Treatment for Opioid Use Disorde Evidence and Ongoing Research

Nadherny/Calciano Youth Symposium
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National Institute on Drug Abuse

OUTLINE

- Opioids and opioid use disorder (OUD)
- Medications for the treatment OUD
- The role of behavioral therapies for OUD
- Current NIDA-funded research

CONFLICTS

None

OPIOIDS AND OPIOID USE DISORDER (OUD)

OPIOIDS: THE BASICS

- Derived from opium poppy (e.g. heroin), synthetic (e.g. fentanyl, methadone)
- Act through endogenous opioid system, mainly mu-opioid receptors
- Cause burst of dopamine (a neurotransmitter) in the shell of the nucleus acumens, critical area of reward circuitry
- Selectively modulate the perception of pain
- Used for 1,000s of years
  - Dysentery, cough, pain

PROBLEMS ASSOCIATED WITH OPIOID MISUSE

- Respiratory depression, death
- Interactions (especially benzodiazepines, alcohol)
- Elevated risk for disease through needle sharing, etc. (HIV, HCV, endocarditis)
- Problems with jobs, family
- Criminal behavior
- Dependence, addiction, opioid use disorder

OUD

Dependence

- Neurons adapt to repeated drug exposure. only function normally when on drug
- Absence causes withdrawal syndrome

+

Addiction

- Compulsive use despite harmful consequences

=

OUD

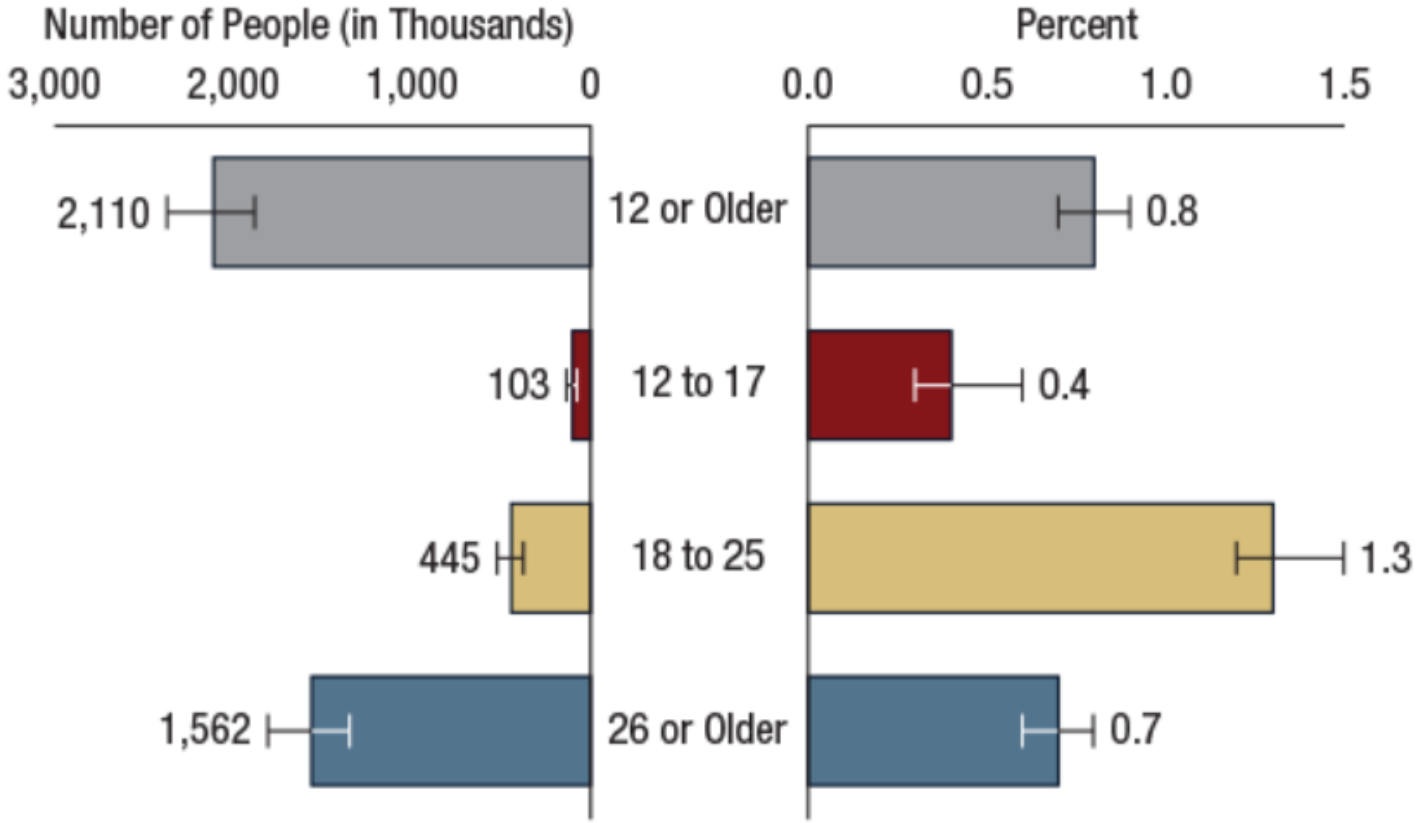
- Mild, moderate, severe according to number of symptoms…

SYMPTOMS OF OUD

- Taking more than intended
- Wanting or trying to control use w/o success
- Spending a lot of time obtaining, taking, recovering
- Using when physically unsafe
- Failing to carry out important roles
- Continuing to use despite relationship or social problems
- Giving up or reducing other activities
- Developing tolerance
- Craving
- Withdrawal symptoms

OUD PREVALENCE BY AGE

Figure 38. Opioid Use Disorder in the Past Year among People Aged 12 or Older, by Age Group: 2017



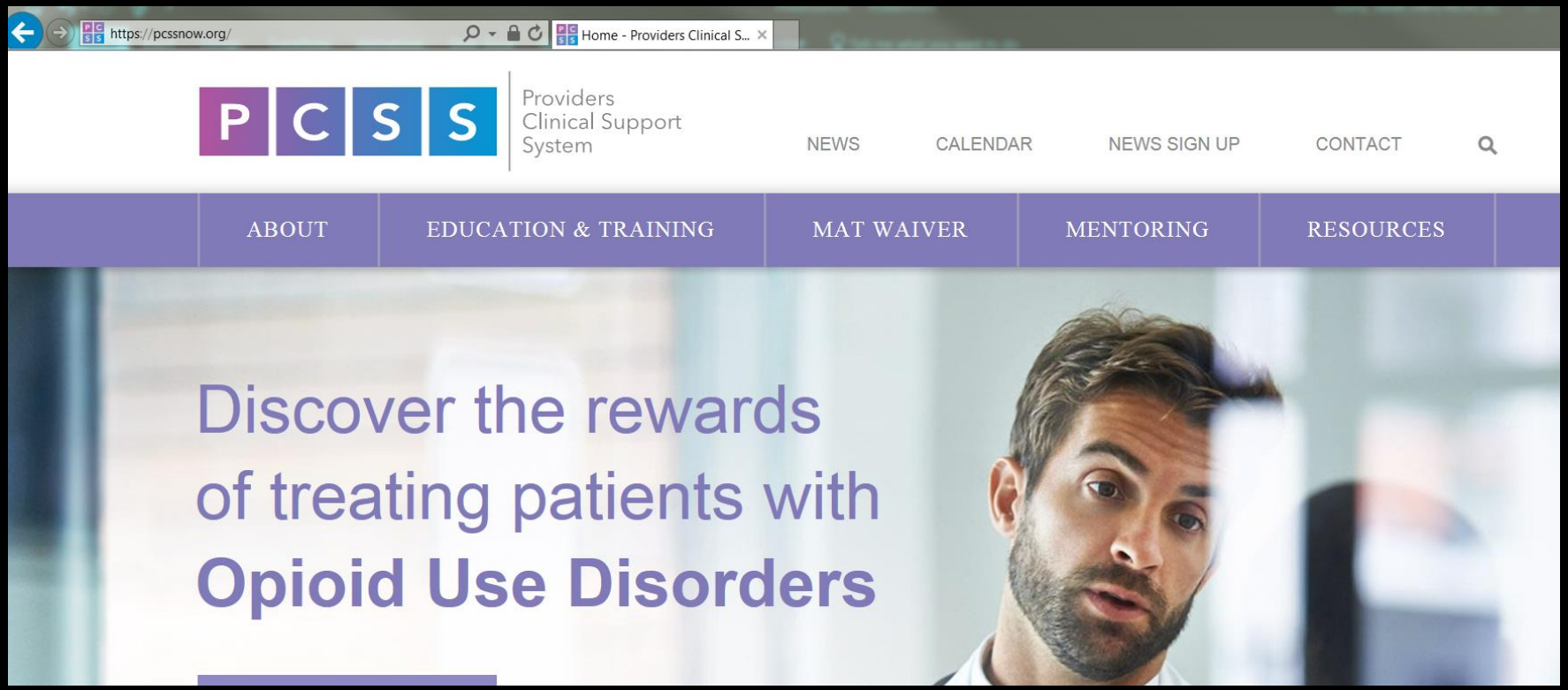
Note: Opioid use disorder is defined as meeting DSM-IV criteria for heroin use disorder or pain reliever use disorder in the past 12 months.

Source: Substance Abuse and Mental Health Services Administration. (2018). *Key substance use and mental health indicators in the United States: Results from the 2017 National Survey on Drug Use and Health* (HHS Publication No. SMA 18-5068, NSDUH Series H-53). Rockville, MD: Center for Behavioral Health Statistics and Quality. Retrieved from **https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report**

MEDICATIONS FOR THE TREATMENT OF OUD

Methadone
Buprenorphine
Naltrexone

RESOURCES FROM THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION



https://pcssnow.org/

WHAT I MEAN BY TREATMENT

- The use of interventions to reduce symptoms and consequences, and to help people regain their lives
  - Medications
  - Behavioral therapies, counseling, education, training, mutual help, etc., when needed/desired
- For many long-term and/or multiple episode

NOT: Overdose reversal (e.g. naloxone) or withdrawal management (AKA detox) *by themselves*

METHADONE

- Developed in the 1960s
- Full agonist - binds to opioid receptors
- Reduces opioid cravings
- Alleviates withdrawal symptoms
- Blunts or blocks the effects of illicit opioids
- Long-acting – at stable daily doses, serum levels allow for 24 hours without withdrawal or overmedication

METHADONE OUTCOMES

- Meta-analyses of 11 moderate to high-quality randomized controlled trials (RCTs)
- 1,969 heroin dependent participants (all adults)

Outcome	Studies/Participants	Results
Retention in treatment	4 studies, 750 patients	RR = 4.44 (95% CI: 3.26-2.04)*
Opioid use (urine or hair)	6 studies, 1,129 participants	RR = 0.66 (95% CI: 0.56-0.78)*
Criminal activity	3 studies, 363 participants	RR = 0.39 (95% CI: 0.12-1.25)
Mortality	4 studies, 576 participants	RR = 0.48 (95% CI: 0.10-2.39)

* Statistically significant

Source: Mattick, *et al.*, 2009, Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858.CD002209.pub2.

METHADONE CONSIDERATIONS

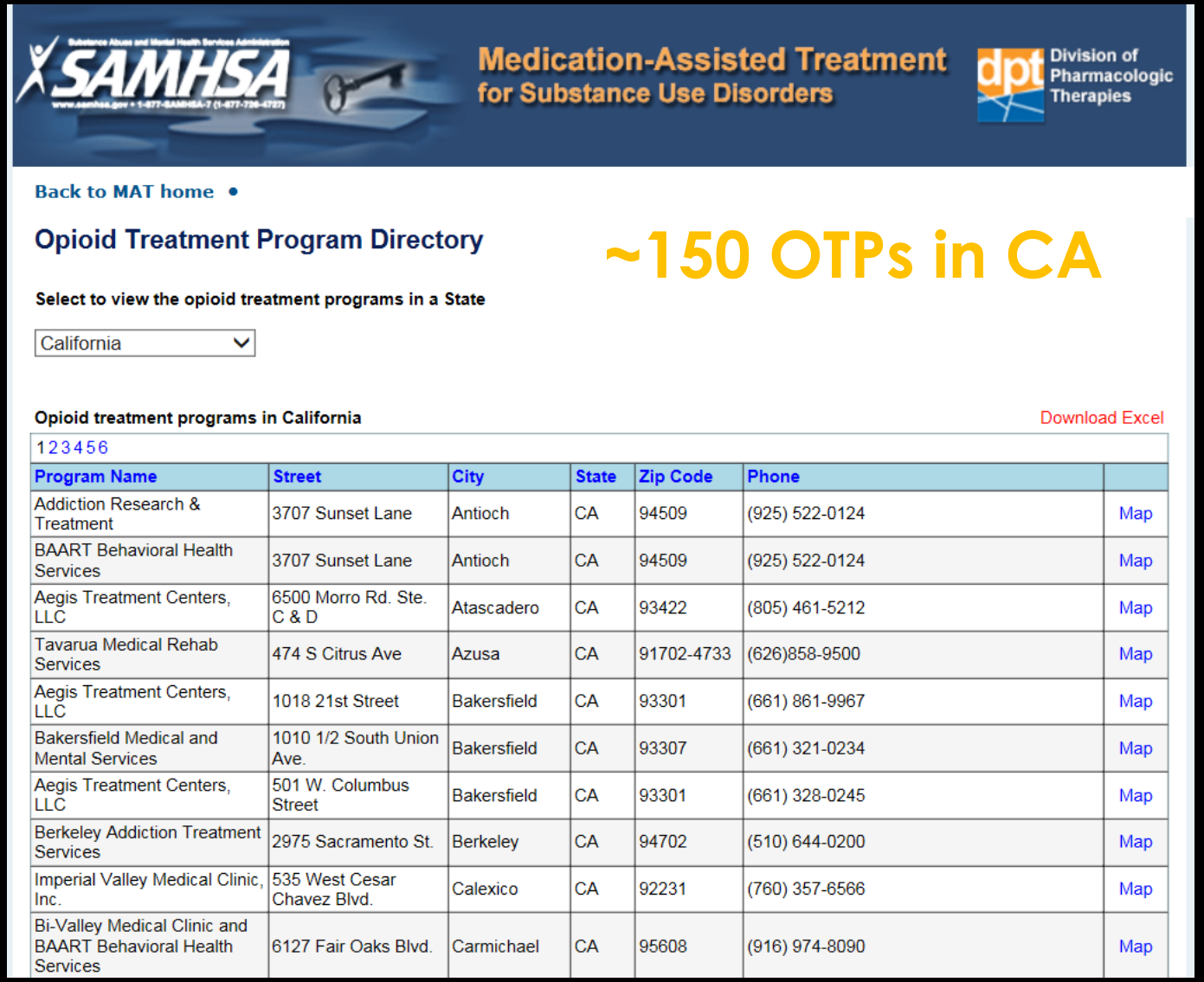
- Daily; in-person, observed dosing at least Initially
- Health issues
  - Respiratory depression, especially during initial dosing and dose titration, exacerbated by co-use of benzodiazepines, alcohol
  - Cardiac risks (QTc prolongation and cardiac arrhythmia)
  - Drug-drug interactions
- Accidental ingestion of take-home doses

METHADONE AND YOUTH

- No trials on those younger than 18
- Per regulations, may be dispensed to those under the age of 18…
  - to treat resumption of use after 2 short-term detoxification or drug-free treatment attempts within the past year; and
  - if parent/guardian/responsible adult designated state consents in writing

WHERE TO RECEIVE TREATMENT WITH METHADONE

- Schedule II narcotic, regulated per 42 CFR 8.12
- Dispensed through Opioid Treatment Programs (OTP)
- SAMHSA, Drug Enforcement Administration, State Opioid Treatment Authorities regulate
  - Licensed physician medical director
  - Adequate medical, counseling, vocational, educational, assessment and treatment services
- 1,611 OTPs in the continental US, serving over 380,000 patients



SAMHSA

Medication-Assisted Treatment for Substance Use Disorders

dpt Division of Pharmacologic Therapies

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Opioid Treatment Program Directory

~150 OTPs in CA

Select to view the opioid treatment programs in a State

California

Opioid treatment programs in California

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1 2 3 4 5 6

Program Name	Street	City	State	Zip Code	Phone	
Addiction Research & Treatment	3707 Sunset Lane	Antioch	CA	94509	(925) 522-0124	Map
BAART Behavioral Health Services	3707 Sunset Lane	Antioch	CA	94509	(925) 522-0124	Map
Aegis Treatment Centers, LLC	6500 Morro Rd. Ste. C & D	Atascadero	CA	93422	(805) 461-5212	Map
Tavarua Medical Rehab Services	474 S Citrus Ave	Azusa	CA	91702-4733	(626)858-9500	Map
Aegis Treatment Centers, LLC	1018 21st Street	Bakersfield	CA	93301	(661) 861-9967	Map
Bakersfield Medical and Mental Services	1010 1/2 South Union Ave.	Bakersfield	CA	93307	(661) 321-0234	Map
Aegis Treatment Centers, LLC	501 W. Columbus Street	Bakersfield	CA	93301	(661) 328-0245	Map
Berkeley Addiction Treatment Services	2975 Sacramento St.	Berkeley	CA	94702	(510) 644-0200	Map
Imperial Valley Medical Clinic, Inc.	535 West Cesar Chavez Blvd.	Calexico	CA	92231	(760) 357-6566	Map
Bi-Valley Medical Clinic and BAART Behavioral Health Services	6127 Fair Oaks Blvd.	Carmichael	CA	95608	(916) 974-8090	Map

https://dpt2.samhsa.gov/treatment/directory.aspx

BUPRENORPHINE

- FDA approved (2002) for age 16 years or older
- Partial agonist treatment
- Less likely to cause respiratory depression than methadone, (though still possible)
- Multiple formulations: Sublingual tablet, buccal film, sublingual film, implant (6 mo.), subcutaneous injection (1 mo.).
  - w/ or w/o naloxone (to deter misuse)
- Reduces opioid cravings
- Reduces withdrawal symptoms
- Blunts or blocks the effects of illicit opioids

BUPRENORPHINE OUTCOMES

Outcome	Results	95% CI
Retention in treatment (5 moderate – high quality studies, 1001 participants)	RR=1.82*	1.15 to 2.90
Use of opioids – urinalysis (3 moderate to high-quality studies, 729 participants)	SMD= -1.17*	-1.85 to -0.49

* Statistically Significant

Source: Mattick et al., 2014 Buprenorphine maintenance vs placebo or methadone maintenance for OUD, Cochrane Database of Systematic Reviews

BUPRENORPHINE AND YOUTH

- One "low-quality" study, RCT
- 9 weeks buprenorphine treatment with 3 week taper compared with 14 day detox with buprenorphine
- 152 patients aged 15-21 years in 6 community programs

Outcome	RR	CI
Treatment drop-out	0.37*	0.26-0.54
Positive urine test at end of treatment	0.97	0.78-1.22
Self-reported heroin use, 12 mo. follow-up	0.73*	0.57-0.95
Enrollment in addiction treatment at 12 mo.	1.33	0.94-1.88

*Statistically significant

Source: Minozzi et al, 2014 Maintenance Treatments for Opiate-Dependent Adolescents (Review) *Cochrane Database of Systematic Reviews, 2014. DOI: 10.1002/14651858.CD006318.pub3.*

- Woody et al. 2008, 2007

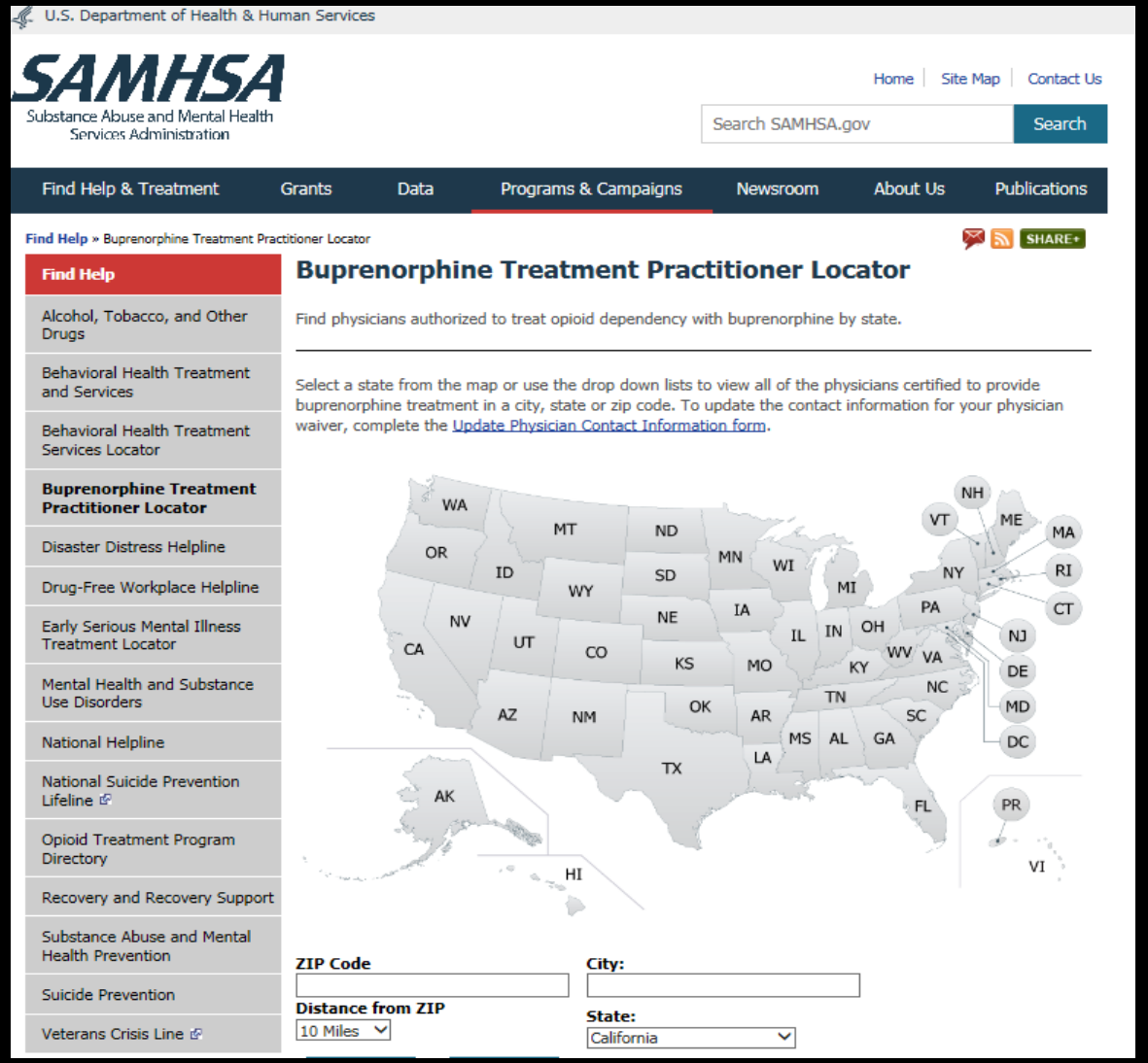
BUPRENORPHINE CONSIDERATIONS

- Respiratory depression, overdoses, especially when used with benzodiazepines, alcohol, other sedatives
- Hepatitis and liver failure, especially with predisposing risk factors
- Adrenal insufficiency
- Physical dependence, potential for misuse/diversion
- Sedating effects, cognition and psychomotor issues
- Drug-drug interactions – especially CYP450 3A4 enzyme inhibitors, others
- Side effects, e.g. oral numbness, constipation, tongue pain, vomiting, intoxication, palpitations, insomnia, excessive sweating, blurred vision

Source: SAMHSA TIP 63

WHERE TO RECEIVE BUPRENORPHINE

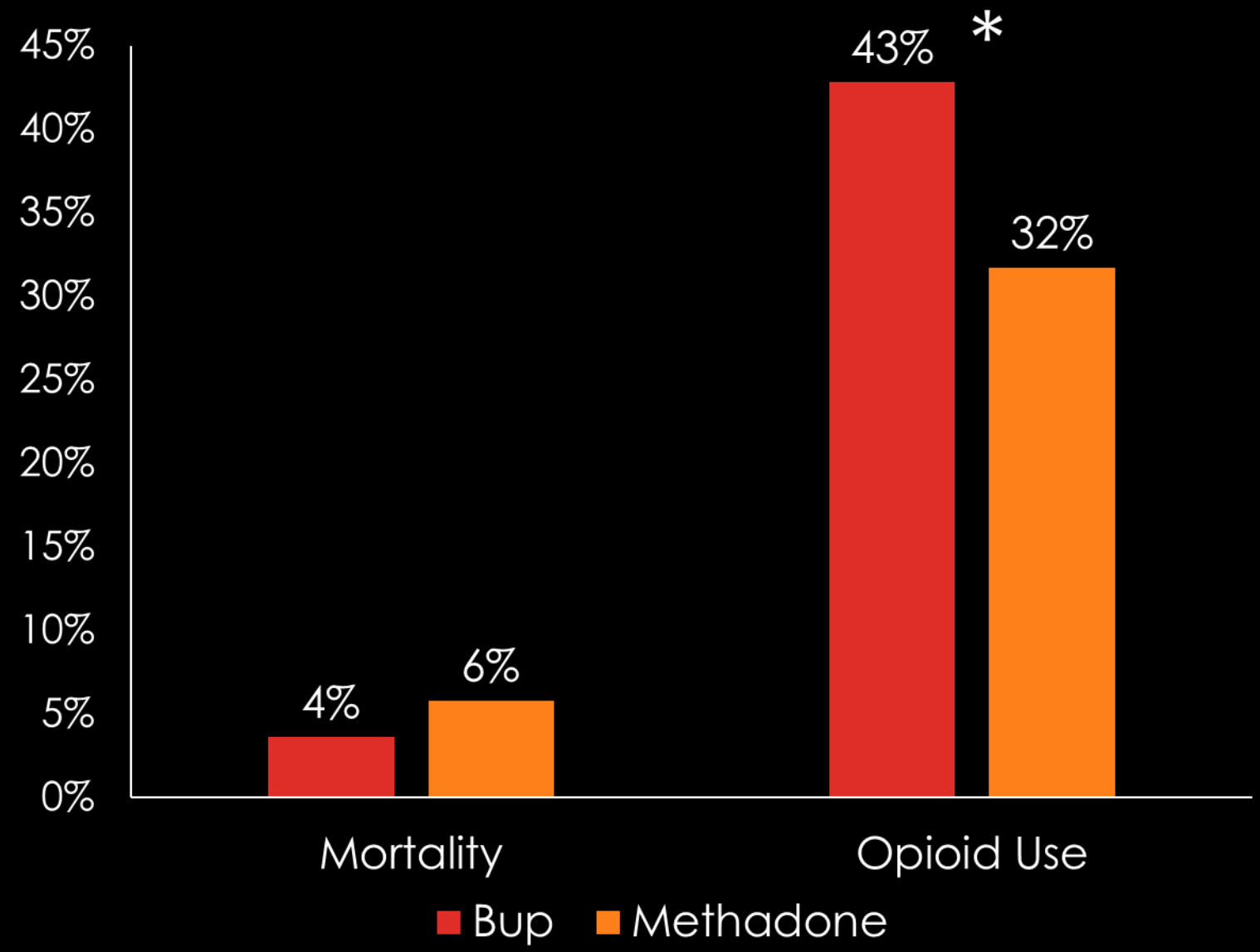
- Schedule III narcotic
- OTPs may offer
- Physician may prescribe (8 hr. training, special license, patient cap)
- NP, PA, if w/in scope of practice (24 hr. training, patient cap)
- Initial dose may be dispensed in ED
- Caveat: Many who can don't prescribe



https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/treatment-physician-locator?field_bup_physician_us_state_value=CA

BUPRENORPHINE, METHADONE LONG-TERM EFFECTS

- 1,269 individuals with OUD entering methadone programs, randomized to buprenorphine or methadone
- 1,080 located, 797 interviewed (73.6% of randomized participants)
- 2-5 years
- Opioid use (yes/no) based on urinalysis



Source: Hser et al., Addiction, 2014 doi:10.1111/add.13238.
* Statistically signifiant.

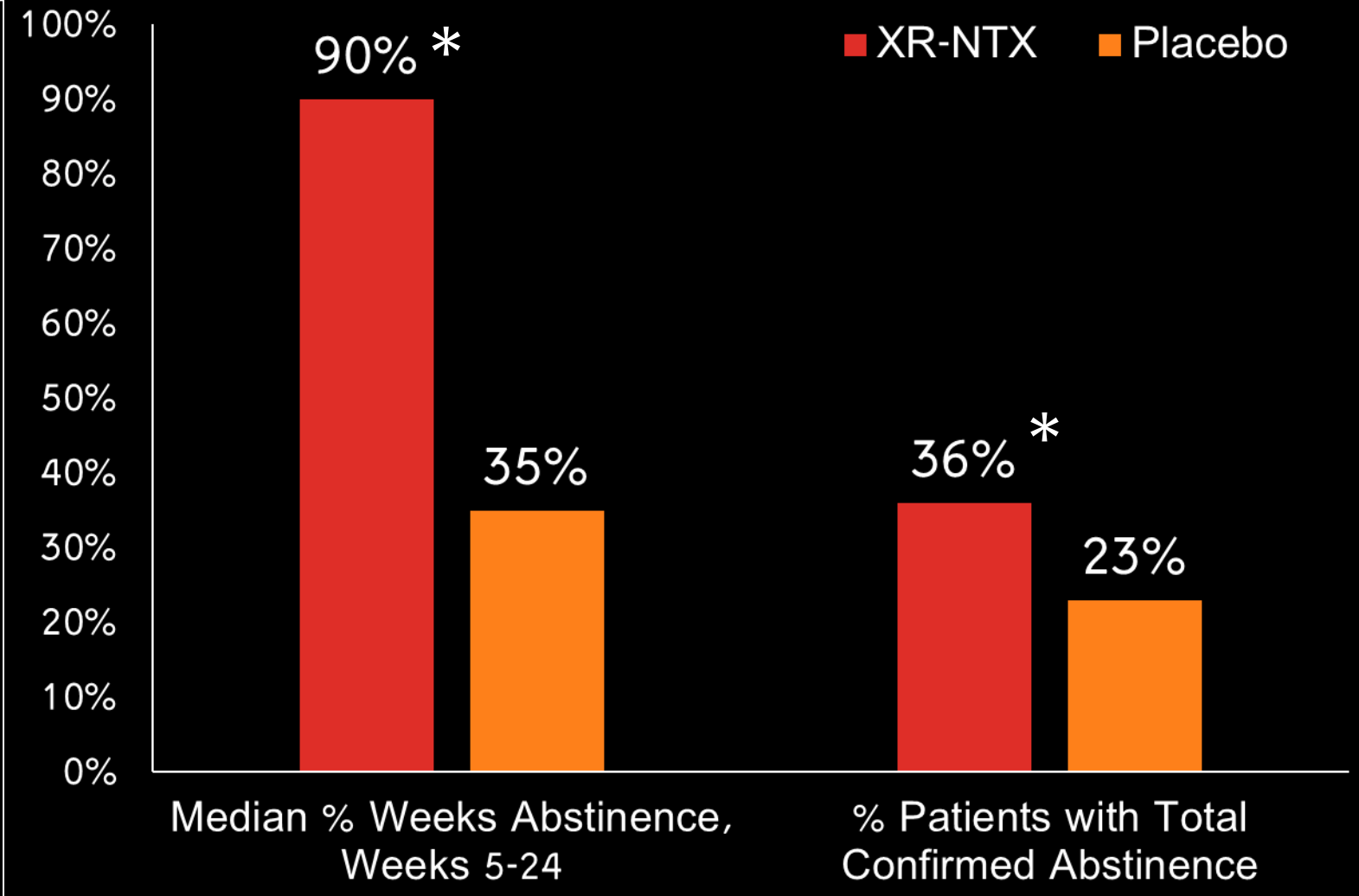
EXTENDED-RELEASE NALTREXONE (XR-NTX)

- FDA approved in 2010
- Intramuscular injection
- Antagonist: Blocks receptors
- Prevents relapse
- Patients must abstain from opioids for 7-10 days to avoid precipitated withdrawal
- No diversion potential
- Can be prescribed by any health care provider who is licensed to prescribe medications
- Also used for alcohol use disorder

Source: SAMHSA TIP 63: Medications for Opioid Use Disorder

XR-NTX OUTCOMES

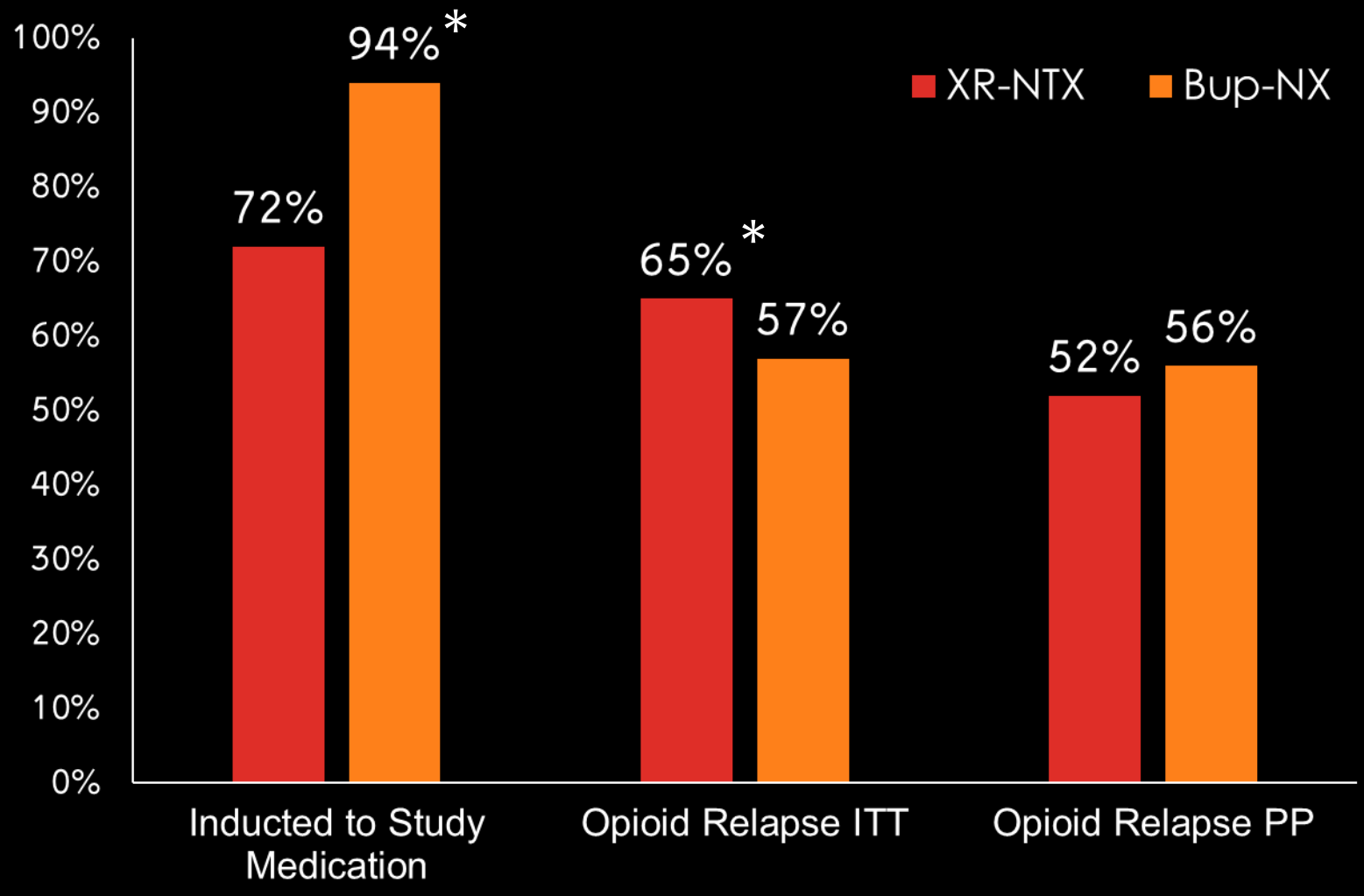
- 250 patients with OUD
  - Completed inpatient withdrawal management
  - Were seeking treatment
  - Had someone to supervise compliance
  - In 13 sites in Russia
- Randomized to XR-NTX plus counseling or counseling alone
- 24 week double-blind RCT, intent to treat analysis
- Drug co. funded, participated in design, conduct of study



Krupitsky et al. 2011 Injectable Extended-Release Naltrexone for Opioid Dependence a Double-Blind, Placebo Controlled, Multicentre Randomized Trial. *The Lancet*: 377:1506-13. *=Statistically significant difference

XR-NTX VS BUPRENORPHINE/NALOXONE

- 570 patients, 18 years+ recruited from inpatient withdrawal management at 8 sites
- Randomized to XR-NTX or bup/nal, both with medical management
- 24 week open label trial
- ITT: Intent to treat
- P.P.: Per Protocol

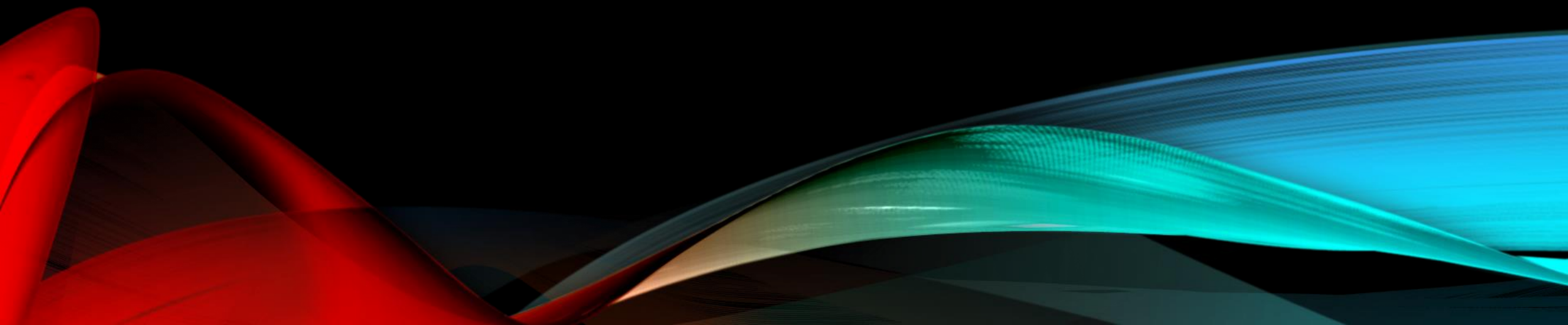


Lee, J. D., et al. (2018). Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): A multicentre, open-label, randomised controlled trial. *Lancet*, 391(10118), 309–318.

XR-NTX, CONTINUED

- Adolescents: No trials, but some case reports
- Side effects include injection site reaction, hypersensitivity reactions, insomnia, hepatic enzyme abnormalities.
- Attempts to override blockade may result in overdose
- Can be prescribed, administered by any healthcare provider licensed to prescribe medications

THE ROLE OF PSYCHOSOCIAL TREATMENTS FOR OUD



PSYCHOSOCIAL TREATMENTS PLUS MOUDS

- Meta-analysis: Does adding psychosocial treatments to agonist medication plus standard counseling improve outcomes? (Minozzi et al. 2011, *Cochrane Database of Systematic Reviews)*
  - E.g. Acceptance and Commitment Therapy, Cognitive Behavioral Therapy, Short-term Interpersonal Therapy, Contingency Management Twelve Step Facilitation
  - 35 studies, 4,319 participants
  - Answer: No
- Literature review: The jury is still out (Carrol and Weiss, Am J. Psychiatry, 2016 https://doi.org/10.1176/appi.ajp.2016.16070792)
  - Need to consider comparator (medical management), power, other outcomes (functioning)
  - Trial participants may not be representative of real-world patients
  - More work needs to be done

PATIENT-CENTERED METHADONE TREATMENT: A RANDOMIZED CLINICAL TRIAL

- Compared patient-centered MMT with treatme
  - Encouraged, not required to attend counsel
  - Counselors as therapists only
  - No "administrative discharge" for rules infra treatment length, failure to pay fees, etc.
- Findings
  - No significant differences in 12 mo. percent screens, cocaine-positive screens, drug risk retention
  - Significant improvement in Quality of Life (V

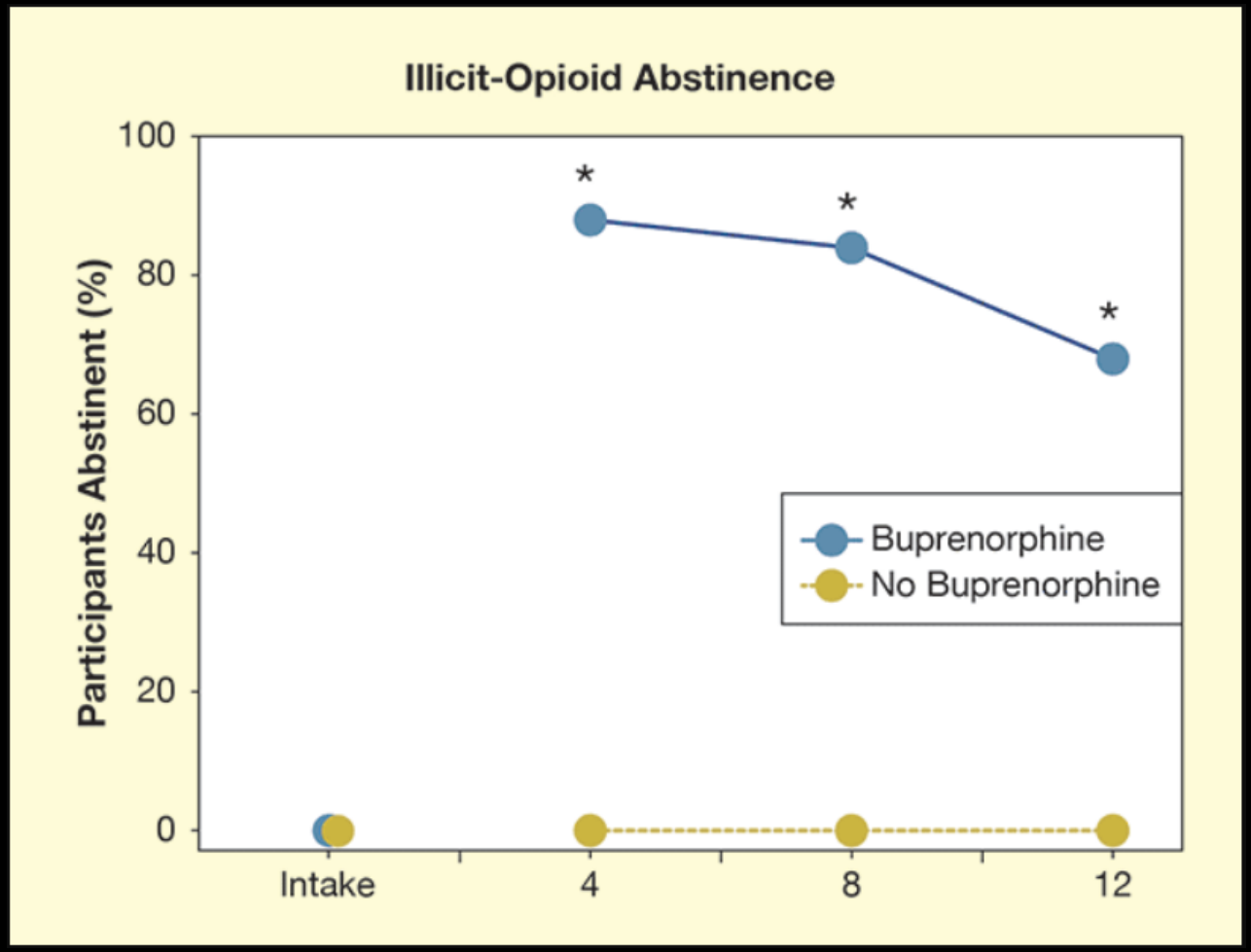
Counseling:

- Evaluate health and substance problem
- Identify issues, create goals and treatment plans
- Help with employment issues
- Lead group counseling
- Provide behavioral treatments
- Refer to support groups
- Set up after-care plans

INTERIM BUPRENORPHINE VS WAITING LIST FOR OPIOID DEPENDENCE(

- Shortage of services for OUD - waitlists
- Can we provide medications in the meantime?
- Earlier studies exist for methadone, several European countries provide
- Does it work for buprenorphine?
- Pilot study randomized 50 patients to buprenorphine or control
- Received medication in secure, automatic pill dispenser
- % illicit-free urines at 4 week intervals

Sigmon et al., NEJM, 2016; Sigmon et Al., Addictive Behaviors, 2015



CONTINGENCY MANAGEMENT

- Based on principals of operant conditioning
- Gives rewards to patients to reinforce positive behaviors, e.g. abstinence
- Voucher-based
  - Patient receives voucher for every drug-free urine
  - Voucher can be exchanged for goods and services consistent with a drug-free lifestyle (e.g. food, movie passes).
- Prize-Based
  - Individuals providing drug-negative urine screens draw from a bowl for a chance to win a prize worth between $1-$100
  - Number of draws starts at one and increases with consecutive drug-negative urines. Resets to one if drug-positive urine screen provided.
  - Can also be used to reinforce other behaviors (e.g. clinic attendance)

National Institute on Drug Abuse, 2018, *Principles of Drug Addiction Treatment*. https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/preface

CONTINGENCY MANAGEMENT FOR COCAINE USE AMONG INDIVIDUALS WITH CUD RECEIVING METHADONE FOR OUD

- Meta-analysis, 4 studies, 163 patients
- Only cocaine use incentivized

Outcome	Effect	95% CI
Sustained cocaine abstinence	RR=3.11*	1.80-5.35
Cocaine free urine analysis	SMD=0.85*	.58-1.10
Heroin free UA	SMD=0.36*	.09-.64

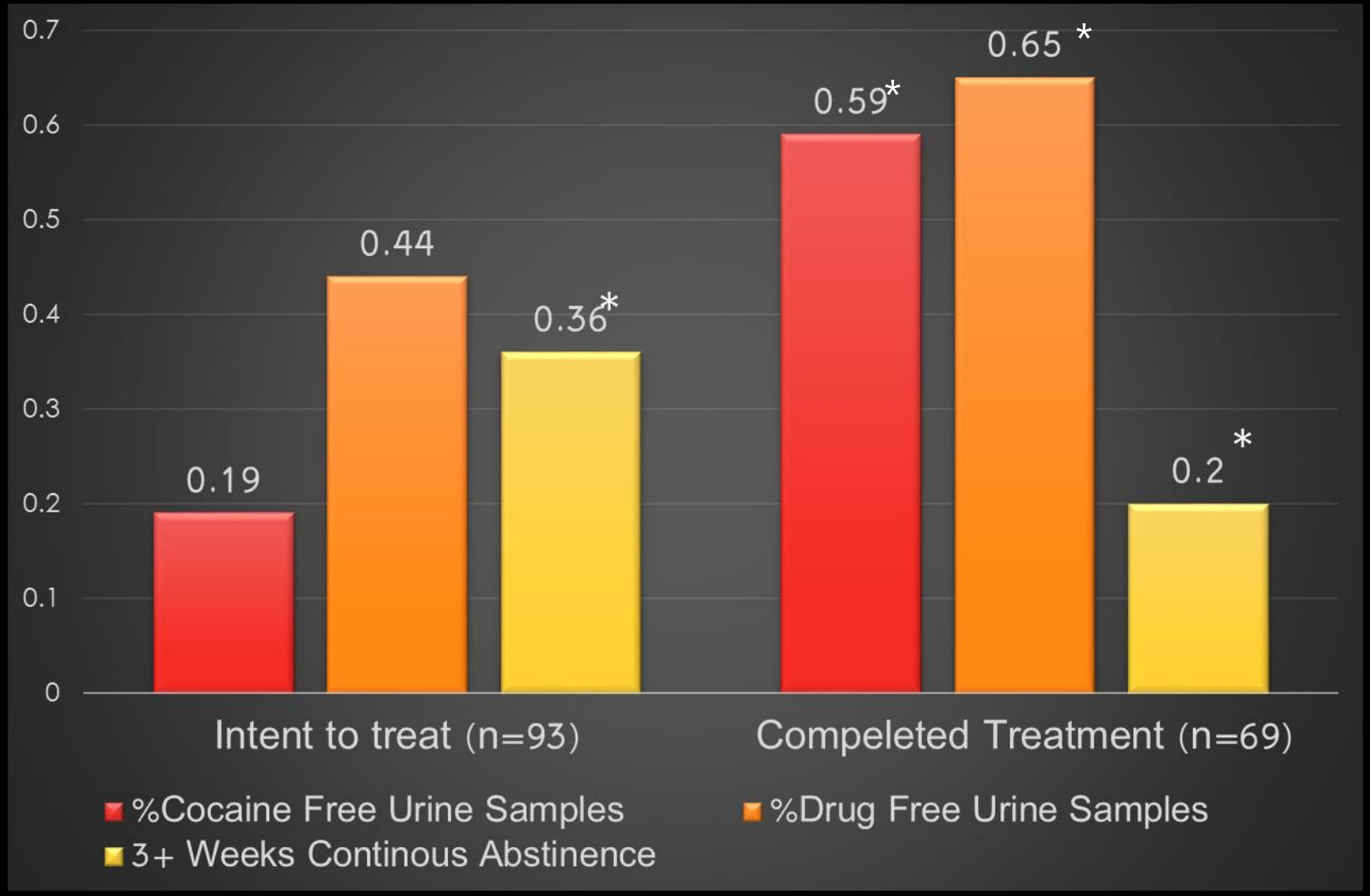
Castells et al 2009, AM J Drug and Alcohol Abuse
DOI: 10.1080/00952990903108215

COGNITIVE BEHAVIORAL THERAPY (CBT)

- Based on theory that learning processes play crucial role in development of maladaptive behavior patterns
- Helps patients identify likely problems, apply coping strategies
- Examples include
  - Exploring positive and negative consequences of continued drug use
  - Self-monitoring to recognize carvings early, identify situations that might lead to drug use
  - Developing strategies to cope with cravings, avoid high-risk situations

National Institute on Drug Abuse, 2018, Principles of Drug Addiction Treatment. https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/preface

COMPUTER-ASSISTED DELIVERY OF CBT FOR COCAINE-DEPENDENT INDIVIDUALS MAINTAINED ON METHADONE



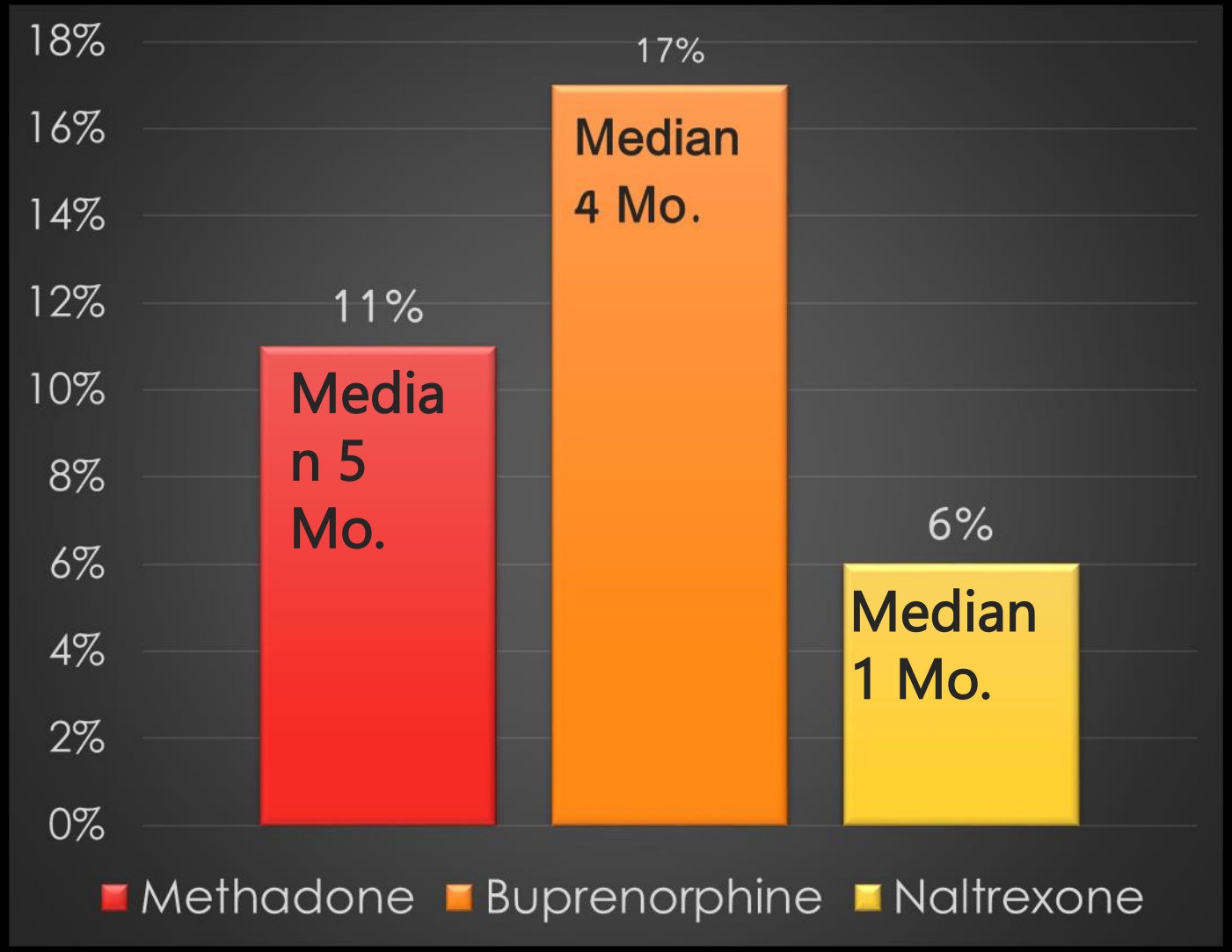
- 101 patients with CUD randomized to standard MMT or MMT + weekly access to computer-based training for cognitive behavioral therapy
- 8 week trial
- Effect sizes

Carroll et al., Am J Psychiatry, 2014

WHAT IF I WANT TO DISCONTINUE MOUDS?

- No universally agreed upon length of treatment
- Cohort studies suggest that many who discontinue MOUDs resume use, *e.g.* 87% within 18 months after MMT (Nosyk et al, 2012).
- Many patients benefit from very long-term, even lifetime treatment
- If you must, TIP 63 recommends:
  - Gradual taper, adjusted if necessary for return to use
  - Psychosocial treatment
  - Possible use of naltrexone once tapered off agonists for sufficient duration

CHALLENGE: PERCENTAGE RECEIVING MOUD AFTER NON-FATAL OVERDOSE, LENGTH OF TREATMENT

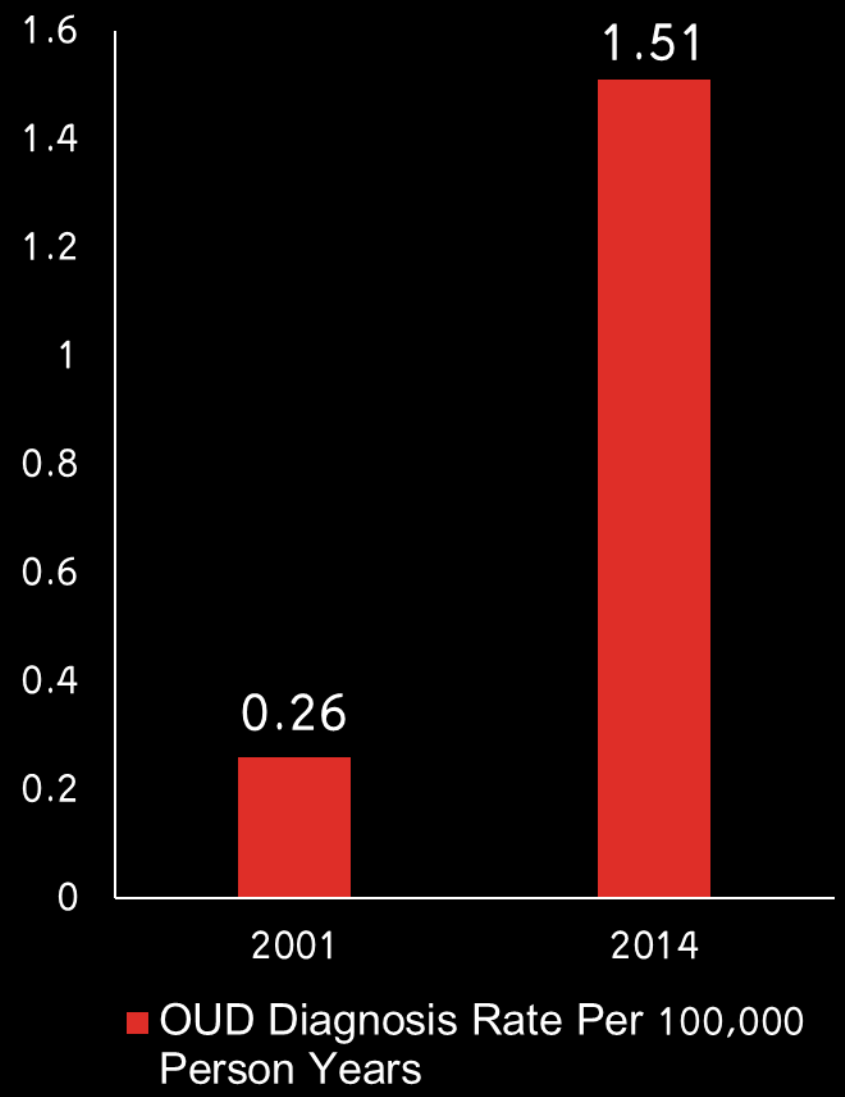


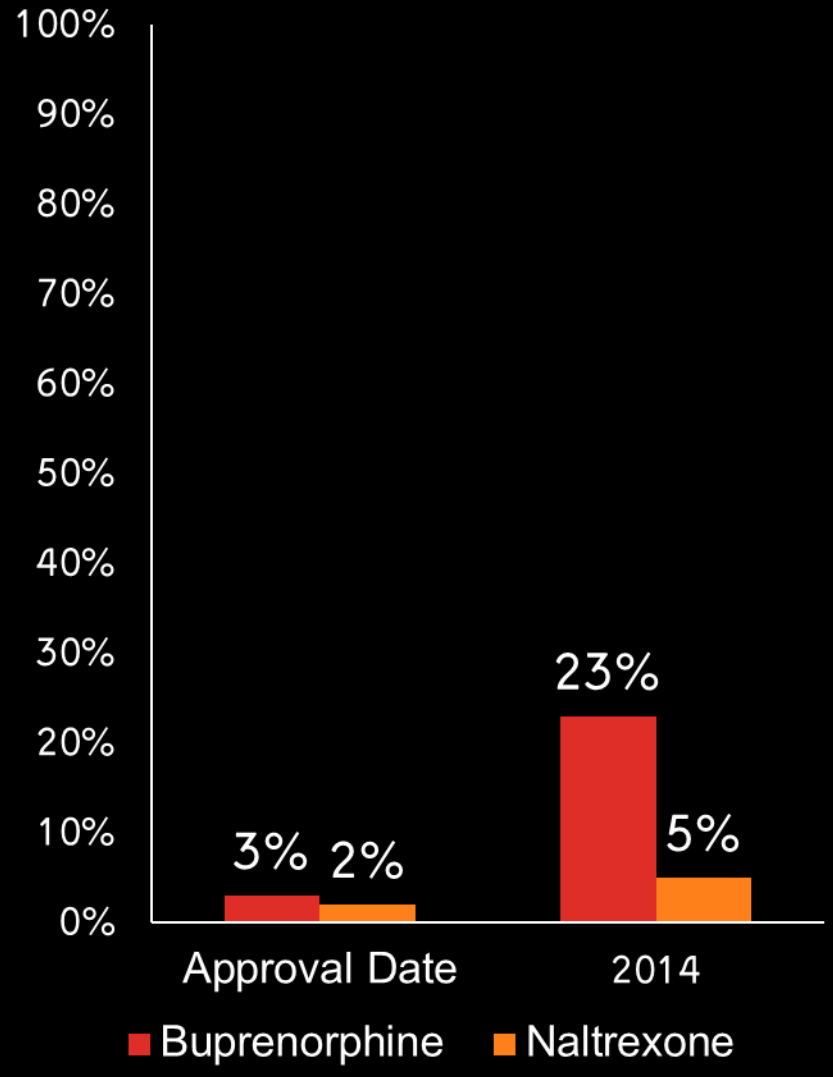
- Retrospective Cohort Analysis
- 17,586 persons in MA
- 30% received at least one mo. of MOUD in 12 mo. post OD

- Source: Larochelle, et al, 2018, Annals of Internal Medicine doi: 10.7326/M17-3107

OUD DIAGNOSIS, MEDICATION RECEIPT FOR ADOLESCENTS AND YOUNG ADULTS

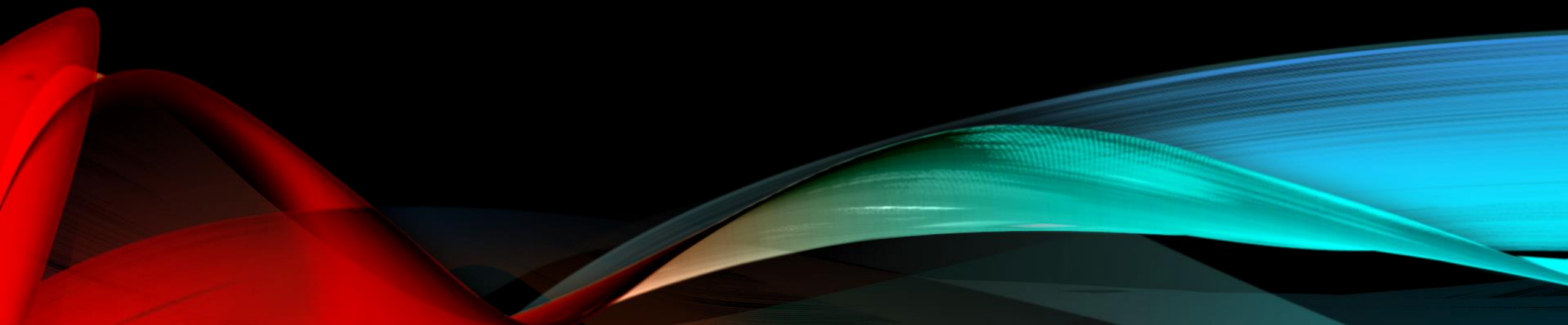
- Commercial claims, large insurer
- Individuals age 13-25 with OUD and 6 months continuous (n=20,822)
- 2001-2014
- 88% age 18+, 22% age 13-15



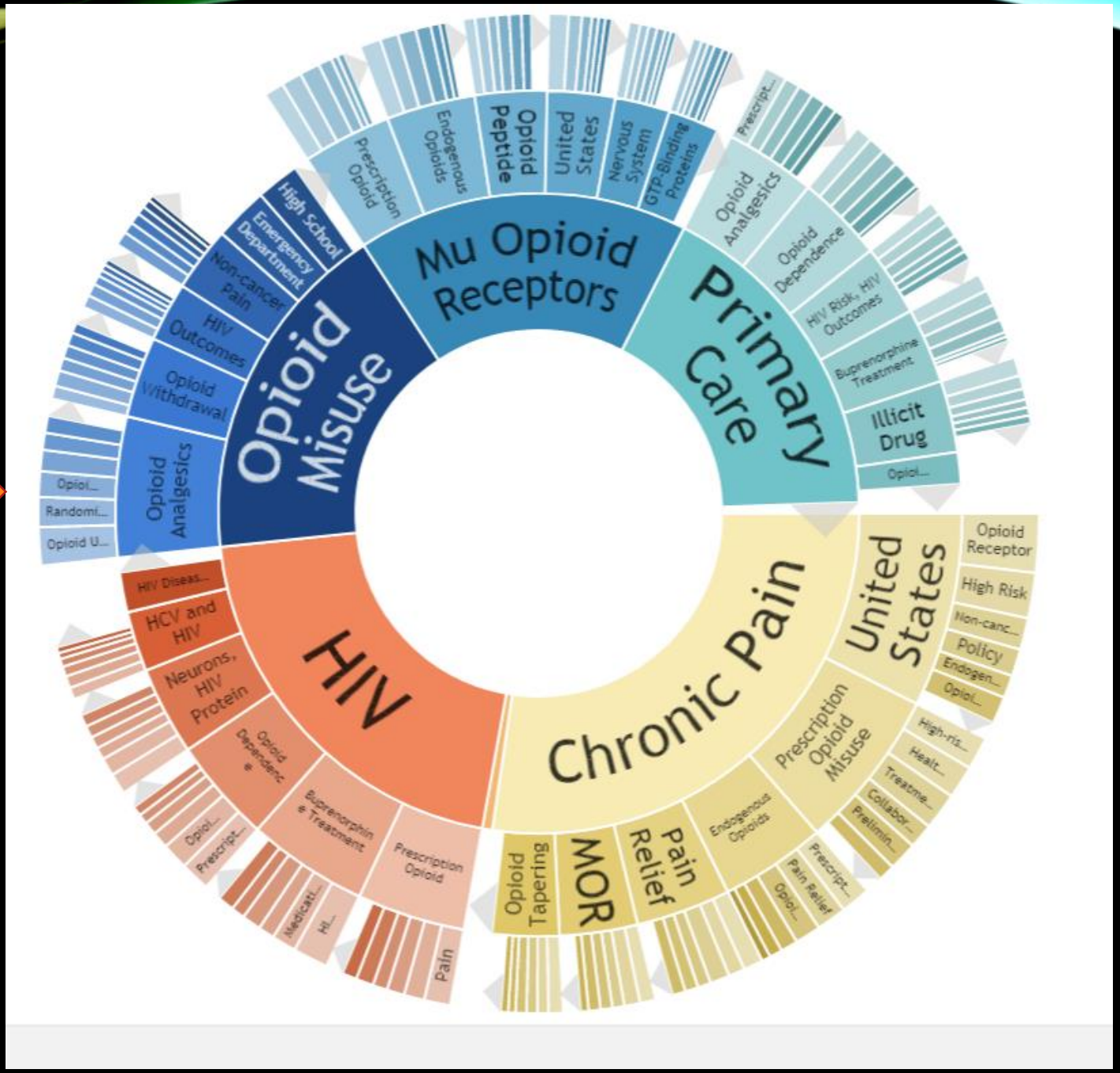


Source: Hadland et al, 2017 *JAMA Pediatrics*

ILLUSTRATIVE CURRENT RESEARCH PROJECTS



- 600+ active grants with opioid, opiate, methadone, buprenorphine, or naltrexone, in the title
- Contracts
- NIDA Intramural Research Program



https://projectreporter.nih.gov/reporter.cfm

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Current FY is 2018

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Principal Investigator (PI) / Project Leader: (Last Name, First Name)
Use '%' for wildcard in PI names
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Organization: LOOKUP
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Department Type: SELECT

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T: Application Type; Act: Activity Code; Project: Admin IC,Serial No.; Year: Support Year/Supplement/Amendment

T	Act	Project	Year	Sub #	Project Title	Contact PI/ Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
5	R21	DA041553	02		PEER-FACILITATED PHYSICAL ACTIVITY INTERVENTION DELIVERED DURING METHADONE MAINTENANCE	ABRANTES, ANA MARIA et al.	BUTLER HOSPITAL (PROVIDENCE, RI)	2017	NIDA	NIDA	$209,717	
1	R34	DA043957	01		PREVENTING INJECTION: AN MHEALTH INTERVENTION THAT LEVERAGES SOCIAL NETWORKS TO PREVENT PROGRESSION TO INJECTION AMONG YOUNG OPIOID USERS	ACOSTA, MICHELLE C et al.	NATIONAL DEVELOPMENT & RES INSTITUTES	2017	NIDA	NIDA	$268,625	
5	K01	DA036452	05		SOCIAL NETWORKS OF YOUTH WHO MISUSE PRESCRIPTION OPIOIDS AND RISK FOR HIV/HCV	AL-TAYYIB, ALIA	DENVER HEALTH AND HOSPITAL AUTHORITY	2018	NIDA	NIDA	$151,618	
5	R01	DA029910	08		PRISON INTERVENTIONS AND HIV PREVENTION COLLABORATION	ALTICE, FREDERICK LEWIS	YALE UNIVERSITY	2017	NIDA	NIDA	$660,401	
1	K08	DA043050	01		LEVERAGING THE ELECTRONIC HEALTH RECORD TO REDUCE OPIOID ANALGESIC PRESCRIPTIONS	BACHHUBER, MARCUS A	ALBERT EINSTEIN COLLEGE OF MEDICINE, INC	2017	NIDA	NIDA	$199,260	
1	K23	DA044324	01		A BEHAVIORAL INTERVENTION TO ENGAGE EMERGING ADULTS IN ADDICTION TREATMENT AFTER A NON-FATAL OPIOID OVERDOSE	BAGLEY, SARAH M	BOSTON MEDICAL CENTER	2017	NIDA	NIDA	$191,121	
1	R36	DA042877	01		THE IMPACT OF PRESCRIPTION OPIOID RECEIPT ON HEROIN INITIATION AMONG VETERANS	BANERJEE, GEETANJOLI	BROWN UNIVERSITY	2017	NIDA	NIDA	$37,190	
5	K23	DA040923	02		IMPROVING OPIOID PRESCRIPTION SAFETY AFTER SURGERY	BARTELS, KARSTEN	UNIVERSITY OF COLORADO DENVER	2017	NIDA	NIDA	$192,097	
5	K23	DA039328	02		DISCONTINUATION FROM CHRONIC OPIOID THERAPY FOR PAIN USING A BUPRENORPHINE TAPER	BARTH, KELLY S.	MEDICAL UNIVERSITY OF SOUTH CAROLINA	2017	NIDA	NIDA	$200,772	

VACCINES

- Goal: Produce antibodies that bind the targeted opioid in blood and extracellular fluid and stop it from getting to the brain
- May be safer, and longer lasting than current medications
- Recent animal studies show promise (Raleigh et al., 2018, J pharmacology and experimental therapeutics, DOI: 10.1124/jpet.117.247049)
- Human study underway 1UG3DA047711-01, Phase 1A/1B Clinical Trials of Multivalent Opioid Vaccine Components (PI Comer)

NEW, REPURPOSED COMPOUNDS, LONG-TERM EFFECTS

- Highly selective D3 receptor antagonists (e.g. VK4-116)
  - Animal studies suggest it inhibits oxycodone reward and reduces withdrawal effects (Yu et al, 2018, Neuropsychopharmacology https://doi.org/10.1038/s41386-018-0284-5)
- Nalmefene (antagonist) implants, 6 month + duration. Lower liver toxicity risk than current MOUDs (1UG3DA047707-01, NALMEFENE IMPLANT FOR THE LONG-TERM TREATMENT OF OPIOID USE DISORDER, PI BEEBE DEVARNEY)

ENHANCING PATIENT EXPERIENCE

- Peer-facilitated physical activity intervention for MMT patients (R33DA041553-03, PI Abrantes)
- Provider-Pharmacy Practice Agreements for the provision of buprenorphine and naltrexone (4R33DA045848-02, PI Green)
- Patient Decision Aid for Medication-Assisted Treatment (PtDAMAT), to help patients understand and choose the approach that meets their needs and values (4R33DA045844-02 PI Hser)
- A Smartphone App to Facilitate Buprenorphine Discontinuation (R21 DA 041153-01)

THANK YOU!