Medication-Assisted Treatment; Saving Lives and Reducing Harm in Our Communities

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Ascension Medical Group

Disclosures

None

Objectives

- Review the current state of the Opioid Crisis
- Discuss the diagnosis of Opioid Use Disorder
- Identify and review the 3 FDA approved evidence based treatments for Opioid Use Disorder
- Review the practical ways a practitioner can provide office based Buprenorphine treatment in their practice

United States Pain Paradigm

- **USA ~4.5%** of world population
- Consume **99%** global hydrocodone
- Consume **73%** global oxycodone
- Consume **2/3** global illicit drugs

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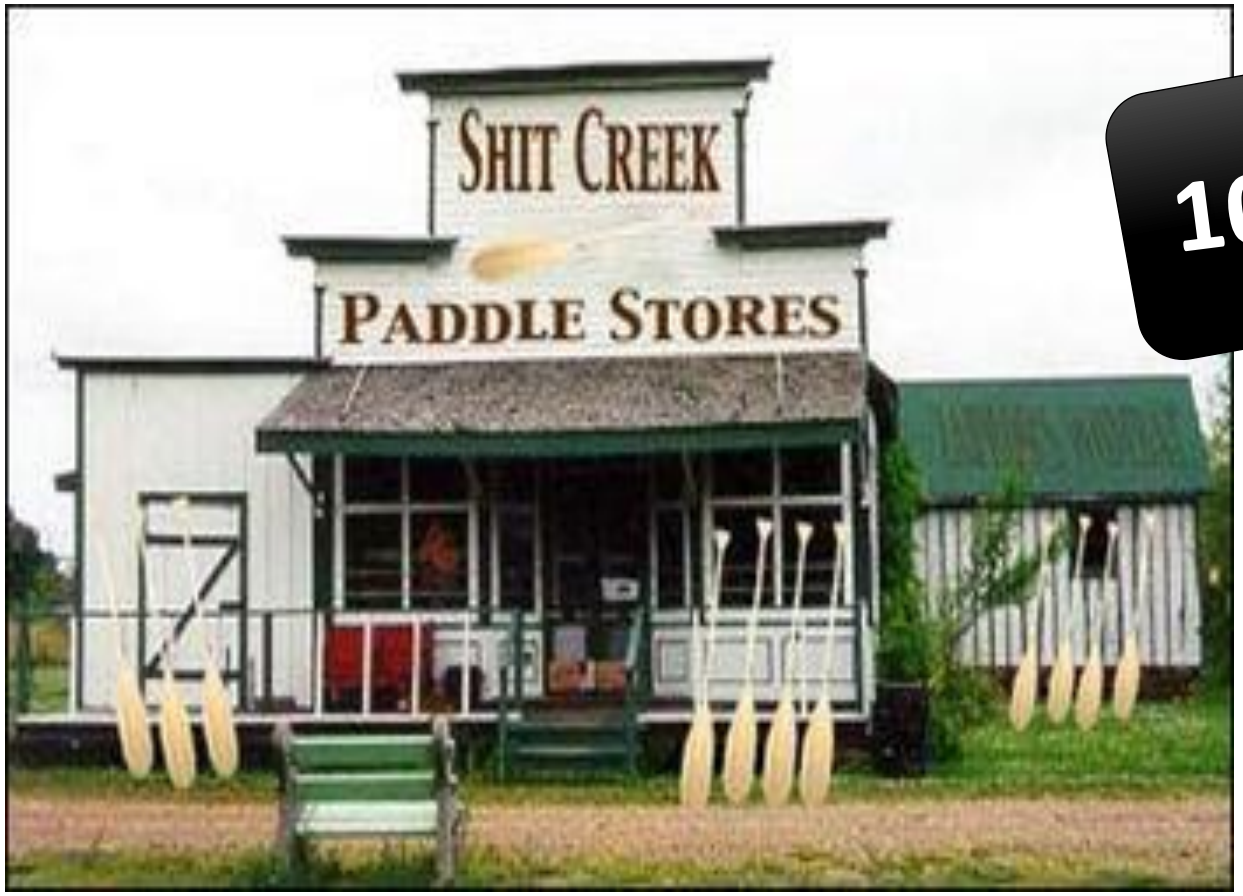
Narcotic Drugs — Estimated World Requirements for 2018 — Statistics for 2016
https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2017/Narcotic_drugs_technical_publication_2017.pdf

Number of Americans on Long-term Opioids



10 Million

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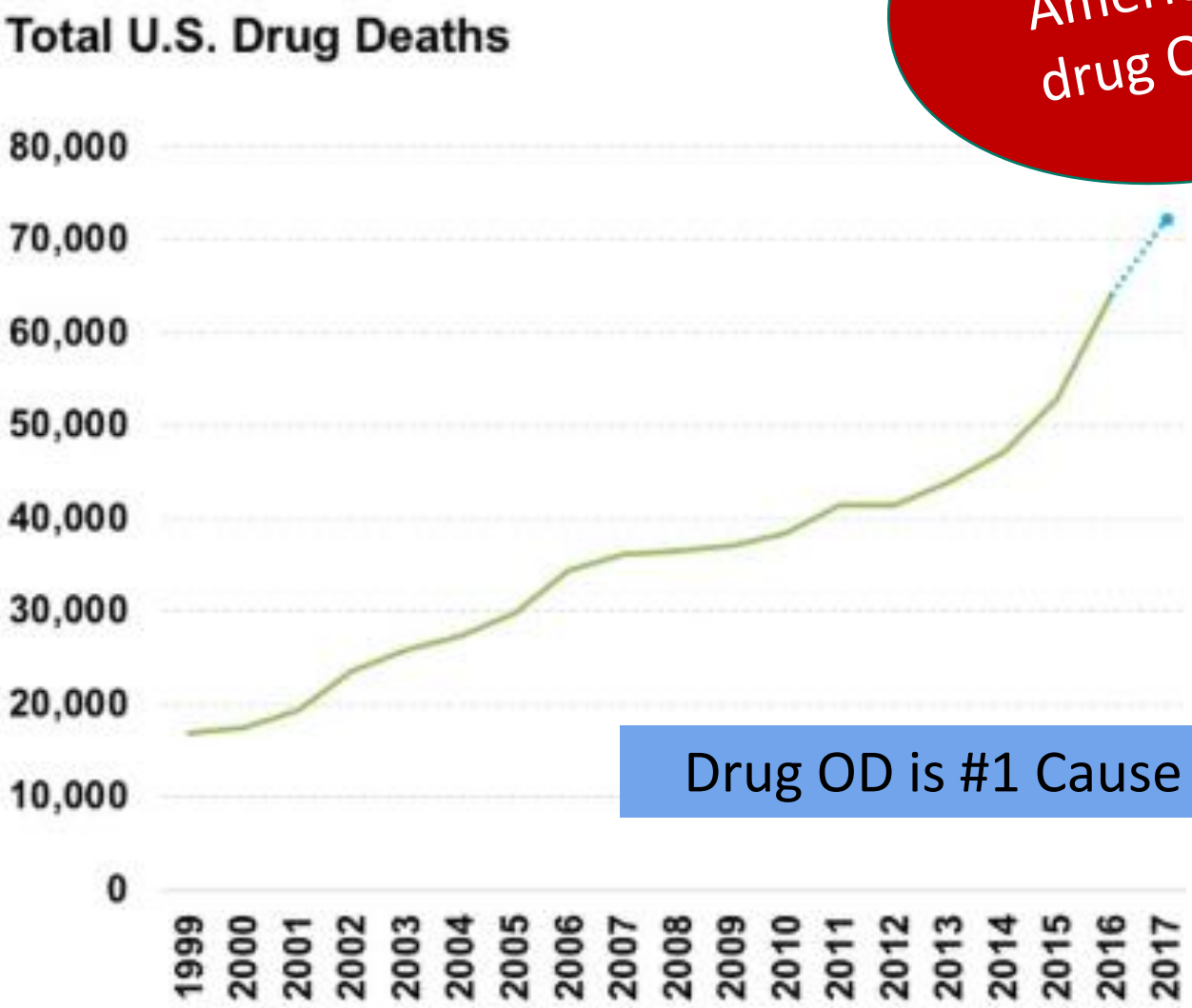
Ann Intern Med. 2017;167:181–191. doi: 10.7326/M17-0598

US Overdose Deaths

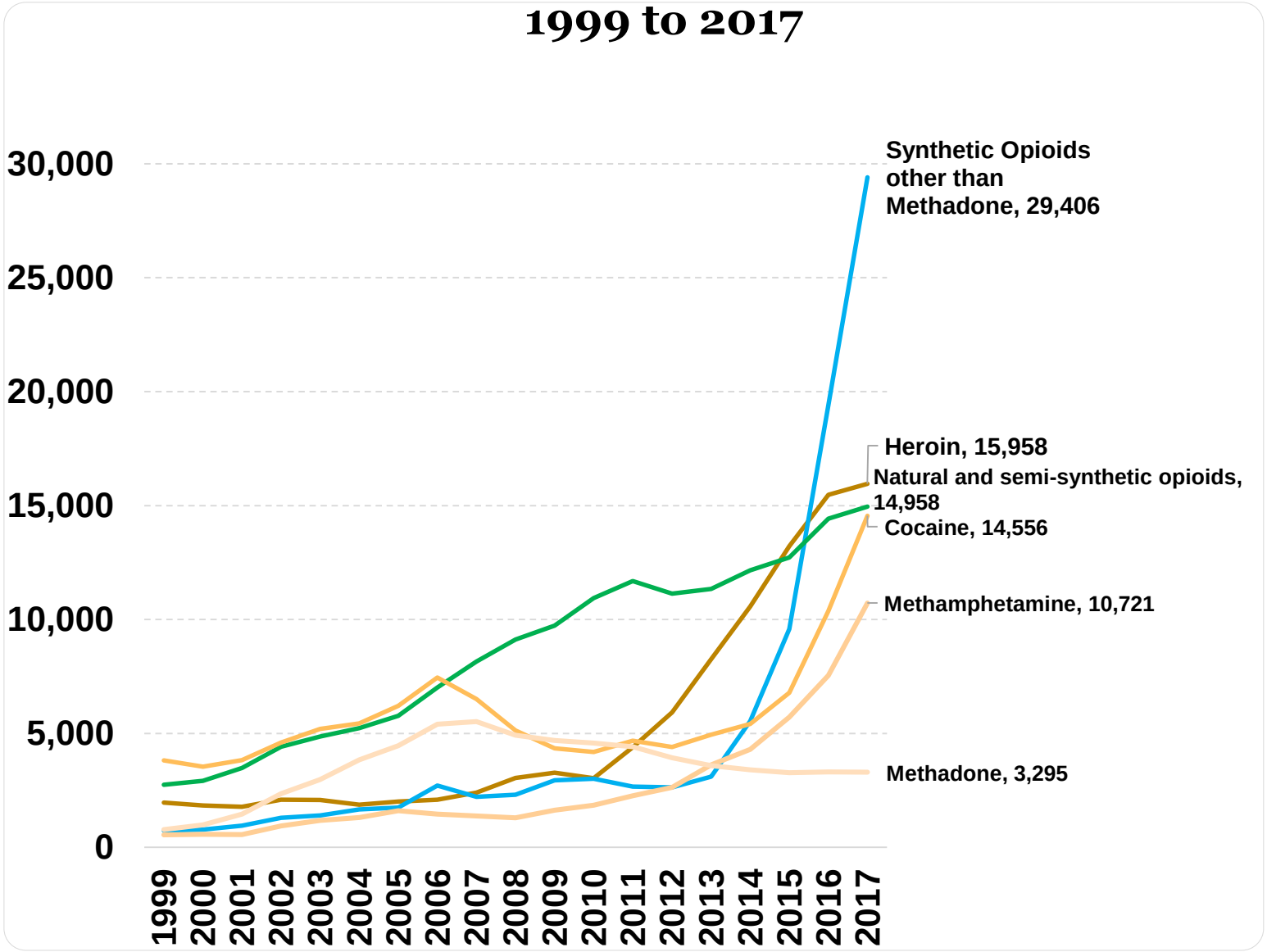
72,000
Americans died from drug OD in 2017



Drug OD is #1 Cause of death <50yo

Drugs Involved in U.S. Overdose Deaths

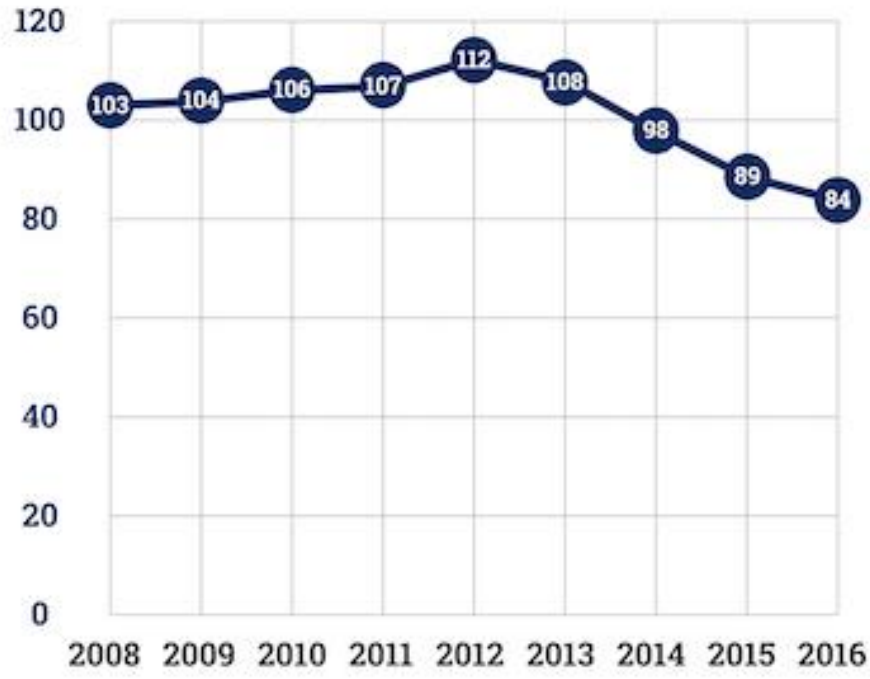
1999 to 2017



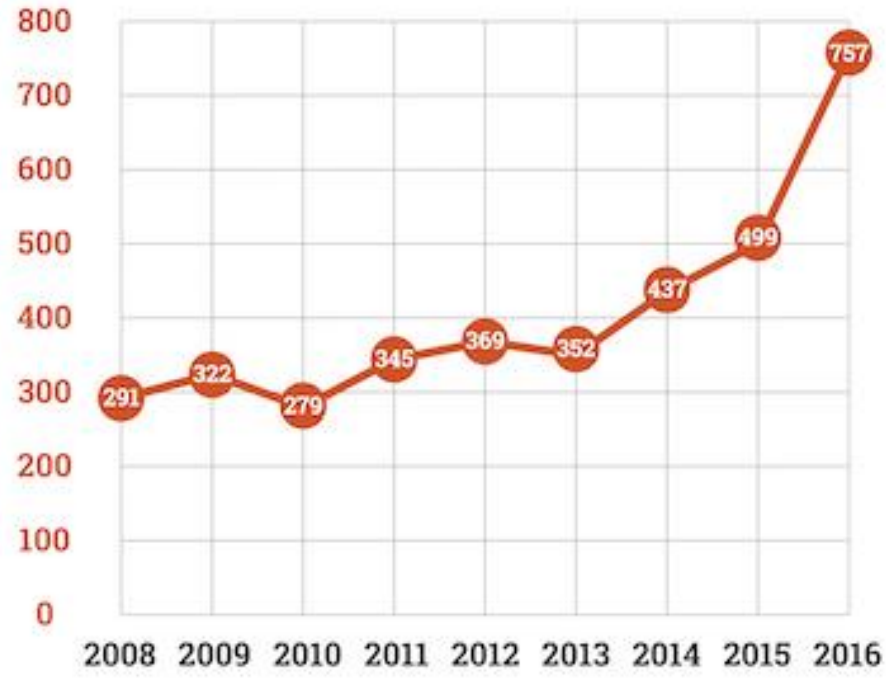
CDC Wonder Data

The Opioid Epidemic in Indiana

Prescriptions per 100 Residents



Opioid Deaths



Source: Centers for Disease Control and Prevention, as calculated by Indiana Management Performance Hub

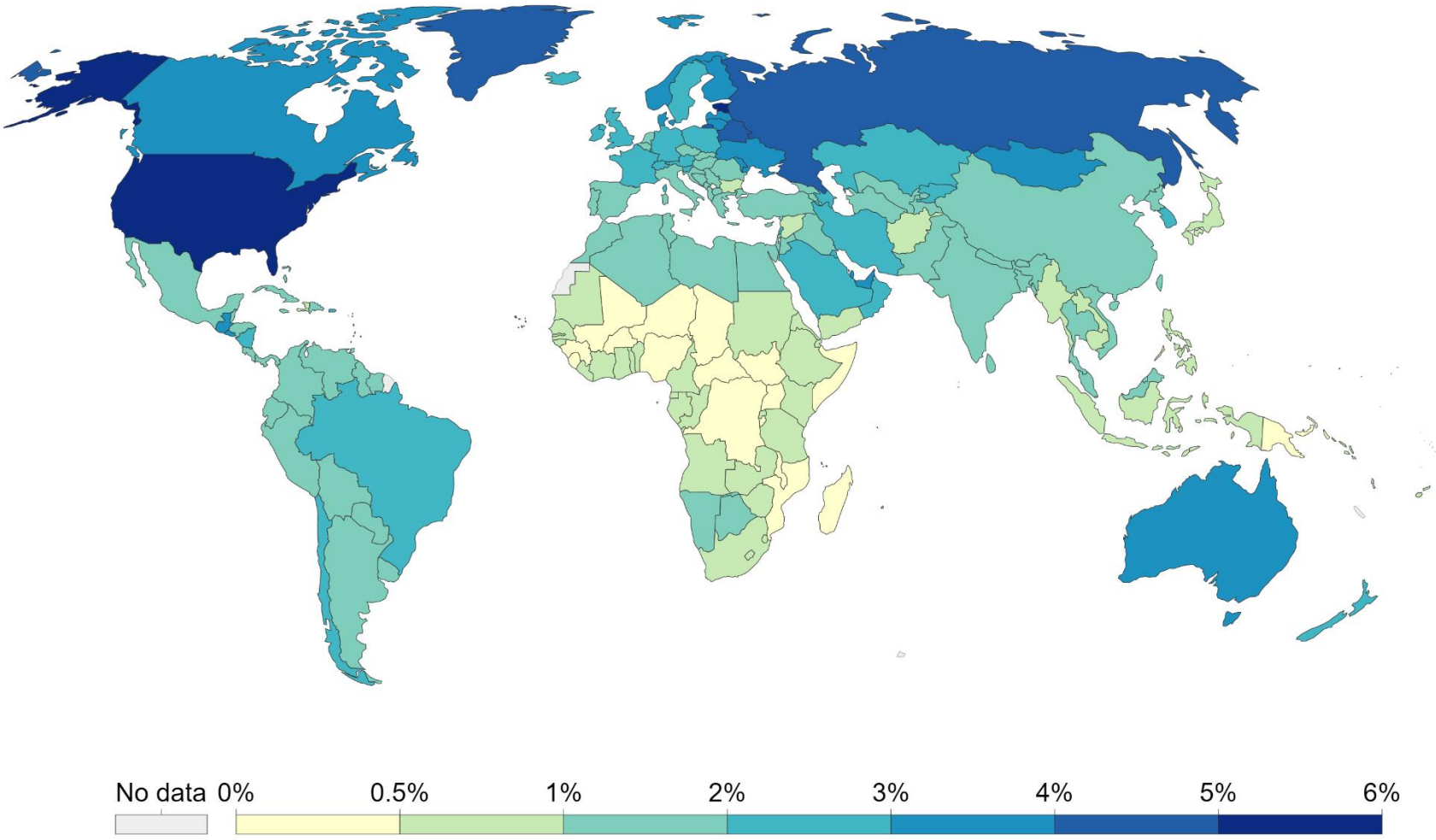
The Human Toll of the Opioid Crisis

Who are these people?

Alcohol and drug use disorders as a share of total disease burden, 2016

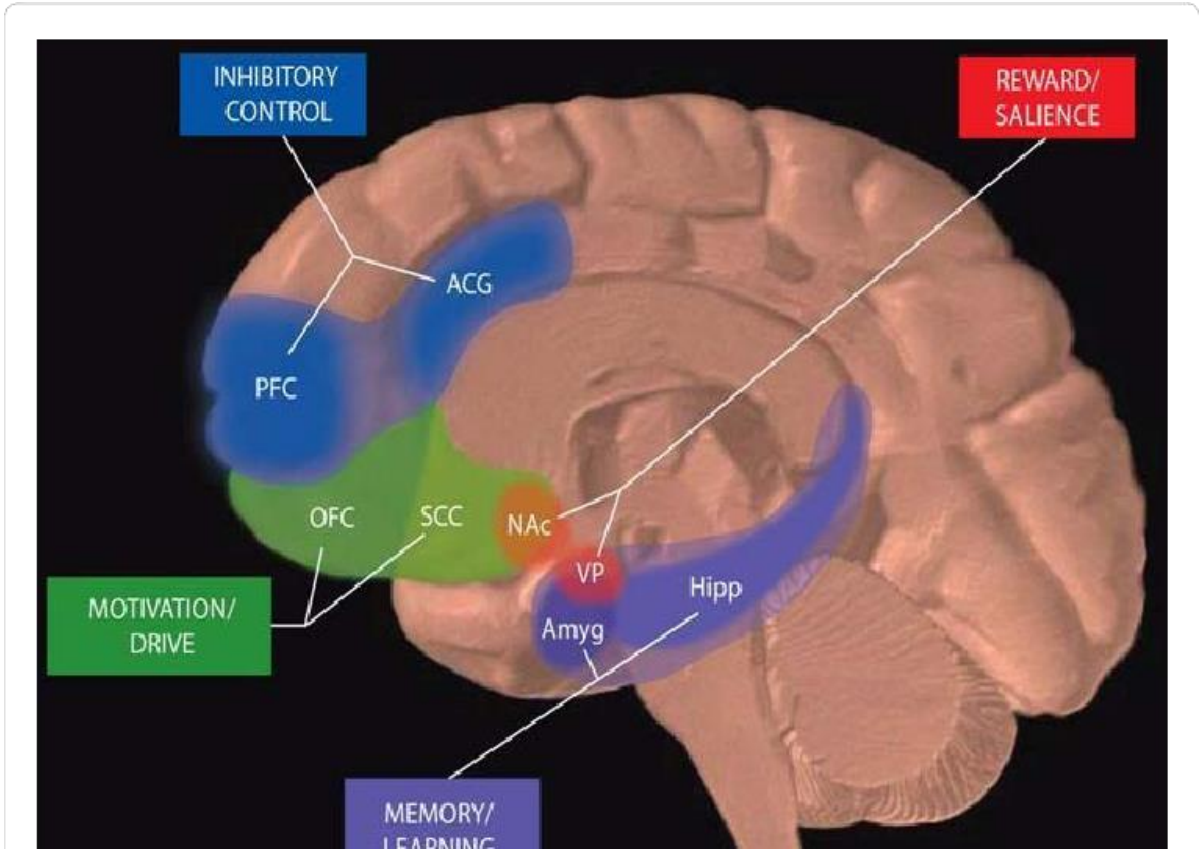
Alcohol and drug use disorders (not including tobacco) as a share of total disease burden. Disease burden is measured in DALYs (Disability-Adjusted Life Years) lost. DALYs measure total burden of disease - both from years of life lost and years lived with a disability. One DALY equals one lost year of healthy life.

Our World in Data



Source: IHME, Global Burden of Disease

Addiction – a primary, chronic disease of brain reward, motivation, memory and related circuitry



https://www.asam.org/resources/definition-of-addiction

Opioid Use Disorder

- Opioid Addiction, Narcotic Addiction, Heroin addiction
- Continued use of opioids despite negative/harmful consequences

Opioid Use Disorder – DSM V

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following

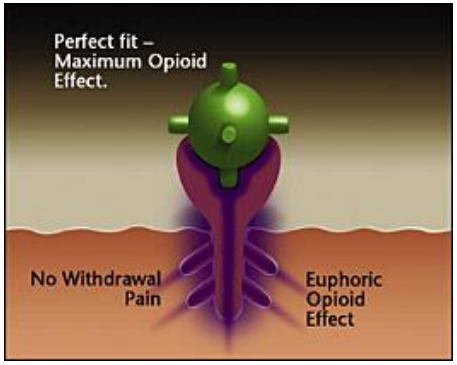
- Opioids are often taken in larger amounts or over a longer period than intended
- Persistent desire or unsuccessful efforts to cut down or control opioid use
- A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects
- Craving, or a strong desire or urge to use opioids.
- Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids
- Important social, occupational, or recreational activities are given up or reduced because of opioid use
- Recurrent opioid use in situations in which it is physically hazardous.
- Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance
- Withdrawal, as manifested by either of the following: a. The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal). b. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms
- Tolerance, as defined by either of the following:
  - Need for increased amounts of opioids to achieve intoxication or desired effect.
  - A markedly diminished effect with continued use of the same amount of an opioid. Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

2-3= Mild 4-5 =Moderate >6 = Severe

Opioid Use Disorder Treatment

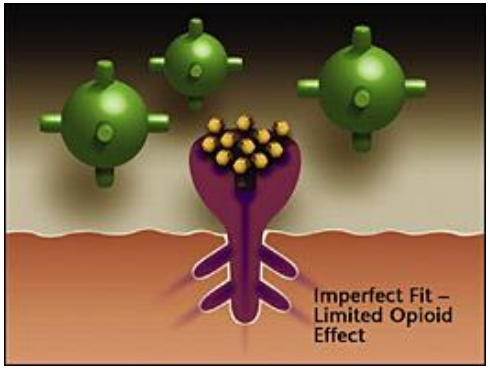
- Behavioral treatment
  - Inpatient detox
  - Residential
  - Partial hospitalization
  - Intensive Outpatient Therapy (IOP)
  - Counselor
  - 12-step meetings (AA, NA, Celebrate Recovery, Smart Recovery)
- Pharmaceutical (FDA approved evidence-based)
  - Methadone
  - Naltrexone
  - Buprenorphine

Medication Assisted Treatment



Methadone

- Opioid Agonist
- Licensed Federal Gov't
- Directly Observed Tx
- Patient Barriers
  - Daily transportation
  - $ / Stigma / Drug culture



Buprenorphine

- Partial Opioid Agonist
- Kappa antagonist
- Prescribed - w/ DEA X
- DEA Schedule 4 / Retail Rx
- Patient Barriers
  - Few Providers/ $$/Mental Health s

Naltrexone

- Opioid Antagonist
- No abuse potential
- Monthly injection
- $$$$
- Any Provider can prescribe
- High drop out rate

Medication Assisted Therapy (MAT)

- ⬇ Death
- ⬇ Decreases Criminality
- ⬇ Decreases HIV, Hep C
- Improves social functioning
- Increases retention in therapy
- Better long-term outcomes
- For every $1 spent on Methadone program – estimated $12 savings (healthcare/criminal justice)

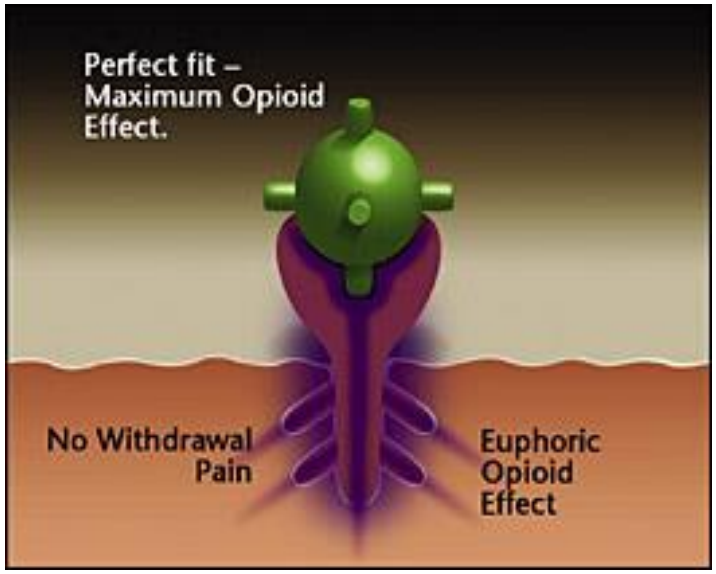
National Institute of Drug Abuse
https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/drug-addiction-treatment-worth-its-cost
National Academies of Sciences, Engineering, and Medicine. 2019. *Medications for Opioid Use Disorder Save Lives*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25310

Medication Assisted Treatment (MAT)

"withholding or failing to have available Medication Assisted Treatment for the treatment of OUD in any care or criminal justice setting is denying appropriate medical treatment"

National Academies of Sciences, Engineering, and Medicine. 2019. *Medications for Opioid Use Disorder Save Lives*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25310

Caring for patients on Methadone



- Verify current daily dose
- Generally continue daily dose
- If missed doses or unknown, consider using 40mg Methadone
- If oversedated, QT prolongation or contraindication, avoid methadone
- Treat acute pain with additional opioids when needed (may require higher doses)
- Communicate with OTP prior to DC with opioids

Naltrexone Treatment

- Full Mu antagonist
- Alcohol or Opioid Use Disorder
- Daily po or Monthly injection
- Opioids will NOT be effective
- Discontinue if planning surgery
- If emergent acute pain, need non-opioid medications, general anesthesia, nerve blocks or ketamine for pain control
- High risk of OD if dose missed and relapse

Buprenorphine Treatment

- Requires DEA X Waiver
  - 8h online course for physicians
  - 24h online course APP's
- Limit of 30 patients first year
- General primary care or specialty practice
- State requirements- Indiana law similar to opioid laws
- Indiana currently has incentive $600 for any physician obtains Buprenorphine Waiver (Overdose Lifeline, https://www.overdose-lifeline.org/ Indiana Pilot Project)

Buprenorphine Treatment

Buprenorphine – **sublingual (tabs/film),** buccal, injection, depot

Buprenorphine (Monotherapy)

- Higher risk of misuse
- Higher street value
- Typically used in pregnancy
- Naloxone allergic

Buprenorphine/naloxone

- Naloxone not absorbed when taken correctly
- Naloxone active if injected IV
- Naloxone is a tamper deterrent to prevent IV use

Buprenorphine Treatment

- Moderate to Severe OUD by DSM V criteria
- Determine if patient wants to decrease their use of opioid pills or heroin
- Check LFT's, Consider screening HIV, Hep B, Hep C
- Pregnancy test
- Review and sign Treatment Agreement
- Avoid all alcohol/benzos/sedatives
- Safe Storage
- Prescribe and educate about Narcan
- Must have process for drug testing (POC cheaper)
- Periodically reassess risks/benefits of treatment and through shared decision-making determine optimal individualized course of treatment

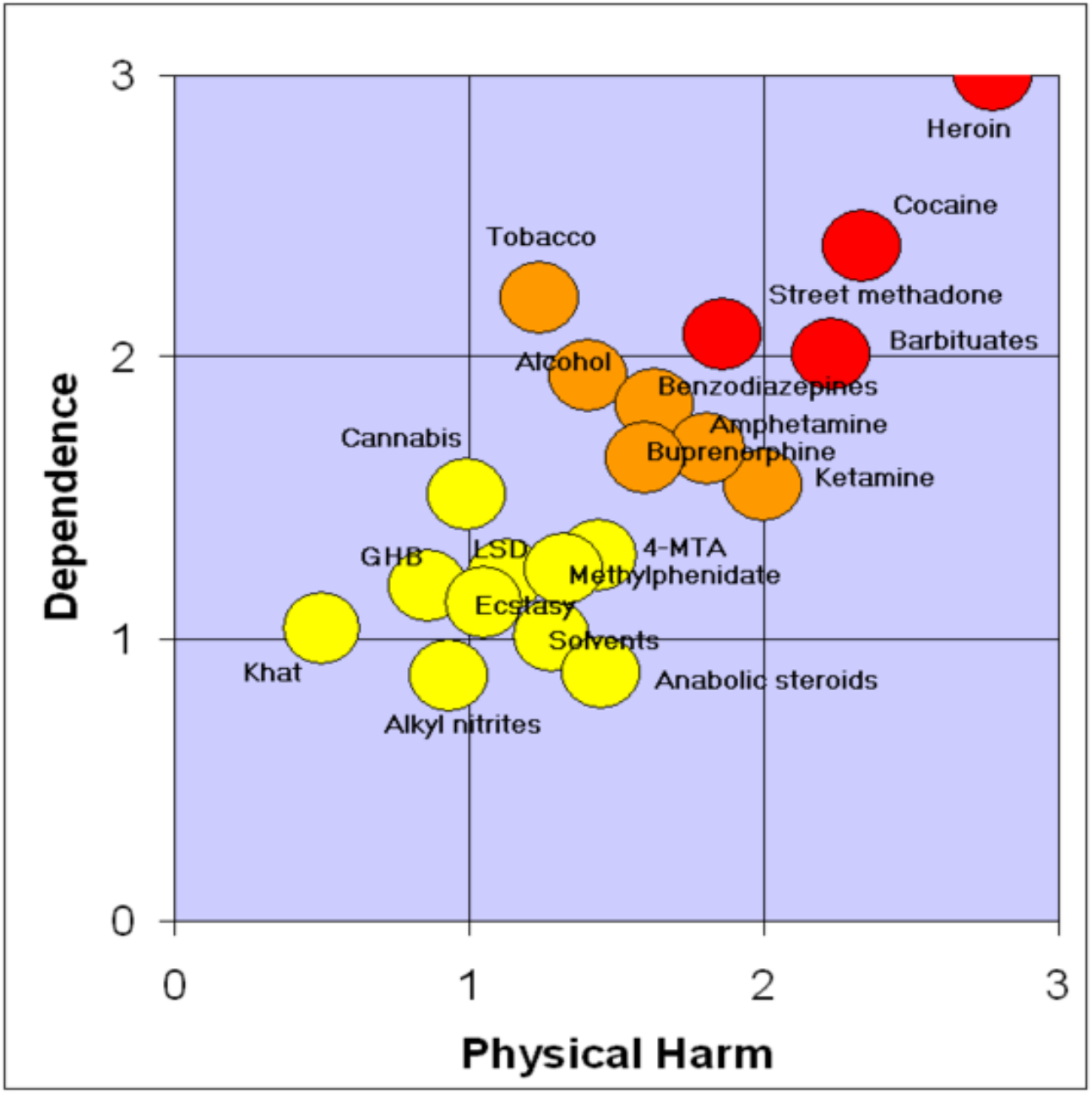
Indiana Buprenorphine Law
SEA 141 – July 2019

Prescribing Physician shall…..

1. Perform initial assessment and physical exam
2. Obtain substance use history and substance use disorder diagnosis
3. Perform mental health assessment
4. Obtain informed consent and establish a treatment agreement
5. If appropriate, prescribe OBOT treatment and require office visits
6. At office visits, prescriber must evaluate progress and compliance with the treatment agreement and document progress
7. Perform toxicology
8. Review INSPECT
9. If female and child bearing potential; Perform pregnancy test and counsel about risks of fetal opioid dependence and NAS
10. Prescribe and Educate about Narcan
11. Provide for an ongoing component of psychosocial supportive therapy

(Hospitals excluded)

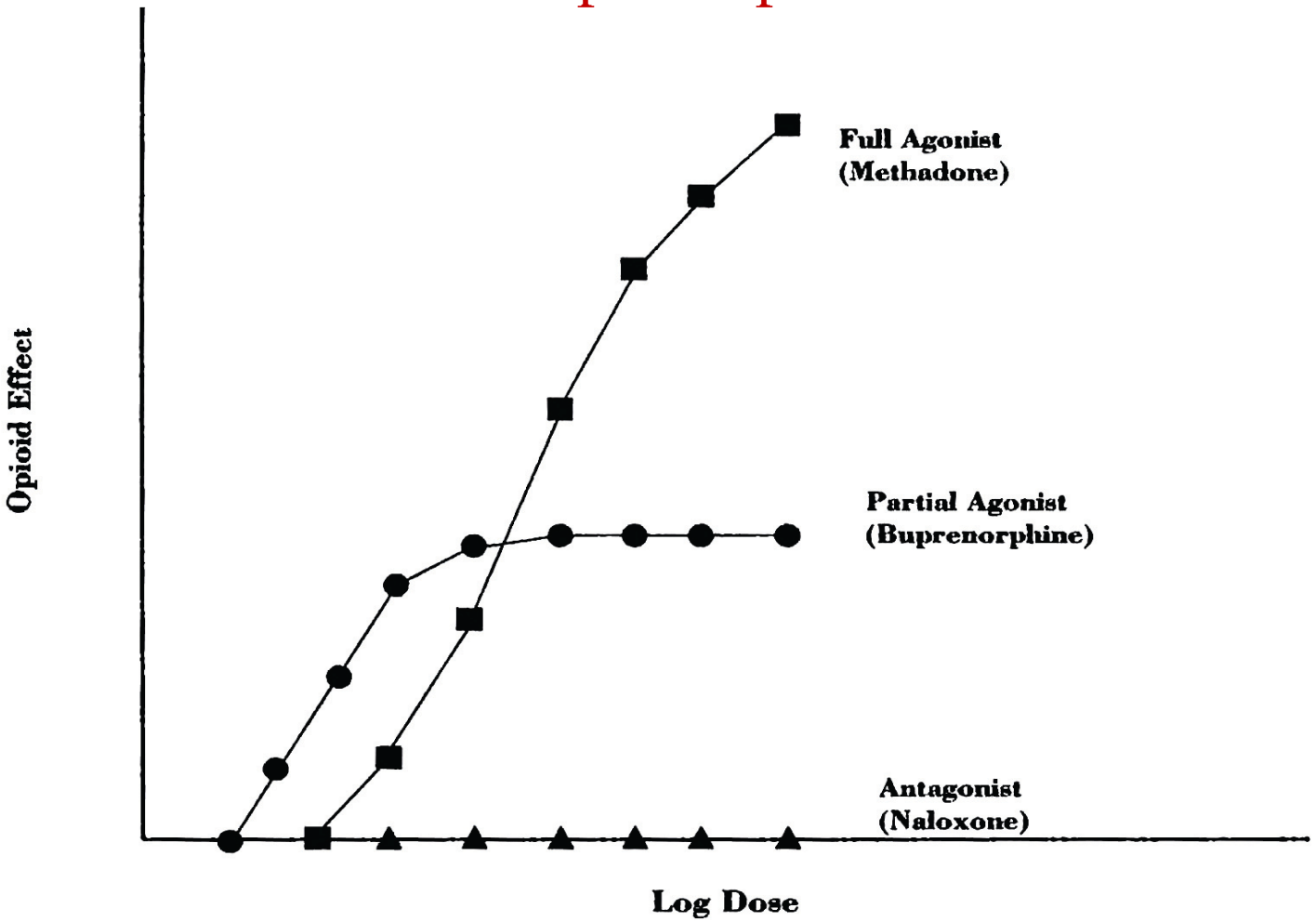
http://iga.in.gov/legislative/2019/bills/senate/141



Nutt, David, Leslie A King, William Saulsbury, Colin Blakemore. "Development of a rational scale to assess the harm of drugs of potential misuse" The Lancet 2007; 369:1047-1053

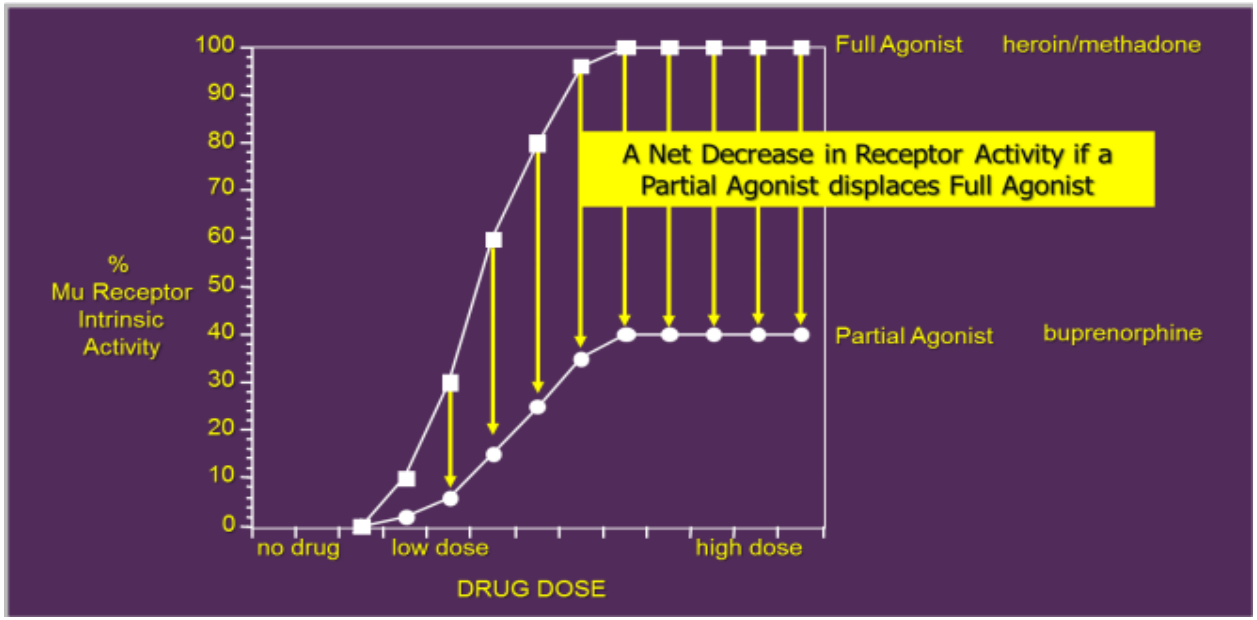
Medication Assisted Treatment
Buprenphine

The Buprenorphine Effect



SAMHSA chart shows how buprenorphine works to ease withdrawal while producing less euphoric opioid effects

Buprenorphine Induction
Prevention of Precipitated Withdrawal



- High Mu receptor affinity, Partial activation
- Must be in mild-moderate withdrawal to prevent precipitated withdrawal with first dose
- Use SOWS or COWS

Clinical Opiate Withdrawal Scale

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name:_____ Date and Time ____/____/____:_____

Reason for this assessment:_____

Resting Pulse Rate: _____beats/minute
Measured after patient is sitting or lying 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

GI Upset: *over last 1/2 hour*
0 no GI symptoms
1 stomach cramps
2 nausea or loose stool
3 vomiting or diarrhea
5 multiple episodes of diarrhea or vomiting

Sweating: *over past 1/2 hour not accounted for by room temperature or patient activity.*
0 no report of chills or flushing
1 subjective report of chills or flushing
2 flushed or observable moistness on face
3 beads of sweat on brow or face
4 sweat streaming off face

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

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 movements of legs/arms
5 unable to sit still for more than a few seconds

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

Pupil size
0 pupils pinned or normal size for room light
1 pupils possibly larger than normal for room light
2 pupils moderately dilated
5 pupils so dilated that only the rim of the iris is visible

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

Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates 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

Gooseflesh skin
0 skin is smooth
3 piloerrection of skin can be felt or hairs standing up on arms
5 prominent piloerrection

Runny nose or tearing *Not accounted for by cold symptoms or allergies*
0 not present
1 nasal stuffiness or unusually moist eyes
2 nose running or tearing
4 nose constantly running or tears streaming down cheeks

Total Score _____

The total score is the sum of all 11 items

Initials of person completing assessment: _____

Score: 5-12 = mild, 13-24 = moderate, 25-36 = moderately severe, more than 36 = severe withdrawal

Subjective Opiate Withdrawal Scale (SOWS)

Instructions: We want to know how you're feeling. In the column below today's date and time, use the scale to write in a number from 0-4 about how you feel about each symptom right now.

Scale: 0 = not at all 1 = a little 2 = moderately 3 = quite a bit 4 = extremely

DATE						
TIME						
SYMPTOM		SCORE	SCORE	SCORE	SCORE	SCORE
1	I feel anxious					
2	I feel like yawning					
3	I am perspiring					
4	My eyes are tearing					
5	My nose is running					
6	I have goosebumps					
7	I am shaking					
8	I have hot flushes					
9	I have cold flushes					
10	My bones and muscles ache					
11	I feel restless					
12	I feel nauseous					
13	I feel like vomiting					
14	My muscles twitch					
15	I have stomach cramps					
16	I feel like using now					
TOTAL						

Mild Withdrawal = score of 1 – 10
Moderate withdrawal = 11 – 20
Severe withdrawal = 21 – 30

Efficacy of Buprenorphine Treatment

- 50% Decreased mortality
- Reduced opioid craving/Lower rates of opioid use
- Less severe NAS
- Improved quality of life
- Decreased HIV, Hep C
- Reduces reinforcement of opioids if used
- Slightly less effective at retaining people in tx than methadone
- Optimal duration of treatment has NOT been established
- All studies tapering/DC of MAT show high relapse rates
- Long-term tx allows return to work, improved health, decreased criminal activity

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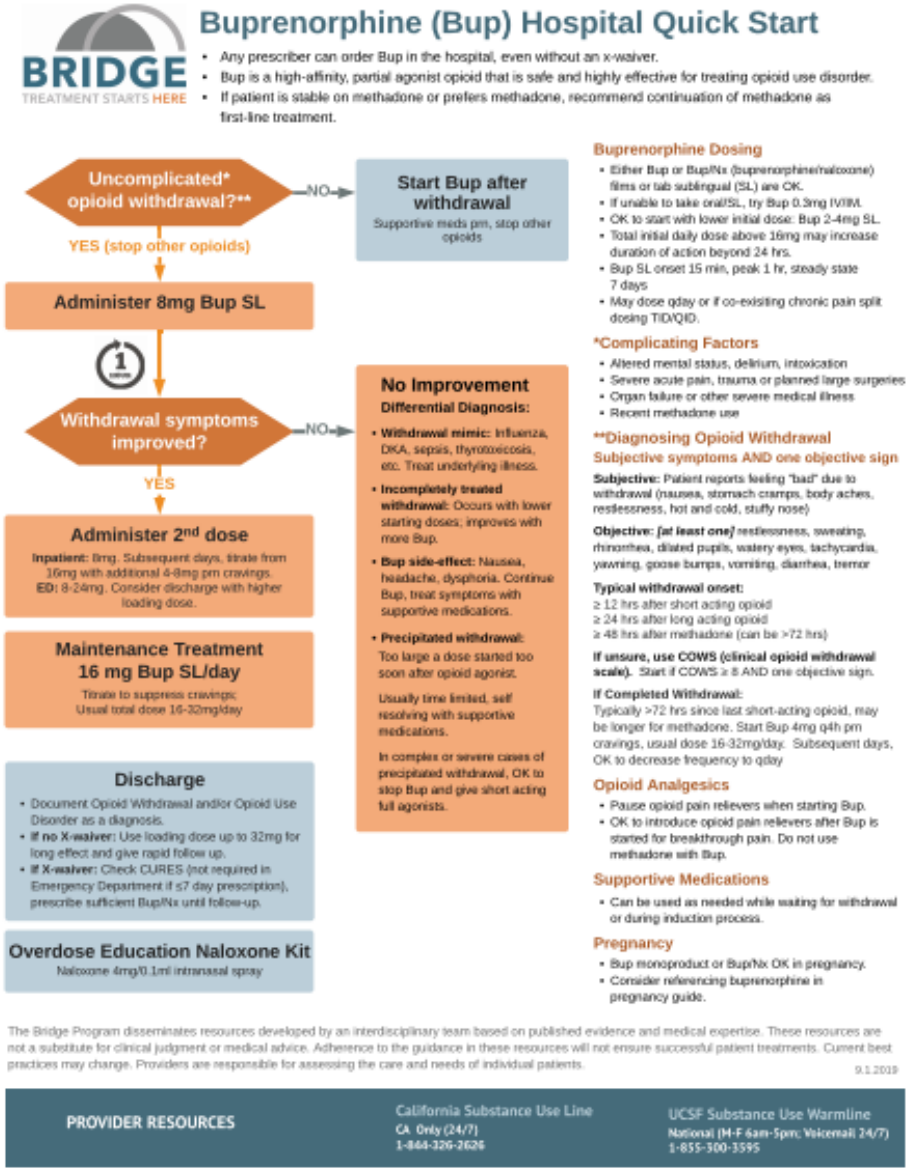
Buprenorphine Treatment Pearls

- New patient can require 45-60 min (UDT, PHQ-9, GAD-7, Intake)
- Home inductions more practical
- Familiarity w/ local mental health/addiction resources
- FU visits q week to q 4 weeks
- Intake assessment, Treatment Agreement, FU questionnaire and frequent POC urine drug testing recommended to standardize and streamline care
- Typical daily dose 8-16mg (4mg-24mg)
- Have plan for substance use- augment tx
  - Buprenorphine only – q 4 weeks
  - Cocaine, Benzos, Meth & Opiods (one week FU X 2-3w)
  - Marijuana- q 2-3weeks pending other aspects recovery

Inpatient Buprenorphine Start



BRIDGE
TREATMENT STARTS HERE

Buprenorphine (Bup) Hospital Quick Start

- Any prescriber can order Bup in the hospital, even without an x-waiver.
- Bup is a high-affinity, partial agonist opioid that is safe and highly effective for treating opioid use disorder.
- If patient is stable on methadone or prefers methadone, recommend continuation of methadone as first-line treatment.

Uncomplicated* opioid withdrawal?** — NO → **Start Bup after withdrawal**
Supportive meds prn, stop other opioids

YES (stop other opioids)

Administer 8mg Bup SL

1 dose

Withdrawal symptoms improved? — NO →

No Improvement
Differential Diagnosis:
- **Withdrawal mimic:** Influenza, DKA, sepsis, thyrotoxicosis, etc. Treat underlying illness.
- **Incompletely treated withdrawal:** Occurs with lower starting doses; improves with more Bup.
- **Bup side-effect:** Nausea, headache, dysphoria. Continue Bup, treat symptoms with supportive medications.
- **Precipitated withdrawal:** Too large a dose started too soon after opioid agonist.

Usually time limited, self resolving with supportive medications.

In complex or severe cases of precipitated withdrawal, OK to stop Bup and give short acting full agonists.

YES

Administer 2nd dose
Inpatient: 8mg. Subsequent days, titrate from 16mg with additional 4-8mg prn cravings.
ED: 8-24mg. Consider discharge with higher loading dose.

Maintenance Treatment
16 mg Bup SL/day
Titrate to suppress cravings;
Usual total dose 16-32mg/day

Discharge
- Document Opioid Withdrawal and/or Opioid Use Disorder as a diagnosis.
- **If no X-waiver:** Use loading dose up to 32mg for long effect and give rapid follow up.
- **If X-waiver:** Check CURES (not required in Emergency Department if ≤7 day prescription), prescribe sufficient Bup/Nx until follow-up.

Overdose Education Naloxone Kit
Naloxone 4mg/0.1ml intranasal spray

Buprenorphine Dosing
- Either Bup or Bup/Nx (buprenorphine/naloxone) films or tab sublingual (SL) are OK.
- If unable to take oral/SL, try Bup 0.3mg IV/IM.
- OK to start with lower initial dose: Bup 2-4mg SL.
- Total initial daily dose above 16mg may increase duration of action beyond 24 hrs.
- Bup SL onset 15 min, peak 1 hr, steady state 7 days
- May dose qday or if co-existing chronic pain split dosing TID/QID.

*Complicating Factors
- Altered mental status, delirium, intoxication
- Severe acute pain, trauma or planned large surgeries
- Organ failure or other severe medical illness
- Recent methadone use

**Diagnosing Opioid Withdrawal
Subjective symptoms AND one objective sign

Subjective: Patient reports feeling "bad" due to withdrawal (nausea, stomach cramps, body aches, restlessness, hot and cold, stuffy nose)

Objective: (at least one) restlessness, sweating, rhinorrhea, dilated pupils, watery eyes, tachycardia, yawning, goose bumps, vomiting, diarrhea, tremor

Typical withdrawal onset:
≥ 12 hrs after short acting opioid
≥ 24 hrs after long acting opioid
≥ 48 hrs after methadone (can be >72 hrs)

If unsure, use COWS (clinical opioid withdrawal scale). Start if COWS ≥ 8 AND one objective sign.

If Completed Withdrawal:
Typically >72 hrs since last short-acting opioid, may be longer for methadone. Start Bup 4mg q4h prn cravings, usual dose 16-32mg/day. Subsequent days, OK to decrease frequency to qday

Opioid Analgesics
- Pause opioid pain relievers when starting Bup.
- OK to introduce opioid pain relievers after Bup is started for breakthrough pain. Do not use methadone with Bup.

Supportive Medications
- Can be used as needed while waiting for withdrawal or during induction process.

Pregnancy
- Bup monoproduct or Bup/Nx OK in pregnancy.
- Consider referencing buprenorphine in pregnancy guide.

The Bridge Program disseminates resources developed by an interdisciplinary team based on published evidence and medical expertise. These resources are not a substitute for clinical judgment or medical advice. Adherence to the guidance in these resources will not ensure successful patient treatments. Current best practices may change. Providers are responsible for assessing the care and needs of individual patients.

9.1.2019

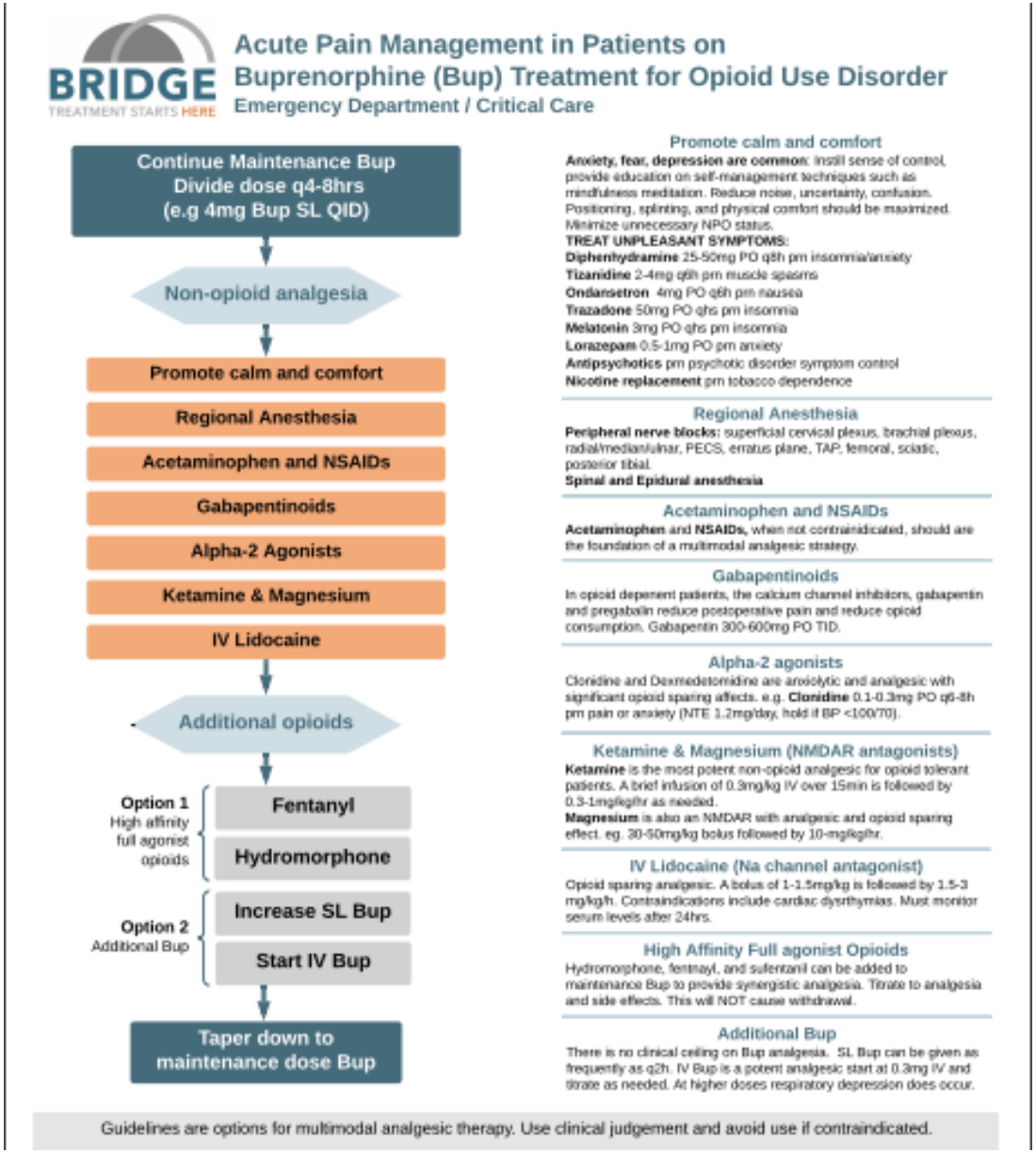
PROVIDER RESOURCES

California Substance Use Line
CA Only (24/7)
1-844-326-2626

UCSF Substance Use Warmline
National (M-F 6am-5pm; Voicemail 24/7)
1-855-300-3595

ED BRIDGE
Emergency Buprenorphine Treatment

Hospital Care for patient on Buprenorphine

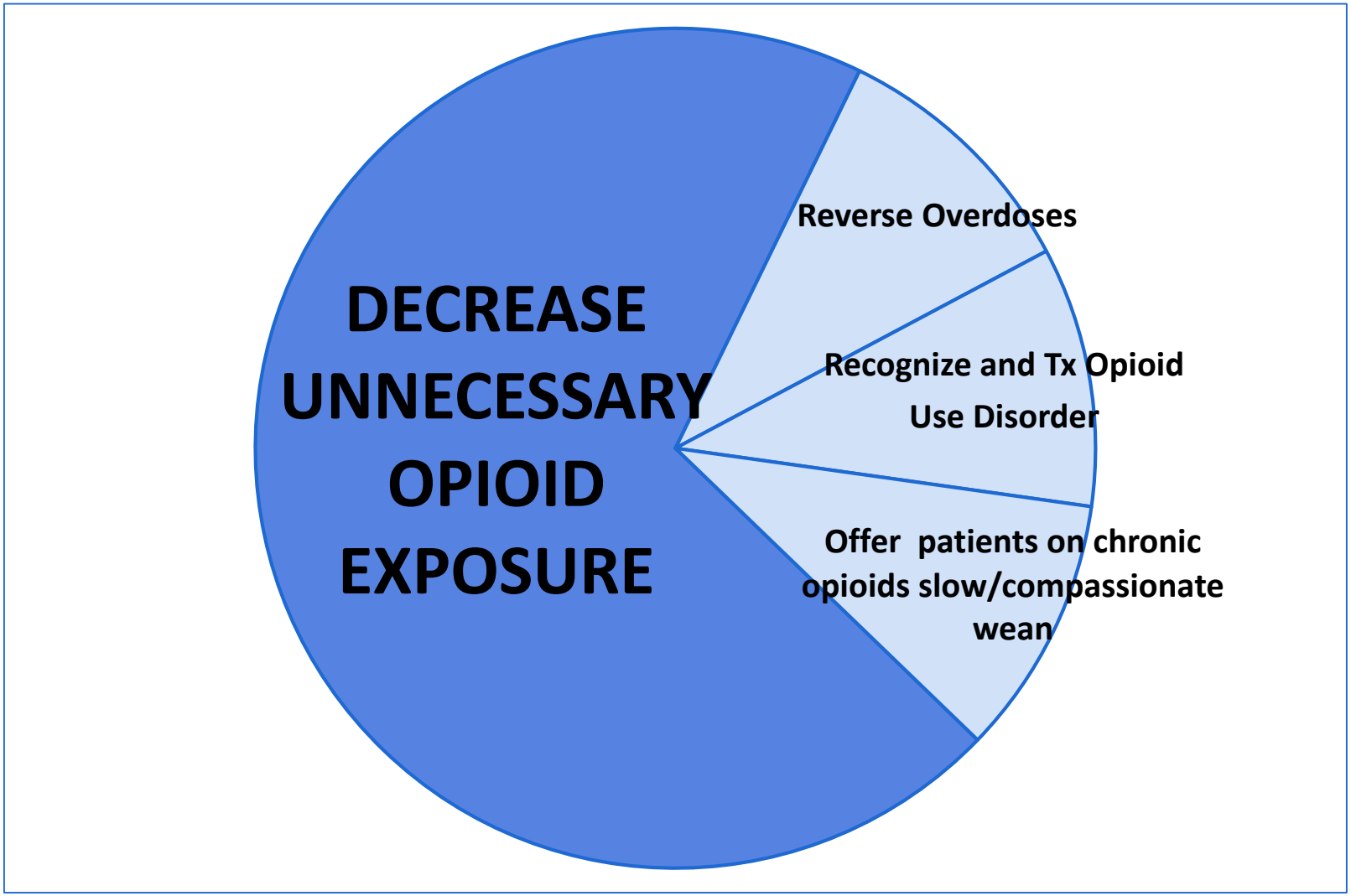


ED BRIDGE
Emergency Buprenorphine Treatment

Naloxone - Overdose reversal medication

- OTC Indiana Pharmacies
- Paid for by insurance if Rx
- Can be carried by anyone
- Should be stocked in Emergency medications in any medical office
- Should be prescribed to any patient on high dose opioids or any patient at high risk of oversedation, All patients on MAT or with OUD

How can we help bend the curve on the opioid epidemic?



Challenges for providers/system

Stigma SUD	→	Addiction is a Brain Disease
Stigma MAT	→	MAT is Harm Reduction
There will be failures	→	Tx of substance abuse is imperfect
Difficult cases	→	Patients with SUD need help and treating persons with SUD make our patients better able to function physically/ psychologically and make communities stronger and safer

Decrease Stigma Substance Use Disorder (SUD)

- Active SUD
- Suspected SUD
- Person in Tx for SUD
- Person in Recovery from SUD
- Person in Long Term Recovery from SUD
- Urine drug test- negative
- Urine drug test positive for X, inconsistent with tx goals (share your concern about how this will affect health and recovery)
- Returned to substance use
- Ask patients about substance use....their concerns about substance use or their treatment / recovery from substance use

Thank you!

Questions