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Not X-Rated Anymore: The Future of Suboxone

Nzinga A. Harrison, MD, DFAPA Co-Founder & Chief Medical Officer, Eleanor Health Author, Un-Addiction: 6 Mind-Changing Conversations That Could Save a Life

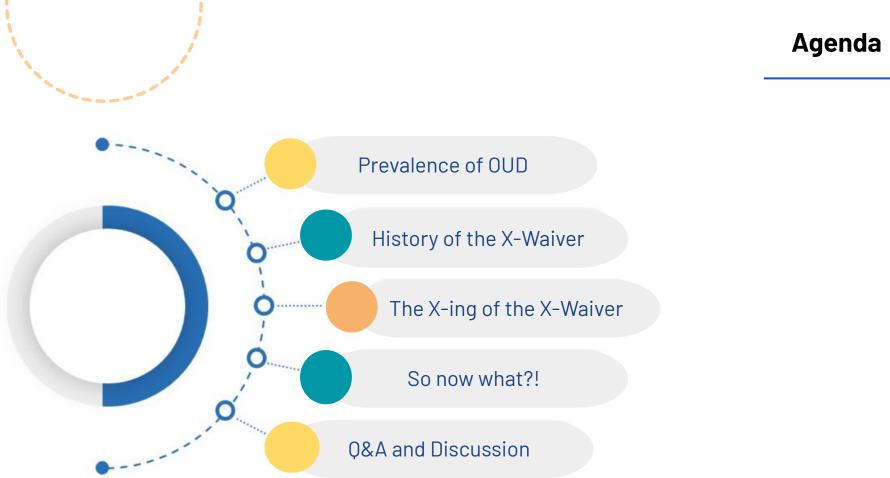


Disclosures

I have no disclosures.



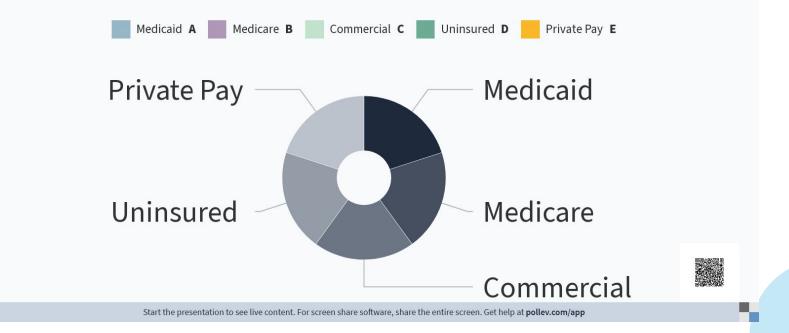
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Prevalence of OUD

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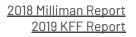
What is the predominant patient population you serve?





National Average

- 5% of U.S. adults say they have misused or been addicted to opioids or prescription painkillers
- Medicaid <u>8.9 per 1000</u>: Prevalence of OUD is higher among
 - Males compared to females (5.7 percent compared to 4.4 percent)
 - Whites compared to African-Americans and Hispanics (6.6 percent compared to 2.7 percent and 2.4 percent)
 - Enrollees in rural areas, states report a growing problem in urban areas
- Medicare <u>5.39 per 1000</u>
- Commercial <u>3.28 per 1000</u>

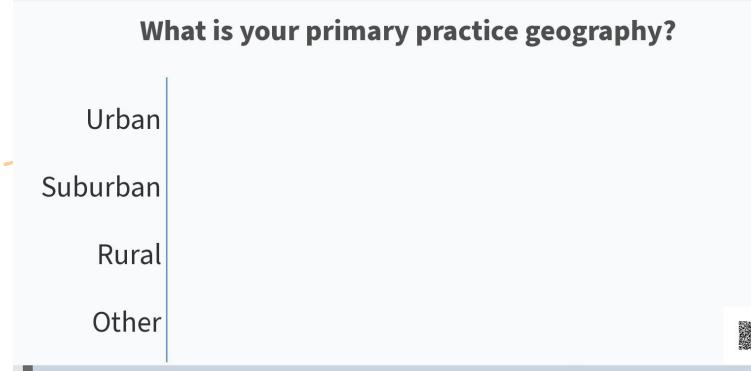


OUD Treatment

- Buprenorphine
 - reduces opioid misuse
 - decreases risk for injection-related infectious diseases
 - decreases risk for fatal and non-fatal overdoses

Only **22%**

of people with opioid use disorder receive medications When poll is active, respond at pollev.com/nzingaharris835
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OUD Treatment Disparities

Race/Ethnicity Disparities

- Following an opioid-related event such as an overdose, infection, or detox admission, White patients received medication for opioid use disorder (OUD):
 - up to 80% more frequently than Black patients and
 - up to 25% more frequently than Hispanic patients
 - Al/Pl not even mentioned

Geographic Disparities

• Rural/Geographic: 56 percent of rural counties do not have a provider who can prescribe buprenorphine, a treatment for opioid use disorder. Further, 2 percent of Americans living in urban areas are without access to a buprenorphine provider, compared with 30 percent of rural residents.

Socioeconomic Disparities

• Socioeconomic : three-quarters of prescriptions for buprenorphine go to those who pay cash or have private insurance

<u>Substantial racial inequalities despite frequent healthcare contact</u> <u>Exploring Urban-Rural Disparities in Accessing Treatment for OUD</u> <u>Stark racial, financial divides found in opioid addiction treatment</u>

History of the X-Waiver



- Allowed physicians for first time in almost a century to prescribe for OUD in an office-based setting
- Requirements
 - o DEA (State)
 - Board Certified in Addiction Psychiatry or Addiction Medicine
 - 8 hours training
 - Researcher
 - Apply for waiver X (federal)
- Waiver: 30, 100, 275
- Worries: Precipitated withdrawal, OD and Diversion

Overdose and Buprenorphine

- Between July 2019 and June 2021 buprenorphine-involved overdose deaths represented 2.6% of the 74,474 opioid-involved overdose deaths recorded in the SUDORS dataset.
- Between April 2020 and June 2021, when buprenorphine prescribing regulations were relaxed in response to the COVID-19 pandemic, monthly opioid-involved overdose deaths increased overall but the proportion of those deaths involving buprenorphine did not increase.
- 92.7% of buprenorphine-involved overdose deaths also involved at least one other drug

X-Waiver Usage

2015 2020 16% of Psychiatrist waivered representing 41.6% of PCPs affiliated with hospital health systems less likely waivered docs and primarily in rural areas to have waiver than unaffiliated (3.6% versus 8.2%) 3% of PCPs waivered Reverse is true for psychiatrists (33.2% versus 26.2%). • 30 Million people living in counties without Suboxone 70% of waivered PCPs in health systems have only a • waivered physician 30-patient limit • 77% of waivered psychiatrists in health systems have only a 30-patient 2019 The number of DATA-waivered providers more than 2022 **doubled** from 32,129 in 2016 to 70,020 in 2019. Approximately 44% of DATA-waivered providers chose to not be publicly listed in the SAMHSA treatment locator tool. Survey study of 126 clinicians attending a ED Docs: 1 in 5 waivered GetWaiveredTX waiver training: 1/3 order Bup for OUD in last 3 months 61 clinicians received an X-waiver; among them, 0 0 <30% felt prepared to initiate Bup 36% were prescribing buprenorphine and 64% 0 were not.

Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder

Geographic location of buprenorphine-waivered physicians and integration with health systems

Survey of Barriers and Facilitators to Prescribing Buprenorphine and Clinician Perceptions on the Drug Addiction Treatment Act of 2000 Waiver

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Before the X-waiver was X'd, were you waivered?

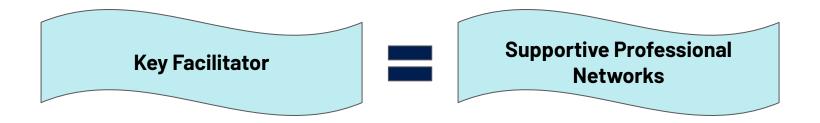


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Barriers to Prescribing Suboxone

- Complexity of X-waiver process
- Perceived lack of professional support
- Referral network as barriers to prescribing buprenorphine



Survey of Barriers and Facilitators to Prescribing Buprenorphine and Clinician Perceptions on the Drug Addiction Treatment Act of 2000 Waiver

The X-ing of the X-Waiver

Waiver Elimination Act



Waiver Elimination Act

Effective June 2023

All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law and SAMHSA encourages them to do so.



Waiver Elimination Act

- No longer need X-DEA number
- No longer have to register with SAMHSA
- No more prescribing limits

Upon submission of new or renewal DEA application, **ALL physicians** must have **one** of the following:

A total of eight hours of training from certain organizations on opioid or other substance use disorders for practitioners renewing or newly applying for a registration from the DEA to prescribe any Schedule II-V controlled medications;

Board certification in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, American Board of Addiction Medicine, or the American Osteopathic Association; or

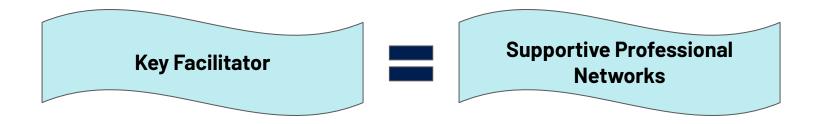
So now what?!



Barriers to Prescribing Suboxone

Complexity of X waiver process

- Perceived lack of professional support
- Referral network as barriers to prescribing buprenorphine



Survey of Barriers and Facilitators to Prescribing Buprenorphine and Clinician Perceptions on the Drug Addiction Treatment Act of 2000 Waiver

What are barriers that are keeping you from prescribing buprenorphine?

Тор



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- Screening
- Induction
 - Fentanyl
 - Precipitated Withdrawal
- Brixadi
- Follow up
- Billing



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Screening for SUD			Screening for mod/severe OUD	
Have you ever felt the need to cut down on your drinking or drug use?	Yes	No	DSM-5 Criteria for Substance Use Disorder (<u>></u> 2 items in 12 months)	
Have people annoyed you by criticizing your drinking or drug use?	Yes	No	 g 1. Failure to fulfill responsibilities ✓ 2. Use in physically hazardous situations ✓ 	
Have you ever felt guilty about drinking or drug use?	Yes	No	 Particle in the second state of the second state of	
Have you ever felt you needed a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover (Eye-Opener)?	Yes	No	Mild=2-3	
			B 6. Cannot cut down ✓ Severe=6+	
1 "yes" = 79% sensitivity for S 77% specificity for S			9 5. Use larger amts or longer than intended ✓ 6. Cannot cut down ✓ 7. ↑ time spent to get, use, and recover ✓ 8. Give up or ↓ other important parts of life ✓ 9. Ongoing use despite problems ✓ 10. Tolerance ✓ 11. Withdrawal ✓	

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.

Resting Pulse Rate: beats / minute Messured after patient is sitting or lying for one minute is (i) pulse Rate 80 ar below (ii) pulse 81 to 100 (iii) pulse 101 to 120 (iii) pulse rate greate than 120	Gl Upset: over last 1/2 hour 0 no GI symptoms 1 stamach cramps 2 nausee or losse stool 0 vomiting or diarrhea 5 multiple episades of diarrhea or vamiting
Sweeting: over past 1/2 hour not accounted for by room temperature or potient activity. © no report of chills or flushing 1 subjective report of chills or flushing 2 tubshed or observable moistness on face 3 backs of sweet on frave or face 4 sweet streaming off face	Tremor: Observation of autstretched hands 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor abservable 3 grass tremor or muscle twitching
Restlessness: Observation during assessment (0) able to sit still 1) reports difficulty sitting still, but is able to do so 1) frequent shifting or extraneous movements of legs/arms (5) unable to sit still for more than a few seconds	Yawning: Observation during assessment on a grawning 1 grawning once or twice during assessment or twice during assessment 2 grawning three or more times during assessment or times/minute
Pupil size: 9 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 9 pupils moderately dilated 9 pupils so dilated that only the rim of the iris is visible	Anxiety or Irritability: Measured ofter patient is sitting or lying for one minute (a) notion reports increasing irritability or anxiousness (c) patient obviously irritabile or anxious (c) patient so irritabile or anxious that participation in the assessment is difficult
Bone or Joint aches: If the patien was having pain previously, only the additinal component attributed to opiates withdrawal is scored in nit affuse discomfort in mild affuse discomfort ip patient reports severe diffuse aching of joints/muscles ip patient is rubbing joints or muscles and is unable to sit still because of discomfort	Gooseflesh skin: Skin is smooth Jilaerrection of skin can be felt or hairs standing up an arms for prominent piloerrection
Runny nose or tearing: Not acounted for by cold symptoms or allergies In or present In asol stuffiness or unusually moist eyes In one scale stuffines or energy In one 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

- This is your history and physical exam
- Can be done virtually by patient report
- Total Score = Sum of all 11 items
 - 5-12 MILD
 - o 13-24 Moderate
 - 25-36 Moderately severe
 - >36 Severe

• Induction

Evaluation	COWS <4	COWS 4-7	COWS>8
 OUD History COWS UDS (POC or send out) Hep C, HIV 	• No induction	 <u>Day 1</u>: 8 mg + 4mg PRN, max 12mg <u>Day 2</u>: 8mg BID <u>Day 4</u>: Nurse Check-In for COWS Adjust to 8mg TID for COWS>0 or craving 	 <u>ASAP</u>: 8mg + 8mg PRN, max 16mg <u>Day 2</u>: 8mg BID <u>Day 4</u>: Nurse Check-In for COWS Adjust to 8mg TID for COWS>0 or craving
Prescril	be Narcan + comfort	meds: NSAID, antihistamine, anti-em	etic, anti-diarrheal
	Recon	nmend hydration and multi-vitamin	
	Mental health s	creening and refer for psychosocial su	upport

Incidence of Precipitated Withdrawal During a Multisite Emergency Department-Initiated Buprenorphine Clinical Trial in the Era of Fentanyl

Quick Start Guide to Prescribing Bup - Brixadi!

Indication	for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

Evaluation	COWS <4	COWS 4+
 OUD History COWS UDS (POC or send out) Hep C, HIV 	• No induction	 <u>Day 1</u>: 4 mg SBX SL, wait 30 minutes → 16mg SQ BRX <u>Day 3</u>: +8mg SQ BRX <u>Day 4-7</u>: +8mg SQ BRX PRN elevated COWS score <u>Day 8+</u>: 1st week total dose (24mg-32mg) SQ q7 days Maximum weekly dose 32mg
Prescri		meds: NSAID, antihistamine, anti-emetic, anti-diarrheal

Mental health screening and refer for psychosocial support

Quick Start Guide to Prescribing Bup - Brixadi!

Patients currently being treated with a transmucosal buprenorphine-containing product may be switched directly to either BRIXADI (weekly) or BRIXADI (monthly).

Daily dose of sublingual buprenorphine	BRIXADI (weekly)	BRIXADI (monthly)
$\leq 6 \text{ mg}$	8 mg	-
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg

Patients may be transitioned from weekly to monthly or from monthly to weekly dosing of BRIXADI based on clinical judgment

BRIXADI (weekly)	BRIXADI (monthly)
16 mg	64 mg
24 mg	96 mg
32 mg	128 mg

Consider Brixadi

From a health equity perspective, special needs populations with significantly negative OUD outcomes disparities that would benefit from a weekly formulation that can be started after only one SL test dose include:

- Individuals being discharged from EDs in communities without adequate access to buprenorphine
 - ED docs are often reticent to prescribe buprenorphine if there is not access to outpatient care within 3 days.
 - a shot of Brixadi would provide coverage for one week follow-up
- **Unhoused individuals**: Face unique barriers to care including requirements for:
 - lengthy intake processes
 - frequent visits with consistent attendance
 - complete abstinence from other substances
- **Incarcerated individuals**: Jails with short stays are particularly reticent to prescribe buprenorphine on initial incarceration because of concerns about:
 - in-jail diversion
 - lack of adequate community access to continue care
 - individuals prescribed buprenorphine during incarceration are less likely to face rearrest and reconviction
 - opioid overdose risk is 10x greater for those recently released from incarceration, a weekly shot to allow time for connection to ongoing services could be life saving

- Fentanyl
 - Increases risk of precipitated withdrawal
 - Increases risk of overdose death
 - More reason to do the induction: anticipatory guidance, comfort meds, higher dose of Bup
- Precipitated Withdrawal
 - Among 1200 enrolled patients, there were 9 cases of PW, or 0.76% (95% CI, 0.35%-1.43%)
 - All patients had urine tests positive for fentanyl, 7 with multiple drugs
 - All patients experiencing PW were discharged after symptoms resolved, with 1 self-directed discharge

- Stabilizing Bup
 - **<u>Goal</u>**: COWS = 0, Craving = 0
 - Increase dose as high 24mg per day as early as Day 4
- Billing not exhaustive!
 - E+M Codes: 9920x-9921x
 - Psychotherapy add-on: 90833, 90838
 - Psychotherapy codes: 90832-90837
 - Presumptive Toxicology: 80305
 - Oral medication administration: H0033
 - Behavioral Health Screening: 96156
 - Telehealth modifiers
 - Medicare G Codes



• What about telemedicine?

YES

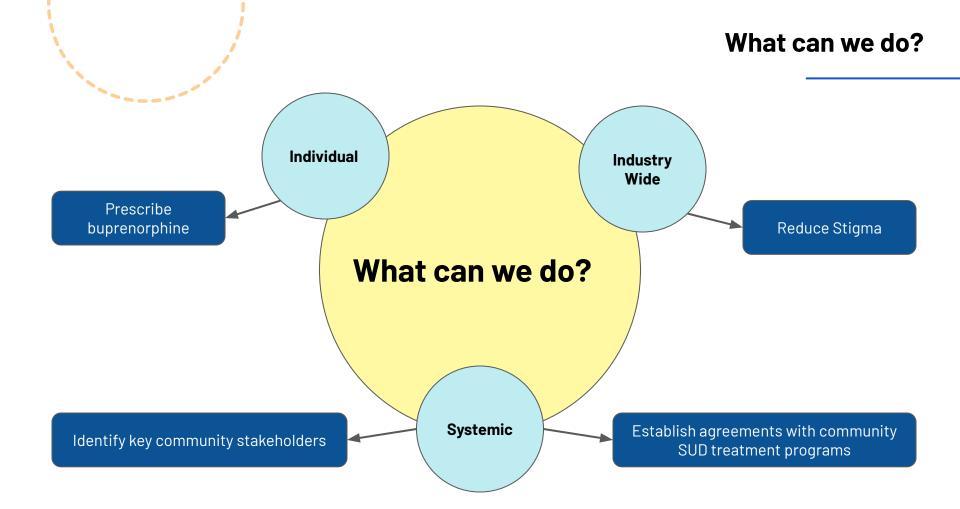
Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic

Ruth Hailu, AB¹; Ateev Mehrotra, MD^{1,2}; Haiden A. Huskamp, PhD¹; <u>et al</u> > Author Affiliations | Article Information JAMA Netw Open. 2023;6(1):e2252381. doi:10.1001/jamanetworkopen.2022.52381

Findings In this cohort study of 11 801 patients with OUD with commercial insurance or Medicare Advantage coverage, there were no significant differences in visit frequency, initiation of medications for OUD, or OUD-related adverse outcomes between those who were treated by clinicians with high vs low telemedicine use across the prepandemic and pandemic periods.

Key Facilitator to Prescribing Suboxone Supportive Professional Key Facilitator Networks Providers Clinical Support PCSS NEWS DISCUSSION FORUM CONTACT Q ABOUT EDUCATION & TRAINING 8 HOUR MOUD COURSE MENTORING **CLINICAL TOOLS** About Mentoring Discussion Forum Ask a Clinical Question One-on-one Mentori Meet Our Mentors Discover the rewards of treating patients with Opioid Use Disorders Lead Mentors Learn More Request a Mento

Survey of Barriers and Facilitators to Prescribing Buprenorphine and Clinician Perceptions on the Drug Addiction Treatment Act of 2000 Waiver



Questions & Discussion



