

Strategies to Improve Methadone OUD Treatment Systems: Take Home Dosing, Office-Based Methadone, and Beyond

“The Mount Sinai Beth Israel MMM Program”

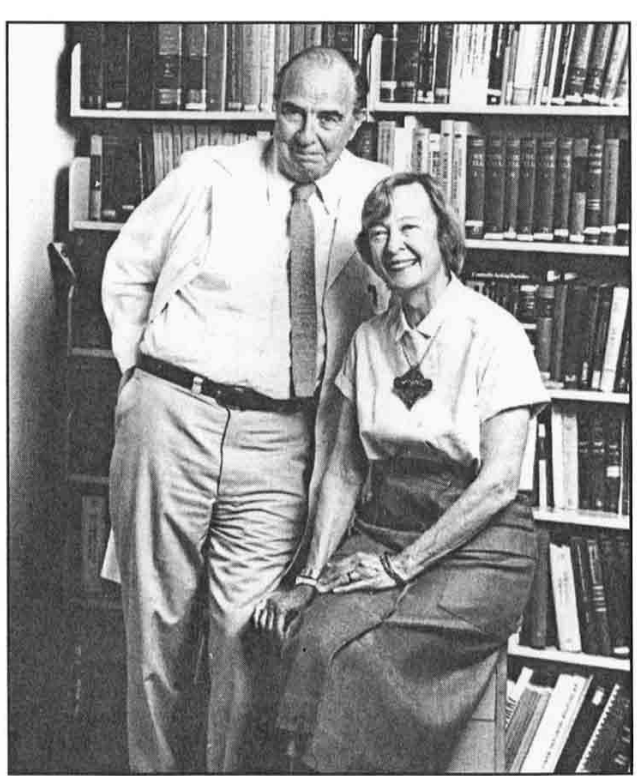
Edwin A. Salsitz, M.D., DFASAM

Associate Clinical Professor

Mount Sinai Beth Israel, NYC

No Disclosures

Drs. Dole, Nyswander, and Kreek



Courtesy Dr. Vincent Dole

**Dr. Vincent Dole and Dr. Marie Nyswander
Methadone Pioneers**



Dr. Mary Jeanne Kreek,
Addiction Laboratory
Rockefeller University



Robert G. Newman, M.D.

President Emeritus Beth Israel Medical Center and Continuum Health Partners

National and International Advocate for Methadone Maintenance Treatment

Medical Maintenance



Herman Joseph, PhD

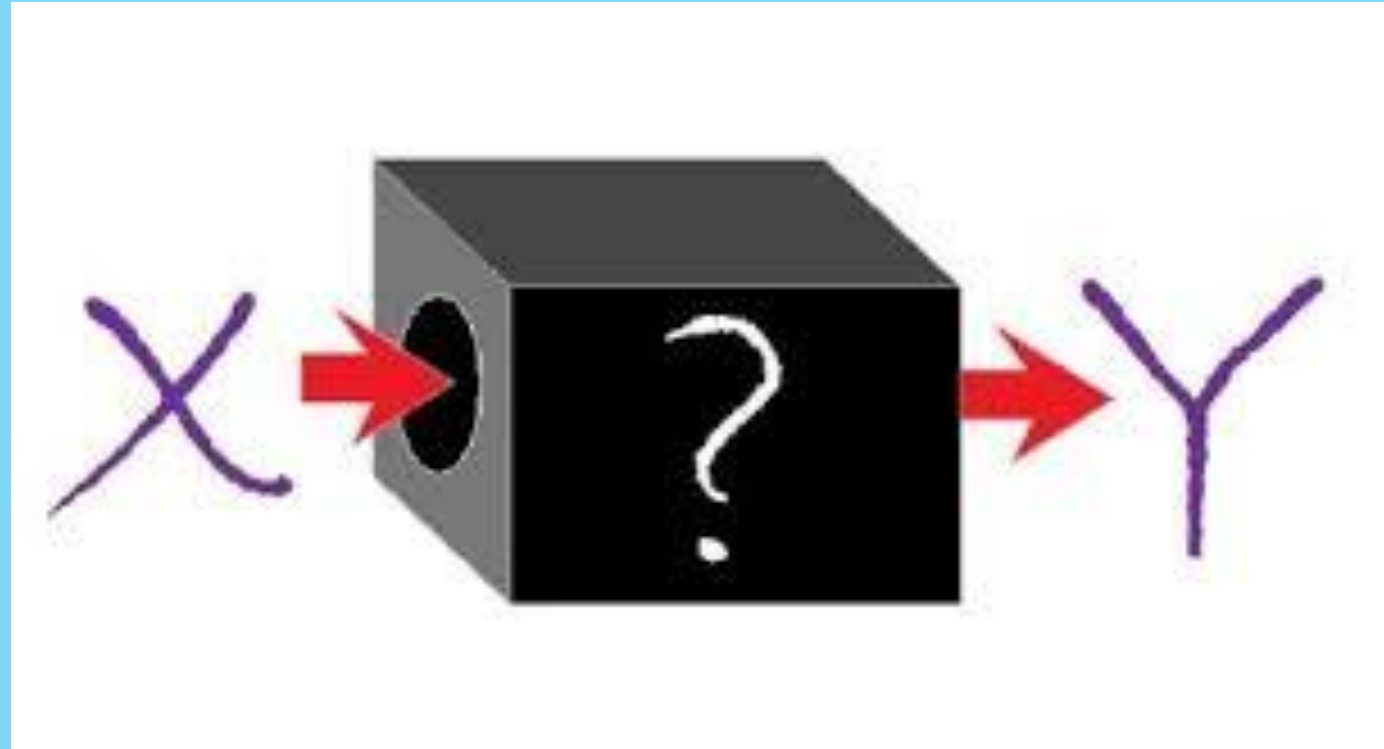


David Novick, M.D.

Methadone Medical Maintenance

- 1983: Dr. Dole acquired an IND from the FDA to provide office based Methadone to a group of stable patients under Dr. Nyswander's care at Rockefeller University
- 1985: The IND and protocol was transferred to Beth Israel and under the leadership of Dr. Novick we started with ~ 20 patients
- 1985: Recruitment of additional patients from the MMTPs
- Regular IRB approvals, and FDA reports
- In the 2000's new patient recruitment was closed by FDA
- 2020: Program closed 35 years

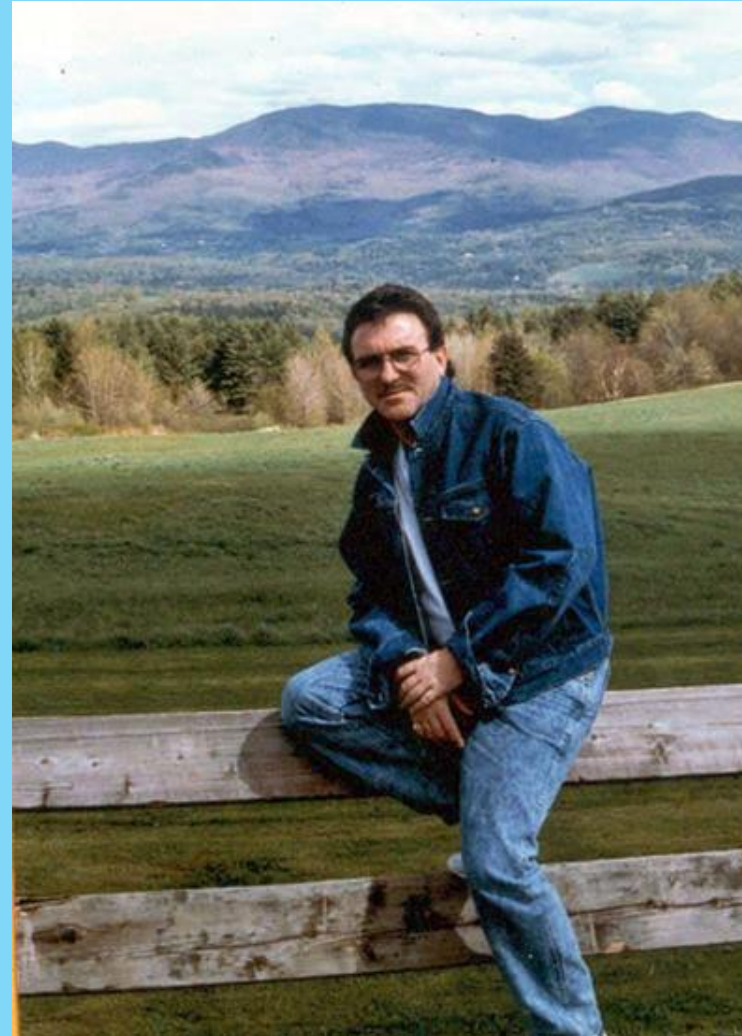
MMTPs/OTPs: The Black Box



My Aha Moment!

Medical Methadone Maintenance

No Prior Lectures, Discussions, Publications, Evidence



Methadone Medical Maintenance

What Exactly Is It?

- 27 day take home from an OTP? Liquid vs Tabs
- 27 day take home from adjoining OTP office?
- Pharmacy Pick Up: Canadian Model
- Satellite of OTP in Primary Care Office
- **OBOT: Not Connected to an OTP(almost Bupe)**
- Flexibility, Come in Before Run Out(Weather), Emphasis On Work Schedule, Stigma↓, Significant Others, Appropriate Bupe transfers, etc.

Medical Maintenance Admission Criteria

- At least 5/4 years in traditional MMTP (OTP)
- Negative urines for the last 3 years
- Working/School etc.
- Adequate income for fees
- Recommendation from clinic
- Not in military reserves
- Stable and safe storage environment

Medical Maintenance Procedures

- Patient given 28 day supply of methadone, by MD, in diskette/tablet form, every 4 weeks.
- Medication prepared by hospital pharmacy in usual Rx type bottle and label
- Routine urine toxicology
- Patient returns before “run out” date
- Primary care provided

Methadone Medical Maintenance



**Imagine Going Through
TSA Inspection at the
Airport with Your Boss**

Medical Maintenance





Medical Maintenance 1988

Methadone Maintenance Patients in General Medical Practice

A Preliminary Report

David M. Novick, MD; Emil F. Pascarelli, MD; Herman Joseph; Edwin A. Salsitz, MD; Beverly L. Richman, MD;
Don C. Des Jarlais, PhD; Mary Anderson, MS; Vincent P. Dole, MD; Marie E. Nyswander, MD†

Medical maintenance is the treatment by primary care physicians of rehabilitated methadone maintenance patients who are stable, employed, not abusing drugs, and not in need of supportive services. In this research project, physicians with experience in drug abuse treatment provided both the pharmacologic treatment of addiction as well as therapy for other medical problems, as needed. Decisions regarding treatment were based on the individual needs of the patient and on currently accepted medical practice rather than on explicit regulations.

We studied the first 40 former heroin addicts who were transferred to this program from more conventional methadone clinics. At a follow-up visit at 12 to 55 months, 33 (82.5%) of 40 patients had remained in treatment; five (12.5%) had been discharged because of cocaine abuse and two (5%) had been voluntarily discharged. Personal benefits of medical maintenance include the dignity of a standard professional atmosphere and a more flexible reporting schedule. This program has the potential for improving treatment of selected methadone maintenance patients.

(JAMA 1988;259:3299-3302)

The purpose of medical maintenance is to provide pharmacologic treatment of heroin addiction in a manner similar to that used for other chronic diseases. The medical problems are treated by the same physician. In this study, decisions regarding treatment were based on the individual needs of the patient and on currently accepted medical practice rather than on explicit regulations. We describe herein the medical maintenance program and the first 40 heroin addicts who entered the program between January 1987 and January 1988.

Patients and Methods

Table 2.—Demographic Features of Medical Maintenance Patients

| Demographic Features | No. (%) of Patients | |
|--|---------------------------------|---------------------|
| | Currently in Treatment (n = 33) | Discharged* (n = 7) |
| Sex | | |
| Male | 27 (82) | 6 (86) |
| Female | 6 (18) | 1 (14) |
| Ethnicity | | |
| Black | 2 (6) | 1 (14) |
| Hispanic | 5 (15) | 0 (0) |
| White | 26 (79) | 6 (86) |
| Married | 25 (76) | 6 (86) |
| Employed† | 31 (94) | 7 (100) |
| Type of job | | |
| Professional | 4 (12) | 1 (14) |
| Business/sales | 4 (12) | 2 (29) |
| Computers | 2 (6) | 1 (14) |
| Crafts | 2 (6) | 0 (0) |
| Service industries | 7 (21) | 2 (29) |
| Other methadone program | 12 (36) | 1 (14) |
| Annual income, \$ | 29 700 ± 13 001 | 36 300 ± 27 600 |
| No. of years of education | 13.5 ± 2.6 | 13.0 ± 3.3 |
| Age at first arrest, y‡ | 20.0 ± 4.2 | 16.3 ± 2.8 |
| No. of arrests | 6.7 ± 5.4 | 9.3 ± 7.1 |
| Age when first used heroin, y | 18.6 ± 5.6 | 17.1 ± 2.0 |
| No. of years of heroin addiction | 9.5 ± 4.9 | 9.4 ± 3.2 |
| Age at entry into methadone maintenance program, y | 30.1 ± 7.3 | 29.7 ± 1.0 |
| No. of years in a methadone maintenance program | 16.5 ± 3.0 | 16.3 ± 3.0 |
| Methadone dose, mg | | |
| 5-30 | 9 (27) | 0 (0) |
| 40-60 | 14 (42) | 5 (71) |
| 70-100 | 10 (30) | 2 (29) |

*Five discharged patients had abused cocaine and two were discharged voluntarily. Six of the seven discharged patients returned to a conventional methadone maintenance clinic.

†One patient is a homemaker and one is semiretired.

‡Differences are significant ($P < .05$). Arrests were mostly for property crimes and/or possession of narcotics.

“Methadone Saved My Life”

“I Never Thought I’d Get To Be __ Yrs Old”

Medical Maintenance HIV 1990

Absence of Antibody to Human Immunodeficiency Virus in Long-term, Socially Rehabilitated Methadone Maintenance Patients

David M. Novick, MD; Herman Joseph; T. Scott Croxson, MD; Edwin A. Salsitz, MD; Grace Wang, MD; Beverly L. Richman, MD; Leonid Poretsky, MD; Janet B. Keefe, MD, PhD; Estella Whimbey, MD

• Human immunodeficiency virus (HIV) infection has become widespread among parenteral drug abusers. We measured antibody to HIV and hepatitis B virus markers in 58 long-term, socially rehabilitated methadone-maintained former heroin addicts. None of the 58 had antibody to HIV, but one or more markers of hepatitis B virus infection were seen in 53 (91%). The duration of methadone maintenance was 16.9 ± 0.5 years, and the median dose of methadone was 60 mg (range, 5 to 100 mg). Before methadone treatment, the patients had abused heroin parenterally for 10.3 ± 1.7 years, and they had engaged in additional high-risk practices for HIV infection. We conclude that successful outcomes during methadone maintenance treatment are associated with sparing of parenteral drug abusers from HIV infection. (*Arch Intern Med.* 1990;150:97-99)

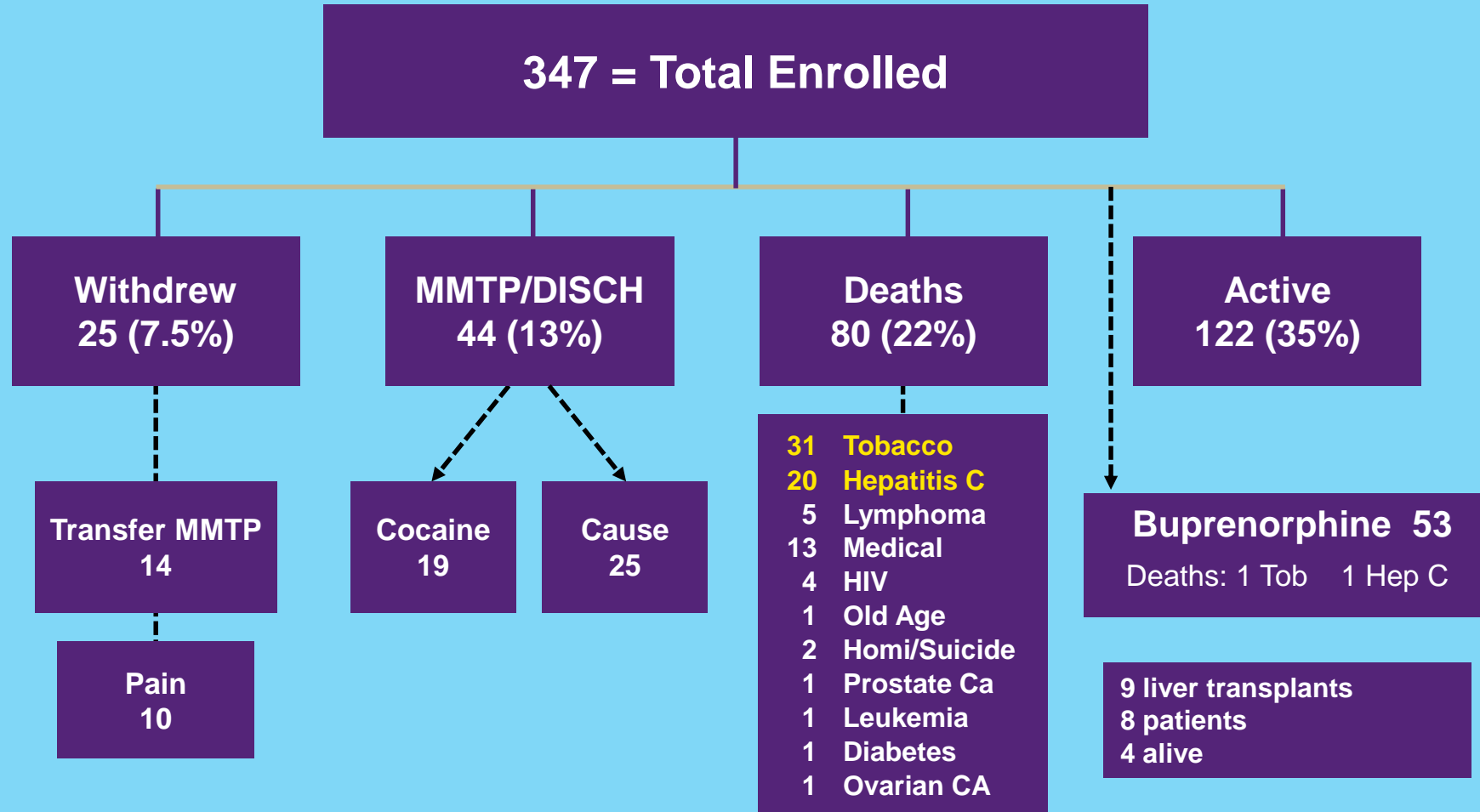
and affords the opportunity for social rehabilitation. Thus, successful methadone maintenance treatment of HIV-seronegative parenteral drug abusers should effect a major risk reduction for HIV infection, but few data¹⁰⁻¹⁴ are available.

We are currently treating long-term, socially rehabilitated methadone maintenance patients.¹⁵ These former heroin addicts are employed, have long records of excellent compliance with methadone treatment, and are no longer abusing drugs or alcohol. In this study we measured antibody to HIV and hepatitis B virus markers in these patients.

PATIENTS AND METHODS

Of the 68 former parenteral heroin addicts in "medical maintenance"¹⁵ as of June 1, 1988, 58 (85%) agreed to participate in this study. In medical maintenance, socially rehabilitated methadone

Medical Maintenance 1983 - 2020



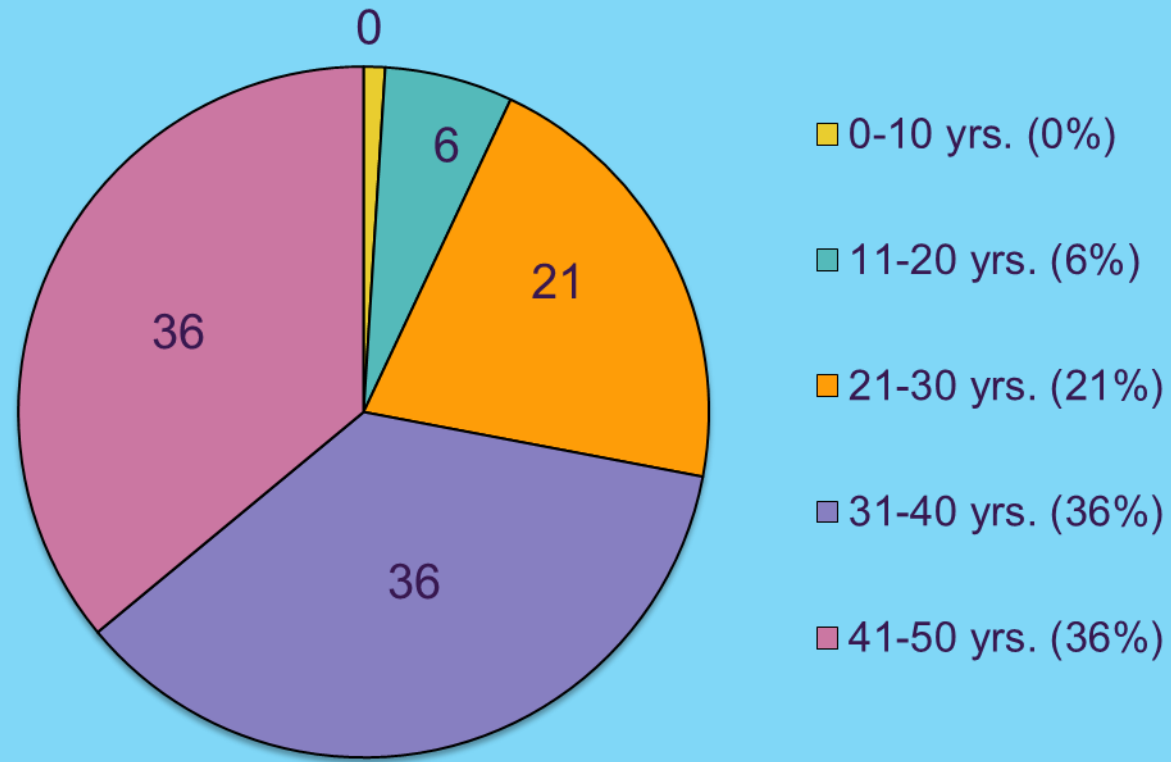
Revised - 2/1/15

Deaths

82 (22%)

| # of Patients | Cause |
|---------------|------------------|
| 31 | Tobacco |
| 19 | Hepatitis C |
| 5 | Lymphoma |
| 13 | Medical |
| 4 | HIV |
| 1 | Old Age |
| 2 | Homicide/Suicide |
| 1 | Prostate Cancer |
| 1 | Leukemia |
| 1 | Diabetes |
| 1 | Ovarian Cancer |

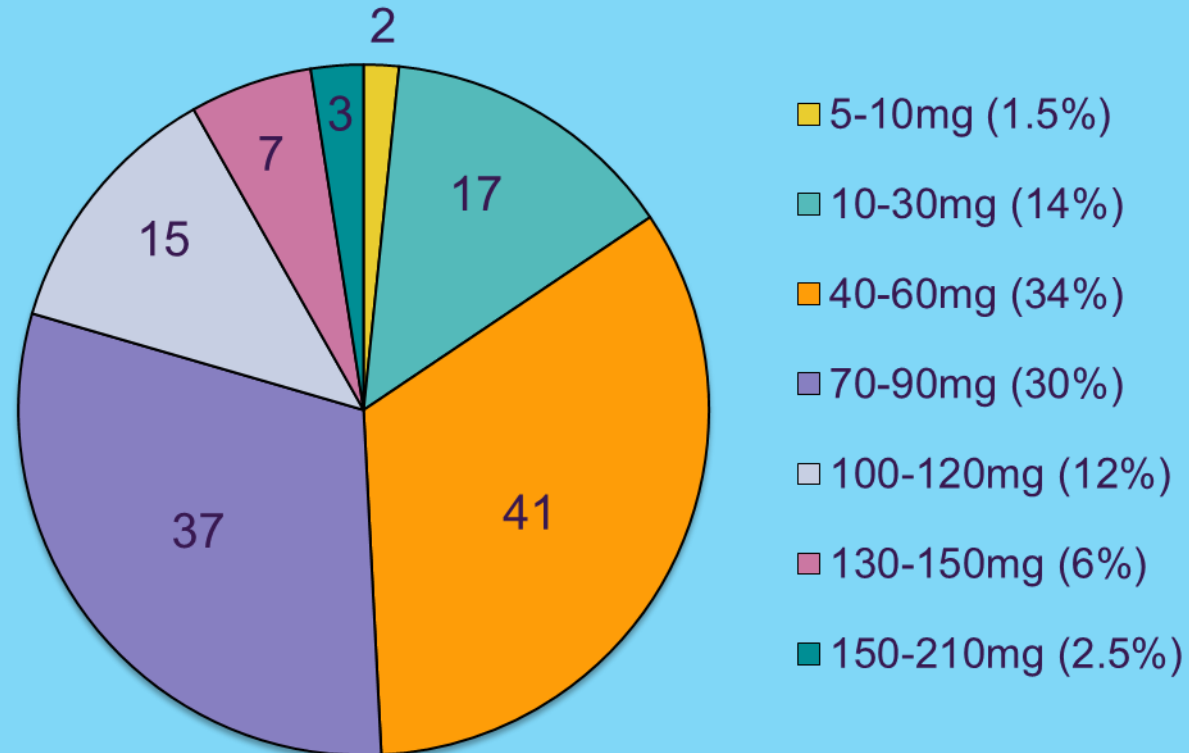
Total Years on Methadone



Courtesy A.W.

Medical Maintenance: Dose N=122

AVERAGE DOSE = 68mg.
RANGE: 5mg–210mg



Courtesy A. W.

Occupations of OBOT OAT Patients

- Teacher
- Electrician
- Plumber
- Social Worker
- Psychologist
- Chauffer
- Computer/IT
- Drug Couselor
- Accountant
- Retail Manager
- Home Security Systems
- Restaurateur
- Fish Dept. Manager
- Movie Editing
- Student(Ph.D)
- HVAC Tech.
- Stamps
- School Principal
- Artist
- Advertising VP
- **Bus Driver—MTA***
- **Sanitation Driver***
- **Con Ed Utility***
- **Subway Signal—MTA***
- Sales
- Secretarial
- Administrator
- Piano Teacher
- Elevator Repair
- Lawyer
- Physician
- Landscape
- Car Salesman/Repair
- Videographer
- Heavy Equipment
- Contractor
- Entrepeneur
- Musician
- Nurse

*** Safety Sensitive—Employers OK**

Methadone Medical Maintenance (MMM):

Treating Chronic Opioid Dependence in Private Medical Practice — A Summary Report (1983–1998)

EDWIN A. SALSITZ, M.D.¹, HERMAN JOSEPH, Ph.D.^{2,3}, BLANCHE FRANK, Ph.D.³, JOHN PEREZ, M.S.³,
BEVERLY L. RICHMAN, M.D.¹, NADIM SALOMON, M.D.¹, MARCIA F. KALIN, M.D.¹, AND DAVID M. NOVICK, M.D.^{2,4,5}

Abstract

Methadone Medical Maintenance (MMM) was implemented in 1983 to enable socially rehabilitated methadone patients to be treated in the offices of private physicians rather than in the traditional clinic system. Over a period of 15 years, 158 methadone patients who fulfilled specific criteria within the clinic system entered this program in New York City. Participating patients reported to their physician once a month and received a one-month supply of methadone tablets rather than a one-day liquid dose in a bottle.

Of the 158 patients who entered this program, 132 (83.5%) were compliant with the regulations and proved to be treatable within the hospital-based private practices of internists participating in the program. Compliant MMM patients found it easier to improve their employment status and business situations, finish their educations, and normalize their lives in MMM as opposed to the traditional clinic system because they had simplified reporting schedules and fewer clinical restrictions. Twelve (8%) compliant patients were able to successfully withdraw from methadone after an average of 17.7 years of treatment in both the traditional clinics and MMM. Twenty compliant patients (13%) died from a variety of causes, 40% of which were related to cigarette smoking. None of the deaths were attributable to long-term methadone treatment. Other causes of death included hepatitis C, AIDS, cancer, homicide, complications of morbid obesity and meningitis.

The 26 noncompliant patients (16.5%) were referred back to their clinics for continued treatment or were discharged for failure to report as directed. A major cause of failure in MMM was abuse of crack/cocaine.

Stigma concerning enrollment in methadone treatment was a major social issue that patients faced. Many refused to inform employers, members of their families, friends, and other physicians who treated them for a variety of conditions that they were methadone patients. The methadone medical maintenance physician, therefore, functions as a medical ombudsman for the patient, educating other physicians who treat the patient about methadone maintenance and its applicability to the patient. Our results can serve as a model for the expansion of office-based MMM treatment.

Key Words: Heroin addiction, methadone, methadone maintenance, methadone medical maintenance, private practice.



"In addition to her heavy dose of 160 milliliters of methadone, Mariella mainlines cocaine five to seven times a day and smokes the occasional rock of crack"

New York Times Magazine-Dec. 5, 1993
Photograph: Eugene Richard
Text: Richard Woodward

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drone, Talkum. Anwendungsgeb.: Zur Anwand. am Beginn eines initiierten Behandl. Konzeptes in der Substitutionstherapie b. Opiat-/Opioidabhängigk. b. Erw. welche die med. u. psych. Versorgung anstreben. Die Substituti-
onsbehandl. m. Methadon sollte v. einem in der Behandl. Opiat-/Opioidabhängiger erfahre. Arzt veranlasst. In Zeiten anfallen, die sich auf die Behandl. der Opiat-/Opioidabhängigk. spezialisiert haben. Gegenanz.: Überempf. gsp.
inhaltsstoffe, Behandl. m. MAO-B-Hemmern, Narkotika-Antagonisten od. Narkotika-Agonisten/Antagonisten (z. B. Pentazocin, Buprenorphin) (außer zur Behandl. einer Überdos.). Nebenwirk.: Zu Beginn häufig Opiat-Entzugssympt. wie
Angstzustände, Anorexie, unwillk. zuck. u. stöß. Beweg., Cefea, orientat. Depress., Diarrhö, Erbrechen, Fieber, Gähnen, Gleichgewichts., Nausea, Rötchen, erweit. Pupillen, Reizhärk., Fäkalurie, Schläfrigk., Kopfweh, Schmerzen, Schweiß-
ausbrüche, starkes Schwitzen, Erhöht. Spinnwebn., Schwindel, verstärkter Tränenfluss, Tremor, Unruhe, Untrübbarkeit, unregelm. Wechsel zw. einem Frostsch. u. Hitzegefühl, Sehr häufig bis häufig: Erregbar., Dysphorie, Benommenh., Se-
dation, Verwirrth., Anorexie, Desorientierth., Kopfschmerzen, Müdigk., Schläfrigk., Unruhe, Sensor., Herzklopfen, Bradykardie, Schwächeanfälle, Ödeme, Atemdepress., Erbrechen, Nausea, Mundtrockenh., Obstipation, Gallenwegspasmen,
Schweißausbrüche, Urinkaria, Hautausschläge, Pruritus, uridiuret. Effekte, Nasenrhitiden, Miktionsschw., eingeschr. Libido u./od. Potenz, Gelegentl. bis sehr selt.: Hämorrhagie, orthostat. Hypotonie, Synkopen, Herzstillstand, Einschnürk.
d. Kreislaufunkt., Schock, Atemstillstand, Flush, Entbl. Lactose u. Sucrose, Weib. Einzeltbl. u. Hirnw. s. Fach- u. Gebrauchsinfo. Vorsichtsvorgangsrichtig. Mat.-Nr.: 9/641863 Stand: Juli 2018, HEXAL AG, 83607 Holzbachern, <http://www.hexal.de>

Courtesy Robert G. Newman, M.D.

One of Medicine's Best-Kept Secrets: Methadone Works

Greatest success stories go untold because of stigma.

6-3-97

By CHRISTOPHER S. WREN

BACK when a subway ride cost 15 cents, Dr. Vincent Dole, a metabolic specialist, and Dr. Marie Nyswander, a psychiatrist, joined forces to try to reverse a worrisome rise in heroin addiction in New York City.

Working at the Rockefeller Institute, as Rockefeller University was then called, the researchers sought to block addicts' craving for heroin by substituting an opioid painkiller developed by German chemists during World War II.

More than three decades later, the synthetic analgesic they first tested in 1964, methadone, is accepted as the closest thing to a heroin cure. About 115,000 Americans take methadone regularly.

Yet by various estimates, only 5 percent to 20 percent of such users stay on it for more than 10 years. Some find they no longer want the medication. Others relapse into drug use. Many are put off by the cumbersome, often petty bureaucracy that administers methadone; misleading rumors that methadone is ruinous to health; and an insidious social stigma that by equating methadone with illicit drugs, forces users to hide the achievement of taking back their lives.

Successful methadone users are

son's "Tonight Show."

"I don't think I missed a day of practice in more than 60 years," he said. "People say, 'Why do you want to play?' and I say, 'That's what I do. I'm a trumpet player.'"

But Mr. Maxwell has a darker story to tell. In the prime of his career, heroin nearly killed him. He has stayed clean by taking methadone every day for nearly 32 years.

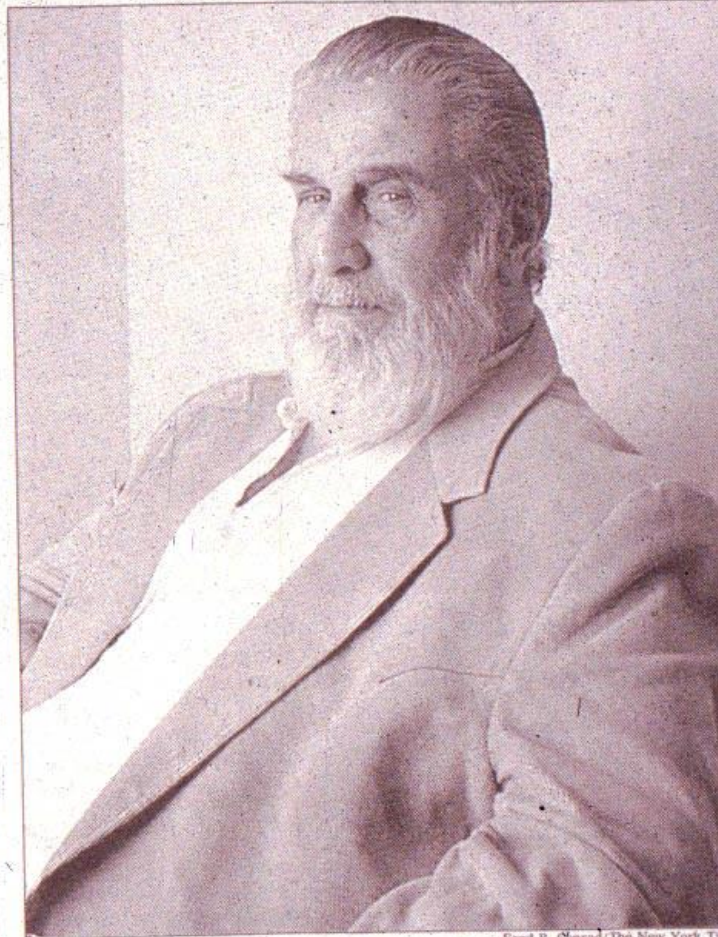
His wife of 55 years has known, of course, but hardly anyone else — not his employers or his neighbors in Great Neck, N.Y., or his best friend, a retired Federal drug agent. "Just for reasons of my career, I didn't talk about it," Mr. Maxwell said.

In that he is hardly alone. Because of its association with heroin, those benefiting most from methadone are least likely to risk their careers or reputations by saying so.

The stigma surrounding methadone was analyzed by Herman Joseph, a research sociologist who worked with Dr. Dole and Dr. Nyswander. Even an innocent yawn, he reported, can jeopardize a methadone user's job if the boss or co-workers mistake it as drowsiness induced by methadone rather than routine fatigue.

Yet the extensive medical literature on methadone does not contain a single report of methadone's failing to block the craving for heroin. "The safety and efficacy of methadone in the treatment of narcotic addiction have been documented more extensively than any other medication in the pharmacopeia," said Dr. Robert G. Newman, president of Beth Israel Medical Center.

Regular doses of methadone break the heroin user's wild swings be-



Fred R. Conrad/The New York Times

Those benefiting most from methadone are least likely to talk about it. Jimmie Maxwell, veteran jazz trumpeter, has taken it for nearly 32 years.

Indeed, Mr. Maxwell was a record a hauntingly mellow jazz album, "Let's Fall In Love," with methadone.

"He's a classic case of someone who responded well to the treatment," Dr. Salsitz said. "He's probably the right kind of person for

Mr. Maxwell said that almost one in his crowd used heroin, more popular with be-bop musicians like Charlie Parker. "Three or four persons were in the same fix as I was in," Mr. Maxwell recalled, "but musicians tended to drink."

But during a tour of the Union with the Benny Goodman Sextet in 1962, Mr. Maxwell contracted debilitating diarrhea that Soviet doctors treated with spirits of opium, which is opium dissolved in alcohol. He completed the tour but returned exhausted to New York where an acquaintance suggested trying a white powder — heroin — to restore his strength. He snorted the next three years, though he called, "I didn't have all the fun when I was using heroin. I felt much better without it."

Heroin left him nearly broke, he considered suicide. Instead, Mr. Maxwell sought help from Dr. Marie Nyswander, who put him in her program in 1965. He has been free of heroin since, he said, without adverse effects. "When I went on the program it just stopped," Mr. Maxwell said. "I had no reason to use drugs."

Though methadone is classified as a narcotic, Mr. Maxwell said it gave him a buzz. "I thought it would make you feel good but it doesn't," he said. "It's a negative feeling that prevents you from feeling better. For years, Mr. Maxwell





TABLE 3. Benefits of Medical Maintenance

Confidentiality

Patients are further removed from the drug subculture

Trusting physician-patient relationship

Ease of travel

General medical problems treated at same location

Expanded employment activities

Stable patients leave the methadone clinic, opening up spaces for
new patients

Makes methadone treatment more attractive by rewarding
progress and allowing the opportunity to earn privileges

Drug Czar Assails Mayor For Opposing Methadone



By Christopher S. Wren

July 25, 1998

See the article in its original context from July 25, 1998, Section B, Page 3 | [Buy Reprints](#)

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In an exchange of blunt language, the nation's drug policy chief said yesterday that Mayor Rudolph W. Giuliani's call to end methadone programs conflicted with the best medical and scientific knowledge. City Hall then responded by accusing him of waging an ineffective war on drugs.

Mayor Giuliani's office responded to General McCaffrey's statement with contempt. "Maybe the reason why our nation's war against drugs has stalled is because our vaunted drug czar favors massive increases in chemical dependency," Deputy Mayor Joseph J. Lhota said.

New York doctors and treatment specialists who believe in methadone object to the Mayor's characterization of it as one more drug. Dr. Edwin A. Salsitz, director of a pilot methadone medical maintenance program at Beth Israel Medical Center, said that the Mayor was confusing methadone maintenance with the social and economic destitution that leads some people to abuse drugs.

"If you come in destitute and are living in a box in the park," Dr. Salsitz said, "how is methadone going to make you want to go to work?"

Addicts with useful job skills resume work once they are on methadone, Dr. Salsitz said. Among his own patients, he listed lawyers, teachers, business owners, electricians, plumbers, a nurse and a pianist.

"My patients are very distraught about what the Mayor is saying," Dr. Salsitz said. "They wish they could call him and say, 'I am working, I am functioning, I am paying my own way and paying my taxes because I am on methadone.' "

Mr. McAllister, of the Committee of Methadone Program Administrators, said the number of employed methadone users in New York City ranged from 30 percent in Queens and Staten Island to 12 percent in a depressed area like the South Bronx.

OAT: Stigma

FEBRUARY 2, 1997

QUOTATION OF THE DAY

“A methadone patient is monitored more closely than a paroled murderer.”

DR. EDWIN A. SALSITZ,
of Beth Israel Hospital
in New York City.

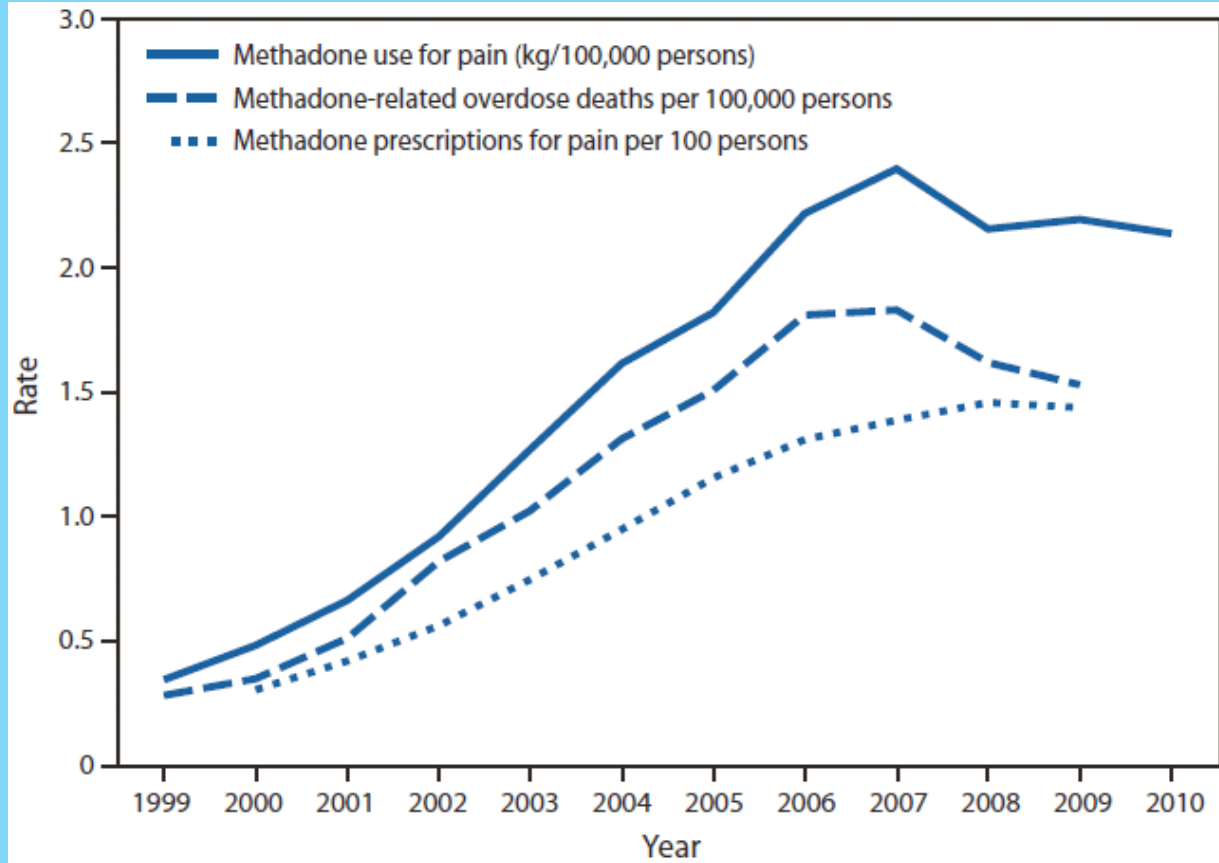
[12.]

Now It Is Time To Meet Our Guests!

Please be mindful of the courage it
takes to lose your anonymity and
speak about one's personal issues.



The Rate Of Overdose Deaths Involving Methadone in the United States in 2009 Was 5.5 Times The Rate in 1999



***METHADONE FOR PAIN, not OTP**

TABLE. Drug-related deaths involving opioids, by type of opioid — Drug Abuse Warning Network Medical Examiner System, 13 states, 2009

| Opioid | No. | Death rate per 100 kg MME | RR | (95% CI) |
|---------------------------|--------------|---------------------------|------|-------------|
| All deaths | | | | |
| Buprenorphine | 20 | 0.8 | 0.02 | (0.01–0.04) |
| Fentanyl | 364 | 7.7 | 0.28 | (0.25–0.32) |
| Hydrocodone | 550 | 14.3 | 0.42 | (0.38–0.47) |
| Hydromorphone | 74 | 9.1 | 0.27 | (0.21–0.34) |
| Morphine | 824 | 20.2 | 0.64 | (0.58–0.70) |
| Oxycodone | 1,097 | 8.7 | 0.26 | (0.24–0.28) |
| Methadone | 1,034 | 33.6 | 1.00 | referent |
| Total* | 3,294 | 10.4 | | |
| Single-drug deaths | | | | |
| Buprenorphine | 2 | 0.1 | 0.01 | (0.00–0.03) |
| Fentanyl | 99 | 2.1 | 0.26 | (0.21–0.33) |
| Hydrocodone | 42 | 1.1 | 0.11 | (0.08–0.16) |
| Hydromorphone | 4 | 0.5 | 0.05 | (0.02–0.14) |
| Morphine | 153 | 3.8 | 0.41 | (0.34–0.50) |
| Oxycodone | 150 | 1.2 | 0.12 | (0.10–0.15) |
| Methadone | 298 | 9.7 | 1.00 | referent |
| Total | 748 | 2.4 | | |

Abbreviations: MME = morphine milligram equivalent; RR = rate ratio; CI = confidence interval.

* Counts for each opioid might not sum to the total shown for all deaths because some deaths involved more than one opioid.

MMWR, 7/6/12

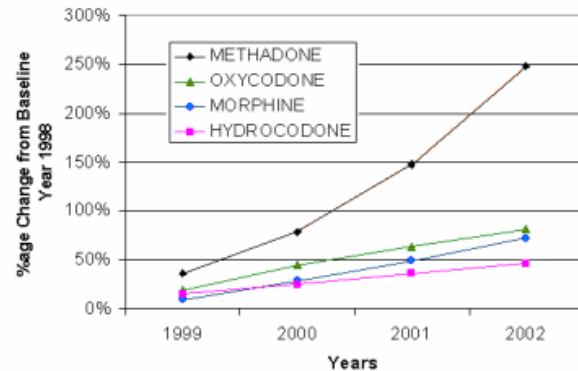
Formulations for pain: 5mg and 10mg. 100mg daily = 300 tablets monthly

Methadone Mortality: OTPs Dispensing vs. Prescribing

Recent Increases in Methadone Use Are Related to Its Use as an Analgesic

The greatest incremental growth in methadone distribution in recent years is associated with use of the drug as an analgesic and its distribution through pharmacies rather than through OTPs (Governale, meeting presentation, 2003; DEA, 2003) (Figure 2). However, the growth in distribution of methadone through pharmacies has been overshadowed by the increase in distribution of oxycodone and hydrocodone.

Figure 2. Percent Change in Distribution of Methadone and Three Comparison Drugs, from Baseline Year 1998 through 2002



Source: Data from IMS Health, National Prescription Audit Plus, courtesy of Laura A. Governale, PharmD.

Increases in Methadone-Associated Mortality Also Are Related to Its Use as an Analgesic

The greatest incremental growth in methadone distribution in recent years is associated with use of the drug as an analgesic and its distribution through pharmacies. In fact, distribution of solid methadone formulations (tablets and diskettes), primarily through pharmacies, has surpassed distribution of the liquid formulations that are the mainstay of dispensing in OTPs. From 1998 through 2002, the volume of methadone distributed through pharmacies increased five-fold, whereas the volume distributed through OTPs increased only 1.5-fold. In 2002 alone, pharmacies accounted for 88 percent of all purchases of methadone tablets (DEA, 2003). Data from the DEA's ARCOS system indicate that the growth in methadone distribution overall has lagged far behind the increases seen for other opioid analgesics, such as oxycodone and hydrocodone products (DEA, 2003).

OTPs and the Revised Federal Regulations Are Not Significant Contributors to Methadone-Associated Mortality

A major concern of the National Assessment participants was whether OTPs and the revised SAMHSA regulations governing the manner in which OTPs administer and dispense methadone have contributed to recent increases in methadone-associated mortality. The SAMHSA regulations effective in 2001 (42 CFR Part 8) allow patients – especially those who are relatively advanced in the course of treatment – to take home doses of methadone on an increased number of days.

“Methadone Does Not Have a
Sense of Humor”



Howard Heit/Douglas Gourlay

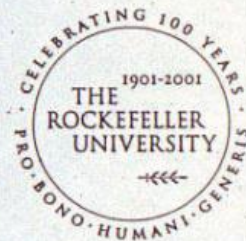
THE ROCKEFELLER UNIVERSITY

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Science for the Benefit of Humankind

John D. Rockefeller, Sr., created the first biomedical research institute in the United States on June 14, 1901. Since then, scientists at The Rockefeller University have:

- Discovered that DNA is the basic material of heredity
- Determined that cancer can be caused by a virus
- Learned how to preserve whole blood, making blood banks possible
- Identified the Rh factor
- Pioneered the modern science of cell biology
- Confirmed the connection between cholesterol and heart disease
- Developed methadone treatment to manage heroin addiction
- Isolated the dendritic cell, a key immune-system cell that may yield new therapies for viral infections and cancer
- Discovered leptin, a hormone that influences appetite, energy use and body weight
- Devised the AIDS cocktail drug therapy



For 100 years, Rockefeller investigators have earned international recognition, and 21 have received Nobel Prizes — most recently in 1999 and 2000.

THE NEW YORK TIMES, THURSDAY, JUNE 14, 2001

Initial Publication (59 years ago)

A **Medical Treatment** for Diacetylmorphine (Heroin) Addiction

A Clinical Trial With Methadone Hydrochloride

Vincent P. Dole, MD, and Marie Nyswander, MD

A group of 22 patients, previously addicted to diacetylmorphine (heroin), have been stabilized with oral methadone hydrochloride. This medication appears to have two useful effects: (1) relief of narcotic hunger, and (2) induction of sufficient tolerance to block the euphoric effect of an average illegal dose of diacetylmorphine.

ough review of evidence available in 1957,¹ concluded that "The advisability of establishing clinics or some equivalent system to dispense opiates to addicts cannot be settled on the basis of objective facts. Any position taken is necessarily based in part on opinion, and on this question opinions are

**JAMA Classics: Celebrating 125 Years
Methadone Maintenance 4 Decades Later
Thousands of Lives Saved But Still Controversial
Commentary by Herbert D. Kleber, MD
JAMA. 2008;300(19):2303-2305**

JAMA. 1965;193(8):646-650

From the Rockefeller Institute, and Manhattan General Division of Beth Israel Hospital, New York.

Reprint requests to Rockefeller Institute, New York 10021 (Dr. Dole).

U.S. Department of Health & Human Services • National Institutes of Health

NIH Consensus Development Program



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Effective Medical Treatment of Opiate Addiction

National Institutes of Health
Consensus Development Conference Statement
November 17-19, 1997

Conclusions:

“...inform the public that dependence
Is a medical disorder that can be effectively
treated with significant benefits for the
patient and society.”

Recommendations:

- Expand Access to MMT
- CJS ↑ Access
- Education of Providers
- ↓ Regulations
- ↑ Funding
- Parity with all medical/psych disorders
- Pregnancy ↑ Access



27 years ago

Methadone Re-Branding?

- What was the previous name of VERIZON?
- NYNEX and NE TELEPHONE
- NORLIM

Morning-Sickness Pill Bendectin Back on the Market with a New Name

By Amy Orciari Herman

Bendectin = Diclegis

1983 off 2013 on

The combination of doxylamine succinate and pyridoxine hydrochloride has once again been approved to treat nausea and vomiting in pregnancy, the FDA has announced. The drug, to be marketed as Diclegis, was previously sold under the name Bendectin.

Bendectin was voluntarily pulled from the market in 1983 over concerns about birth defects; those concerns later proved to be unfounded.

The new approval was based on a randomized trial in which Diclegis outperformed placebo among some 260 pregnant women. In addition, says the FDA, epidemiologic studies show that the drug does not harm the fetus.

Severe sleepiness can occur with Diclegis, so patients should not drive, operate heavy machinery, or perform other activities that require mental alertness while taking the drug.

Clinicians should reassess a patient's continued need for Diclegis as the pregnancy progresses, the FDA advises.

FDA news release (Free)

Why Is This So Important?



Actor Philip Seymour Hoffman, who was found dead February 2, 2014 on the bathroom floor of his New York apartment with a syringe in his left arm, died of acute mixed drug intoxication, **including heroin**, cocaine, benzodiazepines and amphetamine, the New York medical examiner's office said Friday

MOUD Lowers All Cause and Overdose Mortality

