Counseling Issues

Clinical Concepts

**MMT as a Platform for Treating Infectious Disease**

Substance-dependent persons, especially injection-drug users (IDUs), exhibit high risks of contracting infectious disease and are notably noncompliant with antinfective treatment regimens. Tuberculosis, hepatitis C, and HIV have been epidemic in some populations of IDUs and, consequently, among persons entering methadone maintenance treatment (MMT) programs.

Can the MMT clinic environment serve as a platform for effectively treating those infectious diseases?

**Directly Observed Therapy (DOT)**

Most medications for treating infectious disease must be taken in sufficient quantity, on a regular schedule, for a specific period of time to be effective. Self-administration of medication has been problematic in individuals unlikely to adhere to the prescribed regimen, including: alcohol or drug abusers, indigent/homeless persons, or those with a history of nonadherence with following instructions.

Monitoring of patient adherence with properly taking medications by a dispensing healthcare professional – called “directly observed therapy” (DOT) – has been recommended as a strategy for increasing treatment effectiveness. MMT clinics, staffed with nurses and requiring regular attendance by patients to receive methadone, would seem to present optimal settings for DOT.

**Application to TB**

Tuberculosis (TB) continues to be a serious problem among IDUs, with those... Continued on Page 3

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**Social Workers’ Roles in MMT**

Social workers in the United States have a long history of helping substance-dependent individuals and their families. Initially, they focused on alcoholics. As early as 1917, social worker Mary Richmond, a major force in professionalizing the field, rejected the prevalent moralistic view of alcoholism, portraying inebriates as “sinners,” and embraced an “inebriety as disease” model. She stressed the importance of both physical and mental elements in diagnosing the illness.[1]

Richmond viewed social workers as playing important roles in gathering social data about clients and offering necessary assistance to supplement medical treatments.[1,2]

**Obstacles and Frustrations**

According to S. Lala Ashenberg Straussner, DSW, CAS, as polydrug abuse became more prevalent in persons also diagnosed with mental illness, social workers expanded the scope of their activities from helping alcoholics to working with all substance-dependent persons. She is Professor and Coordinator of the Post-Master’s Program in the Treatment of Alcohol and Drug Abusing Clients at New York University Ehrenkranz School of Social Work, New York City. In 2001, Straussner was instrumental in founding the Journal of Social Work Practice in the... Continued on Page 6
**Events to Note**

For additional postings & information, see: www.atforum.com

**January 2003**
AAAP Review Course in Addiction Psychiatry
January 18-19, 2003
Denver, CO
Contact: 913-262-6161; info@aaap.org

24th Ann. Institute on Addictions, Inst. for Integral Development
January 22-25, 2003
Clearwater Beach, Florida
Contact: 800-544-9562

January 28 – February 1, 2002
Colorado Springs, Colorado
Contact: 719-594-9304;
aatod@talley.com

**February 2003**
NCADI/COSA Intl. Conf. on Addiction
February 1-2, 2002
Montgomery, Alabama
Contact: 334-262-1629;
csanccadd@bellsouth.net

American Group Psychotherapy Assoc.
Annual Meeting
February 18-23, 2003
New Orleans, Louisiana
Contact: 877-668-2372

**UPCOMING 2003...**
Anaheim, California
Contact: 800-347-6647 ext. 222

AATOD (Amer. Assn. for the Treatment of Opioid Dependence) 2003 Conference
April 13-16, 2003
Washington, DC
Contact: 856-423-7222 x360;
aatod@talley.com

ASAM 34th Annual Conference
May 1-4, 2003
Toronto, Ontario, Canada
Contact: 301-656-3920; www.asam.org

NAATP (NatI. Assn. of Addict. Treatment Providers) 2003 Annual Conference
May 17-20, 2003
Indian Wells, California
Contact: 717-392-8480

[To post your announcement in A.T. Forum and/or our Web site, fax the information to: 847-392-3937 or submit it via e-mail from www.atforum.com]

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**Straight Talk... from the Editor**

**Your Feedback Needed – Today!**

**Graying of Methadone Revisited**

At one time, opioid-dependent persons did not survive into old age; they either died or were incarcerated. Methadone maintenance treatment (MMT) appears to have reversed that trend.

Today, just as there is a new class of younger addicts entering treatment – in part related to lower-priced, purer heroin, and oxycodone and other opioid analgesic abuse – there also are increasing numbers of older persons who have been in MMT for many years. When we last reported on the “Graying of Methadone” 7 years ago (Fall 1995; Vol. 4, No. 3), more than half of the patients at one of the largest MMT programs worldwide were older than age 40; 16% were more than 50 years of age.

By now, the 50+ population in MMT programs has increased further, bringing with them a set of particular needs. The healthcare, psychological, and socioeconomic concerns of older persons naturally differ from those of youngsters. Also, for the most part, these “seniors” have longer tenures in MMT, which might qualify them for special privileges.

A general question is: Have MMT programs effectively adapted to meeting the needs of older patients? More specifically, we wonder:

- Have MMT clinic accreditation processes and new regulations made life easier for older patients?
- Are more older patients receiving office-based methadone treatment from private physicians (“medical maintenance”)?
- Are counselors being specially trained in helping these patients?
- Is the medical community in general more receptive to older persons on methadone?
- Are methadone doses adjusted to take into account the metabolism of older persons and/or possible interactions with other prescribed medications?

These are just a sampling of questions for which we need answers from MMT patients and staff. Please help us revisit the “Graying of Methadone” in an upcoming article by writing to us, today, via letter, fax, or e-mail. See contact information on page 3, lower left hand column.

**The Elusive Optimal Methadone Dose**

Trends indicate that methadone doses have slowly edged upward during the past decade. This is a positive sign, considering that by the late 1980s dose levels had fallen well below initial recommendations during the 1960s by the originators of MMT – Dole and Nyswander.

Have typical doses finally achieved parity with originally-recommended levels? It has been several years since our last A.T. Forum methadone dose survey (Fall 1998, Vol. 6, No. 3), so the time is right for another one.

We encourage all readers who have the necessary information to respond to the dose-survey questions below.

**How Much Methadone is “Enough”?**

During the past 30 years, the optimal methadone dose for treating opioid dependence has been elusive. Perhaps, this is because the “right” dose is so variable, depending on many factors in each patient, including: medical conditions, drug interactions, and concurrent substance abuse, to name a few.

A mythology of methadone has evolved for determining what is a “necessary” or safe dose, without any scientific basis. Staff in many MMT clinics, as well as patients, have come to believe that doses above preset levels are not only unsuitable but, in a way, “evil.”

Yet, very recent research demonstrated that some patients naturally metabolize methadone more rapidly or completely due to increased action of liver enzymes (see Research Update on next page). Another study showed that patients maintained on low doses of methadone had more psychopathological symptoms – eg, anxiety, depression, physical complaints – and stronger cravings for heroin and alcohol (Lubrano, et al. heroin Add & Rel Clin Probl, August 2002).

In fact heroin/alcohol craving was inversely related to the amount of methadone prescribed. This helps explain why, in many patients, alcohol and illicit drug use can be eliminated only when daily methadone doses are increased to what many would consider very high amounts.

Continued on Page 3
Failings of Clinical Research

Despite the many observational studies indicating that patients often need higher methadone doses for success in MMT, to date, randomized controlled clinical trials focusing on methadone dosing have investigated quantities that would be grossly inadequate for a significant number of patients. Consequently, as noted in past editions of A.T. Forum, we know much about the “science of methadone undermedication,” but very little about truly optimal dose.

It is concerning that there has been no public questioning about the propriety and validity of randomly assigning research subjects to methadone doses, or even a placebo(!), that are almost certain to fail. Consequently, research results have depicted high rates of continued substance abuse and/or study dropouts, which have unfairly reflected poorly on MMT overall.

Methadone Dose Survey - Round III

The first two A.T. Forum dose surveys were well-received and helpful to the field. So, to the extent possible and based on available information, please respond to the following questions:

1. The Highest typical daily methadone dose at my clinic is ___ mg/d.
2. The Lowest typical daily methadone dose is ___ mg/d.
3. The Average typical daily methadone dose is ___ mg/d.
4. What percent of patients at your clinic are receiving the following methadone doses: <60 mg/d __%; 61-80 mg/d __%; 81-100 mg/d __%; 101-200 mg/d __%; >200 mg/d __%.
5. We operate on a ☐ for profit, ☐ non-profit basis (check one).
6. My clinic is located in the state of:

There are several ways to respond: A. provide your answers on the postage-free feedback card in this issue; B. write, fax, or e-mail [info below]; or, C. visit our web site to respond online. As always, your written comments also are important for helping us discuss the results.

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Do some MMT patients require higher daily methadone doses because they naturally digest the drug more rapidly or extensively?

Methadone is metabolized by several enzymes of the Cytochrome P450 system, primarily in the liver by CYP3A4. A new study* examined the relationship between patients requiring different levels of daily methadone for stabilization and the intrinsic activity of this enzyme.

Subjects at the Center for Addictive Problems, Chicago, were selected representing 3 methadone-dosing levels (approx. 10/group): “low” (up to 99 mg/day); “high” (100-199 mg/d); “very high” (200 mg/d and above). All were long-term patients, stabilized on methadone, and abstinent from illicit drugs.

Prior to daily methadone dosing, patients were administered midazolam. (The metabolism of this short-acting benzodiazepine serves as a marker for CYP3A4 enzyme activity.) CYP3A4 activity and methadone serum levels were assessed via blood samples sent to specially equipped laboratories in Switzerland.

Compared with the “low” dose group, patients requiring “very high” methadone doses for stabilization had significantly 76% greater CYP3A4 enzyme activity. There also was a significant difference between the “high” and “very high” dose groups.

In a broader analysis, all patients were divided into those receiving either less than the median 110 mg/d methadone dose (mean 74 mg/d; range 20-100 mg/d) and those receiving more than 110 mg/d (mean 283 mg/d; range 120-1000 mg/d). Those in the higher-dose group had approximately 50% greater CYP3A4 activity.

This study demonstrated that there is a significant correlation between the optimal daily methadone dose required for stabilization in MMT and the metabolic activity of CYP3A4. That is, as the authors concluded, many patients may require higher methadone doses than commonly administered due to a greater intrinsic activity of key enzymes that metabolize the drug.

Clinical Concepts

MMT Beneficial

In an intention-to-treat analysis (which includes those who dropped out of the study), an average 77.1% of patients receiving minimal MMT and 59.5% of those receiving standard MMT completed their INH therapy; whereas, only 13.1% of those receiving routine care did so. See Figure 1. Completion, or adherence to the study medication protocol, required taking at least 80% or more of INH doses during the 6 months, which was considered necessary for effective preventive therapy.

The two MMT groups had significantly better completion rates (p < .0001). The minimal MMT group had a 17.6% greater absolute completion rate than the

Figure 1: Percent of each group completing at least 80% of study medication. Vertical bars represent means; lines represent 95% confidence intervals.
Accountability in Addiction Research

“Not everything that can be counted, and not everything that counts can be counted. What really matters is not always obvious.” – Albert Einstein.

The amount of information in the addiction treatment field has rapidly increased. This presents challenges of navigating efficiently through the growing number of studies and identifying which evidence counts the most; that is, which is most valid and of reliable quality.[1]

Added to this, the change in government oversight of methadone maintenance treatment (MMT) programs requires stricter accountability for patient outcomes, such as decreased illicit drug use and improved psychosocial functioning. Increasingly, programs will need to gather and interpret their own performance data, and adopt scientifically-validated outcome-enhancing practices as part of the ongoing accreditation process.[2]

Where will MMT programs find the research evidence they need? Will they be able to interpret it and put it into practice?

Introducing EBAM

Evidence has been defined as, “the data on which a conclusion or judgment may be based.”[1] More specifically, evidence-based medicine is, “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.”[3] Along those lines, Evidence-Based Addiction Medicine (EBAM) involves treatment practices based on the best available external evidence gathered from authoritative and valid sources.

The decision whether to implement research evidence depends heavily on the quantity and quality of research available, and the assessment skills of the user. According to one observer, “Interpreting and judging medical research also involves subjective, not solely explicit, processes.”[1]

Defining Evidence

Recently, there has been an interest in the parallels of evidence in medicine and in law. Just as a jury needs evidence from reliable witnesses or forensic investigations to arrive at an impartial and fair verdict, valid information is needed to help addiction treatment providers answer healthcare questions and make clinical decisions.

In April 2000, the Agency for Healthcare Research and Quality and the Institute of Medicine hosted an expert meeting to explore similarities in how clinical practitioners, scientists, and legal professionals interpret and use evidence. The result was a special issue of the *Journal of Health Politics, Policy and Law*, titled “Evidence: Its Meaning in Health Care and in Law.”[4]

As the mandates of evidence-based medicine have challenged the medical profession to consider the scientific validity of its methods and procedures, the legal system has been similarly compelled to consider the science underlying medical evidence presented during court testimony.[5] The concept of *accountability* in these efforts has important implications for the addiction treatment field, particularly MMT programs which are always under scrutiny.

During the past decade, several Supreme Court decisions required trial judges to ensure that scientific evidence entered into testimony was supported by valid methods of research inquiry.[6] This triggered a debate about what constitutes so-called “junk science” and unreliable expert opinion.

Previously, healthcare practices that achieved “general acceptance” among practitioners in a field of medicine were acceptable. The new rulings required a much higher level of evidence, and the unsubstantiated testimony of “experts” no longer carried much weight.[6]

According to recent commentary, “Many hoped that analysis of the literature and evidence-based medicine would yield unequivocal medical practice guidelines and put an end to squabbling over the interpretation of evidence.” However, it was found that some areas of medicine lacked sufficient amounts of good evidence and clinical practices were dominated more by hearsay or case reports.[6]

In much of daily clinical practice, including addiction medicine, physicians may rely on biologically plausible assumptions, animal studies, or even a handful of anecdotal reports to guide patient care decisions. Further complicating matters, practitioners vary widely in the standards of evidence they require for making such decisions.[6]

Of interest, when it comes to assessing potential harm caused by a drug or treatment, the FDA’s threshold is much lower than the preponderance of evidence beyond reasonable doubt required by the courts. The mere “possibility” of a drug or treatment having some harmful effect is insufficient and, in some litigation, the courts have explicitly stated that an FDA warning is not adequate evidence to establish causality. In particular, case reports often have been dismissed by some courts as having little probative value (that is, they are unacceptable as proof).[6]

NIDA-CSAT Partnership

To help provide better evidence for the addiction treatment field, last September 2002, the National Institute on Drug Abuse (NIDA) and the Center for Substance Abuse Treatment (CSAT) announced a $1.5-million intra-agency agreement to help ensure that findings from NIDA-sponsored addiction treatment research will be quickly and readily available to practitioners. This funding will help support CSAT’s 14 regional Addiction Technology Transfer Centers (ATTCs).[7]

In an *A.T. Forum* interview with CSAT Director H. Westley Clark, MD, JD, MPH, he noted that part of the role of ATTCs is to help practitioners understand, interpret, and use the research. “CSAT’s focus is on services,” he stated, “while the science emphasis is with NIDA.” Essentially, CSAT is a consumer of provided research evidence and does not determine the design, analysis, or reporting of studies coming from NIDA.

For the most part, Clark believes the quality of available research is adequate:

> “From our perspective the issue is less a matter of the quality of the research, but how we can get that information to change practices in the field.”

For example, very few MMT programs use contingency contracting, although there is a good research base to support it. Conversely, some programs still use negative reinforcers, or punishments, that have not been demonstrated as effective.

However, “being current with the literature and changing one’s behavior are two different things,” Clark observed. There are about 14,000 addiction treatment locations that are consumers of CSAT-provided information, with a wide

Continued on Page 5
range of backgrounds in understanding and using research.

With the accreditation process, MMT clinics are under pressure to guide their practices by research-based evidence, and Clark suggested, “I see research as moving us beyond basic clinical care. For example, by looking at different therapeutic strategies that have been validated by the research.”

However, he also believes that some programs are not ready to act on what leading-edge research is recommending. They need to focus on basic care issues, case management, and quality controls.

In a pragmatic sense, Clark stressed, “It is important not to hold the addiction field to a higher standard than we hold the rest of the healthcare system.” At the same time, he believes that the addiction treatment field has matured to the point where it is time to adopt evidence-based medicine approaches, which other medical disciplines have emphasized for at least the past decade. “When new and effective strategies become evident we need a process by which practitioners are trained in implementing them,” he says.

Addiction Research Adequate?

While Clark is optimistic, it is worthwhile noting that a search of the ATTC web sites (http://www.nattc.org/) did not uncover any information or training specifically addressing principles of evidence-based medicine. Also, it must be recognized that the addiction treatment field, in particular, has been burdened over the years by a predominance of small clinical trials, inconsistent study designs, and inadequate reporting of results.

For example, a team from the Cochrane Collaboration (a worldwide group of scientists specializing in systematic reviews of research literature) recently set out to determine whether tapered methadone dosing is an effective strategy for managing withdrawal from opioids.[8] An extensive search produced 20 randomized controlled clinical trials for analysis. However, the treatment approaches in those trials widely varied, many of the experimental designs were incomparable and enrolled small numbers of patients, and most study reports were missing critical information to fully assess their validity. Outcome data could not be compared and summarized across trials because many results were presented in graphical form only or were missing key statistical data.

Despite their many reservations regarding research quality, the authors did conclude that methadone was beneficial in reducing withdrawal severity. Although, they cautioned, withdrawal was not demonstrated as a long-term treatment and the majority of patients eventually relapsed to heroin use.

Furthermore, recent commentary in the Journal of the American Medical Association has challenged the ethical propriety of enrolling patients in small-scale, poorly designed clinical studies that do not provide valid answers to research questions. Such trials, in which having too few participants distorts the results, are called “statistically underpowered.”[9]

The authors expressed concern that patients are being exposed to the risks and burdens of experimental procedures, and time and money are expended, for purposes that are likely to be of limited clinical value, if any.[9] The extent to which this might apply in the addiction treatment field is worthy of reflection.

Help on the Horizon

Research in addiction medicine is continually evolving, yesterday’s “best practice” may become tomorrow’s outdated relic. Yet, are today’s practices the best possible? As one author noted, “The practice of medicine has lagged behind conceptual and educational advances in relying on scientific evidence to drive clinical decisions.”[10]

Accurately predicting outcomes or benefits of a drug or treatment – for individuals and/or particular clinical settings – is difficult, if not impossible, in many instances. Further complicating matters, it has been suggested that judges of medical research, whether in the courtroom or the clinic, are frequently faced with murky, dubious, narrow, conflicting, or irrelevant evidence. Fortunately, techniques are available for appraising the relevance and validity of individual studies as well as bodies of research evidence, and for linking them to daily practice.[1]

Savvy consumers of medical evidence do not necessarily need to know how to design research studies or perform statistical analyses. Although, they should understand and know how to interpret a number of key concepts, such as: probability tests of hypotheses, confidence intervals, relative versus absolute risks, and numbers needed to treat for a desired result.

Besides the NIDA/CSAT partnership, other assistance is on the horizon. The theme of the next American Association for the Treatment of Opioid Dependence (AATOD), April 13-16, 2003, is “Integrating Evidence-Based Practices Within Opioid Treatment.”

Perhaps, as Clark suggested, the addiction treatment field should not be held to a higher standard than the rest of medicine, but neither should evidence in the field be of a lower quality than in other disciplines. MMT programs are held accountable by government oversight and accreditation processes, so evidence-based addiction medicine (EBAM) approaches are urgently needed.


Next April, A.T. Forum will be conducting a special workshop at the AATOD Conference titled, “Can Addiction Research Be Trusted?” Along with this, an extensive educational booklet on “Understanding EBAM (Evidence-Based Addiction Medicine)” will be introduced to provide essential information and guidelines for assessing and using research evidence in clinical practice.
Counseling Issues
Continued from Page 1

Addictions (see box), for which she still serves as editor.

Straussner believes that more social workers are being hired nationwide by methadone maintenance treatment (MMT) programs, but she is concerned about just how they fit in. Many of these professionals do not stay in the MMT setting very long because they feel they are not being used effectively.

Similarly, Ellen Friedman, ACSW, CASAC, observes that many become frustrated due to a lack of emphasis on resolving psychosocial problems contributing to substance abuse. She notes that in New York City the number of social workers employed by MMT programs ranges from none to many, since their presence is not required by regulation.

Friedman has been in the methadone treatment field since 1975, when she joined the Beth Israel Medical Center, New York, MMT staff. Currently, she is Director of Chemical Dependency and AIDS Mental Health at Greenwich House, a multifaceted addiction services provider in New York City.

Friedman believes that funding to hire social workers is a major obstacle. Although, she says, “Hospital-based MMTs tend to have more social workers, and there has been grant money available to have social workers assist HIV-positive drug-addicted persons.”

Treating the Whole Person

Until recently, Straussner notes, the biological aspect of the biopsychosocial approach to social work was not emphasized. However, neurobiology is becoming more important, largely due to scientific advances during the past decade in understanding brain function in addiction and mental illness (see box at end).

However, Friedman observes that many MMT programs tend to focus on the biology of opioid dependence, considering methadone as the major solution, without treating the whole person or viewing recovery in multidimensional terms. The biopsychosocial approach also looks at a person’s inner strength and how the individual interacts with their environment. The goal is to identify potential areas and local supports for necessary life changes.

Straussner agrees that, from a social worker’s perspective, methadone is not a holistic approach to the problem of opioid addiction. “In some settings, methadone is dispensed without attempts to deal with multiple, psychosocial problems clients may have,” she suggests. “There also has been concern that many clients are denied therapeutic doses of methadone because of stigma surrounding the medication.”

Friedman adds, MMT programs that conceive of themselves as “addiction treatment” rather than merely “methadone medicating” facilities tend to offer more psychosocial services. Also, programs believing that clients are responsible themselves for finding community resources to meet their needs would not hire social workers; whereas, social workers in MMT clinics can play important roles in assisting clients to access community agencies and services.

(Social workers respectfully use the term “client” for persons in therapy for addiction, Straussner notes. Although, hospital or medical staff more commonly use “patient.”)

Attending to Special Needs

Friedman says, “Social workers tend to have broader perspectives in overall assessment of client needs than counselors. They view the client’s problems in psychosocial and socioeconomic terms, rather than just behavioral terms, and also can assess concomitant mental illness. If needed, social workers are well-versed in the referral process for accessing other services.”

Both Friedman and Straussner note that social workers are capable of serving as clinical administrators, supervisors, and advocates for better client care. Few become accredited in addiction counseling; although, as certified social workers they are trained in that capacity. Plus, they have specialized knowledge of group dynamics that might offer new approaches for more traditional therapy groups in dealing with addiction.

Furthermore, Straussner stresses that family dynamics in addiction recovery are very important, even if the family is entirely in the background. Cultural, ethnic, and gender issues – such as, the particular needs of women, lesbians, gays, etc. – need attention for addressing individual client’s concerns and are all part of the social worker’s purview. These aspects of recovery have been largely ignored by MMT programs, and social workers receive special training in such matters.

Evidence of Efficacy?

As in other healthcare disciplines, evidence-based practices are of interest in social work. However, Straussner observes, “Efficacy trials of specific social work interventions have been noticeably scarce.” Currently, there is little evidence to rely upon for recommending specific social work practices in the addiction treatment field.

She believes this is changing and there is a growing emphasis on research in the field. For example, NIDA is providing more funding for studies in the social sciences.

Action Steps

Very little of current social worker training involves methadone, Friedman concedes. Recruiting social workers into MMT programs largely depends on the willingness to adequately compensate these skilled professionals and then using them effectively. MMT programs represent the largest treater of addiction; however, the way things are today, the work environment can be stressful and unproductive due to heavy case loads and administrative paperwork.

Straussner recommends that, besides hiring more staff social workers, MMT clinics should involve social work student interns. “They question existing norms of treatment and, in so doing, may provide new insights for improving client care.” Students must be supervised by practicing social workers, she notes. Although, in some cases, teachers at local universities may be able to act as off-site supervisors.

Friedman concludes, “I think persons in methadone treatment need social workers, just as anybody with a chronic illness really could use a social worker.”


The Journal of Social Work Practice is available from The Haworth Social Work Practice Press. Of special interest, Vol. 1, No. 3 of the Journal also was published as a book: Neurobiology of Addictions, Implications for Clinical Practice (Editors: Spense RT, DiNitto DM, Straussner SLA), ISBN 0-7890-1667-2. This text, bridging the gap between science and practice, is recommended for all professionals in the addiction field. For information and ordering: Tel: 1-800-HAWORTH (outside U.S./Canada call 1-807-722-5857); Web: http://www.HaworthPressInc.com; E-mail: getinfo@haworthpressinc.com. A.T. Forum readers are eligible for a special 38% discount on Haworth publications by mentioning Code BCSO when ordering.
standard MMT group, although this was not statistically significant (confidence intervals overlapped, see figure 1).

In terms of study retention, most patients participating in both forms of MMT stayed in INH therapy 5 or more months on average. Conversely, the vast majority of those in the routine care group remained in treatment less than 2 months. See figure 2.

As with medication adherence, the minimal MMT group appeared to fare much better in terms of retention in the study than those in the standard MMT condition, although the difference was not statistically significant ($p = 0.1924$). Of clinical significance, 87% of the routine care group patients did not complete the study and 47% of those failed to even show up for their initial supply of INH; another 23.5% of routine care non-completers did not return for subsequent monthly medication supplies.

The difference between the minimal and standard MMT retention rates was close to statistical significance, suggesting that less comprehensive approaches to MMT, such as interim methadone treatment, may be of benefit. (If more subjects had been enrolled in this study, a significant advantage of minimal MMT might have been demonstrated. A further limitation was not having a fourth treatment group in which patients received daily observed INH without participating in MMT.)

**Health Benefits Supported**

Steven Batki, MD, lead author of the study, told *A.T. Forum* that the study demonstrated “proof of concept” that MMT can offer significant public health benefits when used as a platform for delivering medical services to IDUs. Batki is currently Professor and Director of Research, Department of Psychiatry at SUNY Upstate Medical University in Syracuse, NY.

However, a temporary approach to MMT, such as only 6-months of treatment in this study, would not be expected to achieve illicit-drug abstinence objectives. Urinalysis results were not fully reported, but Batki observed that, in terms of continued drug abuse, “Essentially, neither of the two methadone treatment groups did very well in a program that limited MMT to 6 months.”

One reason for continued drug use in the MMT patients might be that they did not have the usual incentives for good behavior, such as take-home methadone privileges and a long-term commitment to recovery. Also, the researchers enrolled out-of-treatment drug users who were largely indigent (homeless or with unstable housing), did not specifically apply for MMT, and were newly entering the addiction treatment environment.

How might this approach work in a more stable MMT clinic population?

Batki believes that patients typically found in most MMT clinics would respond much better; therefore, the research study is an underestimate of the potential outcomes. Furthermore, current INH therapy does not require daily dosing, so DOT can be done less frequently.

**DOT for HIV in MMT**

Might the DOT-in-MMT approach work for other infectious diseases?

In their study, Batki et al. excluded patients with concurrent TB and HIV disease. However, there have been other promising investigations in MMT patients with HIV.

A recent pilot study conducted at Albert Einstein College of Medicine, Bronx, NY, reported on a simplified HAART (highly active, multi-drug, antiretroviral therapy) regimen administered to HIV-positive patients under direct observation in an MMT clinic. After only 8 weeks, 4 of the 5 patients had undetectable HIV viral loads.[2]

A larger study, conducted in Ireland, enrolled 39 patients administered HAART as a component of the MMT regimen.[3] At 48 weeks, 51% of antiretroviral-experienced patients and 65% of antiretroviral-naïve patients had achieved maximum viral suppression. The authors termed this approach “DAART” (directly administered antiretroviral therapy), which was an attractive individualized-care solution for patients in whom HAART was previously inaccessible or ineffective.

**Further Research Warranted**

Batki’s latest interest is evaluating benefits of DOT for treating hepatitis C (HCV) in MMT clinics. Controlled clinical trials of this approach have yet to be done and he has a research proposal pending with NIDA. He believes there would not be any obstacles to the delivery of anti-HCV medications by MMT medical staff, as long as there are sufficient staff to provide such services.

Batki is proposing a randomized trial in which half of the patients will receive anti-HCV therapy during MMT clinic visits and a second group will be treated for HCV at a separate medical facility. He also is considering ways of reducing ongoing substance abuse during HCV treatment via a voucher incentive approach, to determine if this might affect antiviral-treatment success.

Another area for future investigation might be a cost-efficiency, economic analysis of DOT in MMT.

For example, in the Batki et al. TB study,[1] there were only 2 cases of active TB (1.8% of all enrolled subjects) found at an average 4-years of followup; both were subjects who did not complete therapy, one each in the minimal MMT and routine care groups. None of the patients in the standard MMT group converted to active TB, whether or not they completed the study.

Any case of active TB might be considered important from a public health perspective. However, it would be helpful to demonstrate that the risk/benefit balance justifies costs of preventive TB therapy or, HCV or HIV treatments within the MMT setting.

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In the Spring 2002 edition of *AT Forum* (Vol. 11, No. 2), as part of a series on “Liver Disease in MMT,” readers were asked to comment on the available support for patients in methadone maintenance treatment (MMT) who have hepatitis C (HCV).

A first question asked about the percentage of patients with HCV who are also receiving treatment for the disorder. The 85 responses submitted were quite varied, ranging from 0% to 100%. On average, 17% of HCV-positive patients were receiving treatment (95% Confidence Interval was 12-22%, meaning the most likely average of those receiving treatment was in this range). However, it should be remembered that *A.T. Forum* surveys are informal and may not be representative of all clinics.

Survey questions also solicited “yes,” “no,” or “don’t know” responses to the following:

- Does your MMT clinic have support programs for patients with HCV?
- Are there HCV-support groups in your community?

Approximately 118 persons responded to each question via feedback cards or at the *A.T. Forum* website (www.atforum.com). The graph depicts a summary of those responses.

Only about a third of clinics (36%) offered HCV support programs, whereas such services were reported in more than half (52%) of communities. Still, in neither case, does this appear to represent extensive availability of support groups or other services for MMT patients, and from 20% to 32% of respondents simply did not know if support was available.

One MMT patient in California, who is also a clinic clerical staff member, commented that there are no clinic-sponsored HCV-support services, although there are groups in the community. One of those groups comes into the clinic every few weeks; however, their basic message is that there is no cure for HCV and patients must be careful not to infect others.

Apparent is much room for improvement in support services and, also, for better informing patients of clinic- and community-based resources.

**Good News for HCV+ MMT Patients**

Late last August, the National Institutes of Health released the “Final Statement” from their panel convened in June 2002 to issue new guidelines on the treatment of HCV. Titled “NIH Consensus Development Conference Statement: Management of Hepatitis C: 2002,” it provides an update to a 1997 statement on the same topic.

The new statement specifically endorses treatment for HCV in persons on methadone. It says, “Access to methadone treatment programs should be fostered for HCV-infected IDUs whether or not they are receiving treatment for HCV. Methadone treatment has been shown to reduce risky behaviors that can spread HCV infection, and it is not a contraindication to HCV treatment. Efforts should be made to promote collaboration between experts in HCV and healthcare providers specializing in substance-abuse treatment.”

Hopefully, these guidelines will be adopted by the medical community to help overcome prior reluctance in treating MMT patients for HCV. Meanwhile, MMT providers and patients should be aware of the document and bring it to the attention of liver treatment specialists.

The full text is available at http://consensus.nih.gov, or by calling 1-888-NIH-CONSENSUS (1-888-644-2667).
Methadone Dose Survey – Round III – Please respond to the following questions:

1. The *Highest* typical daily methadone dose at my clinic is ____mg/d.
2. The *Lowest* typical daily methadone dose is ____mg/d.
3. The *Average* typical daily methadone dose is ____mg/d.
4. What percent of patients at your clinic are receiving the following methadone doses:
   - <60 mg/d ____%; 61-80 mg/d ____%; 81-100 mg/d ____%; 101-200 mg/d ____%; >200 mg/d ____%.
5. We operate on a ☐ for profit, ☐ non-profit basis (check one).
6. My clinic is located in the state of: ____________________________.

☐ Please add me to your mailing list (Mailing within U.S. only) Outside U.S. see www.atforum.com
☐ Check here if you would like to be notified via e-mail when the *A.T. Forum* Web site is updated monthly

E-mail address: ____________________________________________________________________________________

Name: ____________________________

Title: ____________________________

Institution: ______________________

Address: __________________________

City: ____________________________  State: ________  Zip: __________

Country: _________________________  Phone: ____________________
Use the attached card to answer the questions on Methadone Dosing or to be added to the Addiction Treatment Forum mailing list.