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Methadone Treatment at Forty

In the view of a clinician who has been providing methadone therapy since its inception 40 years ago, the status of the treatment today reflects the culmination of two trends: an increase in understanding, skills, and standards on the one hand, and a deterioration of patients' health on the other. A retreat of stigma, greater physician interest, and the evolution of standards are beginning to move the treatment toward the mainstream.

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As methadone maintenance treatment enters its fifth decade, opioid treatment programs (OTPs) are drawing on lessons learned from past successes and failures to continuously improve the treatment modality. Today's patients span an age range wider than ever before, and present with a greater quantity and severity of addictions and health problems. In the face of this, OTPs have access to improved research and technology, and have also developed a greater understanding of the full dimensions of opioid addiction and recovery. We now know that opioid addiction is a chronic disease, so we no longer think of methadone as a short-term bridge to recovery, but instead consider it an intervention that may be beneficial indefinitely.

Today's OTPs must conform to regulations that are more rigorously enforced than those of the past, but also more practical. While requiring treatment providers to document and analyze their outcomes and correct shortcomings, the regulations give clinicians latitude in planning treatment and prescribing methadone dosages. This report describes the current methadone treatment population, surveys the principles of contemporary use of the medication, reviews the history and experience that have brought our understanding and skills to their current high level, and identifies challenges and opportunities for improving the treatment and treatment environment.

TODAY'S METHADONE PATIENTS

Today's methadone patients differ from those of the past. The HIV and hepatitis C epidemics, the rise of polydrug abuse, and a widening age spread among heroin abusers have multiplied the concerns and complexities of treatment. As well, we now have a contingent of very experienced, long-term methadone patients who can function as effective treatment allies to clinicians and their fellow patients

as well as forceful advocates for patients' views and interests.

Patients Are Sicker

Methadone treatment providers today work with a patient population that has unprecedented levels of drug exposure, addiction severity, and physical and mental health comorbidity. While research and clinical experience have equipped clinicians with better understanding, skills, and interventions than ever before, decades of steady deterioration in patients' general health have contributed to a stasis or slight worsening of overall methadone treatment outcomes.

Thirty years ago, the great majority of methadone patients abused only heroin. In New York State today, approximately 30 percent abuse other substances as well, including alcohol, cocaine, methamphetamine, benzodiazepines, and marijuana (New York State Office of Alcoholism and Substance Abuse Services, 2005). Methadone does not reduce abuse of these other drugs, which obviously can impede the behavioral and social normalization that are the main goals of methadone maintenance.

Hepatitis C is now the most prominent and worrisome co-occurring physical disease among methadone patients. In New York City, the prevalence rate for this infection has remained steady, at around 75 percent, since detection by a diagnostic blood test first became possible in the late 1990s. With passing time, though, more and more patients are progressing to a symptomatic disease stage, and the number requiring hospitalization has risen dramatically. In our program, about 600 of the 4,000 patients require a hospital bed each year, with the great majority of these related to hepatitis. Liver disease has replaced HIV as the leading cause of death among our patients.

HIV infection currently affects some 20 percent of patients in our program, down from twice that high in 1992. Despite effective treatments that have greatly reduced mortality from HIV, the impact of HIV or hepatitis on patients' morale and the need to coordinate infectious disease medications with methadone can substantially complicate recovery. For example, rifampin (used to treat tuberculosis), AZT (for AIDS), and interferon (for hepatitis C) all interact with methadone to cause changed blood levels and side effects that can, if not carefully monitored by clinicians, lead some patients to relapse.

Roughly 60 percent of our patients have treat-

able depression or anxiety intertwined with their substance use during the initial treatment phase. This number is much higher today than in the 1970s, either because more patients present with these disorders, we have learned to more consistently identify them, or both. One indication that mental health comorbidity may truly have expanded in the heroin-abusing population is the trend toward increasing use of other drugs along with heroin. In theory, this may reflect an increase in the number of individuals attempting to control their anxiety symptoms with sedatives and self-treat their depression with stimulants. With chronic escalating use, self-medication with these drugs backfires, ultimately exacerbating depressive and anxiety disorders and increasing clinicians' need to monitor patients for suicidal behavior and other severe mental health complications.

Patients Are Younger and Older

During the past several years, more young people aged 18 to 25 have come to OTPs for treatment. These youths bring the cognitive and emotional dynamics of adolescence and early adulthood to the clinic, as well as a very high prevalence of multiple substance abuse.

Programs also are treating patients who are older than ever before. Some seniors have aged while in methadone therapy, and others are presenting for the first time in their 50s, 60s, and 70s. New York State now has 10 patients over 80. Older patients pose a unique set of clinical challenges related to the medical issues of aging, such as diabetes, hypertension, menopause, and reduced mobility.

Patients Are Better Informed

Methadone patients as well as providers have learned much from their experiences over the past four decades. Today's patients, especially those older individuals who have engaged in therapy continuously or repeatedly over many years, constitute a well-informed group of consumers. In New York, they often know about the various models for treating heroin addiction and understand that if one program does not meet their needs, they can try another.

Longer term methadone patients can provide programs with valuable insights on how to meet their clients' needs and on reasonable goals and expectations. To take advantage, some programs have added patients to their advisory boards and organized patient advisory committees (PACs). In some cases, PACs

More patients are progressing to symptomatic stages of hepatitis C.

Today's patients are effective treatment allies.

and other patient liaisons have helped clinics respond to patient and community concerns before they became problematic. Many clinics seek input from their patients via patient satisfaction surveys that ask: “What do you think of the treatment you’re receiving? What is working for you? What isn’t?” New York and other states have ratified patients’ authority to bring their experience to bear by mandating such surveys. Agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Commission on Accreditation of Rehabilitation Facilities (CARF) make collecting patient feedback a requirement for OTP accreditation. PACs are another way to meet this standard, which now is federally mandated.

Today’s patients are effective treatment allies as well through activities that effectively extend the treatment network. Peer support groups, such as Methadone Anonymous, give patients opportunities to interact outside an OTP with others who have been or are going through the treatment process. Another group, The National Alliance of Methadone Advocates, has led the movement to protect patients’ rights and ensure that their perspectives are heard by providers and policymakers.

Patients also form “buddy groups” to support each other during difficult phases of the treatment process. For example, before a patient can begin interferon/ribavirin treatment for hepatitis C, he or she must first undergo several tests, including a liver biopsy. The biopsy procedure can be intimidating, and it is helpful to have a patient who has had the procedure accompany the patient to the surgical center and provide support and advocacy.

TREATMENT GOALS AND FEATURES

The defining characteristic of care in today’s OTPs, distinguishing them from those in the past, is increased tailoring of treatment to each patient’s individual goals and needs. Four decades of clinical experience and research have equipped OTP clinicians with awareness, tools, and skills to adapt care plans to a wide range of physical and mental health comorbidities, family and social circumstances, and recovery expectations.

Treatment Goals

The initial technical goals of methadone treatment are to relieve the patient’s narcotic craving, sup-

press the abstinence syndrome, and block the euphoric effects associated with heroin. The overall goal is to improve the patient’s health and quality of life. Intermediate objectives include improving patients’ access to and utilization of health care, teaching them to reduce their risk for infectious diseases such as HIV and hepatitis, and helping them build healthy relationships and reenter the workforce or school.

The cumulative experience with methadone has led providers to reexamine one of the original assumptions regarding this therapy: that all patients should strive to be drug-free. In recent years, a gathering consensus has endorsed methadone maintenance as a chronic, potentially lifelong treatment. This view harmonizes with recent emphasis on the chronic, episodic nature of heroin addiction.

The public and policymakers are making this conceptual adjustment more slowly, which can lead to some tension over expectations. Many patients, particularly in their first treatment episode, want to taper their methadone dosage when their cravings subside and they see themselves progressing in other areas of their lives. Although some truly can abstain from methadone and still have reasonable hope for stable long-term recovery, overall, research has found that up to 80 percent of patients who quit methadone relapse to opioid abuse within 3 years (Ball and Ross, 1991; Joseph, Stancliff, and Langrod, 2000). In our program, we teach that the measure of success is not whether you take a medicine in the morning, but whether you take care of yourself and your family, act responsibly, and contribute to society. Even those who can thrive without methadone are unlikely to do so unless they remain connected to some form of treatment.

Dose and Schedule

Methadone dosing is a prime area where the principle of individualized treatment has emerged in sharp contrast to past practice. Clinicians today benefit from developments that have greatly enhanced the ability to identify and provide each patient with a dosage that completely suppresses craving and heroin abuse and produces minimal side effects.

First, we have learned that adequate dosage varies greatly. While some individuals do well on as little as 20 mg/day, others require up to 10 or 15 times as much or more. Differences in native metabolism and in the effects of methadone’s interaction with



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Fully individualized dosing, like indefinitely long methadone therapy, is not yet accepted everywhere.

other concurrent medications underlie this wide range (see “Alcohol and Medication Interactions With Buprenorphine and Methadone” in *Science & Practice Perspectives* Vol. 2, No. 2, pp. 10-11). The most frequently encountered interactions occur in patients receiving medications for HIV—some of which speed and some of which slow methadone metabolism—and for hepatitis C. Patients taking interferon for hepatitis C may need upward adjustment in their methadone dosage to counteract a toxic effect of the antiviral medication that mimics opioid withdrawal.

The patient’s response to methadone—whether he or she continues to crave or abuse heroin, or feels excessively drowsy—is the essential indicator of whether the prescribed dosage is too little or too much. To determine this, we talk with the patient to find out if he or she has tried taking opioids while on methadone, and, if so, why and what kind of opioid effect was felt. We ask what time of day drug-taking occurs, which is oftentimes when methadone blood levels are bottoming out.

The move to fully individualized dosing, like the acceptance of indefinitely long methadone therapy,

has not yet happened everywhere. A few states still place ceilings on prescription amounts. A recent study of about 30 OTPs over a 10-year period found that programs where doctors freely determined methadone dosage were more likely to give adequate amounts than programs where public policy limited the options (D’Aunno, Folz-Murphy, and Lin, 1999).

Attention to Co-Occurring Conditions

Today’s OTPs recognize the adverse impact of co-occurring addictions and comorbid illnesses on their patients’ progress in treatment, but, in general, we have yet to evolve broadly applicable standards for responding. Given their very long-term trend toward ever-higher prevalence, these problems are prime candidates for research attention. Unfortunately, even where research has proven one or another approach to be effective, funding limitations prohibit many programs from implementing the best practices.

Co-Occurring Addictions

Some OTPs insist that patients attend groups and honestly address their co-occurring addictions in treat-

ment or else face termination; others do not place limits on treatment and continue to try to motivate patients to stop using nonopioid drugs. Studies have shown that medications can help patients in methadone treatment reduce alcohol and cocaine abuse (amantadine, serotonin reuptake inhibitors). In one study, investigators used a breathalyzer test to determine which patients were the worst abusers of alcohol, then asked these patients to either begin taking Antabuse or transfer to another clinic. All agreed to take Antabuse and, for the length of the 90-day study, none drank alcohol (Bickel et al., 1988).

Whatever a program's policies may be, clinicians need to consider each patient's overall behavior when deciding how to react to his or her abuse of other drugs. A patient who is honest about drug abuse and wants to stop should not be treated in the same manner as one who refuses to attend group meetings or follow through with treatment plans or activities. The former is struggling with craving and making an effort; the latter does not appear motivated to accept treatment.

Co-Occurring Medical Illnesses

Methadone programs that offer comprehensive mental and physical health services obtain significantly better outcomes for their patients (National Institute on Drug Abuse, 1999). One particularly successful model is “one-stop shopping,” where patients receive all services at the same site (Barnett and Hui, 2000). While these principles are well accepted across the field, many smaller programs lack the resources to put them into practice. These programs instead refer patients to other facilities, encourage them to follow up, and hope they do. The hopeful element in today's picture, discussed below, is that mainstream medical practitioners increasingly are willing to treat drug-abusing patients.

Treatment Delivery Systems

Today's OTPs have begun to evolve past the original, rigid treatment delivery system that requires every patient to report to a clinic for each day's methadone dose. In New York and some other locations, clinics are implementing flexible, tiered systems that respond to patients' personal growth and changing circumstances as they advance in recovery.

Medical maintenance, a promising new arrangement, allows individuals who have passed the initial

phases of therapy to obtain treatment in a physician's office. At New York Hospital/Cornell Medical Center in New York City, for example, the patient sees a doctor once a month, leaves a specimen for drug testing, and gets a methadone prescription to fill at a local pharmacy. He or she does not have to choose between tapering and permanent clinic attendance, with its potentially demoralizing exposure to the milieu of recent heroin abuse. The arrangement recognizes that these individuals have achieved significant control over their illness, helps them establish normal physician-patient relationships, and enables them to schedule treatment that doesn't conflict with jobs or other social obligations. As well, our office-based opioid treatment frees up clinic beds for new patients who require more structured services.

Another new model, the treatment phase approach, divides treatment into highly structured stages (Hoffman and Moolchan, 1994). All patients participate in the first three: intensive stabilization, commitment, and rehabilitation. Patients then choose, with the help of their doctor, between two tracks: medical maintenance or tapering. The final phase is reinforcement. OTPs using the treatment phase model frontload their services to the people entering treatment, who have the most need, involving them in good health care, educating them about HIV and hepatitis C, and introducing them to outside resources that will provide the medical care and social services they need. The clinic staff works with patients to formulate treatment plans that address patients' problems in order of urgency, such as criminal justice, mental illness, housing, employment, and education. As the first set of problems ease, the staff implements new services for the next most serious until, eventually, the cumulative improvement eliminates the need for most services.

A MAINSTREAM MEDICAL TREATMENT

Originally greeted with skepticism and suspicion, methadone has survived to become an established treatment for heroin abuse. Although negative perceptions and stigma still persist in an attenuated form—and everyone looks forward to the day when OTPs can produce long-term recovery more quickly and consistently—by and large, heroin abusers, communities, policymakers, and researchers now accept that the therapy's proven efficacy makes it worth trying, supporting, and refining. In this new climate

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of increased tolerance, methadone therapy has entered a transition from the margin toward the mainstream of medicine.

The Partial Retreat of Stigma

The disclosure through scientific research that addiction is a chronic disease, bolstered by examples of successful recovery, has tempered the stigmatizing of methadone patients and their treatment. The shift toward a health-based rather than moral concept of addiction, while not yet complete, has progressed remarkably swiftly, when we consider that it was only in 1997 that the National Institutes of Health first urged this view on the medical establishment (National Institutes of Health, 1997).

Despite this greater tolerance of opioid replacement treatment, methadone diversion and loitering near clinics remain potent sources of negative attitudes toward OTPs. Neighbors tend to notice those individuals who hang around, get arrested, and require ambulance transport to the emergency room, rather than the majority who simply walk in and out of the clinic and get on with their lives. Taxpayers are loath to see their money going to provide addicted individuals with opioids to sell to other drug-abusing individuals. As well, although an investigation determined that diversion from OTPs has not been the primary cause of a recent increase in methadone-related death rates (Center for Substance Abuse Treatment, 2004), communities fear the medication's potential lethality.

Strengthening communication between OTPs and their communities and stakeholders has proved an effective strategy for allaying these legitimate but exaggerated concerns. Many programs now attend planning board, precinct council, and other meetings where they can hear and respond to community worries or complaints. As OTPs have become more integrated into their communities over the decades, we have found natural allies in churches, synagogues, mosques, and even police departments and child welfare agencies. All share the mission of assisting the underserved, and all seek to strengthen messages of sense and tolerance.

Some regulatory authorities now provide their own impetus for OTPs to take active steps to improve the public's perceptions. New York State, for example, requires programs to solicit and address community concerns and criticisms. Center for Substance

Abuse Treatment (CSAT) and accreditation regulations require programs to implement plans to control methadone dose diversion. The programs must know where their patients go after they leave the clinic and also assess their patients for potential diversion.

Physician Engagement

Physician investment in methadone therapy stands at its highest level ever. In the early days, some programs were lucky if they could find a part-time or retired physician to come in and oversee the methadone prescribing. Now, we turn away highly trained doctors.

Many doctors first became interested in methadone in the late 1980s, when studies showed that patients in treatment had lower rates of HIV infection than active heroin injectors (Blix and Gronbladh, 1988; Kreek et al., 1990; Metzger et al., 1993). These doctors initially approached methadone therapy primarily as a way to slow the AIDS epidemic through testing, educating, and counseling intravenous drug abusers. Subsequently, through involvement with the patients and programs, many have become fully engaged in the issues of addiction itself.

Establishing Standards

In the improved treatment climate, no longer constrained to constantly justify their existence, methadone treatment systems have begun to move toward the medical mainstream. We are accomplishing this with the same tools other medical specialties have used to establish and sustain the quality of their services and their prestige: setting standards for staff qualification and program accreditation.

In New York State now, 25 percent of treatment staff in every clinic must be certified alcoholism and substance abuse counselors. In 2001, CSAT introduced a nationwide accreditation system whereby programs must demonstrate to a Federal accrediting agency (e.g., CARF or JCAHO) that they meet standards on measures such as lengths of stay, the number of patients using opioids or other drugs while in treatment, the number of patients able to find employment and stay employed, and so on. By selecting a set of standardized performance measures, the accreditation system enables the field to collectively accomplish what many OTPs have always tried to do individually: by collecting and analyzing information on patients' outcomes, identify which forms of treat-

Accreditation systems must allow for the special challenges OTPs face in different environments.

ment are most successful, learn from past mistakes, and consistently improve success rates.

As the new system evolves and programs seek to obtain accreditation, allowance must be made for the different challenges faced by OTPs working in different environments. Just as we do not measure success the same way for a homeless patient with a 20-year history of incarcerations and a young person in a first treatment episode, we cannot expect programs serving divergent patient populations under contrasting circumstances to meet the same criteria for outcomes.

WISH LIST

As OTPs continue to progress toward outcome-based treatment standards and integration with mainstream medicine, we can anticipate growing success in helping our patients meet the many challenges of their addictions and their lives. The continuation of these trends, together with further increases in the public and professional acceptance of methadone, must be at the top of everyone's wish list for methadone treatment. Beyond that, I believe the following developments could advance the cause dramatically:

- A medication for cocaine addiction.
- Upgrading of the physical facilities and locations of clinics. The current placement of most facilities in cramped spaces in shabby buildings in marginal neighborhoods can make the treatment experience awkward and intimidating. Ideally, clinics should have the physical space to allow staff to give

private, confidential treatment, while also having larger areas for group meetings.

- More effective standardized assessment tools for patients with serious comorbidities, such as poly-substance abuse and mental illness. The Addiction Severity Index and other existing tools are useful, but we need a set of standardized tools that are specifically for methadone treatment, and that all our clinicians, with their array of educational backgrounds, can use to guide the treatment planning process.
- A concerted effort to educate the public on the benefits of methadone treatment. A Federal effort to reduce the stigma associated with methadone treatment could help educate people on the nature of drug addictions and on why methadone is so important, not only to those who abuse drugs, but to society as a whole.

ACKNOWLEDGMENT

The author was supported by funding from the New York State Office of Alcoholism and Substance Abuse Services and the New York State Department of Health, AIDS Institute.

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RESPONSE: STILL ROOM TO IMPROVE AN EFFECTIVE TREATMENT

Warren K. Bickel, Ph.D., George Bigelow, Ph.D., and Kyle Kampman, M.D.

We would greatly benefit from research on treating opioid-addicted individuals' chronic pain.

Warren Bickel: The paper provides a good general overview of the changes that have taken place in methadone treatment over the years. Its basic message is appropriate: Methadone treatment is effective and is being more widely accepted.

George Bigelow: Yes. I do think, though, that the paper overstates the extent to which methadone treatment has entered the medical mainstream. Mr. Marion's program is in New York City, where methadone has a longer history and more public support than many or most other places.

Bickel: I agree. The State of Vermont, for example, has one methadone clinic, which has a waiting list of over a hundred people. Here in Arkansas, we only have two methadone programs in the Little Rock area. This article serves as a reminder that methadone is effective, and therefore we need to do what we can to continue to bolster its acceptance by both the public and the medical and rehabilitation communities.

Kyle Kampman: Many programs still have difficulty recruiting for medical staff positions. And while there may be less stigma today, plenty still exists—not only against methadone and methadone patients, but also extending to physicians and psychiatrists who work with them.

Bigelow: Overall, nationwide, I don't think there is any other medication that is so effective and yet so hard to get as methadone.

Older patients, younger patients

Bigelow: Mr. Marion describes the aging of the methadone population, which of course is testimony to the effectiveness of the treatment. Methadone has significantly extended the life expectancy of opiate abusers. One corollary has been the creation of a group of patients with more concurrent medical disorders of the type that all aging populations have, such as

hypertension and diabetes. Our group recently published a study on this issue and the challenges it will create for treatment providers [Lofwall et al., 2005].

Kampman: Partly because of the medical problems related to aging, and partly due to opioid abusers' high propensity for trauma, we see a lot of patients with pain. Many come to us through referrals from pain management specialists who are apprehensive about treating opiate-dependent patients. Chronic pain is a difficult problem to manage anywhere, and perhaps more so in a methadone clinic. We would greatly benefit from new research in this area.

Bickel: The larger number of new, young opioid-dependent patients speaks to the need to have multiple treatment options. It is not helpful to place a person who has recently become involved with prescription drugs in treatment with patients having extensive histories of drug dependence. We need to expand the range of options, so that different types of patients can receive appropriate treatments.

Bigelow: One respect in which our experience seems to differ from Mr. Marion's is the 60 percent figure he cites for treatable depression among methadone patients. That is considerably higher than we see in Baltimore. I can't think of a reason why there should be such a difference, except perhaps that Mr. Marion's figure reflects assessments made at intake. We find that many of our patients are depressed because of the difficulties of the opioid-abusing lifestyle, but their mood recovers once they are normalized on methadone.

Treatment models and settings

Bickel: I think it is very important to keep in mind that methadone is only one part of the larger treatment picture. The research agenda should include how we can best utilize both methadone and buprenorphine to provide a true continuum of care where every

patient receives treatment in an appropriate modality. The interesting questions in methadone research right now aren't about its efficacy as a pharmacological agent—that was established long ago. They are about the different ways of delivering methadone and how to best incorporate social and behavioral counseling in the treatment.

Bigelow: For example, Mr. Marion talks about methadone medical maintenance, where stabilized patients can transfer their visits from the clinic to a physician's office. I think we should keep striving to develop models like that, so that patients and physicians can have maximum flexibility in the choice of treatments as well as treatment settings.

Bickel: Tom McLellan's group [McLellan et al., 1993] examined the importance of counseling, medical care, and psychosocial services with respect to the outcomes of methadone patients. They concluded you could make methadone treatment outcomes look either horrible or successful based on the quantity and quality of accompanying psychosocial treatments.

Bigelow: I agree. The psychosocial and behavioral treatments that accompany the pharmacotherapies are critically important, if only because they can be applied to the full range of substance abuse disorders. The drawback of a medication such as methadone is

that it is pharmacologically specific—it will only treat opioid addiction—whereas today's patients tend to be polydrug abusers.

Bickel: Our group has been looking at different ways of delivering psychotherapies. Recently we completed a trial where we compared the results of computer-delivered cognitive-behavioral treatment with the same treatment delivered by a therapist, along with a control treatment. So far, the results appear to show that the computer- and therapist-delivered treatments were better than the control, but not significantly different from each other, suggesting that we may be able to use computer technology to expand access to psychotherapies.

Bigelow: The NIDA Clinical Trials Network has conducted a study of the effectiveness of motivational incentives to reduce stimulant abuse in methadone clinics. Though the data are still in review, the incentives appear to have had a positive impact, as measured by the frequency of stimulant-negative urine samples during treatment. Another area where I think significant research is needed is the development of longer acting methadone dosage forms, which would make the medication more convenient while also reducing the risk of overdose and diversion. Unfortunately, I don't think anyone is looking into this. &

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