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

8 Approaches to Providing Comprehensive Care and Maximizing Patient Retention

In This Chapter...

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 today's 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 patients' 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 patient's 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. Patients' 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, patients' 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 patients' 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 patients' 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 patients' 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 patients' 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 patients' conditions and information about other aspects of patients' 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 treatments—especially 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 patients' 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 another's 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 patient's treatment. Some groups keep the same membership but stay together for a short time; others are longer term and have a rolling membership—that 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 group's 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 patient's 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 Abuse's 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)
- "Supportive-expressive dynamic psychotherapy of opiate drug dependence" (Luborsky et al. 1995)
- *Treatment of Opioid Addiction With Methadone: A Counselor's 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 system's 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 patients' 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 patients' environments and circumstances. Many elements of cognitive behavioral therapy (CBT)—for example, emphases on identifying high-risk circumstances that may trigger an event and developing coping responses—are 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 patients' 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 participants' 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, "The use of node-link mapping appears to reduce cultural, racial, and class barriers by providing a visual supplement and a common language that enhances counselor–client interchanges" (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 patient's 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 patients' 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 patients' 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 patient's targeted areas of behavioral change or implemented on a uniform, programwide basis. Tailoring behavioral contingencies to patients' 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—particularly for patients with co-occurring disorders who show little response to counseling alone (O'Brien 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 patients' most recent successes and failures regarding their substance use.
- Adopt a more active therapist role than typically required for co-occurring disorders.
- Strengthen patients' 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 patients' 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 patient's 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 non–drug-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

- Introduce psychoeducation at the beginning of treatment so that it serves as an orientation to both OTP operational and recovery processes.
- Involve family members and selected friends, with a patient's informed consent. Provide guidance in how to support the patient's recovery efforts.
- Adapt educational strategies and materials to the patient's culture and family.
- Discuss methadone and other treatment medications, and dispel the myths related to their use (e.g., "methadone rots the bones," "it's impossible to get off methadone").
- Discuss the implications of continuing substance abuse. Question assumptions about alcohol and drug use, and clarify that such use undermines recovery.
- 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.
- Discuss the power of triggers with patients and families. For example, merely discussing heroin can be a trigger for resuming its use.
- Incorporate special groups to discuss parenting, childcare, women's issues, and coping with HIV/AIDS and HCV infection. Use generic names for HIV/AIDS groups (e.g., "health care issues" group) to avoid stigma.

- 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 "family" should be expanded to include members of the patient's 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 patients' families, family therapy should be provided only by trained staff and reserved for families with serious problems with behaviors or attitudes that contribute to patients' 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 § 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 patients' children and consider routine psychiatric screening and early intervention and treatment for these children. Dawe and colleagues (2000) reported improved parent–child 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 children's 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 "one day at a time." 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, "working" 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 patient's 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 patient's 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 patient's 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 patient's 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 104–193) 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 "violence or threat of violence, dealing drugs, repeated loitering, [and] flagrant noncompliance resulting in an observable, negative impact on the program, staff, and other patients" as well as "nonpayment of fees" and "incarceration or other confinement" as possible causes for administrative discharge (CSAT 1999*b*, pp. 17–18).

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 patient's 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 patients' 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 humanely…

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 § 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 patient's 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 tool—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 patient's extenuating circumstances and point of view. Procedures should be fair and impartial because other patients' 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 patients' 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	2–4
Barbiturates	200	Amobarbital, secobarbital, other barbiturates	200	2–4 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	1–3 for sporadic use; up to 12 for chronic use
Codeine	300	Codeine, morphine	300, 300	1–3
Heroin	300	Morphine, 6-acetylmorphine	300, 10	1–3
Marijuana	100, 50, 20	Tetra-hydro-cannabinol (THC)	15	1–3 for casual use; up to 30 for chronic use
Methadone	300	Methadone	300	2–4
Metham-phetamine	1,000	Methamphetamine, amphetamine	500, 200	2–4
Phencyclidine	25	Phencyclidine	25	2–7 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 program's 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 "gold standard" 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 patients' 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 patient's 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 ("shy bladder syndrome") have a social anxiety disorder that may leave them unable to urinate under observation (Labbate 1996–1997; 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 SAMHSA's 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 § 12(f)(6). The choice of drug-testing methodology is an informed medical judgment decision. It is SAMHSA's 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 longer—for 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 patient's 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 patients' 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 "Development of Written Procedures" below). Patients should be informed during admission and early treatment about how drug-testing specimens are collected and patients' 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 patients' 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 patients' 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 "guns" (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 types—radioimmunoassay (RIA) or EIA—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 patient's 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 99.8°F, the patient's temperature is taken (if the patient's 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 (90.5–99.8°F/32.5–37.7°C), 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 patients' 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 § 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 patient's 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 "Onsite Test Analysis" 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 laboratory's 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 laboratory's 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 manufacturer's 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 "an expensive and potentially inaccurate means to monitor patient treatment and drug abuse states."

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 CLIA—Federal guidelines for any entity doing laboratory analysis of specimens from humans—and 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 patients' 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 clinically—not punitively—for 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 patient's 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 program—recovery 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 [37°C])
- Using temperature and adulterant strips or collection devices that include temperature strips
- Using a temperature "gun" (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 patients' 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.