**Akzeptanzorientierte Drogenarbeit/ Acceptance-Oriented Drug Work**

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Kommentar / Commentary

# Opioid maintenance treatment: a glass half full *but also half empty!*

# [Opioid-Erhaltungs-Behandlung: ein halbvolles, *aber auch halbleeres Glas!*]

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## Introduction

Since the mid-1960s maintenance treatment of opioid dependence – primarily with methadone but also with buprenorphine, slow-release morphine and other agonist medications - has become ever more widely utilized, and is provided today to over 1 million people in a total of 70 countries.(1) In the European Union alone an estimated 680,000 patients received treatment in 2008.(2) And yet, misunderstanding, counter-therapeutic and counter-intuitive policies and practices, and overt hostility towards the illness of addiction, the patients and the providers remain as great as ever. The dichotomy is well illustrated by Germany.

Today Germany, with 72,200 patients (3), has the highest proportion of problem opioid users in the European Union receiving maintenance treatment. And yet, it was not so terribly long ago - November 1986 - that the Minister for Labor, Health and Social Services of North Rhine-Westphalia, Hermann Heinemann, opened a major conference in Düsseldorf by noting, "In Germany the *mere discussion* of providing medication to some heroin-dependent individuals is taboo" (emphases added).(4) That same year the former drug czar of Berlin published a paper with the title, "Abstinence or Maintenance? Why there will never be a methadone program in Germany."(5) In addition to the dramatic growth in number of patients I would point to two specific events that illustrate how swift the change has been in the intervening years:

- Less than ten years after it was prophesized that there would never be methadone maintenance in Germany there was a ceremony in Hamburg to dedicate the naming of the Marie-Nyswander-Weg in honor of the co-discoverer of methadone maintenance treatment! (6) The street can be located easily on any city map; there is none other anywhere in the world that pays tribute to this dedicated, brilliant and courageous physician. It should be noted that the credit for gaining authorization for the street-naming belongs entirely to one man, Josh von Soer Clemm von Hohenberg (1941-2000). Josh, a native Dutchman and a close friend and greatly admired colleague, was loved and respected by those to whom he provided devoted service over the course of some two decades in Hamburg.

- In 1988 Max Klieber, the only child of widowed Dorothea Klieber of Markt Schwaben and for 14 years a heroin addict, committed suicide when his (highly successful!) methadone treatment ended

> abruptly with the arrest of his physician. Years later it was observed, "What would have caused others to plunge into a void of despair was for Dorothea Klieber the impetus to do battle."(7) She established and led parents' groups to lobby vigorously for a change in drug policies, and bombarded parliamentarians and the media with information concerning addiction treatment with methadone. In 2002 Dorothea Klieber received the nation's Presidential Medal of Honor in recognition of her tireless and ultimately successful advocacy of methadone maintenance treatment.(8) (On December 5, 2010, Mrs. Klieber celebrated her 90th birthday!)

I have experienced the very dramatic change in German drug policies personally. In 1989 I was invited to speak in Munich at a drug conference of the 300,000-member national policemen's union. I acknowledged that, "In Germany, and most particularly in Munich, the heartland of the most vehement anti-methadone sentiments, to speak about – and more specifically, to speak in favor of – methadone makes me feel like David in the lions' den (a feeling heightened by the lion in the ubiquitous Bavarian coat of arms that greets passengers arriving at Munich airport!)."(9) Times indeed have changed, I am happy to say, and for years now I have referred to Germany as one of the countries that should serve as an example of how, almost overnight, substitution can be introduced and offered to all who need it - if only there is a will to do so!

And yet, the glass that is half full is also half empty. This was made painfully clear by a 2009 article by Rainer Ullmann of Hamburg which bore the alarming headline: "Treatment [of addiction] once again becomes criminalized".(10) In it he refers to the fact that "… according to the narcotic prescribing regulations the treatment of opiate dependence is permitted only if the goal is a step-wise achievement of abstinence. If abstinence is not pursued, the treatment becomes a *criminal act*" (emphasis added). It seems nothing has changed since the early 1990s when in an article in the Frankfurter Allgemeine I urged (with embarrassingly little impact!), "… we must vigorously refute the notion that abstinence is the only appropriate therapeutic goal." (11)

Dr. Ullmann also referred to a 2007 decision of the State Court of Bayreuth: "The accused [physician] failed to terminate treatment in the face of continued drug use." Imagine the thinking that underlies this decision: it is demanded of the treating physician that s/he respond to a patient's continued misuse of drugs by terminating treatment of drug misuse! It is as if judges were to demand that diabetics have their insulin treatment terminated if their blood sugar exceeds a certain level - especially if there is reason to believe the patient is non-compliant with a prescribed diet!

The Court decision cited by Dr. Ullmann went on to make it clear that the physician's clinical judgment in individual cases is irrelevant: "The mere fact that extensive travel is required to access care, or that the patient's determination to maintain a job may be thwarted, or the danger of slipping back into the drug milieu, do not justify deviation from the regulations." It does not seem an exaggeration to say the German judicial system demands of physicians that they violate the Hippocratic oath by following the dictates of the State, even when they are convinced this will be counter to the interests of their patients and have potentially fatal consequences.

**The Opposition: Intense, Universal and Timeless**

Without detracting from the amazing accomplishments in Germany of the past two decades, it is obvious that the work of maintenance treatment advocates and providers is far from done! The general situation described above is the rule rather than the exception in countries around the world, and if one is to understand and overcome the opposition to maintenance treatment in any particular nation one must recognize its universality and its timelessness. To illustrate, let me begin with some examples of the preoccupation with achieving abstinence.

**The Persistent Abstinence Paradigm**

- 1974: The focus on detoxification in the mid-1970s is epitomized by the statement of a former head of the highest US federal office on drugs, "It is most important to recognize methadone maintenance for the crutch that it is, a *temporary* support which is to be discarded as soon as the client has changed his sick attitudes, values and rationalizations" (emphasis in original).(12)

- 1987: In a lecture to the Psychiatric Clinic of the University of Zurich I noted, "It is the general and almost universal view among professionals and the lay public that abstinence is the only worthy therapeutic goal of any treatment of addiction, and the only criterion for measuring its 'success.'"(13)

- 2006: A UK news article reported, "The methadone lobby has built a pharmacological holding pen that keeps addicts addicted … and only 3% are cured each year."(14)

- 2007: An article in the Lancet observed, "…politically the popular treatments are those that aim to achieve abstinence within weeks or months." (15)

- 2010: A report of the National Treatment Agency of the United Kingdom declared: "No one should be 'parked' indefinitely on methadone or similar opiate substitutes … New clinical protocols will focus practitioners and clients on abstinence as the desired outcome of treatment, and time limits in prescribing will prevent unplanned drift into long-term maintenance."(16)

**Maintenance Treatment: Rejection and Restriction**

While some critics focus their condemnation on the failure to embrace and demand a universal goal of abstinence, others reject the very concept of "maintenance" – regardless of duration of treatment or ultimate therapeutic objectives. Thus,

- 1921: the American Medical Association stated, "The profession condemns the prescribing of narcotics for drug addicts."(17)

- 1974: more than a half-century later, and following the publication of many dozens of favorable reports from around the world of treatment efficacy, there appeared what must still hold the record as the most contemptible criticism of all time. It came from Thomas Szasz, an American professor of psychiatry and respected (though controversial) author and recipient of a special award for excellence from the leading drug policy reform organization in America: "Methadone maintenance is the gas chamber to which the blacks go as willingly as the Jews went in Germany."(18)

To lessen tedious redundancy I shall skip a quarter-century of hostility and go to 1999.

- 1999: In a speech before the US Congress Senator John McCain stated, "Methadone maintenance …feeds the addiction with taxpayer dollars. This is disgusting and it is immoral."(19)

- 2007: An Alabama (USA) newspaper quoted a state senator as saying methadone "should be outlawed," and attributed to an associate commissioner for substance abuse services the statement that methadone "is probably the most hated" medication in the state.(20)

- 2008: A senior politician in Scotland stated: "We have a very high proportion of the drug-abusing population sitting fat, dumb and happy on methadone."(21)

- 2010: A headline in the United Kingdom read: "Prime Minister Cameron to push ahead with 'cold turkey' drug policy."(22)

Furthermore, in those countries where methadone has been accepted it is almost always constrained by a host of rules and regulations that would be unimaginable in other medical fields. Thus:

- There are governmentally-imposed criteria for "eligibility" (e.g., age, years of drug use, specified number of prior "failures" in drug-free treatment, etc.) Consider, for a moment, the State prohibiting by law the prescribing of anti-depressants to suicidal patients who are "too young," have been severely depressed for too short a period of time, or who have not yet "failed" at two or more suicide attempts!

- Physicians are denied the authority to determine and initiate the clinical care they believe is indicated. In Norway, for example, a physician can only "recommend" that substitution be provided; this recommendation is then passed on to a commission of social workers that decides whether or not it is to be accepted.

- In many countries physicians are forbidden to prescribe methadone unless it is in association with extensive ancillary services - services that must be offered to and accepted by all patients, regardless whether the doctor or patient deems them necessary or desirable. Note the inevitable corollary: lack of adequate financial or personnel resources to offer the full "comprehensive" package that is deemed by the regulatory authorities to be optimal causes addicts to be placed on "waiting lists" that can extend for years! The waiting time recently in Seattle, USA (23), and in Israel (24) was 18 months, and in Ireland it is generally two years or more.(25) Would anyone contend that a "waiting list" is better for the addict or the community than providing methadone even in the absence of a full array of comprehensive ancillary services defined by experts as "optimal"? Surely this is the ultimate example of "the best" being made the enemy of "the good."

- The number and frequency of laboratory tests that must be performed are determined by bureaucrats and imposed by *fiat*, as are the steps (including termination of treatment) that are mandated if those tests confirm the diagnosis for which the patient is being treated.

- As already discussed, specific therapeutic goals that must be pursued – and achieved – are imposed on treatment providers and patients alike.

These and many more unique demands and restrictions govern substitution treatment in most countries of the world, and they generally are imposed by individuals who have never seen – let alone treated – a patient. There are other countries that refuse to accept substitution treatment altogether (for example, Russia – which has an estimated 2-3 million opiate dependent citizens). And what is the explanation? Simply, "We do not believe in substitution" – the way some children do not believe in Santa Claus. Furthermore, in recent years even where progress has been made and a country agrees to initiate substitution treatment it is usually on a "pilot" basis, under conditions that regardless of outcome could never be applied on a meaningful scale. A case in point is Cambodia, where in 2010 the visit of UN Secretary General Ban Ki-moon helped celebrate the opening of that country's first "pilot" methadone center. The cost for one year: $US 350,000; professional staff: more than 20; *maximum capacity: 100 patients.*(26)

**The Most Harmful Rejection of All: that of Methadone Providers**

Sadly, the greatest obstacles to gaining acceptance of methadone treatment in many countries of the world are the providers themselves, many of whom refuse (without explanation or apology) to accept and practice evidence-based medicine. A few illustrations will suffice:

- In 1989 the official newsletter of the US National Institute on Drug Abuse (NIDA) stated that an adequate dose of methadone – generally above 60 mg – is "vital" in checking the spread of AIDS.(27) Six years later a survey found over half of all US patients received less than 60 mg/day.(28) Although by 2000 the proportion maintained at below 60 mg was down to 36%, one patient in six was still being maintained at *less than 40 mg/day*! (29)

- A decade after the NIDA dosage recommendation, in 1999, National Treatment Guidelines were issued in UK stating that maintenance for most patients should be 60-120 mg of methadone per day(30); six years later the average daily dose of methadone in UK had *dropped* from 59 mg to 45 mg.(31)

- In a 2007 survey of UK methadone providers it was found that one-third offered methadone dosage *increases* as a "*reward for clean urines*" (emphasis added).(32)

- Many methadone programs (in the US, but also in Spain and Canada and surely many other countries) insist urine collection be *under direct observation* for all patients, regardless how long they have been in treatment and how well they have responded. The unmistakable premise: methadone maintenance patients may never, under any circumstances, be trusted – not even to pee in a bottle!

- Methadone doses commonly are reduced if patients fail to attend scheduled "counseling" sessions or – heaven forbid – are believed to have taken unauthorized drugs; when non-compliance persists patients are simply thrown out of treatment and abandoned.

- And one methadone program – associated with the prestigious Johns Hopkins Medical Center - published the results of a policy of terminating patients who failed to obtain employment in a specified time period. (33)

When those who provide methadone treatment adopt practices such as these it is not surprising that medical colleagues in other disciplines as well as the public at large have a pejorative view towards the treatment and those who prescribe and receive it.

**A Word About Heroin-Assisted Treatment**

My very obvious enthusiasm for methadone reflects the fact that this is the treatment with which I have been deeply involved for more than four decades. It most definitely should *not* be construed as suggesting negativism towards any other form of treatment that offers help and hope and that addicts voluntarily seek. Accordingly, I strongly support the availability of heroin-assisted treatment. I confess, however, that I have problems with the "pilot" studies that have been carried out in Germany, the UK and Canada, which all used a control group of individuals who had failed to respond well to methadone – usually repeatedly. In other words, results of treatment with heroin were compared to those of a treatment which had proven unsuccessful. Furthermore, the motive to volunteer for the trial clearly was the desire to receive heroin – not to receive yet again the treatment that elicited a poor response in the past (and that was readily available

in a non-research setting). One would expect those who got what they wanted to do very much better than those who were disappointed by randomization to the methadone arm. In fact, the most striking outcome of the trials is not that those receiving heroin did better than those who (again!) were given methadone, but rather that so many methadone recipients also responded well!

The selective nature of the subjects was not evident in most of the publicity the trial results received. For example, a Wall Street Journal article describing the Canadian experience headlined, "New study suggests alternative to methadone is more effective," and the story itself leads off with the statement, "The study … found that injections of prescription heroin were more effective in treating longtime addicts than methadone …"(34) Several years earlier the German trial was summarized similarly: "…heroin administration leads to significantly better medical and social outcomes than maintenance with methadone" – without mention of the severe limitations the trial protocol imposed on ability to extrapolate results.(35)

Also, there has been little if any attention given in either professional or lay reporting to the difficulty experienced in recruiting individuals for the trials. While favorable outcomes and consequent adoption of heroin maintenance as an approved treatment option are to be applauded, the difficulty in recruitment suggests it will have an impact on a very small proportion of heroin addicts. It must also be noted that the cost – at least the cost that was associated with the heroin trials that became the basis for approval - might well preclude significant application regardless how impressive the study findings or the potential demand. This, too, has been largely ignored.

The "take-away" message for most readers, I fear – professionals, the lay public and politicians - has been that methadone is *so* ineffective in treating addiction that even providing heroin leads to better results. If my interpretation is correct, the unintended effect of the heroin trials has been to put methadone in even greater disrepute, while having minimal impact on the overwhelming majority of opiate dependent individuals.

**The Bottom Line**

Addiction is a chronic medical condition, which by definition means it can not (yet) be cured. There is nothing new about this concept: in 1920 a New York physician wrote, "There exists at present no 'cure' for the great number of narcotic addicts. … We have prayed over our addicts, cajoled them, exhorted them, imprisoned them, treated them as insane and made them social outcasts – and we've consistently failed!"(36) It is fortunate that while not curable, addiction to opiates is a condition for which treatment exists – treatment we know can be made available rapidly, at relatively low cost, and on a massive scale; treatment that has proven capable of attracting on a voluntary basis a large proportion of the addict population in the most diverse geographical, political and socio-economic settings; a treatment that has a high degree of therapeutic success. And no treatment has the potential to reach and help more opiate dependent people than methadone maintenance.

The primary challenge facing all who are concerned about opioid dependency and its enormous costs to individuals, families and the community as a whole is to maximize the potential impact of this treatment. Regarding this challenge the recently retired Executive Director of the UN Office of Drug Control, Antonio Maria Costa, summed up the key to a successful strategy: "If we see addicts as people affected by illness, the way we do with cancer or diabetes or tuberculosis, if we bring drug addiction into the mainstream of health care in major countries, then we would make real progress in curbing consumption."(37)

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