Best Practices (and worst) in OBOMT - 2013

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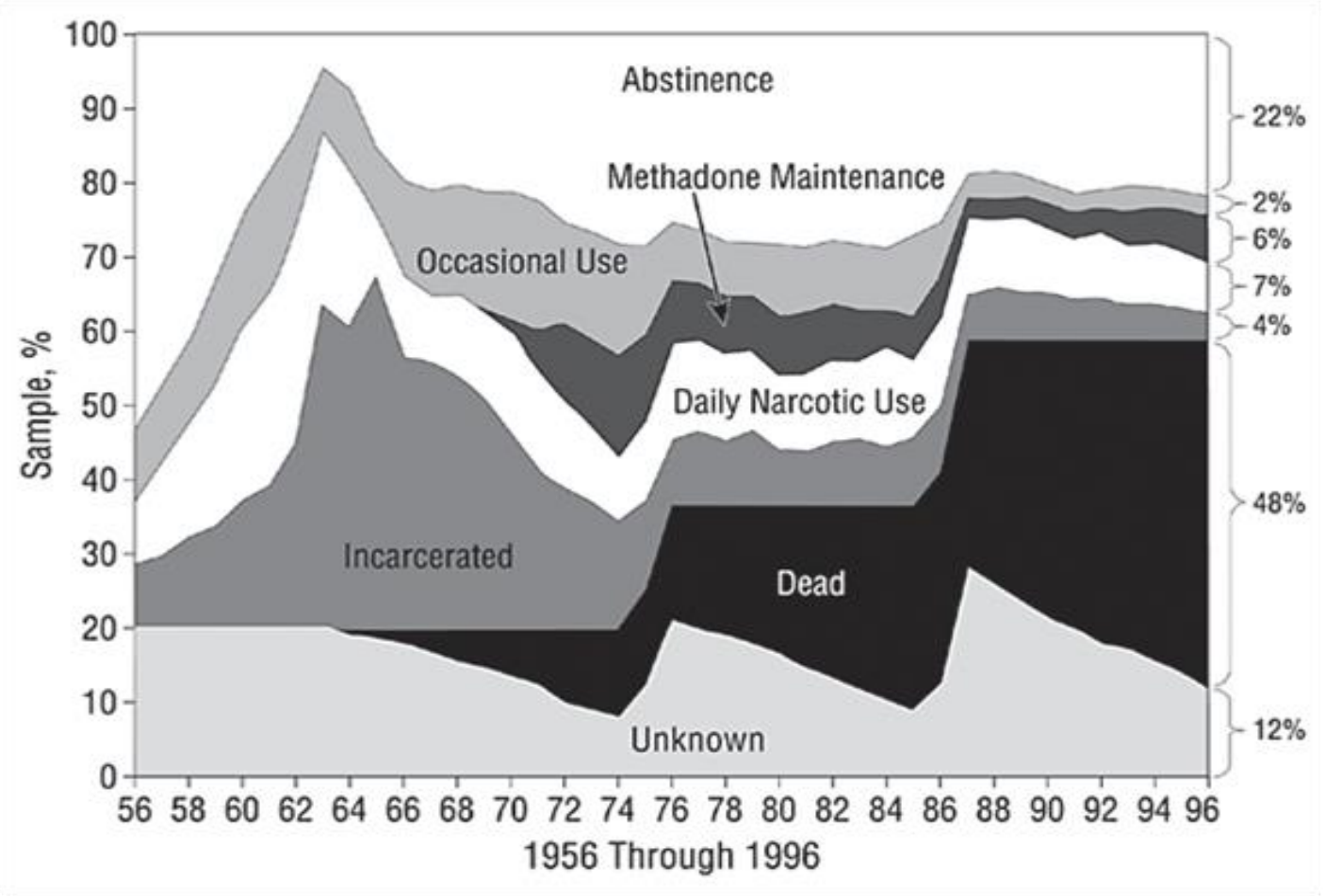
The Natural History of Opioid Addiction:
A public health perspective on the disease of addiction



The Natural History of Opioid Addiction

- High mortality rate
- High incarceration rate
- High relapse rate

BUT ALSO …

- More than 50% eventual “sobriety” rate (if you include stable OMT with abstinent as “sober”)

SO THE GOAL IS …

- Keep them alive, increase sobriety and decrease relapse!

HX of Pharmacotherapy of Addiction

- History of Pharmacotherapy:
  - Secobarbital then Librium (valium … ativan … xanax … klonapin … son of klonapin …)
  - Antabuse
- Risks: Addiction / OD / unsafe / distraction from TX
- No wonder the recovering community is concerned about pharmacotherapy.
- Those who fail to learn from history - **repeat it**.

Treating Addiction as a chronic brain disease - the challenge

- Study the natural history
- Implement screening strategies (CAGE)
- Practice presenting the diagnosis (SOAPE)
- Assess patient's readiness for change
- Negotiate treatment plans
- **Develop comfort with pharmacotherapy**
- Strategies for long-term monitoring

The Pharmacotherapy of Addiction

- "To Prescribe or Not to Prescribe, My Dear Watson … That is the Question!"

- Two Models:
  - THE "***HARM REDUCTION***" MODEL
  - THE "***TREATMENT IMPROVEMENT***" or "***ADJUNT TO TREATMENT***" MODEL

"To Prescribe or Not to Prescribe" : The ***Harm Reduction*** Approach

- Pharmacotherapy first – Addiction TX second
- Criteria that must be met:

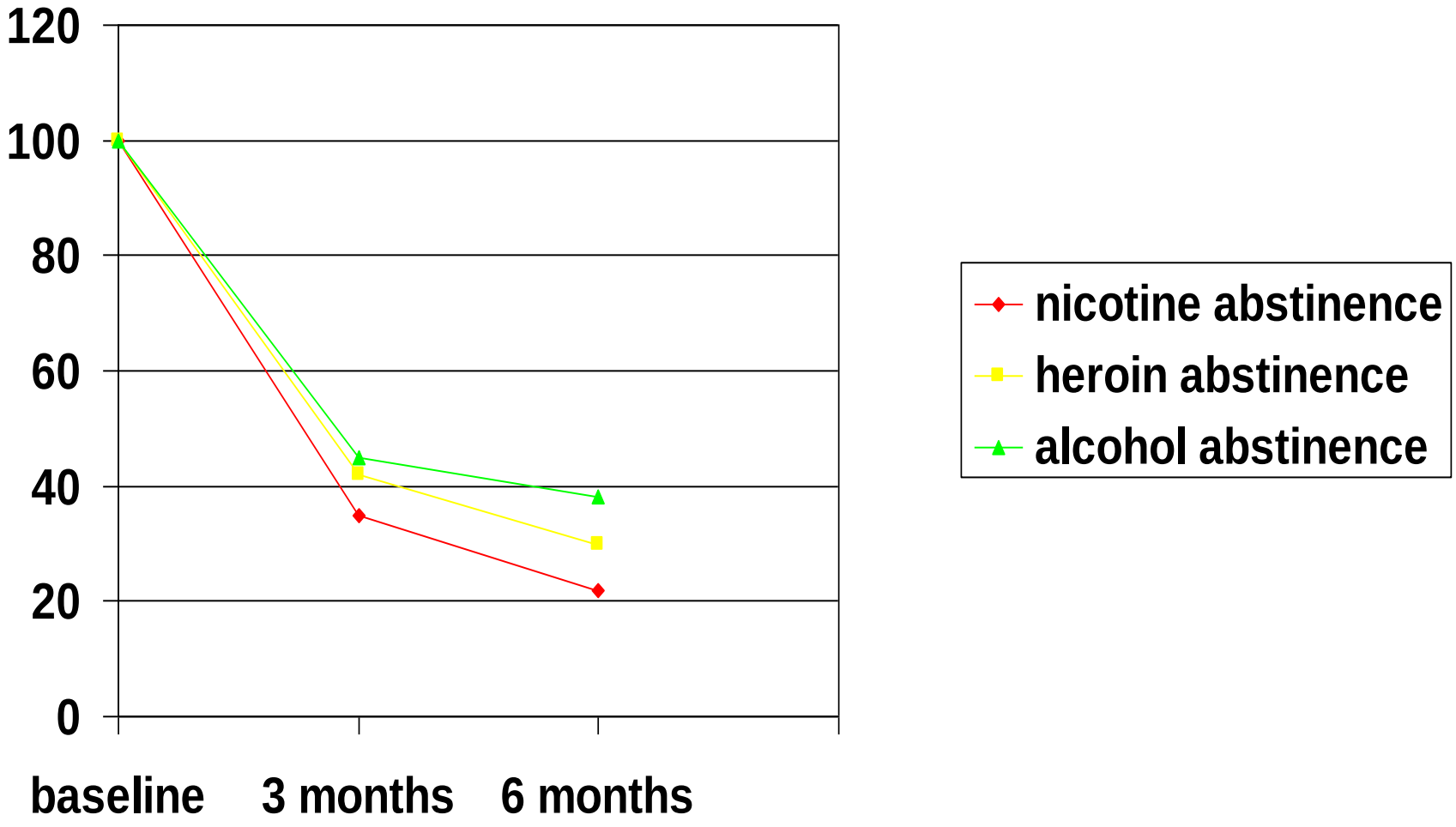
If there is more morbidity in the population ***without*** the pharmacotherapy than there is ***with*** the pharmacotherapy … then provide the pharmacotherapy!

(and gradually introduce additional suggested adjuncts to the pharmacotherapy that might further decrease the morbidity).

"To Prescribe or Not to Prescribe" : The ***Adjunct to Treatment*** Approach

- Addiction TX first – Pharma second
- Criteria that MUST be met:
  - SAFE
    - SOBRIETY / PHYSICALLY / RELAPSE
  - EFFICACIOUS
  - WELL TOLERATED
  - INTEGRATED INTO TX PROGRAM
  - ?? NON-EUPHORIA PRODUCING

Addiction Relapse Rates: ***Duration*** of RX

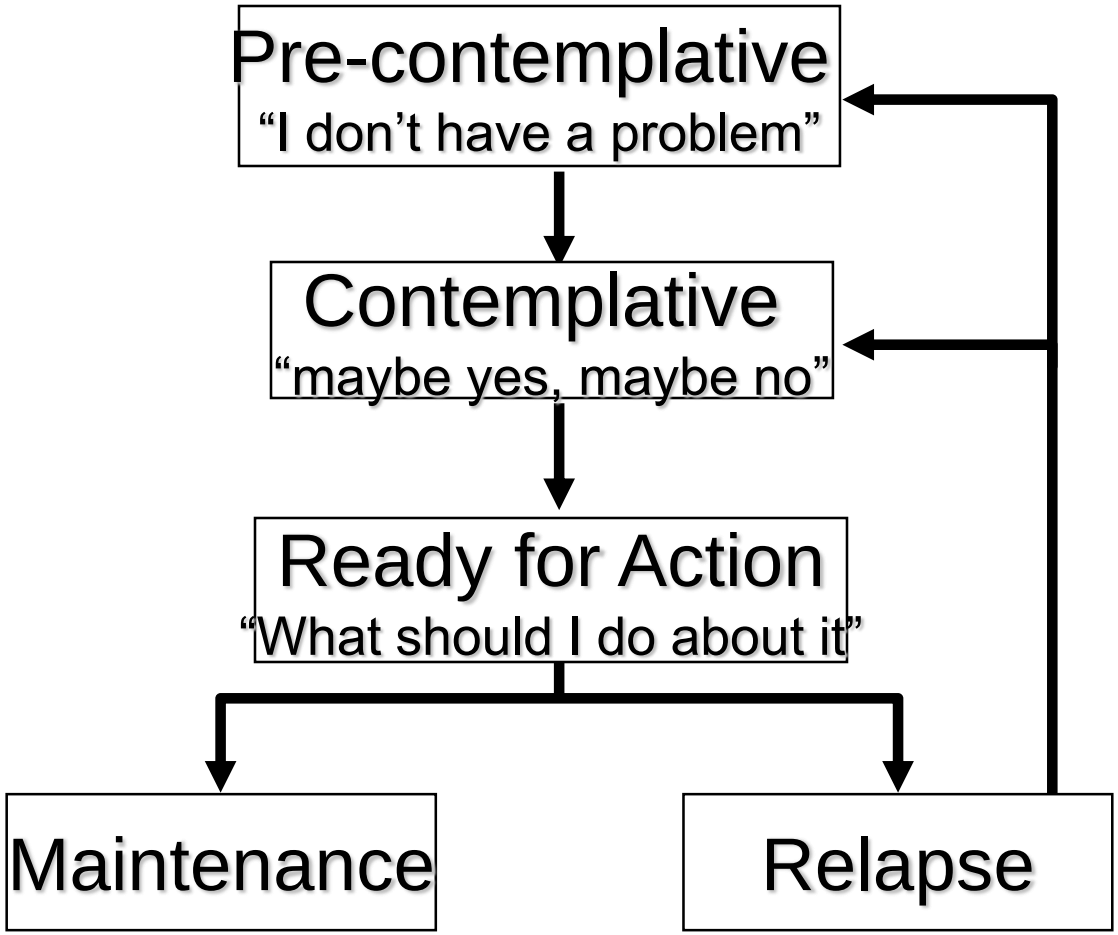


RX for Addiction: ***Duration*** of RX

- Methadone maintenance data:
  - In patient doing well
  - Duration of *two years* or longer
  - Produced improvements in morbidity
- AA data:
  - Lead in Home Group after one year
  - Sponsor others after *two years*

Presenting the Diagnosis

Assessing Readiness



Pharmacotherapy options in opioid addiction

- Opioid antagonist
  - Oral naltrexone
  - Injected naltrexone
  - Combination of oral and injected naltrexone
- Opioid agonist therapy
  - Stabilization and taper
  - Maintenance
- Which agonist to use?
  - Methadone program
  - Buprenorphine program

Opioid Antagonist Therapy

- Oral naltrexone:
  - Advantages: easy, anyone can RX, only involves RX, higher blood levels, less cumbersome, much cheaper, works three times a week to daily.
  - Disadvantages: lower compliance, only demonstrated to have reasonable compliance in coerced populations (i.e. probationer and physician studies)
  - Must be built into parole / probationary language
  - Must have “supervised self admin” in IOP / aftercare
  - Must have “observed self-admin” at PO visits

Opioid Antagonist Therapy

- Injected naltrexone:
  - Advantages: once monthly injections document compliance, gives the sense of control (for the Medical Board / PO / Court), no need to deal with supervised / observed administration.
  - Disadvantages: riskier (it is a procedure), lower blood levels, much more expensive, tricky re: insurance coverage, not many injection centers.
  - Must be built into parole / probationary language

Opioid antagonist therapy - summary

- Easier and cheaper oral by RX
- Monitoring simpler by injection
- ALL patients who are NOT on methadone or buprenorphine SHOULD be on either injection or oral naltrexone
- It MUST be required by probation / parole
- Can medications be required by the Courts?
  - **Require FULL adherence with the treatment plan … then only use treatment programs that routinely put it in the treatment plan.**

Opioid agonist therapy

- Intoxication with opioids (and nicotine) does not produce significant judgment impairment.
- Discrete receptor system (like nicotine, and unlike alcohol, cocaine / amphetamines)
- Potential for replacement therapy -
  - nicotine replacement therapy
  - opioid maintenance therapy
- Is it "*A DRUG FOR A DRUG*"?
  - Yes of course
  - If used right it is "*a medication to help with a sobriety program*" (or to provide harm reduction)

Opioid agonist data

- Duration of therapy -
  - When should people get off?
  - Longer = better.
  - > 1.5 years better than < 1.5 years.
- Need for comprehensive longitudinal gradual approach.
- Need ultimate goal of abstinence.
- Once off an agonist, all patients should take antagonist for 6-24 months.

Opioid agonist maintenance data

- Opiate agonist maintenance therapy, on balance results in improvement in every domain of life function -
  - family
  - health
  - legal
  - employment
  - financial

Longitudinal Monitoring Strategies

- Re-assess patient readiness for change q3m (pre-cont. and contemplative stage patients)
- Periodic liver function and toxicology tests
- Assess participation in Tx. Prog. (release)
- Obtain patient and collateral report of use
- Monitor pharmacotherapy-get indicated labs
- Document, document, document

Opioid maintenance therapy: METHADONE

- Developed in 1960's.
- Licensed in early 1970's.
- The most regulated drug in history.
- The most researched addiction treatment modality in history.
- The most misunderstood addiction tx. ever.

Opiate agonist therapy - methadone

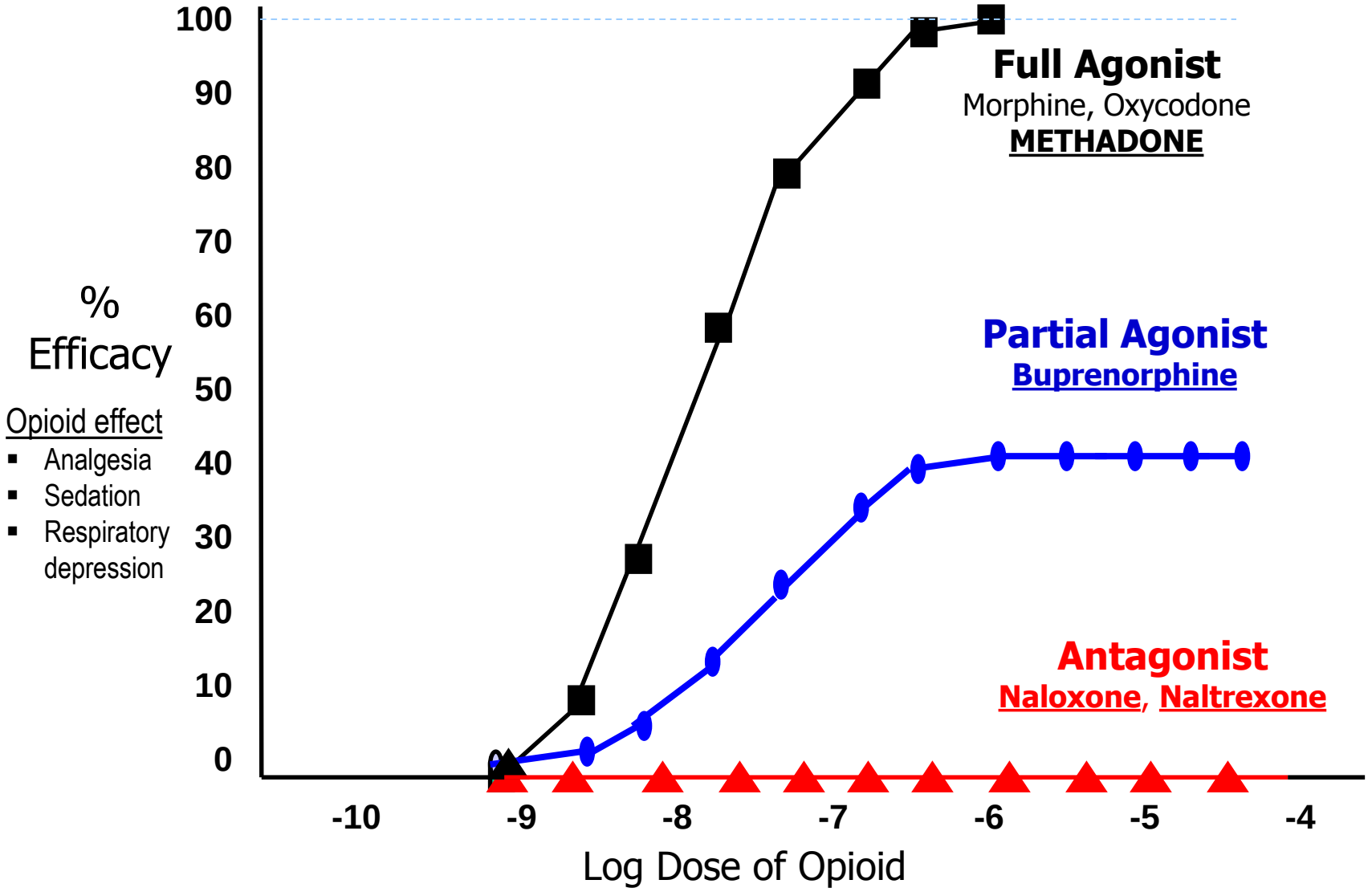
- A “GOOD” methadone program:
  - Release of information for all health care / social service / legal providers … with frequent contact
  - Tox screening monthly or more often – results avail.
  - Counseling
  - Open treatment plan … harm reduction v. abstinence
  - Which treatment goal should be CLEAR (and shared)
  - Dose =/< 120mg/d
  - Discourage other controlled RX drugs (benzos etc.)
  - Increasing intensity of treatment over time if non-adherent

OBOMT – “the highest risk prescribing that is still legal”

OBOMT = Office Based Opioid Maintenance Treatment

(Sl Buprenorphine)

Opioid Intrinsic Activity



SL-Buprenorphine = OBOMT

- 1986 initial research for role in OMT.
- 1 mg Bup ~ 20 – 50 mg morphine (re: **analgesia**)
- Bup originally CV and now CIII (re: **euphoria**)
- SL wafers (2/3 potency of IM)
- 2-16 mg/day (up to 32 mg suggested ***in past***)
- Long T ½ (like OrLamm) – can do QOD dosing
- Comparable to methadone
  - pt satisfaction
  - decrease in craving
  - decrease in heroin use

SL burpenorphine v. methadone

- Advantages v. methadone
  - as efficacious / lower abuse potential (not C II) / less withdrawal upon cessation / less dangerous in over-dose
- Disadvantages v. methadone
  - more expensive / less studied / SL not PO / since prescribed and not administered = much much more diversion
- Buprenorphine diversion = relatively therapeutic (used for TX or to avoid W/D)

SL buprenorphine - indications

- Opioid addiction (DSM IV)
- Physiologic dependence to opioids
- Prior attempts at drug free treatment
- Willingness for assessment / monitoring
- Willingness to be referred to counseling
- Lack of buprenorphine contraindications
  - allergy, current meth >40mg/d,
- Can be Harm Reduction OR Adjunct to Abstinence Model (**BUT KNOW YOUR MODEL)**

Monitoring when RX OBOT

- Document *adherence with TX Plan*.
- Titrate OBOT dose – *rarely needed unless **down***.
- Monitor medications (pill counts).
- No additional controlled drugs / EPDS / Benzos
- Avoid non-planned escalation – NO early refills
- Monitor for scams – Cont. Rx Consent Form
- Perform toxicology tests
- Periodic Pharmacy Website checks
- Corroborate HX:

  Get ROI and call: sponsor / family / TX center / PO

OBOT Treatment Plan

- Know your **model** (adj to abst v. harm red)
- Full adherence with TX Plan
  - Bio-Psycho-Social-Spiritual disease and tx.
  - Take medications as prescribed
  - No additional EPDS – licit / illicit / RX
  - Work a recovery program – counseling / self help activities / patient support
  - If slip or relapse, return to the next level of care

Sl. Bup & what we have learned = ***potency***

- Potency re: PAIN: 1 mg sl-buprenorphine = 20 - 50mg PO Morphine.
- Potency re: EUPHORIA: C III (now), C V (before)
- Potency / dose implications: LOWER doses
  - 2mg -12mg OK for MOST, 16mg per day typical max
- Potency / taper implications:
  - keep dose low and go slow
  - 1st 1/3 dose = 1-2mg/month, 2nd 1/3 1mg/month, last 1/3 0.5 to 1mg/month.
  - Use PRN meds for W/D sx (clonidine / ?tramadol / non-C meds for sleep / NO BENZOS

Rosary Hall/SVCH OBOMT Program

- ADJUNCT TO ABSTINENCE PROGRAM
- Brief inpatient induction (23-48H)
  - Addiction assessment/H&P/Tox & Labs/TX Plan
- Intensive Opt (IOP) – 3h/session, 4Xwk, 6weeks
- Aftercare – 1 ½ h/session, 1Xwk, 12 weeks
- 3 AA meeting/wk, sponsor and home group
- Biweekly OBOMT Clinic for 6 weeks, then monthly
- UDS Q1-3 months random / OARRS check quarterly
- Lack of full adherence – return to next higher LOC

Results: B*uprenorphine/Naloxone Status*

- 18 mo. F/U 77% still remained on B/NOBT
- Those still using Bup/Nx were:
  - 24% Less likely to be relapsed (p=0.01)
  - 21% Less likely to be using heroin (p=0.004)
  - 29% More likely to be AA Affiliated (p=0.02)
  - 31% More likely to have a sponsor (p=0.03)
  - **8%** More likely to have been employed at baseline (p=0.03).
  - **30%** More likely to be employed at follow-up (p=0.03)

Results: *Psycho-social outcome measures*

- Those remaining on Bup/Nx use at follow-up were Less likely to have reported
  - Damaging a close relationship (26 v. 52%, p=0.01)
  - Doing regretful or impulsive things (28 v. 52%, p=0.03)
  - Hurting family (28 v. 60%, p=0.004)
  - Experiencing negative personality changes (26 v. 48%, p= 0.04)
  - Failing to do things expected of them (24 v. 56%, p=0.002)
  - Taking foolish risks (21 v. 56%, p=0.0008)
  - Being unhappy (27 v. 60%, p=0.002)
  - Having spent too much/lost money (27 v. 52%, p=0.02)
  - Were significantly less likely to report having money problems generally (29 v. 56%, p=0.02).

Low SES Patient Additional Data

- Low SES Patients – like a Medicaid Pop.
- 2 yr. induction on grant at 16mg/d Subox
- Budget cut
- 2 yr. induction on grant at 8mg/d Subox
- Treatment retention
  - Induction / residential / IOP / aftercare / clinic
- Retention ***EXACTLY*** the same on 8 v. 16!

OB-OMT – Concerning MD Behaviors

- High dose – "Green / Yellow / Red Light"
  - High dose, low supervision, harm reduction all seem to markedly increase risk of diversion
- "Off label" use for pain management
- CASH for OV … but let insurance pay RX
  - If NO bill for OV, but bill for RX – INVESTIGATE
  - If doc bills for other services but not for OBOT – fraud?
  - What if you suspect fraud?
    - #1 - Certified letter from ***insurer's legal counsel***
    - #2 - Report to Medical Board for ethics violation
    - #3 - Consider formal fraud investigation

Summary – OB-OMT

- Treatment Philosophy:
  - Harm Reduction V. Adjunct to recovery program
- Readiness for behavior change: for RX ***AND*** TX
- Well rounded TX Plan
- Dose bup. typically </= 16mg/d, certainly not > 24mg/d
- A VARIETY of doses … not one size fits all
- Duration of TX:
  - Stabilize/detox, several days or weeks = no good data
  - Maintenance - >/= two years
  - Taper after maintenance ~ 0.5-2 mg/month

Summary – OB-OMT (cont)

- Robust monitoring program necessary
  - Optimize adherence
  - Increase patient sobriety and quality of life
  - Minimize diversion
- Sl-bup diversion:
  - "therapeutic diversion" per investigators
  - "substantial financial cost" to insurers
  - Most is excess medicine due to ***too high a dose***
  - No prescribers can continue to be "ostriches" re: this

Summary – OB-OMT (cont)

- Generic "Subutex" – safe to switch to AFTER period of demonstrated adherence
- ***NO*** "Off label" use for pain management!
  - If there is addiction and pain – "on label"
  - If no addiction and just pain – ***way*** too expensive!!
- Be vigilant for "Concerning MD Behaviors" and intervene with them or through their medical / pharmacy boards