

Methadone Today

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Unprofessional Clinics Play Censor

by Beth Francisco

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It has been awhile since I have written anything for the newsletter, but something has been bothering me. As you know, one of the reasons for publication of *Methadone Today* is for patients to express their views and even blow off steam about issues that affect them. A couple of clinics across the country (not many in the scheme of things) have decided not to allow their patients to read the newsletters because of patients expressing negative views about clinics in general or because we have printed articles that the clinic disagrees with.

The interesting thing I have found about the clinics that have disallowed the newsletter is that they are the very clinics that patients describe as "bad." The good clinics will read negative comments and try to change things for the better so that patients will feel positive about their treatment. Not so with the marginal clinic.

It is unfortunate that some clinics refuse to be professional and comment on the articles they disagree with instead of censoring their patients' reading*. But I understand that certain clinics don't want anything to rock the boat or shake things up, and they certainly don't want to lose control. A negative article is simply an excuse to get rid of the newsletter, which contains good information for patients wishing to participate in their treatment.

Another interesting point is that treatment is supposed to help patients become responsible and increase their self esteem. Asserting opinions is one way to do both. Creating robots who have no opinions of their own has never been a positive treatment outcome.

Good clinics look past the negative comments and realize that the articles are not about them. Bad clinics recognize themselves in the comments and apparently feel they have no options other than to ban any material that makes a patient think. Adults agree to disagree. Children take their toys and go home.

*We welcome clinic staff to send in their comments for publication.

Current Concepts--Methadone Dose Debate

Reprinted from *Addiction Treatment Forum V. XII, N. 1 (Winter 2003)*. [Edited for space--see www.atforum.com for entire article]

Medical practitioners rarely deny patients adequate medication for their disorders. Yet, this has not always been the case with methadone maintenance treatment (MMT).

Some MMT patients have had their methadone doses taken away or reduced as punishment for disobeying instructions.... Perhaps worse, many patients have been under medicated with methadone and then personally blamed for not avoiding illicit drugs and/or remaining in treatment.

Should such practices be allowed to continue?

Basic Observations

A common theme in *Addiction Treatment Forum* is the urgent need for science to outweigh stigma, prejudice, and misunderstanding. And, the scientific advantages of MMT, discovered more than 35 years ago, are straightforward.

A large number of research studies have demonstrated that *adequate* doses of oral methadone ward off withdrawal symptoms and relieve opioid cravings for 24 hours or more, without making the person feel "high" or drugged. Unfortunately, even after all this time, what constitutes an "adequate" dose of this medication is still being debated by practitioners, patients, researchers, and regulators.

During the past several years, this topic has been discussed by a series of articles in *A.T. Forum* and other sources. Research, spanning many years, has consistently and unquestionably demonstrated the following:

- patients receiving *inadequate* methadone doses will continue to use heroin, alcohol, and other addictive substances;
- these patients will not be responsive to behavioral therapies or remain in MMT for extended lengths of time;
- conversely, when methadone doses are raised to individually-determined *adequate* levels, patients vastly improve on all measures of treatment success.

Given these basic observations, why would there be continuing debate about methadone dosing policies and practices?

(Cont. p. 3)

Dear Methadone Today,



Last week when I passed out at the drug store and was taken to the E.R., my husband and I were very happy to have my professional looking medical alert card [see p. 4 to order yours]. The first uncaring doctor saw me as a drug addict; he kept saying, "snap out of it, I know you bought more methadone off the street. . . all you addicts do--don't tell me you didn't, because you are so out of it." He had me drink charcoal, then started with, "I'm going to Narcan you."

Finally my husband arrived (he counted the doctor saying that he was going to Narcan me 11 times) and asked for my purse, which was still behind the nurses station (unsupervised, I might add) because they said I probably had drugs in it. He got my card out, showed the SOB doctor, then my labs came back. No drugs!--just like I had been saying--just a raging infection, plus a 104⁰ fever.

I was admitted to ICU because of the severity of my infection, and they needed to monitor my breathing--after spending 3 or 4 hours being threatened, I can imagine it was out of whack. I never got an

apology, but we are almost sure if we didn't have the card and if the blood tests took any longer, I would have been Narcaned. Thanks for offering such an important card for anyone on a methadone clinic.

- Kecia & Brian

Dear Kecia and Brian,

Of course, we are not M.D.'s, but a competent E.R. doctor should be able to distinguish between an opioid overdose and symptoms of a raging infection. From his attitude, it is pretty clear that his misdiagnosis was the result of personal prejudice against drug addicts and close mindedness, rather than simple incompetence.

It is bad enough that the doctor was insulting, had a condescending attitude, etc. (the term "bedside manner" is often used). Even if you WERE suffering the effects of a drug overdose, you still deserve to be treated respectfully, but he actually let his personal opinions negatively impact his ability to diagnose and properly treat you. An experienced E.R. doctor is well (Cont. p. 2)

Buprenorphine Study Demonstrates Treatment's Benefits, Reveals Harmful Swedish Policies

by Dr. Andrew Byrne, General Practitioner
(New South Wales, Australia)

**Kakko J, Svanborg KD, Kreek MJ, Heilig M. 1-year retention and social function after buprenorphine-associated relapse prevention treatment for heroin dependence in Sweden: a randomized, placebo-controlled trial. (2003) Lancet 361:662-668.*

The Swedes have produced some of the most quoted data showing the life saving properties of methadone maintenance, partly because this treatment is so severely restricted in Sweden. Thus trial candidates who are randomized NOT to receive prescription treatment, or who are discharged from treatment, rarely receive agonist maintenance therapy which might be available elsewhere in the normal course of medical practice.

From work performed in the 1980s, Grönbladh and colleagues showed a very high mortality in those rejected from methadone treatment--almost 8% per year. In an even more rigorous and controlled study using sublingual buprenorphine, Kakko et al have found what the accompanying *Lancet* editorial calls: "massive 20% mortality at one year in the placebo group versus 0% in the buprenorphine group [which] is immensely concerning". Indeed, a trial using placebo in heroin addiction treatment would likely be considered unethical in most countries.

This trial provides strong support for buprenorphine maintenance since at a fixed dose of 16mg daily, it had a 12-month retention rate of 75% and no deaths, compared with placebo: 0% retention at 2 months and four out of twenty being dead by 12 months. All 'placebo' (actually '6 day reduction') cases had access to intensive levels of psychosocial supports, some of which were reported to have induced paradoxical cravings.

The mortality rate is even more worrying considering that these candidates were chosen from over 400 applicants based on less severe dependency and less poly drug/alcohol use. Thus none of the chosen candidates was suitable for the stringent Swedish criteria for methadone prescription (4 years hospital-documented multiple daily heroin use). All but one were injectors.

All of the placebo patients showed positive urine tests for opiates before dropping out of treatment. Thus none was an early abstinence success--despite this being the consented aim of the trial. About 75% of urine tests of the buprenorphine patients were negative for illicit substances tested for. Thus despite continued, if much less frequent, drug use was still associated with good retention and reduced health problems measured in a variety of ways by these researchers.

Swedish drug policy is based on the belief that all drug addicts can and should stop using certain proscribed drugs immediately (abstinence orientated, or 'zero tolerance'). While this has been long abandoned in most other countries, Sweden continues despite their own research showing excess deaths, continued drug use and high rates of viral disease transmission when such policies are pursued. One fails to understand how in such a modern democracy such ill-founded policies are used.

Yet the world's two most persuasive studies are from their own country showing that if heroin addicts are left untreated (or "treated" in the compulsory manner used in Sweden) then the result is a high mortality of young Swedes from a totally preventable and treatable cause, drug overdose.

Editor's Note: Sweden is not the only "modern democracy" with extremely restrictive rules regarding when addicts may obtain methadone treatment. Their neighbor, Norway, actually has even

more restrictive criteria addicts must meet to be considered for methadone treatment. Despite the meager number of treatment slots available in Norway, some treatment slots remain unfilled because it is virtually impossible to meet this criteria. Paradoxically, these two countries are very socially progressive in other respects (i.e., universal health care coverage), but have a huge blind spot when it comes to drug addiction and drug addiction treatment.

Hopefully, Sweden [and even Norway] will soon accept their own studies and ease restrictions on methadone treatment or at least permit buprenorphine treatment without such excessive restrictions. It is difficult to understand why buprenorphine studies are being performed in a country that still does not permit methadone treatment for the vast majority of opiate addicts, a treatment that has been approved and accepted by most of the modern world for decades.

Dear Kecia (from p. 1). aware that severe infection coupled with high fever can exhibit various symptoms--some which at first glance may appear to be symptoms of alcohol or drug intoxication (i.e.: delirium, mental and physical impairment, fading in and out of consciousness, fainting, breathing difficulty, etc.). It is disturbing that he simply assumed that the symptoms were the result of opioid intoxication, when many medical conditions can produce such symptoms (i.e., high blood sugar in a diabetic, snake or spider bites, inner ear infections, etc.).

The decision whether to administer Narcan should be taken very seriously. We won't go into all the consequences and dangers of administering Narcan to someone dependent on opioids; suffice it to say that your Medical Alert card warns against administering Narcan or any other opiate antagonist for very good reasons. Even if your symptoms were the result of an opioid overdose, Narcan would still be contraindicated in your case judging from what you stated above--if you are able to drink charcoal, you are obviously not in a coma, in cardiac arrest, etc.*

Does this hospital have a survey you can fill out, in which you rate the treatment you received? Some hospital even mail a survey to recent patients, asking for your comments--negative or positive--about various aspects of your treatment. If so, we would suggest you fill out the survey--usually, there is a space to write in additional comments, where you could describe the specifics you mentioned above and complain about the atrocious treatment you received.

Patients may obtain a personalized, laminated **Medical Alert** card from *Methadone Today* by filling out the order form on p. 4.

**Narcan should only be used on a methadone maintained patient in a life threatening emergency (i.e., coma), where Narcan is absolutely necessary to save the patient's life, prevent brain damage, etc. The situation you describe does not fit this--Narcan is contraindicated in such cases, since administration of Narcan could actually throw you into a life-threatening emergency.*

Buprenorphine (from p. 4).

Unless the issue of health insurance coverage of substance abuse treatment is addressed by government regulations, it seems that the full potential of buprenorphine treatment will not be realized. Without insurance coverage of buprenorphine treatment, buprenorphine will only be available to a handful of affluent opiate addicts. The issue of medication patents and excessive prescription drug costs has been spotlighted by certain politicians and the media, but this is a larger problem that is not likely to be remedied anytime soon.

Methadone Dose Debate (from p. 1).

Individual Differences

Methadone prescribing practices have followed philosophical, moral, or psychological rationales, rather than available scientific evidence. The stigma, prejudices, and controversies surrounding MMT seem to have diverted attention from the fact that it is nothing more than a medicine, following well-established principles of pharmacology such as noted in *Goodman & Gilman's; The Pharmacological Basis of Therapeutics*, a classic text on the subject:

"Optimal treatment will result only when the physician is aware of the sources of variation in response to drugs and when the dosage regimen is designed on the basis of the best available data about the diagnosis, severity and stage of the disease, presence of concurrent disease or drug treatment, and predefined goals of acceptable efficacy and limits of acceptable toxicity. If objectively assessable expectations of drug therapy are not set before therapy is initiated, therapy is likely to be ineffective...."

Individuals differ in how any drug affects them. Absorption, digestion, and excretion of a drug may account for half or more of the differences in how people eventually respond to the therapy. There are many factors that can influence the potency and effect of oral methadone, as with any drug.

Given the many factors potentially affecting individual response to methadone, research suggests that there can be a 17-fold difference between individual patients. That is, whereas 60 mg/d may be adequate for one patient, another individual might require more than 1000 mg/d for optimum effect. The notion of a particular dose range, or upward limit on dose, being suitable for *all* patients is scientifically implausible.

Arbitrary Limitations

The first patients treated during the early 1960s required 150 to 180 mg of daily oral methadone to avert abstinence syndrome and achieve normal functionality. By 1968, more than 1000 patients had been treated, and daily methadone doses averaging between 80 mg and 120 mg appeared to be optimum for most patients, although some required more or less than that amount. It should be noted, however, that heroin was less potent and more costly in those days than it is today; consequently, opioid dependence was likely less severe in those early patients.*

During the 1970s, regulatory constraints and stigmatization of MMT led to dosing practices that had no basis in science. A methadone dose ceiling of 100 mg/d was imposed, without any justification from research data, and exceptions to that required special permission from regulatory agencies. In an apparent overreaction to regulations, by the early 1980s, more than 40% of MMT patients were administered maintenance doses less than 40 mg/d. Even the most recent survey in year 2000 showed that 13% were still receiving less than 40 mg/d and more than a third of patients were receiving less than 60 mg/d.

Although average methadone dose levels slowly moved upward during the 1990s, the latest data from 2000 indicate that only about a third of MMT patients receive doses at or above the 80 mg/d lower threshold established by Dole and his colleagues in the 1960s. However, it is unknown how many receive greater than 100 mg/d, and the upcoming A.T. Forum dosing survey results may shed light on this.



New Research Directions

Clinical trials over the years have compared and contrasted differing methadone doses. Earlier trials had serious limitations in their methods and the range of doses examined.

Newer research has examined the potential benefits and dimensions of higher, adequate methadone doses. In the largest, long-term study, researchers identified 164 patients with excessive rates of continued opioid dependence, despite methadone doses of up to 100 mg/d. Using clinically-guided criteria, methadone doses were increased to an average of 211 mg/d (range 120-780 mg/d).

Quite dramatically, illicit-opioid-positive urinalysis rates in this "high dose" group decreased by 84% (from 87% to 3%). Moreover, the one-year retention-in-treatment was 86%. This compared with only 35% retention and 19% reduction in illicit-opioid use in a control group of patients randomly drawn from the clinic population (mean dose in this group was 69 mg/d; range 10-100 mg/d).

A recently reported 152-week follow-up of the "high dose" patients found that average doses had been increased to 285 mg/d (ranging up to 1100 mg/d). Retention in treatment was 61% and only 16% exhibited opioid-positive urinalyses, which are exceptionally favorable long-term outcomes.

To date, only a handful of limited-scope studies have examined higher dosing levels--all producing very positive results. Hopefully, this line of clinical research will continue, with sufficient funding and on a larger scale.

How Much Methadone is "Adequate"?

In sum, thinking of "high dose" as being above a certain threshold is misleading. Patients differ widely when considering "adequate" dose ranges, and enlightened outlooks avoid value judgments of what is too high.

Methadone dosing practices may be changing. The most recent survey data indicates that *accredited* MMT clinics are less likely to provide low doses to their patients. Although accreditation agencies do not dictate dosing practices, this suggests that "best practices" are closely associated with outcomes achievable with more adequate methadone dosing. It is something to consider.

***Editor's Note:** The theory that the higher purity of today's heroin relative to the 1960s is the major reason why the "optimum" dose for most patients appeared to be 80-120 mg/d, as opposed to today where a significant number of patients require a dose above 120 mg/d, may be overstated. At that time, the notion of an optimum dose was different (e.g., if the dose prevented the onset of withdrawal, the dose was generally considered adequate, even if the patient continues to experience opiate cravings), so some of the patients determined to be at an "optimum" dose, may have actually been under dosed. Also, hepatitis C, now epidemic among MMT patients did not exist back then. In some stages, hepatitis C causes methadone to be metabolized faster, necessitating a higher dose.

Buprenorphine--Cost Among Other Problems

The federal government has permitted buprenorphine to be prescribed by private doctors without the often excessive rules and regulations attached to methadone and LAAM treatment. At first glance, buprenorphine should be accessible and affordable

--perhaps not to all who need it--but to a large percentage of opiate addicts. To be fair, it has been generally acknowledged that buprenorphine treatment would be targeted toward affluent middle class or at least working class addicts--many of whom are unable or unwilling to obtain treatment from a methadone clinic. Not surprisingly, given the stigma attached to such clinics, these individuals--especially those addicted to prescription opiates--believe that methadone clinics are only for poor, homeless, and/or i.v. heroin addicts).

On the surface, the relatively lenient regulation of buprenorphine treatment would address the problems leading to excessive treatment cost that often exists with methadone treatment. Allowing private physicians to prescribe buprenorphine without having to obtain accreditation would avoid the problem of treatment provider monopolies that exist with methadone treatment, as well as high treatment costs passed down to patients as a consequence of excessive regulations. Methadone treatment providers often must spend large amounts simply to comply with federal accreditation and paperwork requirements. In many areas, methadone clinics can charge whatever they wish without having to worry that the patients will go to a doctor who will charge less. There are other reasons for excessive treatment costs, but a thorough discussion is beyond the realm of this article.

But in fact, buprenorphine treatment has turned out to be even more costly and therefore, often even less accessible than methadone treatment. The problem, in a nutshell, is a medication patent. The monopoly problem again rears its ugly head--but this time, the pharmaceutical company that markets and distributes the medication is the one with the monopoly, not the treatment provider. Of course, this is not an issue unique to buprenorphine or medications used to treat drug addiction: if you are lucky, a similar medication already exists, in which the patent has already run out. Thus, there is competition in the form of generic equivalents of the same medication. This problem does not exist with methadone, as the patent on methadone ran out decades ago.

Hopefully, many health insurance companies will elect to cover buprenorphine. Most health insurance policies with prescription drug benefits cover the entire cost of medications, less

a fixed dollar co-pay, for which the policyholder is responsible. Increasingly, however, insurance policies distinguish between brand name and generic medications--requiring the policyholder to pay a higher co-pay for brand name medications. Still in most cases, such prescription drug coverage will save buprenorphine patients a great deal of money.

It is questionable whether many health insurance policies will cover buprenorphine treatment. Some health insurance companies do not cover substance abuse treatment at all or will only cover a few specifically approved treatment modalities. It is possible that some insurance companies will elect to cover short term buprenorphine treatment when utilized for "detox" purposes, where the patient is tapered off buprenorphine over a short period of time. The prospect of insurance policies covering buprenorphine maintenance appears grim when many insurance companies will not cover methadone treatment, given that the monthly cost of buprenorphine treatment including the medication is significantly higher than the monthly cost of methadone treatment. **(Cont. p. 2)**

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