DO NOT CONFUSE

NALOXONE

Can be bought without a prescription in many states

NALTREXONE

Cannot be bought without a prescription

[USES]

NALOXONE

- Injected into a patient suffering from an opioid overdose
- Works rapidly to take the effect of the drug away
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- Is primarily used as alcohol and drug recovery treatment
- It has been in use for over 30 years
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Overview of medications for OUD: utilizing assessment tools like COWS

John Paul Moses III, MBA, MSN, RN, APRN-Rx, FNP-BC, CARN-AP
Ryan Nakamura, BA

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HAWAIʻI HEALTH & HARM REDUCTION CENTER

The New Chapter for Life Foundation and The CHOW Project

Reducing Harm, Promoting Health, Creating Wellness and Fighting Stigma in Hawaii and the Pacific

DISCLOSURE STATEMENT

I, MOSES, JP & Nakamura, R. have a financial interests, arrangements, or relationships that could be perceived as a conflict of interest within the context of this presentation: Primary Care Plus and Psychiatric Associates, entities owned in part by me, receive referrals from HHHRC when patient elects to be seen in Aiea.

One Definition of Harm Reduction

Harm reduction is a philosophy and set of strategies for working with individuals engaged in potentially harmful behaviors. The main objective is to reduce the potential dangers and health risks associated with such behaviors, even for those who are not willing or able to completely stop. Harm reduction uses a non-judgmental, holistic and individualized approach to support incremental change and increase the health and well-being of individuals and communities.

- Pupukahi I Holomua, Harm Reduction Conference Planning Committee, Honolulu, HI 2009

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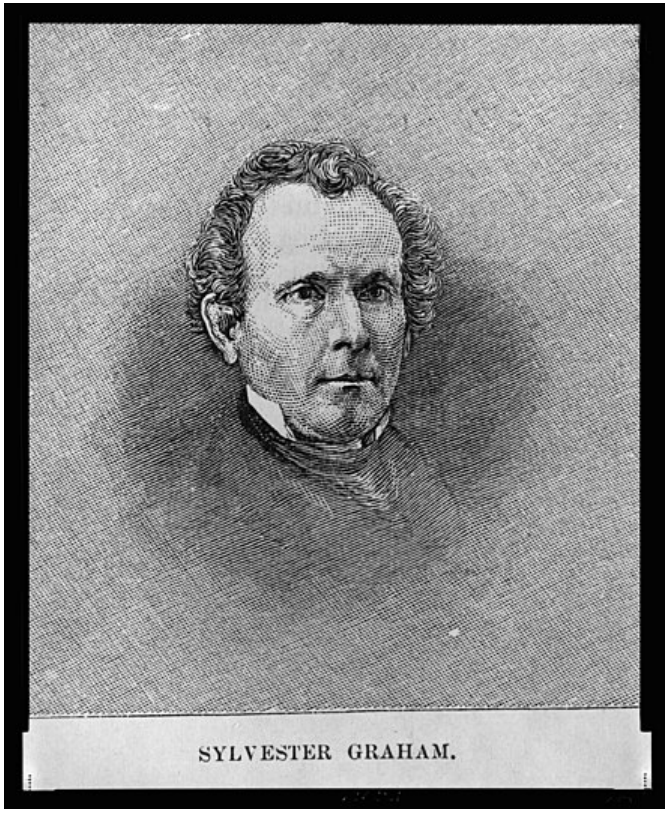


1820 – Philadelphia Temperance Movement

HISTORICAL PERSPECTIVE

DEFINITIONS

- SUD - chronic, progressive, fatal brain disease characterized by:
  - compulsive drug craving, seeking and use despite harmful consequences
  - MAT – Medication Assisted Treatment
    - AKA TREATMENT
  - Drug of choice – the patients' preferred substance – hint – patients are not always honest, Use ADAD

Sources-(National Institute on Drug Abuse, 2008) (Monroe, Kenaga, Dietrich, Carter, & Cowan, 2009) (DuPont, McLellan, White, Merlo, & Gold, 2013)

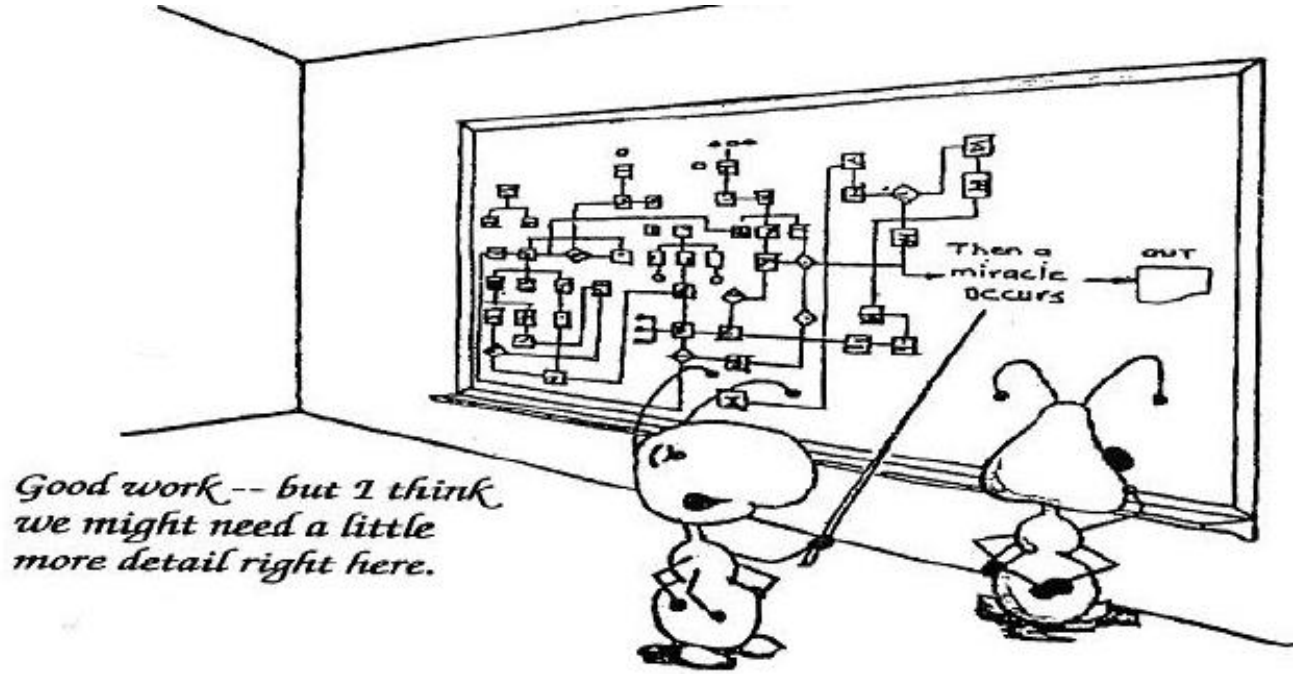
DEFINITIONS

Substance (drug) dependence- abuse of drugs or alcohol that continues even when significant problems related to their use have developed.

Signs of dependence include:

- Tolerance to or need for increased amounts of the drug to get an effect
- Withdrawal symptoms that happen if you decrease or stop using the drug that you find difficult to cut down or quit
- Spending a lot of time to get, use, and recover from the effects of using drugs
- Withdrawal from social and recreational activities
- Continued use of the drug even though you are aware of the physical, psychological, and family or social problems that are caused by your ongoing drug abuse

Sources-(National Institute on Drug Abuse, 2008) (Monroe, Kenaga, Dietrich, Carter, & Cowan, 2009) (DuPont, McLellan, White, Merlo, & Gold, 2013)


Then a miracle occurs
OUT
Good work -- but I think we might need a little more detail right here.

40 Million

18 Million

4.2 Million

1.8 Million

1.8 Million

426,000

400,000

Nicotine
Alcohol
Marijuana (THC)
Cocaine
Heroin
Benzodiazepines

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FDA APPROVED PHARMACOTHERAPIES FOR SUD

- Tobacco – nicotine replacement, varenicline, buPROPion
- Alcohol – disulfiram, acamprosate, naltrexone
- Opioid – methadone, buprenorphine, naltrexone

Source-Douaihy, A. B., Kelly, T. M., & Sullivan, C. (2013). Medications for substance use disorders. Social work in public health, 28(3-4), 264–278. doi:10.1080/19371918.2013.759031

BEST PRACTICE

- Pharmacotherapies
- Professional Behavioral Therapies
- Mutual Assistance Groups/Programs

Source-(National Institute on Drug Abuse, 2019)

Opioids

Opiate (n)

"An unlocked door in the prison of identity. It leads to the jail yard."

Ambrose Bierce
The Devil's Dictionary **(1906)**

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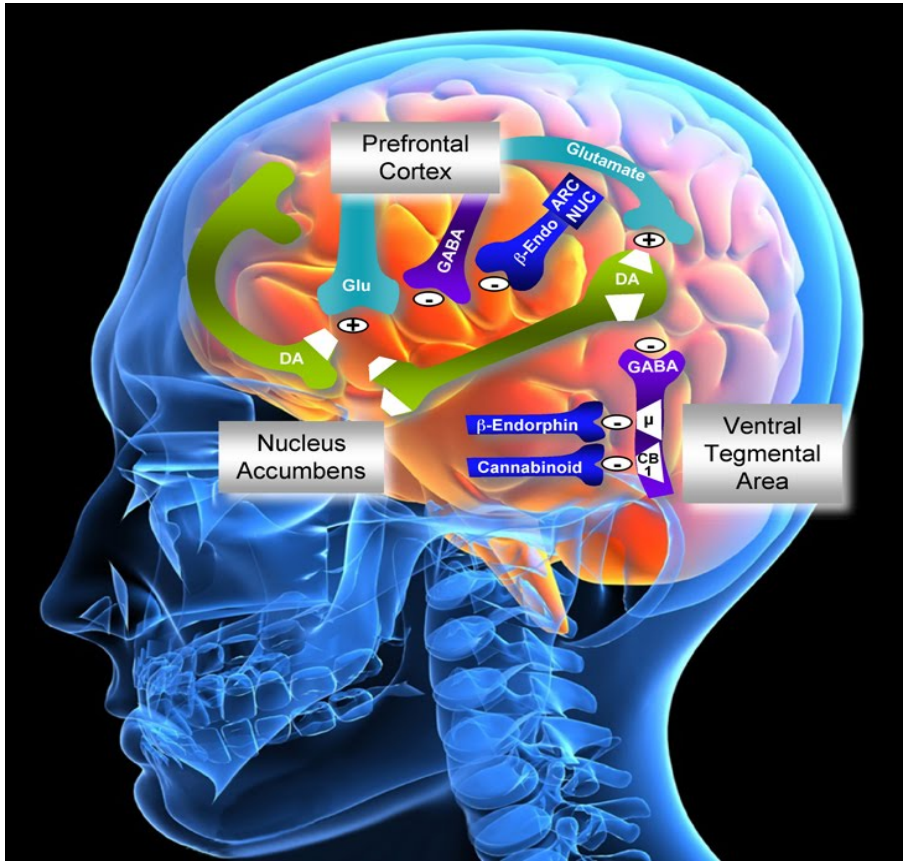
System Structure

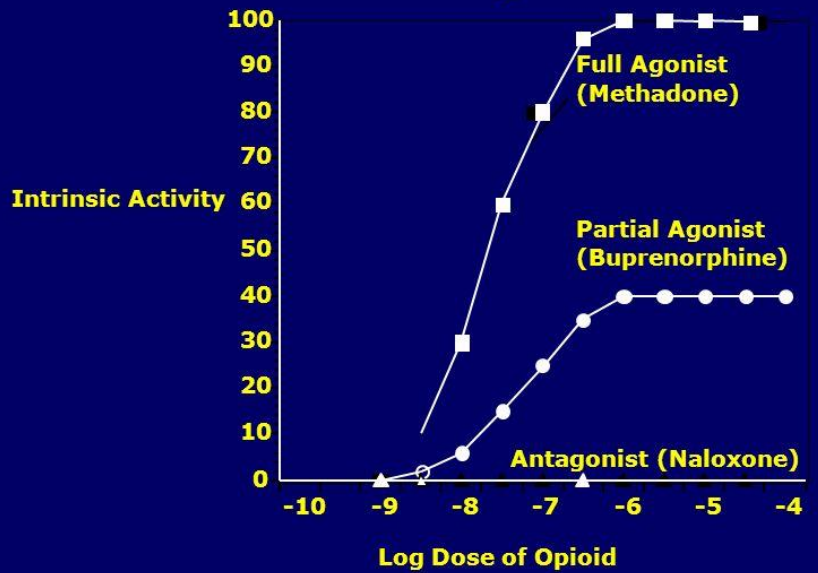


Sources- (Abuse., 2008; McClure & Bickel, 2014; National Institute on Drug Abuse (NIDA), 2015)

PHARMACOLOGICAL ASSISTANCE - OPIOIDS

- Vivitrol® (injectable **naltrexone**)
  - 30 day IM injection (compliance)
- Suboxone® (buprenorphine and naloxone)
  - Mu and kappa opioid receptor modulators
  - Partial agonist
  - Also used for pain control
- Methadone
  - Mu receptor agonist – no “ceiling effect”
  - Kappa receptor agonist too – start bowel plan EARLY

Intrinsic Activity: Full Agonist, Partial Agonist and Antagonist



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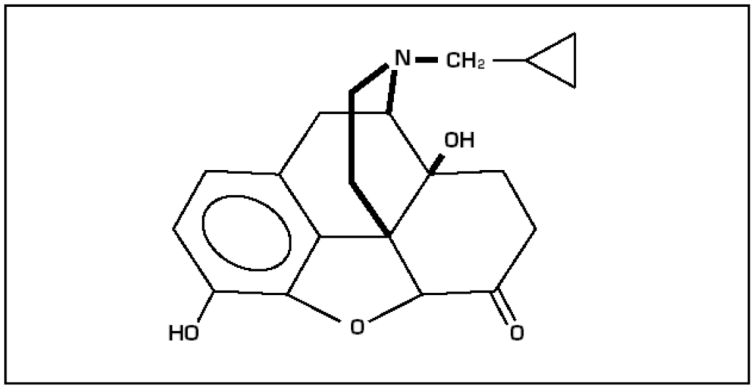
- It has been in use for over 30 years
- Injected and slowly released into the body

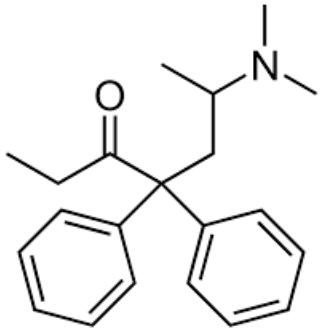
Naltrexone/Vivitrol®

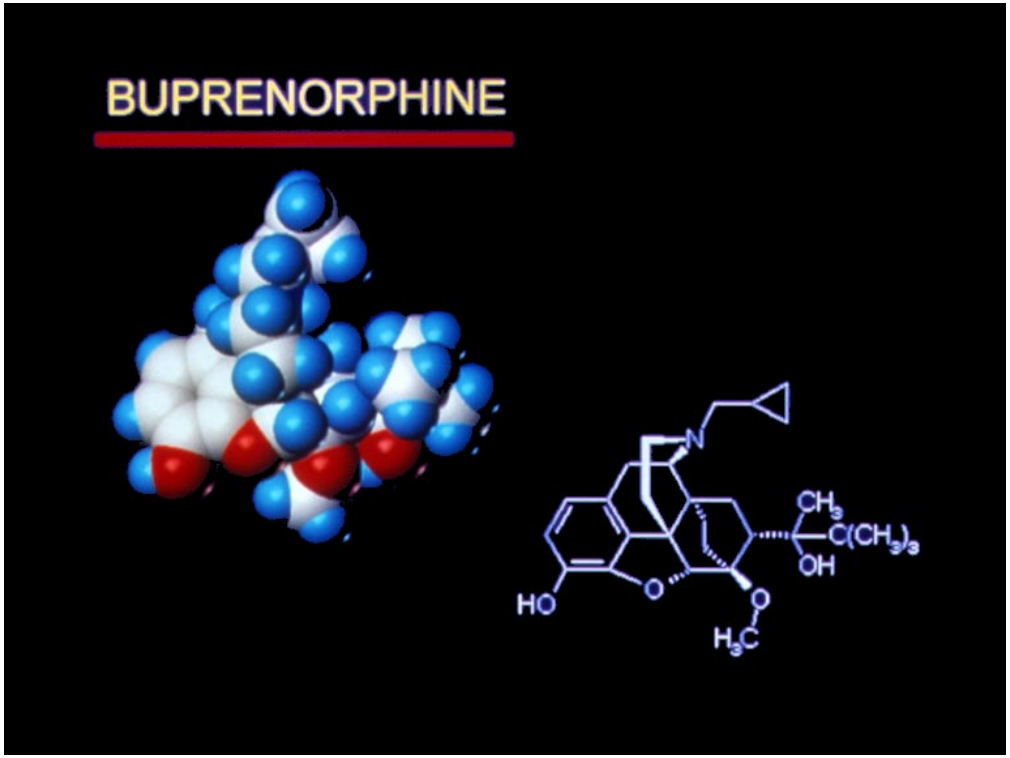
- Mu, kappa, and delta opioid receptor antagonist
- Indications:
  - Prevention of relapse to opioid dependence, following opioid detoxification
  - Treatment of alcohol dependence
- “Harm reduction is to abstinence as Suboxone is to Naltrexone”
- Vivitrol® ~ long acting injectable



Methadone

- Mu opioid receptor agonist - no “ceiling effect”
- Kappa opioid receptor agonist too - start bowel plan EARLY
- Longest half life of prescribed opioids
- Indications:
  - Moderate to severe pain non-responsive to non-narcotic drugs
  - Detoxification and treatment of OUD
- Tolerance and paresthesia





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FORMULATIONS

Formulation	Route	Indication
Buprenorphine + naloxone		
Suboxone	Sublingual film	Opioid use disorder
Zubsolv	Sublingual tablet	Opioid use disorder
Bunavail	Buccal film	Opioid use disorder
Buprenorphine		
Subutex	Sublingual tablet	Opioid use disorder
Belbuca	Buccal film	Pain management
Buprenex	Intravenous	Pain management
Butrans	Transdermal patch	Pain management
Probuphine	30-day subcutaneous implant	Opioid use disorder

Suboxone® - buprenorphine/naloxone

Company: Reckitt Benckiser
Approval Status: Approved October 2002
Specific Treatments: Opiate Dependence
Off Patent: 2018

SubLOCADE® & pROBUPHINE

Sublocade™
(buprenorphine extended-release)
injection for subcutaneous use Ⓒ
100mg·300mg

Probuphine®
(buprenorphine) implant Ⓒ

300 mg monthly for the first 2 months following induction and dose adjustment with transmucosal buprenorphine

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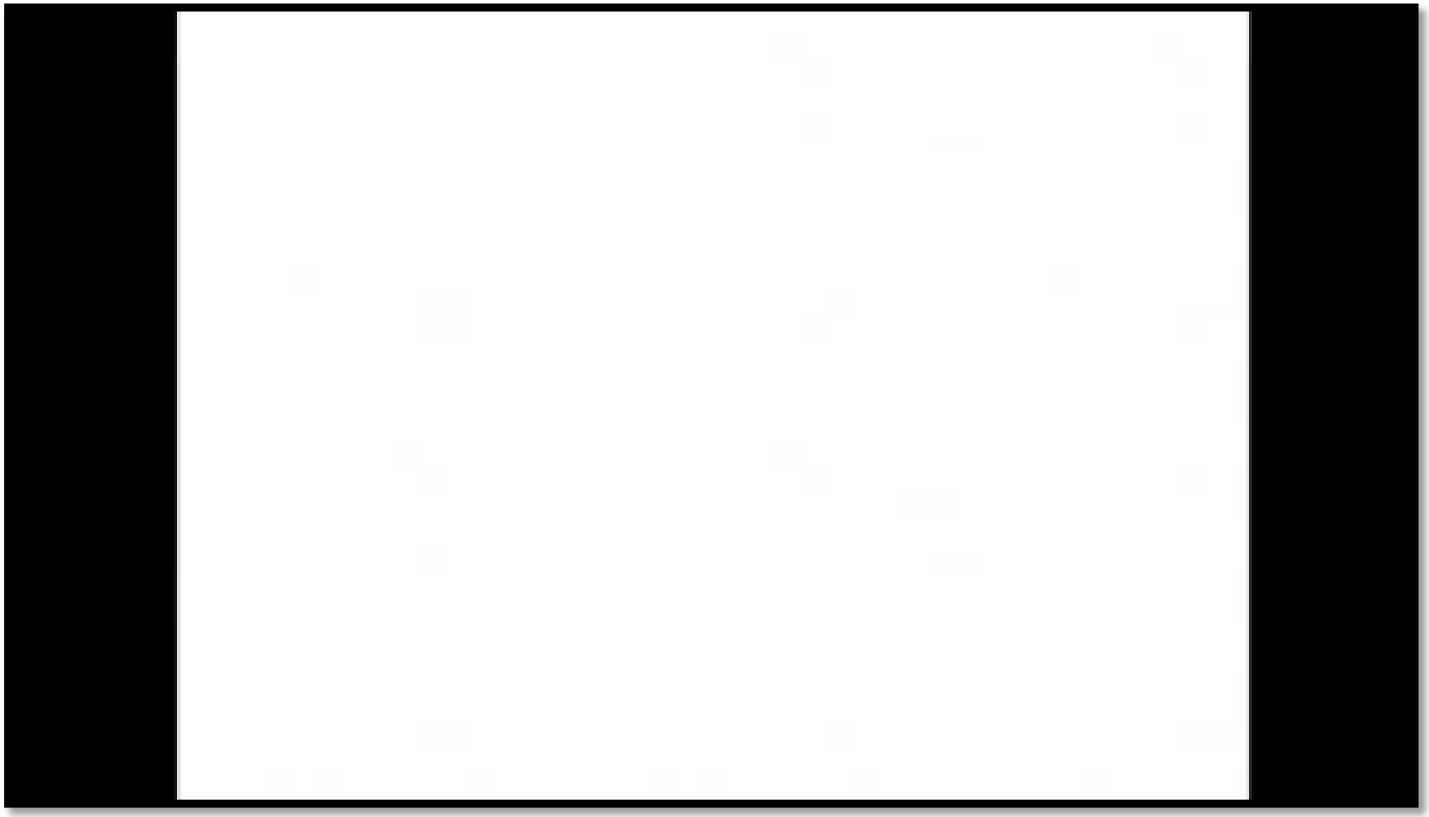
Mechanism Of Action



INDUCTION

- Measure withdrawal, several scales available such as:
  - Clinical Opioid Withdrawal Scale (COWS 12–16 is mild/moderate and appears sufficient to avoid precipitated withdrawal)
- Hours of abstinence since last full mu opioid use
- 12-16 short-acting, 17-24 intermediate-acting, 30-48 methadone
- BUP dose: 2 – 4mg initial, 16mg max day #1
- Monitor: 1+ hours
- Follow-up: phone + visit in 3 – 4 days

Clinical Opioid Withdrawal Scale

- Inpatient/Outpatient tool used to rate s/sxs of opioid withdrawal
- Helps determine severity of withdrawal
- Subjectivity vs. Objectivity
  - Be conservative!
- Symptoms present similar to severe flu infection
- Used for in-office buprenorphine inductions

Appendix A - Clinical Opioid Withdrawal Score (COWS)

PATIENT NAME:	DATE OF ASSESSMENT:
PATIENT DATE OF BIRTH:	MEDICAL RECORD NUMBER:

Clinical Opioid Withdrawal Score (COWS)

For each item, write in the number that best describes the patient's signs or symptom. Rate only the apparent relationship to opiate withdrawal. *For example: If heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.*

Enter scores at time zero, 30 minutes after first dose, 2 hours after first dose, etc.	Time:	Time:	Time:	Time:
Resting Pulse Rate: *Record beats per minute after patient is sitting or lying down for one minute* • 0 - pulse rate 80 or below • 1 - pulse rate 81–100 • 2 - pulse rate 101–120 • 4 - pulse rate greater than 120				
Sweating: *Over past ½ hour not accounted for by room temperature or activity* • 0 - no chills or flushing • 1 - subjective chills or flushing • 2 - flushed or observable moistness on face • 3 - beads of sweat on brow or face • 4 - sweat streaming off face				
Restlessness: *Observation during assessment* • 0 - able to sit still • 1 - reports difficulty sitting still, but is able to do so • 3 - frequent shifting or extraneous movement of legs/arms • 5 - unable to sit still for more than a few seconds				
Pupil size • 0 - pupils pinned or normal size for light • 1 - pupils possibly larger than normal for light • 2 - pupils moderately dilated • 5 - pupils dilated that only rim of the iris is visible				
Bone or joint aches: *If patient was having pain previously, only the additional component attributed to opiate withdrawal is scored* • 0 - not present • 1 - mild/diffuse discomfort • 2 - patient reports severe diffuse aching of joints/muscles • 4 - patient is rubbing joints or muscles and is unable to sit still because of discomfort				
Runny nose or tearing: *Not accounted for by cold symptoms or allergy* • 0 - none present • 1 - nasal stuffiness or unusually moist eyes • 2 - nose running or tearing • 4 - nose constantly running or tears streaming down cheeks				
GI upset: *Over last ½ hour* • 0 - no GI symptoms • 1 - stomach cramps • 2 - nausea or loose stool • 3 - vomiting or diarrhea • 5 - multiple episodes of diarrhea or vomiting				
Tremor: *Observation of outstretched hands* • 0 - no tremor • 1 - tremor can be felt, but not observed • 2 - slight tremor observable • 4 - gross tremor or muscle twitching				
Yawning: *Observation during assessment* • 0 - no yawning • 1 - yawning once or twice during assessment • 2 - yawning three or more times during assessment • 4 - yawning several times/minute				
Anxiety or irritability • 0 - none • 1 - patient reports increasing irritability or anxiousness • 2 - patient obviously irritable or anxious • 4 - patient so irritable or anxious that participation in the assessment is difficult				
Gooseflesh skin • 0 - skin is smooth • 3 - piloerrection of skin can be felt or hairs standing up on arms • 5 - prominent piloerrection				
5—12 = mild; ***13—24 = moderate;*** ***25—36 = moderately severe;*** ***> 36 = severe withdrawal*** **TOTAL** OBSERVER INITIALS				

Journal of Psychoactive Drugs Volume 35 (2), April - June 2003Source: Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *Psychoactive Drugs, 35*(2), 253–9.

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Anecdotal Case Review

- Patient is a 51yo Native Hawaiian/caucasian female who was referred to us from CARES line
- Telehealth consult set up with assistance from patient's sister
- Last oxycodone use 8/13
  - Telehealth conducted 8/16
- COWS initially scored at **38** (severe withdrawal) at 10:40AM
  - Medications ordered and picked up by sister
- One film of Suboxone 8/2mg taken at 12:48PM
- Second film of Suboxone 8/2mg taken at 1:48PM
- Recommended third film of Suboxone 8/2mg as needed if symptoms persist
- COWS scored at **5** at 3:32PM
- No withdrawal symptoms reported at 1 week f/u appointment
  - Taking 1/2 film QID (16/4mg per day)

Maintenance

- Treatment contract
- Sole provider for Scheduled medications
- Staged interval increasing
- Random UDS with mass spectrometry confirmation
- Dose range usually 8mg to 24 mg per day
- Consider long term therapy benefit

TAPERING

- Shared decision-making
- Support systems in place
- Criteria for returning to previous dose
- Consider other psychoactive medications to treat comorbidities as they appear
- What is desired outcome (abstinence v harm reduction)

THE SYSTEMS VIEW

Figure 8.1 An Example of Poor Design

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Ancillary Medications-----PLEASE!

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WITHDRAWAL MEDICATION IS NOT TREATMENT

- EXAMPLES
  - Use of withdrawal medications will be discussed at the end if we have time.
  - Examples: chlordiazepoxide, ondansetron, folic acid, thiamine, hydroxyzine PAMOATE, Topiramate, gabapentin, alprazolam

Source-Douaihy, A. B., Kelly, T. M., & Sullivan, C. (2013). Medications for substance use disorders. Social work in public health, 28(3-4), 264–278. doi:10.1080/19371918.2013.759031

Ancillary Medications

Ondansetron – antiemetic

- MOA - serotonin (5-HT3) receptor antagonist, which decreases vagal stimulation
- First line antiemetic for most withdrawal syndromes
- Adverse effects
  - QT prolongation
  - serotonin syndrome
  - headache
  - constipation

Ancillary Medications

Hydroxyzine Pamoate (Not HCL) - Antihistamine

MOA for anxiety - competes with histamine for binding at H1-receptor sites on the effector cell surface. The sedative properties of hydroxyzine occur as a result of suppression of certain subcortical regions of the brain. Secondary to its central anticholinergic actions, hydroxyzine may be effective as an antiemetic

ADR/SE - Dry mouth (pilocarpine?)

- Drowsiness (usually transitory, improves with tolerance
- Involuntary motor activity (tremor, convulsions) usually with doses considerably higher than those recommended
- Clinically significant respiratory depression has not been reported at recommended doses

Ancillary Medications

Topiramate – Anti-seizure
WITHDRAWAL and MOOD MANAGEMENT – OFF LABEL!

1. Blocks voltage-dependent sodium and calcium channels.
2. Inhibits the excitatory glutamate pathway while enhancing the inhibitory effect of GABA.
3. Moreover, it inhibits carbonic anhydrase activity. (The relevant mechanism of action responsible for efficient migraine prophylaxis remains to be determine)

Tiredness, drowsiness, dizziness, loss of coordination, tingling of the hands/feet, loss of appetite, bad taste in your mouth, diarrhea, and weight loss may occur

MANY CURRENT RESEARCH STUDIES ON OTHER USES FOR THIS MEDICATION. IT IS ALREADY SHOWING PROMISE IN WEIGHT LOSS, ALCOHOL/OPIOID/BENZO WITHDRWAL AND MOOD DISORDERS

Ancillary Medications

Topiramate – Anti-seizure
WITHDRAWAL and MOOD MANAGEMENT – OFF LABEL!

- Alprazolam is successful in reducing anxiety but has a high addictive/misuse potential.
- Topiramate is a novel anticonvulsant which has been used as a mood stabilizer.
- Other anticonvulsants, such as carbamazepine and valproate, have been used in alcohol and benzodiazepine withdrawal.
- Topiramate has recently been used in alcohol, cocaine and opiates withdrawal.
- There has been also one report of topiramate use in midazolam withdrawal.
- (In our case of a patient with recurrent major depressive disorder, subthreshold anxiety disorder and addiction to alprazolam, topiramate appears to be efficient and safe in alprazolam withdrawal)

Ancillary Medications

Alprazolam - benzodiazepine

Alprazolam (Xanax) - psychoactive drugs that work to slow down the central nervous system by activating GABA receptors. This provides a variety of useful tranquilizing effects. Aside from relieving symptoms of alcohol withdrawal, benzodiazepines are also commonly prescribed to treat insomnia, muscle spasms, involuntary movement disorders, anxiety disorders, and convulsive disorders.

ADR/SE - Drowsiness, dizziness (these effects will be less pronounced after a few days, avoid driving a car or engaging in other dangerous activities if these occur); GI upset (take drug with food); fatigue; depression; dreams; crying; nervousness

Although benzodiazepines have gotten their reputation tarnished over the past 15 years, they are still useful in many cases. As with opioids, I never start a person on benzodiazepines without an exit strategy. When I have a polysubstance abuser, I generally try to address all substance recovery at the same time, including nicotine. The transition from one benzo to another using topiramate is beyond the scope of this lecture, he may see me afterwards as it is off label.

Summary

- All FDA approved medications are to be used as PART of a comprehensive treatment program that includes and mutual support groups
- Buprenorphine and Naltrexone both show promise in multiple harm reduction studies
- Buprenorphine treatment may be initiated by any prescriber who completed special training required by the DATA 2000 (stay tuned for COVID driven changes)

Case Study Introduction

Project ECHO® (Extension for Community Healthcare Outcomes)

SUD/ Harm Reduction in the Community- Initial Case Presentation Form

Presentation Date: 27 Sep 2021 Site: Hawaii Health and Harm Reduction Center Clinician: JP Moses, APRN-Rx, CARN-AP

General Information/Demographics

Patient ECHO ID: MOSES1	**Age:** 57	**Sex at Birth:** ☑ Male ☐ Female	**Gender Identity:** Male
Race: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian / Other Pacific Islander ☑ White			**Ethnicity:** ☐ Hispanic or Latino ☑ Not Hispanic or Latino
Insurance: ☐ None ☐ Medicare ☑ Medicaid ☐ Commercial Health Insurance ☐ Other:_____			

Social history: Housing? N ->Y Employment/ Disabled? Unemployed Other pertinent details: Cell Block encounter 8/8/2019.

HPI- Please list any additional pertinent information about the patient: Opioid use disorder, stimulant dependence with stimulant induced mood disorder, alcohol use disorder, HCV chronic, chronic pain syndrome in right hip r/t MVA, homelessness.

Nicotine Dependence? ☐ Yes ☑ No E-cig use? ☐ Yes ☑ No

<table>
<tr><td>Psychiatric Diagnoses</td><td>☑ Depression ☑ Anxiety ☐ Schizophrenia ☐ Other:
History of hospital admission for BH? ☑ Yes ☐ No Number of times: 3
History of Suicide Attempt? ☑ Yes ☐ No Method/ year: Remote history x3</td></tr>
<tr><td>MH/BH Screening & Assessment</td><td>☐ Mental Status Exam:
<table>
<tr><td>Appearance: Disheveled</td><td>Mood: Depressed</td><td>Memory: Intact</td></tr>
<tr><td>Behavior: Calm/Cooperative</td><td>Affect: Congruent</td><td>Attention: Intact</td></tr>
<tr><td>Motor: Normal</td><td>Thought Process: Linear</td><td>Insight: Good</td></tr>
<tr><td>Speech: Appropriate</td><td>Thought Content: Appropriate</td><td>Judgement: Fair</td></tr>
</table></td></tr>
<tr><td rowspan="3">Substance Use History</td><td>Does the person have a substance use disorder? ☑ Yes ☐ No</td></tr>
<tr><td>If yes, ☑ Alcohol ☑ Opiates ☑ Stimulants ☐ Benzodiazepines ☑ Marijuana
☐ Other:
If yes, date of last use (for each): Alcohol (current), Opiates (7/2021), Methamphetamine (current)</td></tr>
<tr><td>History of injecting drugs? ☑ Yes ☐ No
Does patient utilize syringe exchange program (SEP)? ☑ Yes ☐ No
Narcan Access? ☑ Yes ☐ No</td><td>If yes, Drug of choice & date of last injection drug use:
Heroin & Methamphetamine/July 2021, present</td></tr>
</table>

Body Mass Index	Height: 67in	Weight: 125.1 lbs	BMI: 19.6

Medical Diagnoses		
	☐ Diabetes Mellitus	☐ Hepatitis B, Chronic
	☐ Dyslipidemia	☐ Seizure Disorder
	☐ HIV	☐ Traumatic Brain Injury
	☑ HCV	☑ Other Relevant Diagnoses: HCV, HTN

Current Medications/ Supplements:	Previously Treatments Tried (i.e., detox, residential, meds)
Sublocade 100mg/1.5mL PFS	Residential Tx at Hina Mauka 11/2020
Lisinopril 10mg	Methadone Tx for OUD
Escitalopram 10mg	

Allergies: NKDA

Laboratory

Basic Labs	Date	Results	Basic Labs	Date	Results
WBC	4/29/21	6.12	Alk Phos	5/3/21	124
HBG	4/29/21	13.2 (L)	AST	5/3/21	18
HCT	4/29/21	40.2	ALT	5/3/21	10
Platelets	4/29/21	221	Total Bili	5/3/21	0.2
Creatinine	4/29/21	0.9	AFP	5/3/21	<2.7
GFR	4/29/21	95	HIV Ab	5/3/21	Negative
Glucose	4/29/21	112 (H)	HCV RNA	5/3/21	**Not Det**
Protime/INR	4/29/21	12.7/1.0(L)	HCV Genotype	5/3/21	Cancelled
Total Protein	5/3/21	6.9			
Albumin	5/3/21	4.4			

Other Pertinent Labs

INCONSISTENT RESULTS - DETECTED DRUG/MEDICATION NOT REPORTED				
Analyte Detected	Potential Brand Name Drugs	Amount Detected	Typical Detection Window	Comments
MORPHINE	Avinza, Kadian	16305 ng/ml	1 to 4 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
HYDROMORPHONE	Dilaudid, Exalgo	36 ng/ml	1 to 4 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
CODEINE	Codrix, Tylenol III, Tylenol IV	476 ng/ml	1 to 4 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
NORBUPRENORPHINE	Butrans, Suboxone, Subutex	32 ng/ml	1 to 6 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
METHADONE	Dolophine, Methadose	423 ng/ml	1 to 5 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
EDDP	Dolophine, Methadose	320 ng/ml	1 to 5 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
AMPHETAMINE	Adderall, Vyvanse	1030 ng/ml	1 to 4 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
METHAMPHETAMINE D ISOMER		99.9 %		Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
METHAMPHETAMINE L ISOMER		0.1 %		Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
METHAMPHETAMINE		4217 ng/ml	1 to 4 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
THCA	Marinol, Dronabinol	199 ng/ml		Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
ETHYL GLUCURONIDE		9292 ng/ml	1 to 80 hours after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
ETHYL SULFATE		5741 ng/ml	1 to 80 hours after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
COTININE	Habitrol, Nicotine, Nicotrol	28 ng/ml		Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.

*Urine Toxicology Report from Precision Diagnostic Laboratories 4/3/2020

Consistent Results - Reported Medication Detected			
REPORTED PRESCRIPTION	ANTICIPATED POSITIVES	AMOUNT DETECTED	DETECTION WINDOW
Buprenorphine	Buprenorphine	Positive	
Buprenorphine	Norbuprenorphine	Positive	
Escitalopram (Lexapro)	Citalopram	Positive	
Sublocade	Buprenorphine	Positive	
Sublocade	Norbuprenorphine	Positive	
Inconsistent Results - Expected Positive for Reported Medication			
REPORTED PRESCRIPTION	ANTICIPATED POSITIVES	AMOUNT DETECTED	DETECTION WINDOW
Inconsistent Results - Unexpected Positive			
DETECTED ANALYTE	AMOUNT DETECTED		DETECTION WINDOW
THC	397 ng/mL		

*Urine Toxicology Report from S&G Labs 4/1/2021

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What are the primary questions you have regarding this patient?

1. Harm reduction or abstinence-based model of care?
2. When do we consider the patient in recovery?

Treatment Plan:

- Referred to addiction medicine services by cell block and street outreach teams
- Executed medication management contract and planned for buprenorphine management (no induction necessary)
- Applied for residential treatment at Hina Mauka; ASAM level of care: 3.0
- Transition to Sublocade (LAI) once stable on buccal films
- Harm reduction approach but now focusing on abstinence

Notable Results:

- Hepatitis C treated in clinic and now cured
- Patient compliant with Sublocade monthly and working with a sponsor
- Patient is housed and actively looking for employment
- Stable on Sublocade for approximately 3 months but now using methamphetamine again

The End!