A.T.F. Dosage Survey

The Results Are In...
...and the results show that the vast majority of MMTP clinics around the country still have room to grow before achieving dosage practices widely recommended by researchers and authorities in the field.

Last spring and summer we solicited input from readers regarding the methadone dosage practices at their MMTP clinics. The response card asked a few simple questions:

1. The HIGHEST typical daily methadone dose?
2. The LOWEST typical daily methadone dose?
3. The AVERAGE daily methadone dose?

We also asked whether the clinic operated on a for-profit or a non-profit/public basis, and for information regarding the location of the clinic so we could divide the responses into regions.

A total of 203 reader response cards was returned.

What's a Proper Dose?
There has been a long-standing debate about what is an "adequate" or "optimal" methadone dose. Dole and Nyswander, the developers of MMTP in the early 1960s, recommended maintenance doses of 80 to 120 mg daily. Fairly recent research by Caplehorn and Bell demonstrated that patients at 80 mg or more were twice as likely to remain in treatment compared to those taking 60 to 79 mg. And, those in the latter group were twice as likely to stay in treatment as those receiving less than 60 mg.

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Current Comments

Dr. Elizabeth Khuri: MMTP for Youths

A.T. Forum interviewed Elizabeth T. Khuri, M.D. about her pioneering experiences in treating young opiate addicts with methadone. Dr. Khuri is Clinical Director of the Adolescent Development Program (ADP Clinic) at Cornell Medical Center, and Associate Professor of Clinical Public Health at Cornell University Medical College among other professional appointments.

A.T. FORUM: Dr. Khuri, at what point in the development of Methadone Maintenance Treatment were younger people involved?

ELIZABETH KHURI, M.D.: In the late 1960s, Dr. Marie Nyswander was struck by the fact that there were many young heroin addicts under age 21 who were absolutely ineligible for methadone maintenance under FDA regulations. Nyswander and [Dr. Vincent] Dole, in their very pioneering way, started a clinic designated for young people in about 1960. I joined in 1970, and Dr. Robert Millman was working on this project with me and Nyswander (with Dole's continuing support). This clinic was started at Rockefeller University. Later, Dr. Robert Millman and I moved the clinic to Cornell University, to the Department of Public Health and Pediatrics.

A.T.F.: What was your program like in those earlier days?

KHURI: The range of age was originally 14 to 21. By the winter of 1970, the FDA lowered the minimum age requirement for treatment as an adult to 18. So when we moved to Cornell we had 21 patients 14 to 18 years old.
We offered comprehensive support-
MMTP Counselors; Respond to New Survey Question

Thank You...

...to the 203 respondents who completed and mailed the dosage survey cards. Based on the results of our survey and articles in this edition of A.T.F., we offer the following observation: Methadone may be the most regulated and administratively encumbered, and the most controversial and misunderstood medication in the current arsenal of our so-called "modern medical establishment." Why is there so little standardization among methadone programs across the U.S. regarding the most efficacious dose? As always, we invite your commentary. Write to us at: AT Forum; 1515 Woodfield Rd., Suite 740; Schaumburg, IL 60173.

MMTP COUNSELORS; Now It's Your Turn

Here's a chance to make YOUR voices heard. Our feedback card in this issue asks a basic question: "What's your caseload? Do you believe that your counselor to patient ratio is good, difficult or typical compared to other MMTP clinics?"

Simply indicate your responses on the feedback card, fill in the other information and mail it. We also encourage you to enter a brief explanation on the feedback card, or in an accompanying note, so we can share the rationales behind your responses with our readers. Any names and clinic identification will be held in confidence and not reported, unless you specifically indicate otherwise.

Stewart B. Leavitt, Ph.D., Editor

Meeting Notes

NAPARE: "Building on Strengths"
The next NAPARE (National Association for Perinatal Addiction Research and Education) Nationwide Conference will be December 11-14, 1993 (with pre-conferences on December 10th) at the Chicago Hilton Hotel & Towers. Call 312/541-1272 for information.

TASC: "Framing the Future/ Finding Common Ground"
The "Fourth National Conference on Drugs and Crime," sponsored by the National Consortium of TASC Programs (NCTP), convenes in Dallas, Texas, February 27 to March 3, 1994.

For information, call NCTP at 202/347-3529.

National Methadone Conference: "Changing Lives - Healthy Communities"
Remember April 20-23, 1994, Washington, D.C., for the next National Methadone Conference. The Grand Hyatt Washington will be the site, and the conference will focus on the critical role methadone treatment plays in a comprehensive health care system in today's world.

Call Audrey Cannamela at 202/296-6611 for information.

Viewpoint

Ethical Issues of Methadone Maintenance: Perception vs. Reality

The following is excerpted and edited from an article by John T. Carroll, CAC. He is a Certified Addictions Counselor with over 19 years of clinical experience. Mr. Carroll is currently the Division Director of Substance Abuse Services at the Crozer-Chester Medical Center.

The issues of ethics and social responsibility are not commonly associated with the provision of methadone maintenance. Historically, methadone providers have sometimes been viewed as immoral and without scruples. Such feelings came from three negative perceptions which are still pervasive among critics today.

The first perception is that current methadone providers are akin to those methadone clinics of the 1970s. Methadone treatment in the 90s has changed! Comprehensive services are the norm and patients are delivered an array of services under the "one-stop shopping" concept. Furthermore, vigilant government regulation has intensified with a substantial number of inspections throughout the year.

The second perception is that methadone maintenance providers give drugs to drug addicts. This arose from the thinking of previous decades when all people in recovery had to be drug free. This thinking has changed. Also, " Fellowships" now sponsor "Double Trouble" meetings, and the use of medications is more understood and less chastised in the recovery network.

The last perception is that methadone providers are in the business of selling addiction and that they actually addict their patients to the drug. In reality, methadone maintenance is a substitution therapy which capitalizes on the cross tolerance phenomenon. The patient seeking help is already addicted and the methadone providers do not addict anybody.

One issue of both ethics and social responsibility that methadone providers constantly grapple with is length of stay. It is determined by patient response to treatment. In favorable circumstances, patients can satisfactorily rid themselves of their narcotic addiction by the slow weaning of their methadone dosages. These people are the successful cases. The chronic people who do not consistently

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A current study by Capehorn, Bell and others found that the relative odds of using heroin were reduced by 2% for every 1 mg increase in the maintenance dose of methadone. The odds of using heroin for patients maintained on 40 mg of methadone were 2.2 times greater than those of patients maintained on 80 mg [see "Methadone dose and heroin use during maintenance treatment." Addiction 1993, Jan;88(1):119-124.]

According to the State Methadone Maintenance Treatment Guidelines published in 1992 under the auspices of the Center for Substance Abuse Treatment (CSAT), "The majority of patients will ultimately fall into a range of effective doses. ... Optimum dose would, for most patients, be around 80 mg, plus or minus 20 mg." See chart for this idealized optimum.

A study by D'Anuno and Vaughn ["Variations in Methadone Treatment Practices: Results From a National Study," JAMA, Jan. 8, 1992, 253-258] found that average dose was 45 mg. The mean upper limit of dose [highest] was 79 mg. One purpose of our survey was to further explore the results of this earlier study. Have methadone dosage trends changed remarkably since 1988?

Results & Observations

The chart accompanying this article shows some of our results. Statistical analysis showed that the means for high, low and average dosages were significantly different (p<.01) even though (as can be seen on the chart) there was a large overlap of their ranges.

Average Dose... the mean (average) of 56.58 mg is below the optimum 60 to 100 mgs recommended in the guidelines and literature. Also of concern, the median (mid-point) of 60 mg indicates that 50% of clinics dose patients at less than the lower limit of the recommended range. However, our mean is higher than the 45 mg average reported by D'Anuno and Vaughn.

HIGHEST TYPICAL DOSE... Our survey produced a mean of 89.10 mg (cf. 79 mg in the D'Anuno and Vaughn study).

LOWEST TYPICAL DOSE... This question was asked for informational purposes only, since we had no other studies with which to compare our findings. The reported mean is 21.79 mg with a range of 2 to 67 mg. For many clinics, this number represented the dose for patients undergoing detoxification.

Commentary

While "average" dosages and "highest typical" dosages may have increased since the D'Anuno and Vaughn study 5 years ago, things have not changed dramatically and the dosages today are still well below those widely advocated as mentioned above.

Looking at the reported ranges in our survey, there appears to be a broad "grey area" — a 22 mg/d overlap among clinics for what is considered a high, low, or average dosage [see chart] — spanning from 45 mg to 67 mg. Thus, depending on the particular clinic, a dose in this range may

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What is the Future of MMTP Under Health Care Reform?

by Mark Parrino, M.P.A., President
The American Methadone Treatment Association

National Health Care Reform and Managed Care Initiatives are creating new anxieties for methadone treatment providers. Clinical personnel are providing a richer mix of services to patients in need of more intensive care.

Program Administrators are questioning the impact that health care reform will have on their respective outpatient programs.

While the outcome of the Clinton Administration’s proposals are uncertain, the following points should provide some guidance:

- Funds from the existing substance abuse block grant could be diverted to pay for mental health and other health care services. This could severely cut back subsidies to publicly funded methadone treatment programs. Individual states would also be allowed to transfer current drug and alcohol treatment dollars into newly formed “regional health alliances” to promote integrated health care.

- The proposed substance abuse benefit does not provide adequate coverage for pregnant addicted women, women with children or homeless addicted people. In fact, funding for such critical patient populations may be restricted.

- The Administration’s proposal would merge drug and alcohol benefits with a mental health benefit. People who would need access to both substance abuse and mental health services would be restricted to only one set of benefits. A number of our patients could easily exhaust either benefit category, and the patient would lose access to any additional care. Hopefully, the drug and alcohol benefits will remain distinct from mental health benefits.

- The proposed plan appears to support the provision of substance abuse services through the existing network of drug treatment programs. Methadone maintenance treatment programs would need to be designated as “essential providers” in order to effectively compete with health maintenance organizations. HMOs do not have a good track record in treating methadone main-

tained patients. Free-standing methadone programs will be at even greater risk without an “essential provider” designation.

- The proposed plan contains a cost-sharing requirement which would apply to outpatient methadone treatment programs, and would include even the poorest patients. In fact, patients in the lowest cost-sharing category of the three schedules would be required to pay $10.00 for every outpatient counseling session. A number of national organizations, including the American Methadone Treatment Association, will recommend eliminating such cost-sharing requirements, since this provision would be financially prohibitive for most of our patients, especially at the higher cost-sharing levels. It is also uncertain if the existing Federal

Research Notes

Methadone Dose Level Not Linked to Smoking

Cigarette smoking has been shown to increase after the acute administration of methadone, and there has been concern that higher doses of methadone might lead to increased smoking. In this study, however, maintenance doses were not correlated with smoking levels. “This suggests that the acute effects of methadone on smoking are nullified as clients habituate to dose level, and that decisions regarding appropriate methadone dosage can be made on other grounds.” (Stark, M.J. and Campbell, B.K. “Cigarette smoking and methadone dose levels.” Am J Drug Alcohol Abuse 1993; 19[2]:209-217 [from abstract])

Are Contingency Contracts Useful?

A study of 60 patients evaluated the outcome of mandatory contingency contracts in an MMTP. Unremitting drug use resulted in methadone dosing decreases and, ultimately, detox and discharge. The contracts did not decrease the overall number of positive urines, but opiate use did decrease significantly for subjects on more stringent contracts. (Saxon, A.J., et. al. “Outcome of contingency contracting for illicit drug use in a methadone maintenance program,” Drug Alcohol Depend 1993 Feb; 31[3]:205-214 [from abstract])
be considered either their highest, lowest or average.
This implies that a patient admitted to a particular clinic may receive a dose of 45 mg/d, and the clinic will consider that to be their highest dose. At another clinic, a patient may receive 67 mg/d and they will consider it their lowest, entry level dose. What accounts for the wide variation of high and average dosage practices among U.S. methadone clinics? Are there such widely varying and unique populations of patients at particular clinics to account for the differences?

Why would a daily methadone dose of 45 mg be considered low at one clinic and high at another? Why would what is considered an “average dose” range from 30 mg to 80 mg, when 60 to 100 mg is widely advocated in the literature as the “optimum” range of dose?
These questions may need further research and/or study by governing bodies and clinicians involved in methadone regulation and administration.

LAAM Approved... With Restraints
The FDA and NIDA have authorized the use of LAAM (Levo-Alpha-Acetyl-Methadol) in the maintenance treatment of narcotic addicts. The effects of orally administered LAAM do not start until several hours after administration and last an average of 2 to 3 days. Certain important limitations have been imposed on its current use in approved clinic settings:
• LAAM is NOT APPROVED for use during pregnancy or while nursing infants. Before being admitted to LAAM maintenance, any woman of childbearing potential must be tested for pregnancy. Thereafter, monthly pregnancy tests must be performed on these patients.
• The current regulation does not allow ANY take-home privileges for LAAM. For take-home purposes, patients may be switched to methadone.
• LAAM maintenance is prohibited for patients under 18 years of age.
• Patients may not be administered LAAM more frequently than every other day. The usual dosing regimen is three times per week. A physician must authorize the dosage dispensed, according to approved product labeling, and justify any deviations.
• LAAM is not approved for detoxification purposes.
While a “longer-acting methadone” appeals to many, there are some widespread concerns and reservations. According to the government regulation, the costs of administering LAAM (considering pregnancy tests, physicians’ time, etc.) will greatly exceed the costs of current methadone treatment programs (by $4.6 million/year). On the other hand, proponents hope that clinic administrative costs will be lowered by the less frequent visits of LAAM patients and that more treatment slots might become available.
For those interested, the complete text of 21 CFR Part 291 regarding LAAM appeared in the Federal Register, Vol. 58, No. 137, Tuesday, July 20, 1993, pp. 38704 - 38711.

Comments by Survey Respondents
Following is a sampling of comments from readers on their survey response cards:

"We encourage our clients to get to a dose level that holds them so that they don’t use on the outside." - Arizona
"In the last ten years we have seen our average dose increase from 40 mg to 62 mg. At the same time, we made it easier to request an increase in medication. Our ‘clean,’ drug-free rate is 75% to 80% of our population." - Arizona
"Most maintenance doses are in the 50 to 65 mg range and mutually agreed upon by patient, physician and counselor." - California
"Patients are given sufficient medication to suppress all symptoms. There is no magic attached to [our] 100 mg limit." - Florida
"We are in the process of increasing the maintenance dose. Many, if not most, of our clients need high level dosages to function better." - Illinois
"The majority of our clients would like the maximum dose level raised to 100 mg. I’m having a hard time convincing our director to make this change." - Maryland
"We believe in 'adequate dose' meaning the dose that blocks withdrawal symptoms and keeps the patient off heroin." - New York
"We attempt to stabilize the patient on the lowest possible dose." - New York
"Historically, our dose setting has followed the quality of heroin in this area, which has been low. However, recently the quality has increased and our dose setting has followed suit." - Illinois
"I don't agree with a counselor lowering my dose without my consent. I was taken from 60 to 35mg without notice. That's not a blockage dose." - Patient
"As doses get lower, patients tend to substitute alcohol abuse." - New Jersey
"There is much I could say about administration attitudes but choose not to, thanks to negative feedback (e.g., punishment in terms of my pick-up schedule, petty grudges and biases from certain nurses which result in long waits and covert harassment." - Patient

In our next edition, we will further explore the results of our survey as they relate to regional and clinic operating differences (i.e., for-profit vs. non-profit/public), along with further comments sent-in by survey respondents.
Methadone Patients’ Rights vs. Diversion & Regulation
by Lisa Mejor-Torres

Methadone diversion (from legitimate commerce into the illegal marketplace) has been accepted as a major issue of concern in regulating methadone maintenance treatment. Government bureaus (the Food and Drug Administration and the Drug Enforcement Agency in particular), state regulators, treatment providers and law enforcement officials presume that the diversion of methadone onto the streets of America constitutes a substantial threat to public health and safety. Yet, there is a distinct absence of research to substantiate the threatened harm or to justify the extent of regulatory intrusion in methadone treatment.

The majority of federal and state regulations require programs to maintain extensive documentation and record-keeping systems which consume enormous effort and significant hours of work by program personnel. Further, the regulations require compliance with many safety and storage procedures while virtually ignoring issues of treatment quality, staff competency or patient welfare. Compliance with regulatory requirements often occurs at the expense of patient care.

Government regulations are so intertwined with treatment practices as to be almost impossible to distinguish in origin. For example, the regulations require special approval for take-home medication in excess of 100 mg/day. While the purpose of this regulation is no doubt related to diversion concerns, in practice, the effect is punitive to those patients who metabolize the medication more rapidly and therefore require higher effective dosages. As a result, patients are routinely discouraged from dosages exceeding 50 milligrams, and many patients are receiving insufficient and ineffective dosages for reasons unrelated and contrary to established dosage practices.

Unless retention in treatment is also established as a treatment priority, and take-home medication schedules are liberalized, patients who are unable to make or maintain the demanding adjustment in lifestyle to daily clinic attendance will continue to “opt out” of treatment. Premature detoxification from methadone maintenance results in a costly and demoralizing cycle of relapse into active drug addiction, including intravenous drug use with the risks of HIV/AIDS infection.

The market for illegal methadone is created by market forces of supply and demand. It is active addicts who create the demand for illegal methadone. Inaccessibility to treatment, combined with the medication’s known effectiveness and its unavailability actually raises the demand and places premium prices on illicit methadone. Inflated prices desolate addicts are willing to pay for methadone often become irresistibly tempting for MMTP patients, a majority of whom are indigent. In other words, much of the currently implemented activities geared toward preventing diversion actually contribute to its increase!

Methadone as a medication is a success, but as a treatment there is simply a lack of resources and commitment to deliver effective, quality treatment. Unfortunately, regulations aimed at preventing diversion ultimately dictate how programs’ limited resources will be allocated. Much of current methadone maintenance treatment practice accompanying the medication is counter-therapeutic and inconsistent with rehabilitation. The result is a discouragingly high recidivism rate; most patients relapse because they have not acquired the life skills to maintain a drug-free existence when the effects treatment.

Although the need for some precautious to discourage methadone diversion may be appropriate, it is time to assess whether the means currently being employed are justified. The price patients must pay, in the name of preventing diversion, has become intolerable.

Lisa Mejor-Torres is an east coast attorney and methadone patients’ rights advocate. She is a participant on several local and national committees dealing with the federal and state regulation of methadone. For more information, she can be contacted at 201/413-9013.

The above article was excerpted from a much longer document. For a complete, unabridged, copy of the original article, check the appropriate box on the feedback card in this issue and mail it in.
respond are a much different story. Several questions need to be considered when cessation of methadone is being considered:

1. Who is at fault, the program or the patient, if a person does not favorably respond to the program and the program a death sentence? The most troubling aspect is the potential of HIV/AIDS for the IV addict. And, a punitively discharged methadone patient has the tendency to abandon all precautions when in relapse. Methadone providers must face this reality when considering forced termination for noncompliance.

The narcotic addicted patient population presents circumstances that test the resources of the addiction treatment professional. Ethical treatment and social responsibility remain the cornerstones for comprehensive methadone maintenance providers.

We quickly discovered that many of our young patients required just as high a dose — at least 70 to 80 mgs — as the so called "adult patients," in order to allay craving and blockade the heroin effect.

Perhaps equally important in the beginning was dealing with basics: food, clothing and shelter. For high school dropouts we had vocational help and educational help so they could get part-time jobs and return to school. We also offered legal services, and the most important thing I think we offered for that age group was cultural and recreational programs because we felt very strongly that these kids needed alternatives for pleasure.

A.T.F.: In these days, what was the typical dosage of methadone?

KHURE: We were trained by Dole and Nyswander and believed that high doses were more efficacious in that they blockaded heroin and relieved drug hunger. But we thought that, since these young people had been using heroin for a shorter period of time and at less intense levels, lower dosages would work well. The average doses at first were 40 to 50 mgs. But we quickly discovered that many of the patients required just as high a dose — at least 70 to 80 mgs — as the so called "adult patients," in order to allay craving and blockade the heroin effect.

A.T.F.: What sort of successes were you having in your program?

KHURE: We felt we had excellent success in that 75 to 80% of our patients went back to school, after having been dropouts or truant, or got jobs. Those who did not become "involved" had
Continued from Page 7

more severe psychiatric disorders. Most important was that they stayed on methadone and stopped using heroin.

A.T.F.: What trends have you observed over the years?

KHURI: In the late 1970s heroin addiction seemed to decrease among youths in New York City. The 1980s brought the rise of cocaine which became the first drug of use after alcohol. The combination of alcohol and cocaine was what many young people started with.

These young people become heroin addicts secondarily after their initial bout with cocaine addiction. They tend to be older [today] than they were in the early days before we had cocaine.

Whereas, the average age of our patients before was under 18, the average age today at intake is about 20. That’s still a full 15 years younger than the average patient age, which is in the mid-30s at a typical methadone maintenance clinic in New York City. However, we are still the principal treatment center, in fact the only treatment center I know of, with a dedicated program for youth aged 16 to 24.

A.T.F.: Isn’t your sort of program expensive?

KHURI: We think it should be more expensive than it is. Our cost per patient per year is approximately $6,000. It formerly was over $7,000, but the emphasis is on cutting down services now because of the fiscal constraints of the 1990s. We feel the cost should really be $8,000, a bargain compared to the alternatives.

A.T.F.: Why is yours still the only MMTP in the country focusing specifically on younger heroin addicts?

KHURI: I feel rather strongly that there should be treatment programs for youths that include methadone maintenance as part of the spectrum of services. I certainly don’t think methadone is the only answer for treating adolescents. But I think that there is such antagonism towards methadone, and such fear of using it for a younger population no matter how hard core they are, that it’s been under-utilized as a treatment.

Often the addiction treatment community waits too long until the young people have AIDS, or are dead, or have developed a criminal lifestyle before they realize the chronicity of opioid addiction and the fact that methadone should have been used as treatment earlier, as the case histories of our young patients bear out. Our young patients went on to have productive, in many cases even professional careers, because there was an intervention of methadone maintenance for maybe as long as 5 to 6 years at a crucial time in their lives.

A.T.F.: Has the prevalence of HIV/AIDS changed your approach?

KHURI: An important change is that we do not emphasize methadone withdrawal as a goal. Not that we ever pushed it, but we are now extremely cautious about it because we see so many young people withdrawing from their methadone, even against advice, and coming back to us HIV positive. I feel I have a responsibility to educate patients about their disease; to teach them that relapse in this age of AIDS is dangerous.

My basic philosophy about methadone is that it must be in the context of caring comprehensive services and even if you remove the medication, it doesn’t mean that someone doesn’t need the services anymore to prevent relapse. In fact, they need them more. They need the counseling and the support and the family of a good methadone clinic with what Mary Jeanne Kreek calls the “smile factor.” It’s that inevitable quality of a methadone clinic which makes it a nice place to go, a place of honor and pleasure, and not a place of shame.

For a complete, unabridged transcript of this condensed interview, check off the appropriate box on the feedback card in this issue, fill-in the information and mail it in.

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