiologic activity at cell receptors in the central nervous system normally stimulated by opioids. Methadone and LAAM are opioid agonists.

opioid antagonist. Drug that binds to cell receptors in the central nervous system that normally are bound by opioid psychoactive substances and that blocks the activity of opioids at these receptors without producing the physiologic activity produced by opioid agonists. Naltrexone is an opioid antagonist.

opioid partial agonist. Drug that binds to, but incompletely activates, opiate receptors in the central nervous system, producing effects similar to those of a full opioid agonist but, at increasing doses, does not produce as great an agonist effect as do increased doses of a full agonist. Buprenorphine is a partial opioid agonist.

opioid treatment program (OTP). SAMHSA-certified program, usually comprising a facility, staff, administration, patients, and services, that engages in supervised assessment and treatment, using methadone, buprenorphine, LAAM, or naltrexone, of individuals who are addicted to opioids. An OTP can exist in a number of settings, including, but not limited to, intensive outpatient, residential, and hospital settings. Services may include medically supervised withdrawal and/or maintenance treatment, along with various levels of medical, psychiatric, psychosocial, and other types of supportive care.

oral-fluid drug testing. Method of identifying evidence of opioid and other psychoactive substance use and measuring the levels of substances or medications in the body by examining patient saliva for the presence and concentrations of identifiable drugs and their metabolites. Oral-fluid testing must be approved for drug testing by the OTP medical director for patient and program needs.

orientation. See ***patient orientation.***

outcome-based evaluation. Measurement of program effectiveness based on patient response to treatment, such as measures of reduction in opioid and nonopioid drug use and improvement in social function. An outcome-based evaluation system requires that the measures and instruments that are used reflect a consensus of the field, provide incentives to programs to submit data, and include ways to validate and aggregate clinic-level data for national and regional evaluation purposes. Compare ***process-based evaluation.***

outpatient psychosocial program. In this TIP, an approach to MAT that may involve the use of opioid addiction treatment medication for medically supervised withdrawal but not for ongoing maintenance pharmacotherapy. Counseling and other psychosocial interventions are the primary features of outpatient psychosocial treatment programs.

OxyContin®. Long-acting class II opioid drug usually obtained by prescription for treatment of pain. OxyContin is one of several prescription opioids increasingly obtained by illicit means and abused by people addicted to opioids.

-P-

pain management. Treatment of acute or chronic pain by various treatment methods, often including administration of opioid medications.

patient. Any individual undergoing MAT in an opioid treatment program (42 CFR, Part 8 § 2).

patient advocacy. Term applied to two levels of activity in addiction treatment: (1) a social or political movement working for changes in legislation, policy, and funding to reflect patient concerns and protect their rights (i.e., advocacy ***for*** patients) and (2) a philosophy of substance abuse treatment practice maintaining that patients should be involved actively in their own treatment and have rights in its planning and implementation (i.e., advocacy ***by*** patients). Much of advocacy is about shifting the system from the directive model to one in which the patient is an empowered, involved participant in treatment decisions. This fits with the growing emphasis on individualized treatment.

patient exception. Special permission requested from and decided by SAMHSA for a substance abuse treatment program to dispense or arrange for the offsite delivery of maintenance medication to a patient in an emergency or hardship situation when the patient does not meet regulatory requirements for such services. Patient exceptions are requested on SAMHSA form SMA-168. In most States, patient exceptions are contingent on the approval of the appropriate State Methadone Authority.

patient handbook. Document provided to a patient in an OTP that contains the information he or she should know to understand MAT, program offerings, program structure, and patient limits and privileges, as well as rights and responsibilities of patients and treatment providers.

patient matching. See ***patientñtreatment matching.***

patient motivation for change. Relative readiness to modify oneís lifestyle and the sincerity and purposefulness of a patient in an OTP toward achieving the goals of MAT.

patient orientation. Planned introduction to the structure, services, offerings, and methods used in an OTP and to patientsí and treatment providersí rights and responsibilities within the program.

patient referral. Alternative to providing all necessary treatment services and levels of care at the program site by collaboratively outsourcing some services to other settings and providers. When a patient must obtain comprehensive services in multiple settings,

treatment program staff members should arrange the referrals, monitor patient progress, and coordinate care.

patientñtreatment matching. Process of individualizing therapeutic resources to patient needs and preferences, ideally by a participatory process involving both the treatment provider and patient. Because many people addicted to opioids have multiple needs, effective patientñtreatment matching in an OTP is a three-step process: (1) assessing, (2) selecting the most suitable treatment modality and site, and (3) identifying the most appropriate services.

pharmacology. Science that addresses the origin, nature, chemistry, effects, and uses of medications and drugs.

pharmacotherapy. Treatment of disease with prescribed medications.

preliminary assessment. Basic assessment occurring before admission to a treatment program, in which an individualís eligibility for entry and level of any psychosocial crisis are determined.

prevalence. Number of cases of a disease in a population, either at a point in time (point prevalence) or over a period (period prevalence). ***Prevalence rate*** is the fraction of people in a population who have a disease or condition at one time (the numerator of the rate is the number of existing cases of the condition at a specified time and the denominator is the total population).

process-based evaluation. Evaluation of program effectiveness based on compliance with procedural standards. Compare ***outcome-based evaluation.***

psychiatric comorbidity. See ***co-occurring disorder.***

psychoactive drug. A substance that affects the mind, thoughts, feelings, and sometimes behaviors.

psychotherapy. Treatment service provided to patients in a comprehensive opioid treatment program, either directly or by referral, in which a trained therapist evaluates and treats patients for diagnosed psychiatric problems. Compare ***counseling.***

-R-

readmission. Reenrollment of a patient who previously left an opioid treatment program. Readmission usually is preceded by a review of the patientís records to determine whether and how the individualís treatment plan should be modified.

referral. See ***patient referral***.

rehabilitative phase. Phase of MAT in which patients who are stabilized on opioid treatment medication continue to eliminate addictive substances from their lives while gaining control of other major life domains (e.g., medical problems, co-occurring disorders, vocational and educational needs, family circumstances, legal issues).

relapse. Breakdown or setback in a personís attempt to change or modify a particular behavior; an unfolding process in which the resumption of compulsive substance use is the last event in a series of maladaptive responses to internal or external stressors or stimuli.

remission. State in which a mental or physical disorder has been overcome or a disease process halted.

residential treatment. Therapy received within the context of a cooperative living arrangement. Residential treatment programs vary in duration and intensity of services and general philosophy.

retention in treatment. Period during which a patient is able and willing to remain in therapy, which is influenced by a combination of patient and program characteristics. Retention in treatment should be considered the product of a continuing

therapeutic relationship between recovering patients and their treatment providers.

-S-

saliva testing. See ***oral-fluid drug testing***.

screening. Process of determining whether a prospective patient has a substance use disorder before admission to treatment. Screening usually involves use of one or more standardized techniques, most of which include a questionnaire or a structured interview. Screening also may include observation of known presenting complaints and symptoms that are indicators of substance use disorders.

sedative. Medication with central nervous system sedating and tranquilizing properties. An example is any of the benzodiazepines. Most sedatives also promote sleep. Overdoses of sedatives can lead to dangerous respiratory depression (slowed breathing).

self-help program. See ***mutual-help program***.

self-medication. Medically unsanctioned use of drugs by a person to relieve any of a variety of problems (e.g., pain, depression).

serum half-life. Time required for the amount of a compound (e.g., an opioid) in blood serum to be halved through metabolism or excretion.

side effect. Consequence (especially an adverse result) other than that for which a drug is usedóespecially the result produced on a tissue or organ system other than that being targeted.

stabilization (stability). Process of providing immediate assistance (as with an opioid agonist) to eliminate withdrawal symptoms and drug craving.

stand-alone clinic. Facility that generally offers a comprehensive range of medication and psychosocial services for patients who are opioid addicted, including all levels of care and phases of treatment. Compare ***hospital-based treatment.***

State Authority. Agency (sometimes referred to as a ìSingle State Agencyî) designated by the governor or another official assigned by the governor to exercise the responsibility and authority within a State or territory for governing the treatment of addiction to opioid drugs (adapted from 42 CFR, Part 8 ß 2).

stigma. Negative association attached to an activity or condition; a cause of shame or embarrassment. Stigma commonly is associated with opioid addiction and MAT.

stimulant. Agent, drug, or medication that produces stimulation. In this TIP, stimulant usually refers to drugs that stimulate the central nervous system (e.g., amphetamines, cocaine).

substance addiction. See ***opioid addiction.***

substance dependence. See ***dependence.***

substance use disorder (frequently referred to as substance abuse or dependence). Maladaptive pattern of drug or alcohol use manifested by recurrent, significant adverse consequences related to the repeated use of these drugs or alcohol. The substance-related problem must have persisted and occurred repeatedly during a 12-month period. It can occur sporadically and mainly be associated with social or interpersonal problems, or it can occur regularly and be associated with medical and mental problems, often including tolerance and withdrawal.

supportive-care phase. Phase of MAT in which patients maintain abstinence from substances and continue on maintenance medication while receiving other types of intervention as needed to resume primary responsibility for other aspects of their lives.

-T-

take-home medication. Opioid addiction treatment medication dispensed to patients for unsupervised self-administration.

tapering phase. Phase of MAT in which patients receiving medication maintenance attempt gradually to eliminate their treatment medication (e.g., methadone) while remaining abstinent from illicit substances.

therapeutic alliance. Joining of patients and their treatment providers in an effective collaboration to assess and treat patientsí substance use disorders.

therapeutic community (TC). Consciously designed social environment or residential treatment setting in which social and group processes are harnessed with treatment intent. A TC promotes abstinence from substance use and seeks to decrease antisocial behavior and effect a global change in lifestyle, including attitudes and values. A TC views substance abuse as a disorder of the whole person, reflecting problems in conduct, attitudes, moods, values, and emotional management. Treatment focuses on drug abstinence, coupled with social and psychological change requiring a multidimensional effort along with intensive mutual help and support.

therapeutic dosage. Combination of amount of medication and frequency and timing of administration that is determined by laboratory analysis, professional observation, or patient self-report to be beneficial to control and ameliorate symptoms of withdrawal from addiction and drug-seeking behavior. Therapeutic dosage levels should be determined by what each patient needs to remain stable.

tolerance. Condition of needing increased amounts of an opioid to achieve intoxication or a desired effect; condition in which continued use of the same amount of a substance has a markedly diminished effect.

treatment barrier. Anything that hinders treatment. Examples include financial problems, language difficulties, ethnic and social attitudes, logistics (caring for children, transportation), and unhelpful patient behaviors (tardiness, missed appointments).

treatment efficacy. Ability of an intervention or medication in expert hands and under ideal circumstances to produce the desired therapeutic effect.

treatment eligibility. Relative qualification of a prospective patient for admission to an OTP according to Federal, State, or third-party payer requirements. In general, Federal guidelines are minimum requirements and restrict admission to individuals who have been demonstrably dependent on opioids for 1 year; however, certain high-risk populations including pregnant women are admitted more quickly.

treatment intensity. Frequency and methods for delivery of therapeutic services. OTPs aim to establish levels of treatment intensity that match patientsí needs.

treatment outcomes. Observable results of therapy, including decreased use of illicit psychoactive substances, improved physical and emotional health, decreased antisocial activities, and improved social functioning; considered the best indicator of treatment program effectiveness.

treatment plan. Documented therapeutic approach for each patient that outlines attainable short-term goals mutually acceptable to the patient and the OTP and that specifies the services to be provided and their frequency and schedule (adapted from 42 CFR, Part 8 ß 2).

treatment retention. See ***retention in treatment.***

12-Step program. Self-help program requiring mastery of a set of steps to achieve and maintain abstinence, based on the program

of Alcoholics Anonymous. Many addiction treatment programs use a 12-Step structure or philosophy as a construct for treatment design.

-U-

urine drug testing. Most common laboratory assessment technique in addiction treatment, which involves analysis of urine samples from patients for the presence or absence of specific drugs. Originally used as a measure of program effectiveness, urine testing now is used to make programmatic decisions, monitor psychoactive substance use, adjust medication dosage, and decide whether a patient is responsible enough to receive take-home medication. Methods of urine testing vary widely.

-V-

voluntary discharge. Departure from an OTP that is initiated by the patient. Tapering from medication is negotiated among the patient, program physician, and treatment providers.

-W-

withdrawal. Reduction and elimination of substance use. See ***medically supervised withdrawal, withdrawal syndrome.***

withdrawal syndrome (or withdrawal). Predictable constellation of signs and symptoms after abrupt discontinuation of or rapid decrease in use of a substance that has been used consistently for a period. Signs and symptoms of withdrawal are usually opposite to the direct pharmacological effects of a psychoactive substance.

Appendix D: Ethical Considerations in MAT

Medication-assisted treatment for opioid addiction (MAT) is firmly rooted in medical treatment models. Treatment decisions by MAT providers should be based on four accepted principles of medical ethics, which can be listed briefly as beneficence, autonomy, nonmalfeasance, and justice (Beauchamp and Childress 2001).

Fundamental Ethical Principles

Beneficence (Benefit)

According to Beauchamp and Childress (2001), the medical principle of beneficence emphasizes that treatment providers should act for the benefit of patients by providing competent, timely care within the bounds of accepted treatment practice. The principle of beneficence is satisfied when treatment providers make proper diagnoses and offer evidence-based treatments, that is, treatments drawn from research that provides statistical data about outcomes or from consensus-based standards of care. Beneficence is compromised when diagnoses are questionable or when outcome data do not validate a diagnosis or treatment. When MAT is carried out according to best-practice standards, the principle of beneficence is satisfied (Bell and Zador 2000).

Autonomy

Autonomy, like beneficence, springs from the ideal of promoting patientsí best interests. However, whereas beneficence emphasizes the application of provider knowledge and skills to improve patient health, autonomy emphasizes respect for patientsí rights to decide what treatment is in their best interests (Beauchamp and Childress 2001).

Standard medical practice places great value on patient autonomy. Usually, patientsí and physiciansí goals for treatment are identical, but, when they differ, physicians generally accord patients the right to make

their own choices and accept the fact that patientsí values may differ from physiciansí values. For example, a physician might focus on extending a patientís life, whereas the patient might be more concerned with the quality of that life.

Exceptions to the principle of autonomy in standard medical practice are limited to circumstances in which patientsí decisions might endanger themselves or others or in which patients may lack the capacity (because of physical or mental impairment) to make rational choices. Normally, standard medical practice does not permit an exception when patients make the ìwrongî choice and the physician ìknows better.î The physician may educate or perhaps attempt to persuade a patient but may not make decisions for the patient.

NonmalfeasanceóìFirst, Do No Harm î

The principle of nonmalfeasance emphasizes that health care providers should not harm or injure patients (Beauchamp and Childress 2001). Opioid treatment programs (OTPs) are on strong footing in terms of this principle. Before entering MAT, patients have been ingesting illicit opioids (and often other substances) and exposing themselves to serious health risks. Patients entering MAT are also at risk of arrest and imprisonment for illegal activities to support their addictions.

Once enrolled in OTPs, patients begin ingesting medications that have been manufactured in a regulated setting. The risks associated with injecting or otherwise ingesting substances of abuse produced under unknown conditions are gradually eliminated. Patients come under the care of professionals who monitor adverse drug reactions and attend to other health care needs. However, MAT carries risks of its own, including an increased risk of death in the induction phase of pharmacotherapy if medication dosage is not adjusted carefully (see chapter 5).

Justice

The principle of justice emphasizes that treatment providers should act with fairness (Beauchamp and Childress 2001). Sometimes this principle is expressed as the duty of providers to treat patients in similar circumstances equally and to use resources equitably. When treatment resources are limited, it may be unclear how to apply this principle in MAT. The principle of justice also applies when treatment providers consider the involuntary discharge of patients.

Besides emphasizing that clinicians should act fairly toward patients, the principle of justice imposes a responsibility to advocate politically and socially for resources (including adequate funding and better treatment by other medical providers) to meet the needs of patients in MAT.

Ethics in Practice

Conflict Between Beneficence and Autonomy

A conflict arises between the principles of beneficence and autonomy when a treatment provider and a patient disagree about what is in the patientís best interest and how treatment should progress. Exhibit D-1 describes such a clash in which a provider believes that stopping all illicit drug use is feasible and in the patientís best interest but the patient disagrees or cannot comply. One or both of the following questions express the source of controversy:

- What is the proper balance between respect for a patientís autonomy and a providerís responsibility for that patientís health?
- Should the patient or the clinician decide what is in a patientís best interests?

Patients in MAT who stop their opioid abuse but not their abuse of other substances (i.e., ìnoncompliantî or ìnonrespondingî patients) are a major research focus. The literature is replete with studies of strategies, such as contingency contracting (see chapter 8), that use patientsí dependence on their treatment

Exhibit D-1

Case Example

R.S., a 35-year-old man who has been in MAT for 18 months, is in his second MAT episode. The first ended when he was arrested and imprisoned for armed robbery. R.S. has not missed medication appointments but is less attentive to counseling sessions. He regularly uses alcohol and marijuana and occasionally cocaine. R.S. is unwilling to stop using alcohol and drugs. His position is that he has stopped his use of illicit opioids entirely, which was his goal entering treatment. His other drug use is his choice, and the clinic should ìget off his back.î

medication to compel their compliance with treatment-related mandates. These strategies ìare based on the assumption that patients have the necessary skills to produce drug-free urine samples but often lack sufficient motivationî (Iguchi et al. 1996, p. 315). Examples of mandates enforced by contingency contracting include adoption of and adherence to a drug-free lifestyle (Iguchi et al. 1997), attendance at additional therapy-related sessions (with or without a significant other) (Iguchi et al. 1996; Kidorf et al. 1997), and performance of employment-related tasks (Kidorf et al. 1998). Training in substance abuse treatment provides treatment providers with an awareness and understanding of patientsí tendencies toward denial, minimization, and rationalization of their substance use. A working familiarity with such studies provides treatment providers with a reasonable basis to choose beneficence over autonomy when they conclude that they know better than patients what is in patientsí best interest.

The conflict between beneficence and autonomy is not unique to MAT, but it is especially acute in MAT because of the fundamental power imbalance between treatment providers and patients. Patients in OTPs depend on their medication and may fear the effects of withdrawal from it. That dependence gives providers (and the principle of beneficence) the upper hand. Patients who refuse to comply with provider views of what is in their best interests risk administrative discharge or other sanctions. Until recently, only an OTP could provide patients with medication, ensuring the OTPís hold over patients. Often no other facility exists from which to obtain MAT.

Why do treatment providers in OTPs lean toward the principle of beneficence and away from the principle of autonomy in their approach to patients? The following factors may apply:

- A longstanding, complex regulatory system that favors a rule-governed perspective in OTPs
- Belief that patients in denial cannot act in their best interests
- Disagreement about goals between patients and treatment providers
- Attention to community concerns
- Effects of noncompliant patients on staff, patients in compliance, and new patients
- Discomfort with the disease model (see below)
- View of patients in MAT as failures
- Limited research examining the precept that complete abstinence is in patientsí best interests.

Clinicians Who Are Uneasy With the Disease Model

MAT providers generally embrace the concept of addiction as a chronic relapsing disease; however, unlike medical professionals treating other chronic illnesses, some providers appear uncomfortable with the idea of alleviation of symptoms without cure (Hunt and Rosenbaum 1998, p. 202). These providers might draw on lessons from physicians caring for patients with other chronic diseases. How do they deal with noncompliant patients who fail to alter their diets or lifestyles, for example? Based on the disease model underlying comprehensive maintenance treatment, total abstinence may be unrealistic in the short run for some patients. When OTPs refuse to recognize that immediate abstinence is unrealistic and punish patients for the continuing but reduced presence of symptoms, they are not defining addiction as a disease. The long-term goal is always reducing or eliminating the use of illicit opioids and other illicit drugs and the problematic use of prescription drugs; but, in the short run, patients should be supported as they reduce their substance use.

Research suggests that many patients are aware that they may relinquish their autonomy when they enter MAT. A study about the attitudes of patients receiving methadone found that many see OTPs as institutions that control and punish more than they helpóOTPs are agents of conventional society (Hunt and Rosenbaum 1998).

In the opinion of Bell (2000, p. 1741), ìPatients need protection because many are reluctant to complain because they have a sense of powerlessness and do not want to jeopardize their treatment.î Providers at OTPs should be aware of any bias toward the principle of beneficence and away from the principle of autonomy. Rather than assuming that the tilt toward beneficence is always correct, treatment providers and administrators should ask themselves in each case whether they are striking a proper balance between these two fundamental principles.

Some Patientsí Perspectives

ì[C]lients often felt that the relationship between themselves and their counselors was less focused on therapy than power; less about psychological growth, getting help and a sense of well-being than about social control, conforming to rules and regulations, and punishment.î (Hunt and Rosenbaum 1998, p. 209)

ì[Study participants] were also aware and fearful that having once adopted the culture of the clinic they would become dependent on it, and more significantly on the goodwill of individual counselors. This dependence was particularly troubling to them because of the increasing insecurity of subsidized slots. Many users expressed concern about once having entered the system and accepting its lifestyle with little or no warning they would be ejected from it. . . . [M]any study participants felt, precisely because of the asymmetrical relationship between the client and the clinic, the staff used this as a way of exacting compliance.î (Hunt and Rosenbaum 1998, pp. 200ñ201)

Other Conflicts Among the Four Principles of Medical Ethics

Involuntary discharge

An OTPís decision to discharge a patient against his or her wishes calls into question all four ethical principles. Involuntary discharge appears to breach practitionersí duties to put patient health first, do no harm, and respect patientsí wishes, as well as to avoid harm to the community from reintroducing the effects of untreated opioid use (especially criminal behavior and potential disease transmission). Yet an OTP often must balance the interests of individuals facing discharge with those of other patients, staff, future patients, and the larger community and society.

Threats to safety

When a patient commits or threatens an act of violence against another patient (on OTP premises) or against staff (on or off OTP premises), comes to treatment armed with a weapon, or deals drugs at or near an OTP, that patient poses a threat to the safety of the program, its staff, and its patients. Involuntary discharge of such a patient, although not in his or her best interests, takes into account the OTPís ethical responsibility to the rest of its patients (current and future), its staff, and others. The consensus panel believes that patient behavior threatening the safety of patients and staff or the status of the program in the community is grounds for patient discharge. OTP administrators may need to make difficult judgments about what constitutes threatening behavior (especially in light of deficits in interpersonal skills and possible untreated co-occurring disorders) and evidence of drug dealing. But an OTPís responsibility to provide good treatment for its other patientsóindeed, its responsibility to remain a viable resource in the communityórequires that these limits be set and enforced.

Failure to pay

Involuntary discharge for failure to pay treatment fees presents a more difficult ethical issue involving the limited financial resources of many patients and the uneven public funding of MAT. Patients discharged for inability to pay or because their OTPs have lost funding might have been doing well, and terminating treatment, in most cases, will halt their recovery or precipitate relapse (Knight et al. 1996***a***). Although involuntary discharge for failure to pay fees appears to violate the principles of autonomy, beneficence, and nonmalfeasance, the unfortunate reality is that OTPs must operate within fiscal constraints. If OTPs continue to deliver uncompensated care, they may face financial ruinóa consequence that would jeopardize treatment for all patients (including those who continue to pay). Nonetheless, OTPs considering patient discharge for nonpayment should address the principle of nonmalfeasance, at least in part, by mitigating harm to patients, for example, by working out payment schedules, assisting with access to insurance or other funding sources, or facilitating transfer to lower cost facilities. In 2003, the American Association for the Treatment of Opioid Dependence (AATOD) released new recommendations addressing involuntary withdrawal from treatment for nonpayment of fees (www.dmhas.state.ct.us/opioid/withdrawal.htm).

Failure to respond

Another difficult ethical issue occurs when an OTP proposes to discharge a patient involuntarily for failure to respond to treatment. No matter which principle the OTP follows, it will fail to uphold anotheróperhaps even the very principle it is seeking to uphold. An OTP has at least two choices, and all four ethical principles are implicated.

- **To discharge.** When an OTP discharges a noncompliant patient, it risks violating the principle of beneficence because discharge might lead to a poorer health outcome for

that patient and perhaps repercussions for the community. Indeed, because research has shown that discharge from MAT leads to poor outcomes, by pursuing the principle of beneficence to its logical conclusion of involuntary discharge, the OTP may be putting a patientís health at greater risk. The OTP may be violating the principle of nonmalfeasance as well, especially if it is unaware of the possible consequences of involuntary discharge.

Involuntary discharge of noncompliant patients often occurs when OTPs have waiting lists. When limited slots existóbecause of the limits of public sector funding or regulatory caps on slotsóand applicants are waiting for treatment, pressure mounts to discharge patients who are not fully compliant with treatment regimens. Concerns about the fairness of continuing to treat a patient who is unwilling or unable to take full advantage of treatment appeal to the principle of justice.

- **Not to discharge.** Arguably, when treatment providers do not discharge noncompliant patients but continue treating them, they risk violating the principle of beneficence because they are not providing care they believe will promote patient health. By ignoring the effect noncompliant patients have on the therapeutic milieu for other patients, providers are violating the principle of beneficence for those other patients. Treatment providers who continue to treat noncompliant patients also violate the principle of justice by denying treatment to potential patients on the waiting list.

  OTPs should decide how to respond to treatment noncompliance based on factors and principles discussed above and patientsí specific circumstances. No single decision is correct in all cases. The OTP has an ethical responsibility to consider these principles and the effect of discharge on patients and the program.

Take-home privileges

The decisions a medical director makes about take-home privileges, although not as stark as those related to involuntary termination, also require that all four ethical principles be weighed. Patients are usually interested in increasing their autonomy and ability to carry out normal daily activities by reducing visits to their OTP for medication, but the medical director must consider what is safest for patients. Take-home medication privileges might benefit a patient by reducing his or her exposure to an OTPís less stable patients and making it easier for the patient to lead a normal life, by providing an incentive to further enhance recovery, and by expressing a programís confidence in the patientís progress. However, increased take-home privileges may pose a risk to a patient of overmedication and lethal use and to people in the community of drug diversion or accidental life-threatening ingestion by intolerant individuals (e.g., children). Federal regulations governing OTPs require that a medical director deciding whether to allow or increase patient take-home privileges consult the principle of nonmalfeasance by considering the risk of harm to patients or others (42 Code of Federal Regulations, Part 8 ß 12(i)(2)).

The longstanding concern with methadone diversion also is rooted in the principle of justice. OTPs are under considerable public scrutiny. If an OTP gives take-home privileges to irresponsible patients and those patients, their family members, or others in the community are harmed, the OTPís operations may be restricted or the OTP might be shut down. When an OTP closes its doors, its responsible patientsóand the staff and ultimately the communityósuffer. Therefore, it is important to consider a patientís behavior carefullyónot just the time in treatmentóbefore allowing take-home medication.

A word about due process

The decision to discharge a patient involuntarily or adjust take-home privileges might require that a treatment provider or administrator resolve factual disputes or differences in interpretation between a staff member and a patient or between two patients. It is important that an OTP provide a forum so that patients can

receive a fair hearing on their versions of disputed events, including a review of the evidence and proposed sanctions. Some States require additional due-process procedures.

Ethics: Conclusion

OTP staff members can avoid or minimize some ethical dilemmas by remaining aware of sources of potential conflict, keeping ethical principles in mind, familiarizing themselves with the ethical standards of their profession, and discussing potential conflicts with patients and other staff members. The goal always is reducing or eliminating the use of illicit opioids and other illicit drugs and the problematic use of prescription drugs. Exhibit D-2 presents the canon of ethics adopted by AATOD. Exhibit D-3 provides Internet links to the ethical guidelines of other treatment-centered organizations.

Exhibit D-2

AATOD Canon of Ethics

- Ensure that patients are treated with compassion, respect, and dignity regardless of race, creed, age, sex, handicaps, or sexual orientation.
- Retain competent and responsible personnel who adhere to a strict code of ethics, including but not limited to prohibiting of fraternization with patients, exploitation of patients, and criminal behavior.
- Subscribe to the treatment principles published in TIP 43, ***Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs***, which serves as a resource in making therapeutic decisions.
- Provide patients with accurate and complete information regarding methadone treatment, the nature of available services, and the availability of alternative treatment modalities before admission and throughout the treatment process.
- Ensure that discharge from treatment is conducted in accordance with sound and medically acceptable practice. The patient is assured of due process if the discharge is administrative in nature.
- Provide a safe and clean environment for patients and staff that is conducive to the therapeutic process.
- Remain in compliance with the required Federal, State, and local operating standards.
- Take all necessary and appropriate measures to maintain individual patient records and information in a confidential and professional manner.
- Strive to maintain good relations with the surrounding community, and pursue every reasonable action to encourage responsible patient behavior and community safety.

Exhibit D-3

Ethical Codes of Selected Treatment-Oriented Organizations and Their Web Sites

American Medical Association's Code of Ethics
www.ama-assn.org/ama/pub/category/8600.html

American Nurses Association's Code of Ethics
nursingworld.org/ethics/chcode.htm

American Psychological Association's Code of Ethics
www.apa.org/ethics

Mental Health Counselors' Code of Ethics
www.counseling.org

National Association of Alcohol and Drug Abuse Counselors' Code of Ethics
www.naadac.org

National Association of Social Workers' Code of Ethics
www.socialworkers.org/pubs/code/code.asp

Public Policy of the American Society of Addiction Medicine, Principles of Medical Ethics
www.asam.org/ppol/Principles%20of%20Medical%20Ethics.htm

Appendix E: Resource Panel

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Behavioral Health Care
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Washington, D.C.

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Certification Administrator
National Association of Alcoholism & Drug Abuse Counselors
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Brent Bowman
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Notes: Because the entire volume is about medication-assisted treatment for opioid addiction, the use of these terms as entry points has been minimized in this index. Commonly known acronyms are listed as main headings. Page references for information contained in exhibits appear in ***italics***.

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CSAT TIPs and Publications Based on TIPs

What Is a TIP?

Treatment Improvement Protocols (TIPs) are the products of a systematic and innovative process that brings together clinicians, researchers, program managers, policymakers, and other Federal and non-Federal experts to reach consensus on state-of-the-art treatment practices. TIPs are developed under CSAT's Knowledge Application Program to improve the treatment capabilities of the Nation's alcohol and drug abuse treatment service system.

What Is a Quick Guide?

A Quick Guide clearly and concisely presents the primary information from a TIP in a pocket-sized booklet. Each Quick Guide is divided into sections to help readers quickly locate relevant material. Some contain glossaries of terms or lists of resources. Page numbers from the original TIP are referenced so providers can refer back to the source document for more information.

What Are KAP Keys?

Also based on TIPs, KAP Keys are handy, durable tools. Keys may include assessment or screening instruments, checklists, and summaries of treatment phases. Printed on coated paper, each KAP Keys set is fastened together with a key ring and can be kept within a treatment provider's reach and consulted frequently. The Keys allow you—the busy clinician or program administrator—to locate information easily and to use this information to enhance treatment services.

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TIP 2* **Pregnant, Substance-Using Women**—*BKD107*

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TIP 6 **Screening for Infectious Diseases Among Substance Abusers**—*BKD131*

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TIP 8* **Intensive Outpatient Treatment for Alcohol and Other Drug Abuse**—*BKD139*

TIP 9 **Assessment and Treatment of Patients With Coexisting Mental Illness and Alcohol and Other Drug Abuse**—*Replaced by TIP 42*

TIP 10 **Assessment and Treatment of Cocaine-Abusing Methadone-Maintained Patients**—*Replaced by TIP 43*

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Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs

This TIP, ***Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs***, incorporates the many changes in medication-assisted treatment for opioid addiction (MAT) that have occurred over the most active decade of change since the inception of this treatment modality approximately 40 years ago. The TIP describes the nature and dimensions of opioid use disorders and their treatment in the United States, including basic principles of MAT and historical and regulatory developments. It presents consensus panel recommendations and evidence-based best practices for treatment of opioid addiction in opioid treatment programs (OTPs). It also examines related medical, psychiatric, sociological, and substance use disorders and their treatment as part of a comprehensive maintenance treatment program. The TIP includes a discussion of the ethical considerations that arise in most OTPs, and it provides a useful summary of areas for emphasis in successfully administering MAT in OTPs.

Collateral Products
Based on TIP 43

Quick Guide for Clinicians
KAP Keys for Clinicians

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