

**Does Treatment Work?**

Carl Christensen MD PhD, FASAM  
 Medical Director, Dawn Farm  
 Clinical Associate Professor, WSU School of Medicine  
 Medical Director, Mich Health Recovery Prof Program  
 Advisory Board, Families Against Narcotics, Wayne Co.


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- Email [ccmdphd@mac.com](mailto:ccmdphd@mac.com)
- I will send you a Dropbox link with the PPT and all articles/abstracts

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**Disclaimers**



- Methadone provider, WSU
- Medical Director, Dawn Farm (12 step)
- Buprenorphine provide
- Naltrexone provider


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**Treatment: What Are We Looking For?**

- Harm Reduction
- Abstinence
- Recovery

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**What is Recovery?**



Journal of Substance Abuse Treatment 35 (2007) 221–228

Special Section: Defining and Measuring "Recovery" Special article

**What is recovery? A working definition from the Betty Ford Institute The Betty Ford Institute Consensus Panel<sup>11</sup>**

Received 16 February 2007; received in revised form 4 June 2007

**Abstract**

There is an unknown but very large number of individuals who have experienced and successfully resolved dependence on alcohol or other drugs. These individuals refer to their new sober and productive lifestyle as "recovery." Although widely used, the lack of a standard definition for this term has hindered public understanding and research on the topic that might foster more and better recovery-oriented interventions. To this end, a group of interested researchers, treatment providers, recovery advocates, and policymakers was convened by the Betty Ford Institute to develop an initial definition of recovery as a starting point for better communication, research, and public understanding. Recovery is defined in this article as a voluntarily maintained lifestyle characterized by sobriety, personal health, and citizenship. This article presents the operational definitions, rationales, and research implications for each of the three elements of this definition. © 2007 Published by Elsevier Inc.

Keywords: Recovery; Addiction; Substance use disorders; Addiction treatment

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**A voluntarily maintained lifestyle with:**

- Sobriety (abstinence)
- Health (physical, mental and social well-being)
- Citizenship (giving back = spirituality)
- Quality of Life?
- <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3188817/>

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### What is the Gold Standard of Research?

- Level I: randomized, double blinded, controlled experimental trial
- Level IIA: level I without randomization
- Level IIB: population studies: don't control the research (case-control and cohort)
- Level IIC: no control group
- Level III: opinions of respected experts (Cochrane and other hot air)

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- Level IIC: no control group
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### Ethics of Treatment

- Non-maleficence: first, do no harm
- Beneficence: do the right thing
- Autonomy: based on informed consent, the patient chooses their treatment
- JUSTICE: division of medical resources

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### Addiction is Not Withdrawal. Addiction is:

- Craving
- Compulsion
- Loss of Control
- Use Despite Consequences
- Chronicity


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### “Addiction isn’t a Disease”

**Addiction is not a disease: A neuroscientist argues that it's time to change our minds on the roots of substance abuse**


A psychologist and former addict insists that the illness model for addiction is wrong, and dangerously so

SHARE YOUR THOUGHTS | 19



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### Treatment of Opioid Dependence



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## How Do You Treat Addiction?

### Medication Assisted Therapy: opiates

- **Agonists**
  - Methadone
  - Buprenorphine +/- Naloxone
- **Antagonists (NOT FOR PREGNANCY)**
  - Naltrexone
    - Rivea (tablets)
    - Vivitrol (injections)

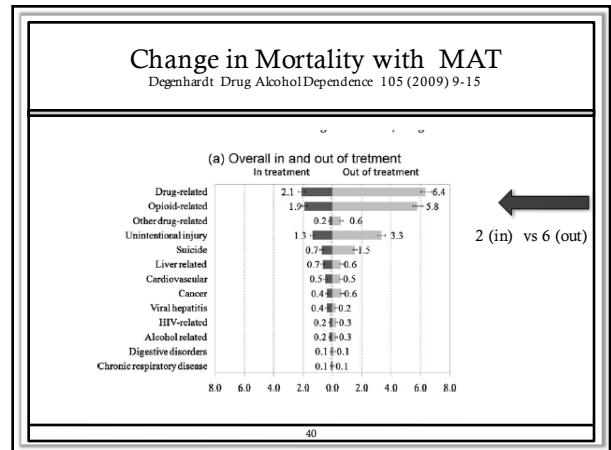
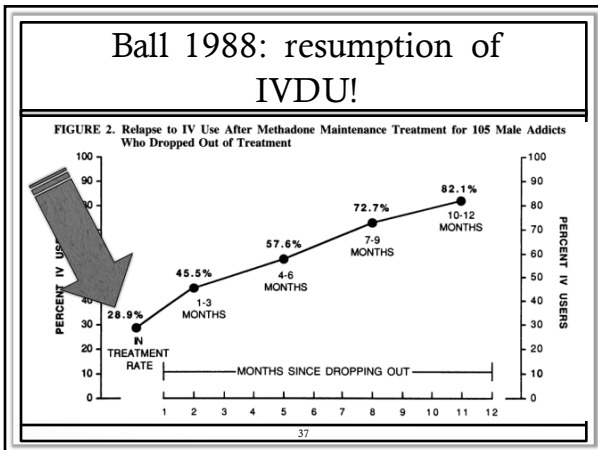
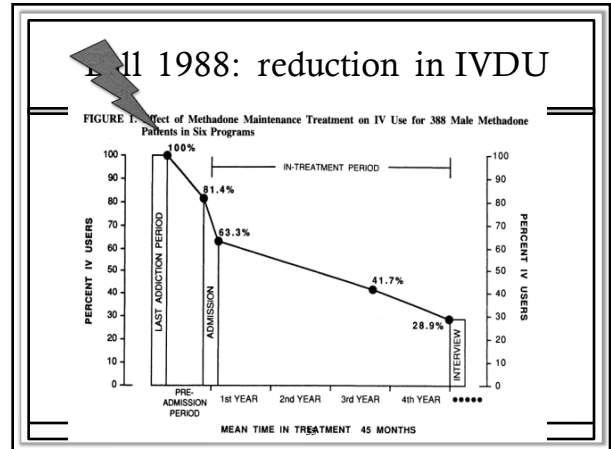
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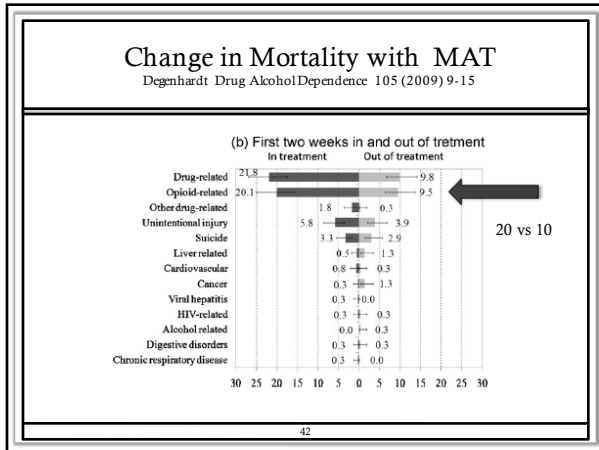
## Benefits of Methadone Maintenance Therapy (MMT)

<http://www.jstor.org/stable/2137033?origin=JSTOR-pdf>

- Reduction in death rates
- Reduction in IVDU
- Reduction in # of crime days
- Reduced HIV seroconversion / HCV conversion
- Reduction to relapse to IVDU
- Improvement in health, employment & functional level [Am J Drug Alcohol Abuse 2007;33\(5\):631-42](#)

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### Mortality and M.A.T (bup and MTD)

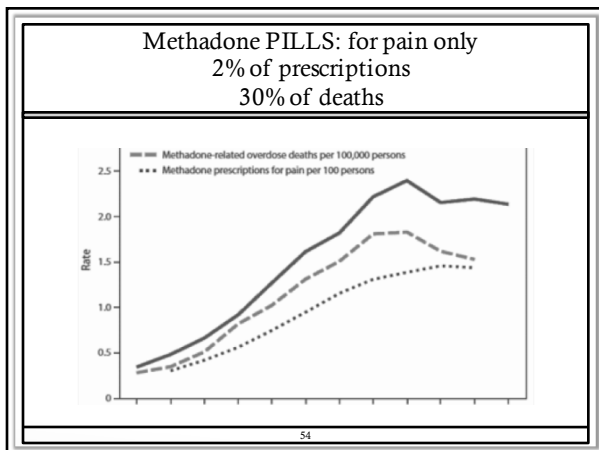
122, 885 patients: overdose mortality

METHADONE		BUPRENORPHINE	
In treatment	Out of treatment	In Treatment	Out of Treatment
3	13	1	5

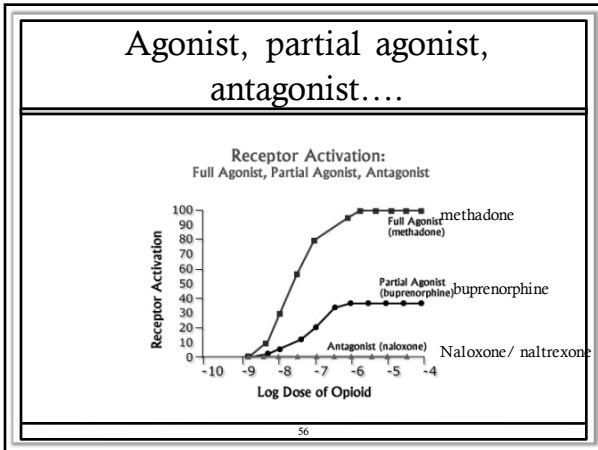
Soudo L. et al. Mortality Risk during and after opioid substitution treatment: systematic review and metaanalysis of cohort studies. BMJ 2017; 357: J1550

- ### Take Home Points:
- Mortality appears to decrease (29%) after starting medication assisted treatment .
  - Mortality INCREASES after leaving treatment.
  - Both the first two weeks IN treatment (methadone) and OUT of treatment (methadone and buprenorphine) are the most dangerous periods.

- ### Quality of Life with Methadone Maintenance Therapy (MMT): ????
- High mortality (>20%) and continued drug use in patients who attended MMT. J Addict Dis 2011 Jan; 30(1): 17-26
  - Patients in Taiwan had improvement in QOL with MMT.
    - Chou et al. BMC Psychiatry 2013, 13: 190
  - MMT patients get "better faster" than buprenorphine patients Am J Drug Abuse 2007; 33(5): 631-642.
  - MMT patients regain cognitive function
    - PLOS ONE 2014; 9; (40): e94589

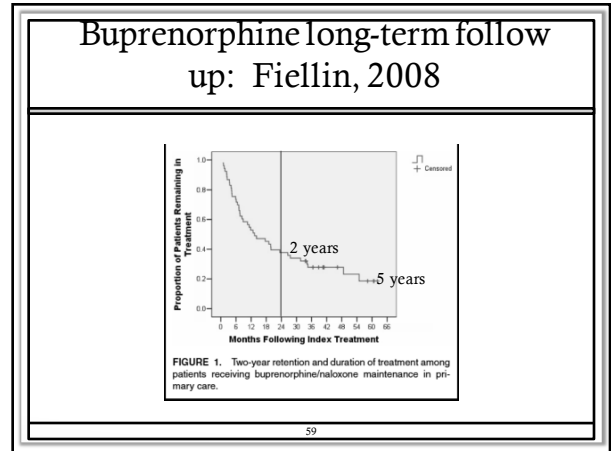


- ### Buprenorphine
- A partial opiate agonist
  - Less effective for withdrawal
    - Less analgesic effect
    - Less respiratory depression
    - 4000+ PER YEAR WITH METHADONE
    - Few OD deaths with buprenorphine
    - Relative Risk of death: >4
      - Drug Alcohol Dep 2009: 104, 73-77
      - [http://buprenorphine.samhsa.gov/UPDAT ED\\_Bup\\_Lit\\_Review\\_Feb\\_07\\_rev.pdf](http://buprenorphine.samhsa.gov/UPDAT ED_Bup_Lit_Review_Feb_07_rev.pdf)



- ### Sublingual Buprenorphine/Naloxone for Dependence:
- Available in 3 branded forms:
    - Generic buprenorphine (Subutex®): sublingual **OFF MARKET**: Medicaid may concerns about diversion.
    - Bunavail®: sublingual buprenorphine + naloxone (Narcan®): prevents IV use\*
    - Suboxone®: sublingual buprenorphine + naloxone (Narcan®): prevents IV use\*
    - Zubsolv®: prevents IV use\*
  - ANY of these will precipitate sudden withdrawal: only give when patient is going INTO withdrawal!

- ### Buprenorphine:
- Formulations approved for PAIN:
    - Buprenex®: parenteral, used in the hospital setting.
    - Butrans®: weekly patch, 10 to 20 mcg/hr
    - Belbuca®: buccal film from 75 – 900 mcg/24 hr.



- ### Buprenorphine long-term follow up: Fiellin, 2008
- Of those who remained in treatment:
    - 91% were negative for opioids
    - 96% were negative for cocaine!
    - Satisfaction score: “86%”

- ### Methadone vs. Bupx: Cochrane database
- “Buprenorphine is an effective treatment for heroin use in a maintenance therapy approach compared with placebo. **However, methadone maintenance treatment at high dose is associated with higher rates of retention in treatment and better suppression of heroin than buprenorphine maintenance treatment.**”
  - Methadone, however, has been found to be associated with **more frequent overdose and death** (4.8 vs 0.9/1000 patient-years) (Bell, 2009)

## What about pregnancy?

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### Treatment Improvement Protocol (TIP)#40: SAMHSA

- Methadone is currently the standard of care in the United States for the treatment of heroin addiction in pregnant women.
- If such specialized services are refused by a patient or are unavailable in the community, maintenance treatment with the buprenorphine monotherapy formulation may be considered as an alternative.

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## MOTHER STUDY

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

### Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure

Hendrée E. Jones, Ph.D., Karol Kaltenbach, Ph.D., Sarah H. Heil, Ph.D., Susan M. Stine, M.D., Ph.D., Mara G. Coyle, M.D., Amelia M. Arria, Ph.D., C. O'Grady, Ph.D., Peter Selby, M.B., B.S., Peter R. Martin, M.D., and Gabriele Fischer, M.D.

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### Methadone vs. Buprenorphine: the MOTHER study

MS = morphine; NAS = neonatal abstinence syndrome

Measure	Methadone	Buprenorphine
Amount of MS required	10.4	1.1
# of days in hospital	17.5	10
Duration of treatment for NAS	9.9	4.1
Birthweight	2878	3093
% preterm delivery	19	7*
Positive drug screen at delivery	15%	9%*
Dropped out (why?)	18%	33

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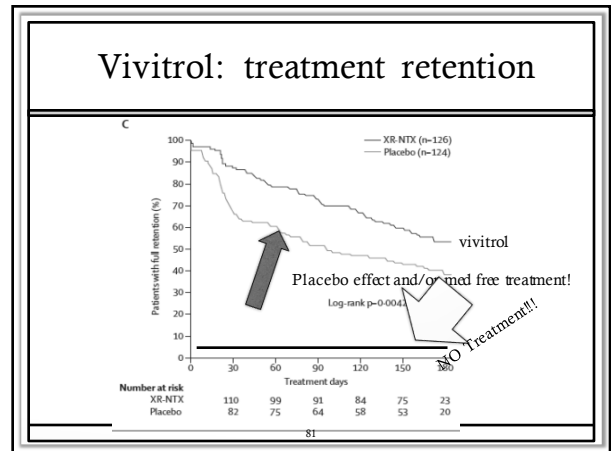
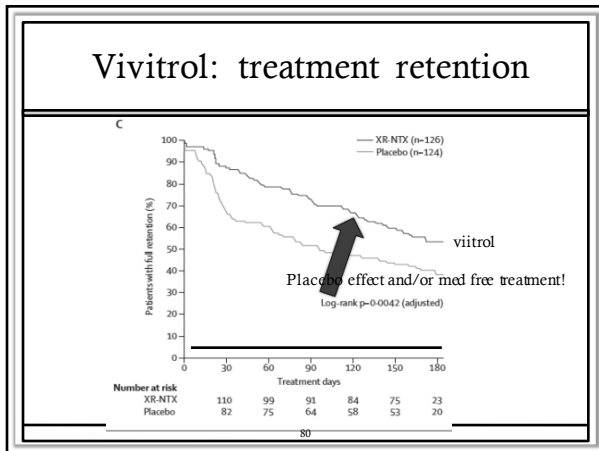
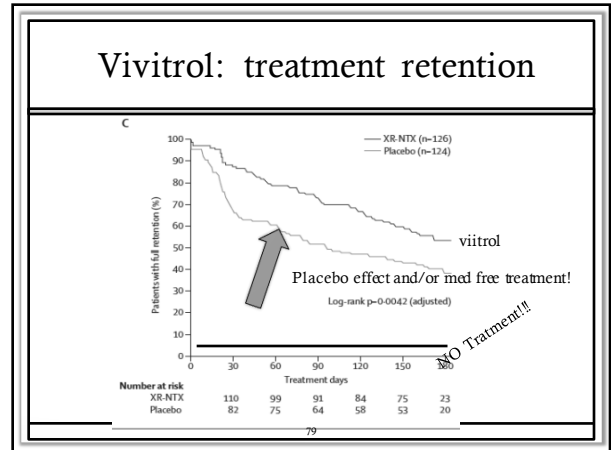
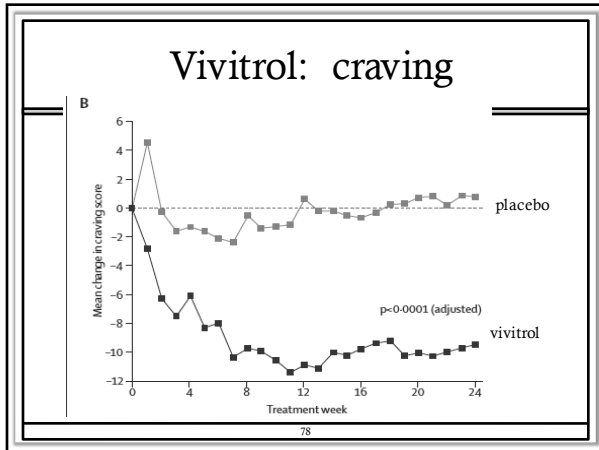
## Vivitrol® (naltrexone) for opioid dependence

Krupitsky et al, Lancet 2011; 377: 1506-13  
Comer et al, Arch Gen Psychiatry 2006; 63: 210-218

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### Vivitrol: abstinence

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Doc, when can I get off this sh\*t (medication)?

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### Detoxing During Pregnancy?

Luty 2003

- 101 women underwent detox during pregnancy
- 40 successfully detoxed.
- No adverse fetal effects documented
- But: only 1/101 patients documented to be abstinent at time of delivery!

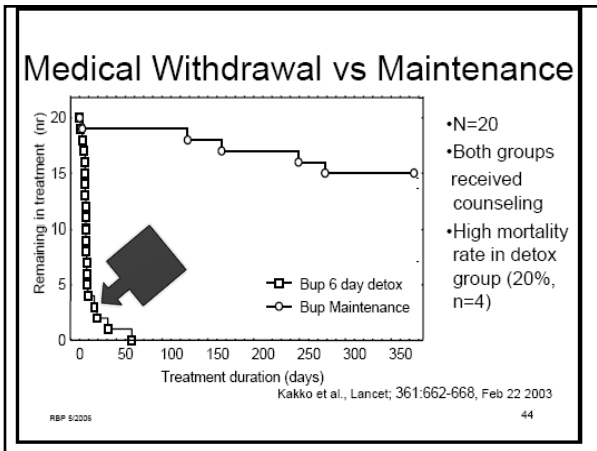
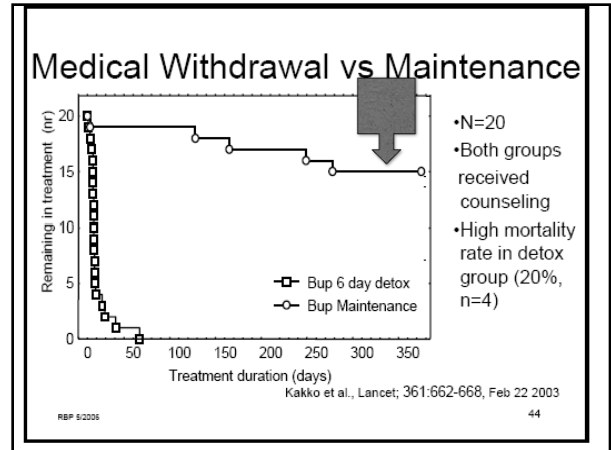
• Luty et al, J Sub Abuse Treat 24 (2003); 363 - 367

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### Detox from heroin using buprenorphine: Kakko

- 40 heroin addicts in Sweden were recruited.
- All were given buprenorphine and offered counseling.
- 20 were allowed to taper off.
- 20 remained on buprenorphine and continued counseling..
- A year later.....

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### Can you taper off buprenorphine without relapse?

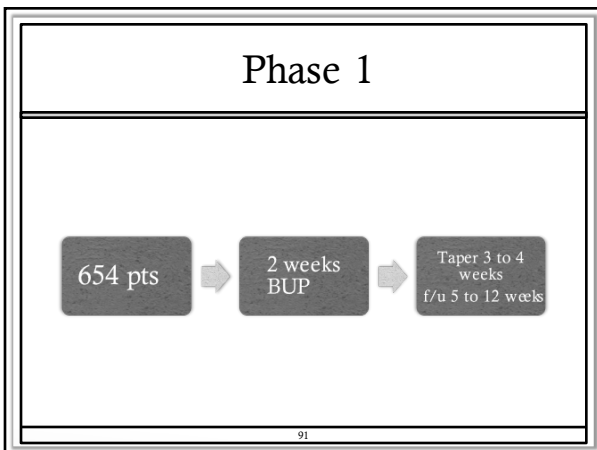
ONLINE FIRST

#### Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence

A 2-Phase Randomized Controlled Trial

Roger D. Weiss, MD; Jennifer Sharpe Potter, PhD; David A. Fiellin, MD; Marilyn Byrne, MSW; Hilary S. Connery, MD, PhD; William Dickinson, DO; John Gardin, PhD; Margaret L. Griffin, PhD; Marc N. Gourevitch, MD, MPH; Deborah L. Haller, PhD; Albert L. Hanson, MSW; Zhen Huang, MS; Petra Jacobs, MD; Andrey S. Kozlowski, PhD; Robert Lindblad, MD; Elmore F. McCance-Katz, MD; Scott E. Probst, MSW; Jeffrey Selzer, MD; Eugene C. Somoza, MD, PhD; Susan C. Sonne, PharmD; Walter Ling, MD

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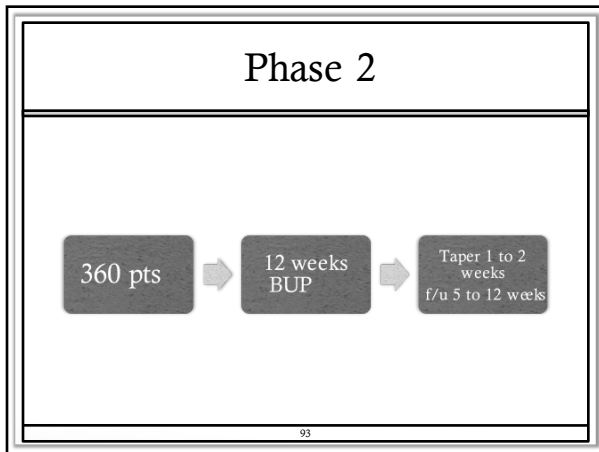


### Outcome Phase 1

- Only 43 of 653 patients remained abstinent (6.6%)
- All others relapsed!!
- On to Phase 2!

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### Outcomes Phase 2

- 49% stayed abstinent when they went back on buprenorphine!
- But when they were taken off buprenorphine again, only 8.6% remained abstinent!

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### Conclusions

- Buprenorphine was effective (≈ 50%) at treating prescription pill addiction.
- Chronic pain was not a barrier to success.
- Less than 10% were able to remain abstinent during 2 attempts to taper off buprenorphine.

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### Conclusions

- “MAT” is effective-at decreasing opioid use.
- Stopping MAT will usually result in relapse & increased chance of death.
  - Why would you expect otherwise?
- Methadone is better at keeping you in treatment. Buprenorphine has a superior safety profile.
- Vivitrol® (injectable naltrexone) is effective at reducing opioid use.

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### Abstinence Based Programs

- The previous administration favored MAT; no one is sure what the current administration will do.
- Advocates of abstinence based programs are often “on the ropes” and accused of religiosity and cultism (Glaser)
- Accusations of 1 to 5% success have been made with claims of greater harm than “spontaneous remission”.
- Any exceptions to this?

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### Physicians Health Programs\* (PHP): the Gold Standard

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## PHP


- Physicians, nurses, pharmacists (varies by state)
- Evaluation, treatment (IOP/residential)
- Require mutual help groups: 12 step or SMART
- Monitor ~weekly
- 3 to 5 year contracts
- Similar to pilots and lawyers
- MOST do not allow MAT
- Immediate intervention for positive urine drug screens.

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## 80-90% SUCCESS!

### Drug Testing

- The majority (79%) had no positive tests for alcohol or other drugs during the monitoring period
- 14% had just one positive test
- 7% had more than one positive test
- Similar in all four groups
- This means that regardless of their drug of choice about two thirds of the physicians who had a positive test for alcohol or other drugs never had a second or subsequent positive test.



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## Comparison to Bupx

	Suboxone Maintenance*	PHP Care
Relapse	Anticipated	Zero-tolerance
Other Substance Use	Common (alcohol, MJ, etc)	Prohibited
% Urines Positive at 6 months	Opiates 50% Cocaine 40% Benzos 10%	Opiates .1% Cocaine .02% Benzos .05%

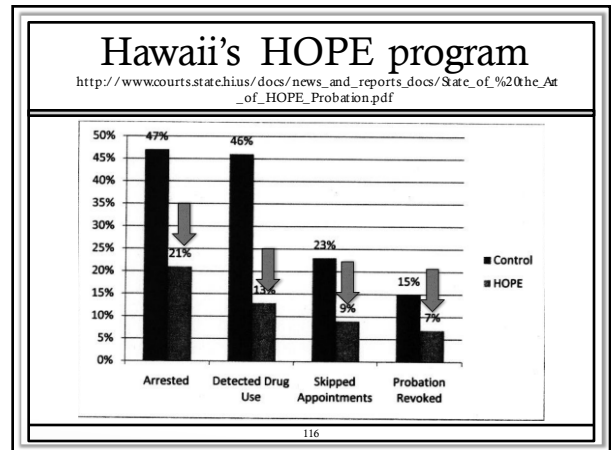
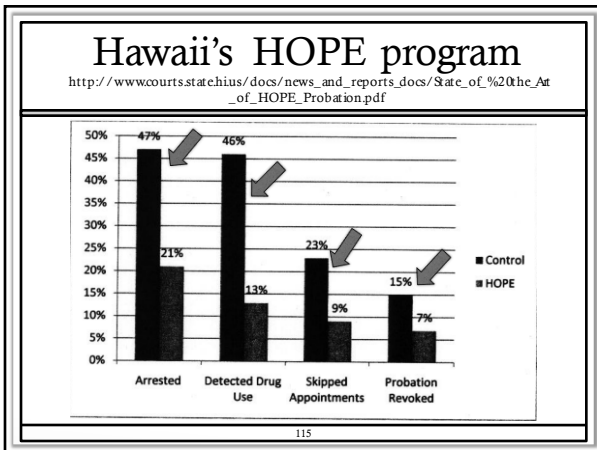
Fudala, et al. Office-Based Tx of Opiate Addiction w/ Suboxone. NEJM 2003

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## Why do PHPs work?

- “They work because doctors have more to lose”.
- “They work because doctors are smarter”
- “They work because doctors can afford treatment”.
- “They work because doctors get special treatment”


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## Swift and Certain (SAC)

**Jason Tashae**  
Founder, Justice Codes

**10 Things You Need To Know About Washington's Innovative Parole Program**



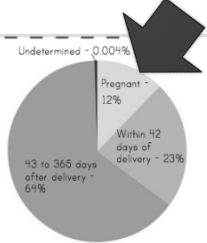
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## Why does it work?

- Chronic disease model-3 to 5 years of monitoring and treatment.
- Mutual help groups (12 step and SMART)
- Caduceus groups-reduce isolation
- Rapid response through drug screens & workplace
- Leverage (including negative reinforcement)

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## What Happens When you Stop Monitoring?



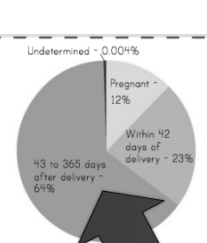
**PREGNANCY STATUS AT TIME OF DEATH AMONG COLORADO MATERNAL DEATHS, 2004-2012, N=211**

Category	Percentage	Count
Undetermined	0.00%	1
Pregnant	12%	26
Within 42 days of delivery	23%	48
43 to 365 days after delivery	64%	136

Source: Colorado Birth and Death Certificate Data, May 2014

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Source: Colorado Birth and Death Certificate Data, May 2014

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## PHPs: More Harm than Good?

<http://disruptedphysician.com/>  
<http://www.medscape.com/viewarticle/849772>



**Disrupted Physician**  
 The Physician WellNess Movement and Illegitimate Authority: The Need for Revolt and Reconstruction

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## The Opioid Epidemic & Naloxone (Narcan®) Rescue

Developed for Families Against Narcotics  
<http://www.familiesagainstnarcotics.org/>

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### Naltrexone vs. Naloxone

Naltrexone	Naloxone
<ul style="list-style-type: none"> <li>• Oral (Rivea®) or IM (Vivitrol®)</li> <li>• Slow onset</li> <li>• Long acting (hours to weeks)</li> <li>• Tightest binding to brain</li> <li>• Used for PREVENTION of overdose (FDA)</li> </ul>	<ul style="list-style-type: none"> <li>• IV, IM, SC or IN (Narcan®, Evzio®)</li> <li>• Rapid Onset</li> <li>• Short acting (minutes)</li> <li>• Less tightly bound</li> <li>• Used for TREATMENT of overdose (FDA)</li> </ul>


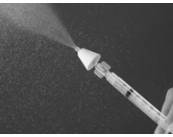
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### What Does Narcan NOT Do?

- It will not reverse an overdose from alcohol, sedatives (Benzodiazepines such as Xanax, Valium and Klonopin), muscle relaxants, or stimulants like Cocaine or Amphetamines.
- If there is more than one drug involved (usually Benzodiazepines and Opioids), it may partially revive the patient until EMS arrives.

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### Naloxone formulations: (0.4 mg)

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### Intranasal (I.N.): ADAPT (4mg/2mg!)



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### Who is at Greatest Risk?

- **Abstinence > 2 weeks:** treatment; jail; relapse.
- **Discontinuing MAT:** methadone; buprenorphine; Vivitrol® (naltrexone).
- **Mixing opioids with sedatives:** alcohol, benzodiazepines, muscle relaxers
- **FENTANYL**
  - 50% of UDS samples with heroin are pos for Fentanyl

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### Fentanyl on Urine Drug Screen Pregnant Patient

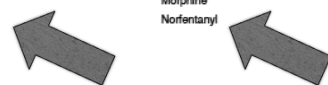
1. Illicit Drugs  
Marijuana Metabolite(THCA)

2. Medications Or Metabolites Detected But Not Listed On Requisition

Codine  
Fentanyl!

Morphine  
Norfentanyl!

Hydromorphone



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### How To Do A Naloxone Rescue

- Make Sure They are Not Breathing
- (always) Call 911
- Do Rescue Breaths (not compressions)
- Give Naloxone
- Resume Rescue Breaths
- Repeat Naloxone every 3 mins
- To review videos: go to ccmdphd on YouTube

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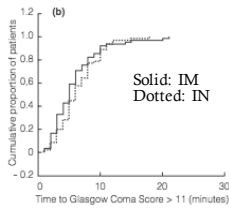
### Rescue Breathing

- Flat on Back
- Tilt the head back
- If no mask-pinch nose
- Give 2 breaths, one second each.
- Chest wall should move 1 inch
- Abdomen should NOT move

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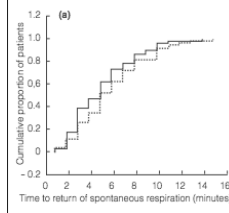
### Which One Is Better?

#### Time to “Come To”



Solid: IM  
Dotted: IN

#### Time to Resume Breathing



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### After EMS arrives.....

- Watch out for needles!
- Clean up all blood!
- You now have a “window of opportunity”.....

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### Treatments for Alcohol Dependence

- Alcoholics Anonymous
- Anti-AA (SMART, Rational Recovery, etc)
- CBT
- MET
- Medications for Alcohol Dependence

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### Cochrane Database?

- **AUTHORS' CONCLUSIONS:** No experimental studies unequivocally demonstrated the effectiveness of AA or TSF approaches for reducing alcohol dependence or problems compared with other treatments, but there were some limitations with these studies. Furthermore, many different interventions were often compared in the same study and too many hypotheses were tested at the same time to identify factors which determine treatment success.
  - Ferri, 2006.
- WHY?

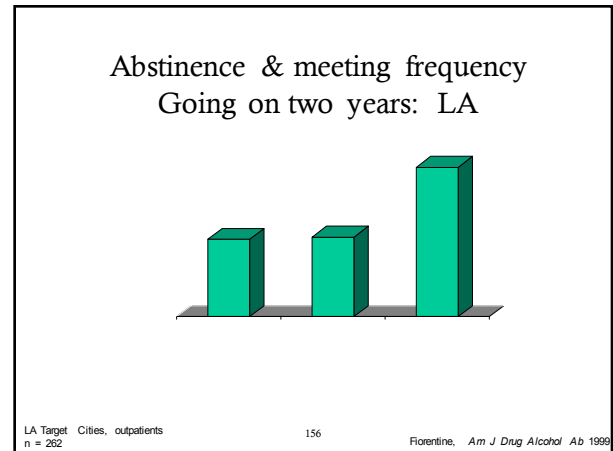
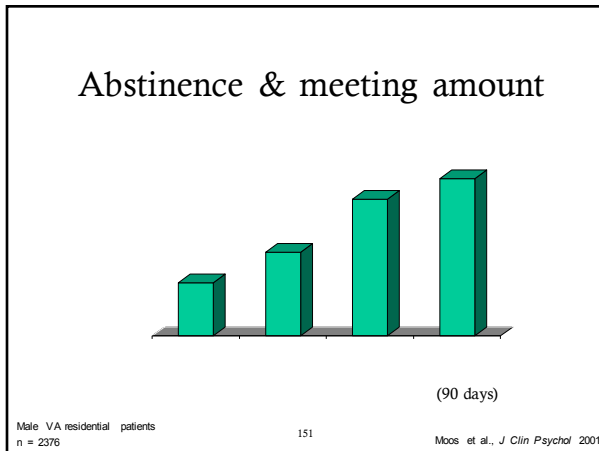
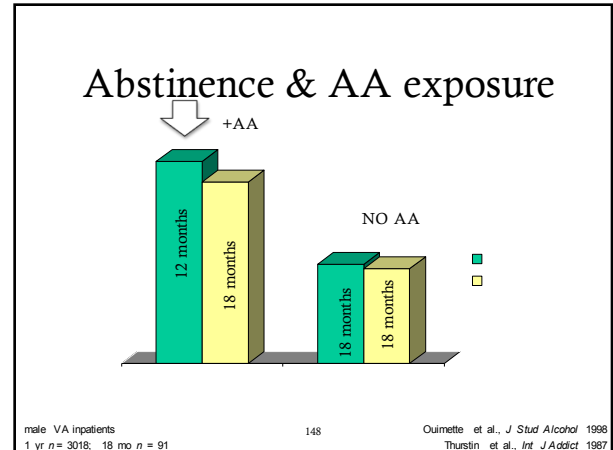
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## AA Effectiveness – Faith Meets Science

Lee Ann Kaskutas, Dr.P.H.  
**Alcohol Research Group, Emeryville, CA**  
**School of Public Health, UC Berkeley**

Presented at the Annual Meeting and Conference of the Federation of State  
 Physician Health Programs (FSPHP)  
 April 25, 2012  
 Fort Worth, TX

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## Project MATCH

- Randomized patients to CBT, MET and TSF
  - CBT: cognitive behavioral therapy
  - MET: motivational enhancement therapy
  - TSF: twelve step facilitation
- No differences were found between groups. There was no control group.
- It has been argued that natural recovery would be as effective. (Stanton Peele)

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## Project MATCH

- "Everybody can now project their own views about alcoholism onto this study."
  - G Marlatt, PhD\*
- "The study would be stronger with a control group, but is not invalid without one."\*\*\*

\* [https://en.wikipedia.org/wiki/Project\\_MATCH](https://en.wikipedia.org/wiki/Project_MATCH)

\*\*\*<https://stats.stackexchange.com/questions/268318/3treatments-without-a-control-group>

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*Alcohol. 2013 January 1; 54(1): 51-59. doi:10.1080/08897077.2012.691450.*

**The 10 Year Course of AA Participation and Long-Term Outcomes: A Follow-up Study of Outpatient Subjects in Project MATCH**

Maria E. Pagano, Ph.D., Case Western Reserve University School of Medicine, Department of Psychiatry, Division of Child Psychiatry, WO Walker Building, 10524 Euclid Ave., Cleveland, OH, 44106  
 William L. White, M.A., Chestnut Health Systems, 3329 Surratt Key Circle #203, Punta Gorda, FL, 33955  
 John F. Kelly, Ph.D., Center for Addiction Medicine, Department of Psychiatry, Harvard Medical School, 60 Starbuck St., Boston, MA, 02114  
 Robert L. Stout, Ph.D., Decision Sciences Institute, Pacific Institute for Research Evaluation, 1005 Main Street Pawluskate, RI, 02860  
 Rebecca R. Carter, B.A. and Case Western Reserve University School of Medicine, Department of Psychiatry, Division of Child Psychiatry, WO Walker Building, 10524 Euclid Ave., Cleveland, OH, 44106  
 J. Scott Tonigan, Ph.D., The University of New Mexico, Center on Alcoholism, Substance Abuse, and Addiction, 2050 Yale SE, Albuquerque, NM, 87106  
 Maria E. Pagano: maria.pagano@case.edu

**Abstract**  
 This study investigates the 10-year course and impact of AA-related helping (AAH), step-work, and meeting attendance on long-term outcomes. Data were derived from 276 inpatient-working alcoholics recruited from an inpatient unit in Project MATCH and followed for 10-year post-treatment. Alcohol consumption, AA participation, and other-related behavior were assessed at baseline, end of 6-month treatment period, and one-year three years, and 10-year post-treatment. Controlling for explanatory baseline and time-varying variables, results showed significant direct effects of AAH and meeting attendance on reduced alcohol outcomes and a direct effect of AAH on improved other-related interest.

**Keywords**  
 Alcoholics Anonymous; Project MATCH; Meeting Attendance; Step-work; AA-related helping

**INTRODUCTION**  
 Alcoholics Anonymous (AA) has distinguished itself within the alcohol problems arena through its membership size and geographical dispersion (more than 2.1 million members

Correspondence to: Maria E. Pagano, maria.pagano@case.edu

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# Medications for alcohol dependence

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## Alcohol Metabolism and Disulfiram

Ethanol → Acetaldehyde → C02

(1) (2)

1: **alcohol dehydrogenase:**  
 • M>W; younger>older; protective  
 • metabolizes 1 drink/hour

2: **aldehyde dehydrogenase:**  
 • Detoxifies acetaldehyde  
 • Inhibited by Disulfiram (Antabuse)



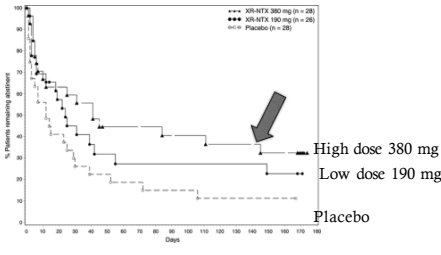
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## Naltrexone (Rivea®, Vivitrol)

- Blocks the opiate (μ) receptor
- Prevents you from using opiates
- Also blocks your endogenous (own) opiates: endorphins
- Opiate receptors responsible for alcohol craving
- Oral naltrexone: Has been shown to reduce drinking (but only in research studies)

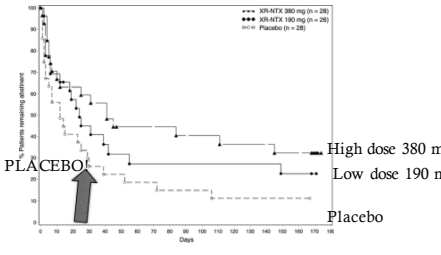
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## Injectable naltrexone: O'Malley 2007

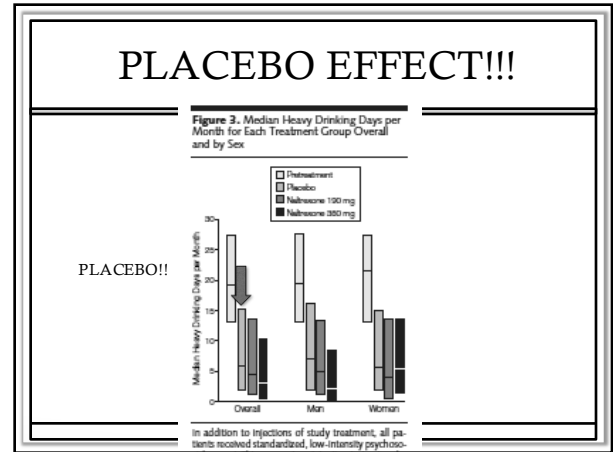
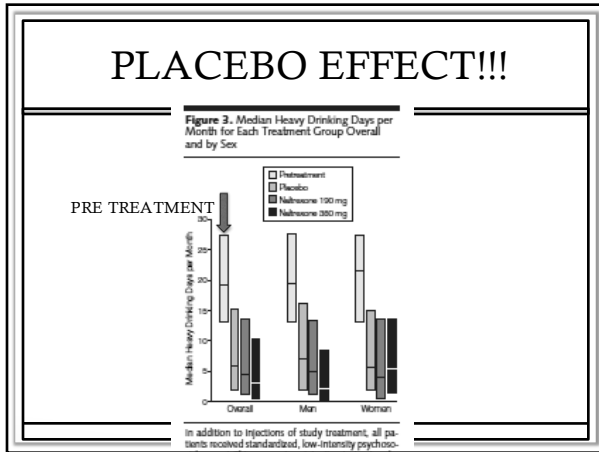


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## Injectable naltrexone: O'Malley 2007



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### Acamprosate (Campral®)

- Thought that it worked through GABA
- Not known how it works-NMDA/Glutamate
- May decrease “number of drinking days”
- May reduce craving
- Often being used by patients being admitted to detox units.

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### The COMBINE trial

- Combinations of:
  - CBT
  - Placebo medication
  - Naltrexone
  - Acamprosate

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### COMBINE Trial: take a pill!!!!

- Patients receiving naltrexone or CBI + placebo had higher percent days abstinent (80.6 and 79.2) compared to the other groups; the combination of naltrexone and CBI was not more effective (77.1) than either intervention alone.
- Acamprosate, alone or combined with naltrexone or CBI, was not more effective than placebo.

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### The Sinclair Method: “pharmacologic extinction”

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### The Sinclair Method:

“pharmacologic extinction”

- Taking/injecting naltrexone BEFORE you stop drinking leads to craving→relapse.
- Taking oral naltrexone one hour before drinking leads to extinction of reward (pleasure)
- Other activities are not affected
- Claims better response than with abstinence based tx.
- NOT designed for those who should not drink at all!

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### Baclofen

- Used for muscle spasticity in spinal cord injuries
- Acts similar to alcohol and benzodiazepines, but binds to its own site in the brain.
- Withdrawal cannot be treated; withdrawal seizures may occur
- Has been used at high doses for alcohol dependence.
- Reports of decrease in daily drinking with high dose.
- Reports of poisoning with high dose.

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### Why Treat Addiction?

**Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation**

A. Thomas McLellan; David C. Lewis; Charles P. O'Brien; et al.  
JAMA. 2000;284(13):1689-1695 (doi:10.1001/jama.284.13.1689)

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### Drug Dependence, a Chronic Medical Illness: McLellan 2000

- Only about 40% of patients will be abstinent at one year after treatment.
- Failure rates may be due to lack of aftercare, often due to insurance difficulties
- Low economic status, psych comorbidity and lack of family/social supports also predict relapse.
- Relapse is often viewed as “inevitable” and drug dependence as “hopeless”\*

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### Drug Dependence, a Chronic Medical Illness: McLellan 2000

- ONLY 60% OF TYPE I DIABETICS ADHERE TO MEDICATION SCHEDULE
- LESS THAN 40% OF ASTHMATICS ADHERE TO TREATMENT REGIMEN
- LESS THAN 40% OF HYPERTENSIVES ADHERE TO THEIR TREATMENT REGIMEN
- DRUG DEPENDENCE =40 TO 60% ADHERENCE

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### Addiction: a chronic illness

- If you were to stop taking your insulin, and you wound up in a coma in the ICU, your doctor would say:
- “you need to go back on insulin! You could have died!”
- If you were to stop your Suboxone/methadone/12 step treatment, and wind up in the ICU, your doctor would say:
- “You’re an addict. You’re hopeless!!!!”

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**Chronic, Treatable but  
Incurable Diseases**

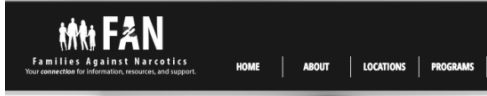
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- Obesity
- Hypertension
- Diabetes
- Asthma
- Addiction

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**Families Against Narcotics**

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**NORTHWEST WAYNE**

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**Contact info: Carl  
Christensen**

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- [ccmdphd@mac.com](mailto:ccmdphd@mac.com)
- Voice mail: 734 448 0226
- Christensen Recovery Services:  
[www.christensenrecovery.com](http://www.christensenrecovery.com)

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