A Pharmacy-Based Approach to Caring for Individuals with Opioid-Use Disorder

March 2, 2023

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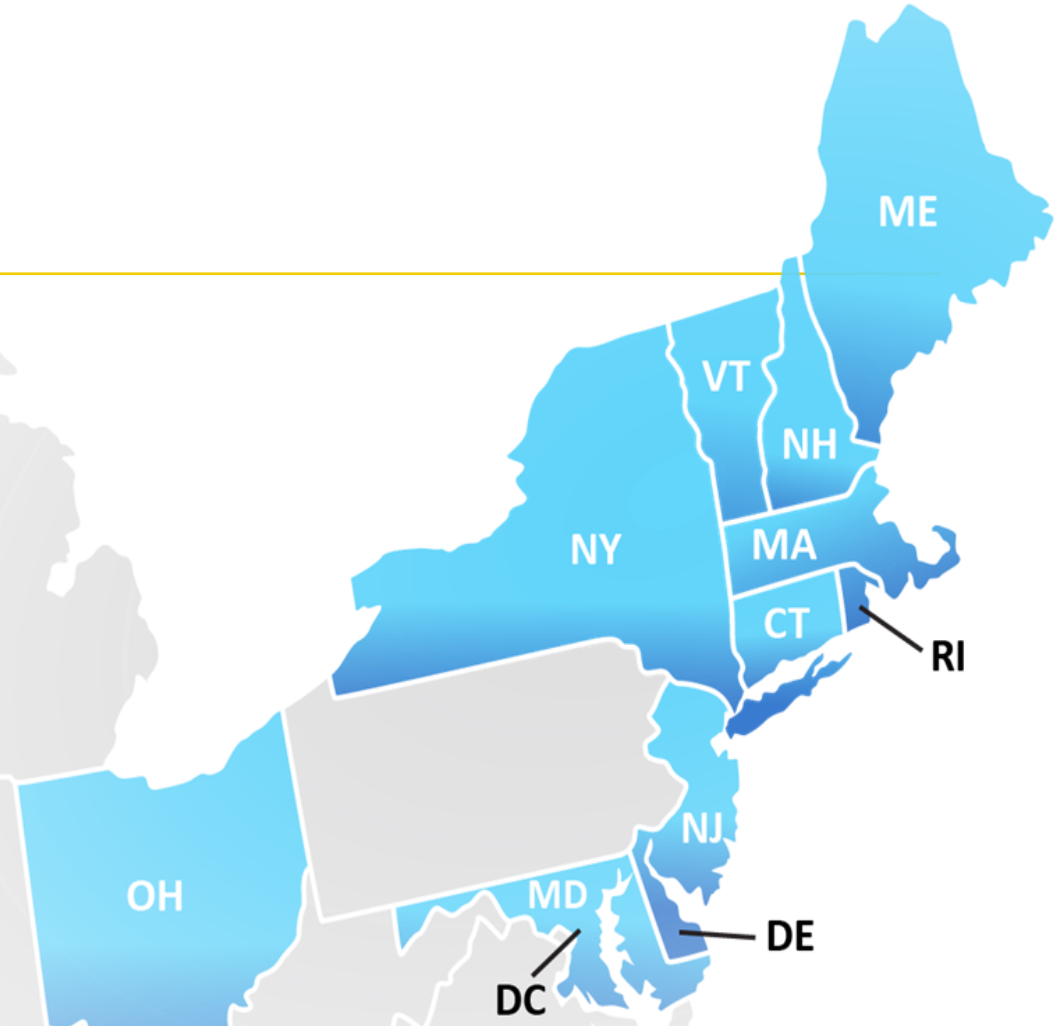

Working to ensure high-quality, safe healthcare for
20% of the nation's Medicare FFS beneficiaries

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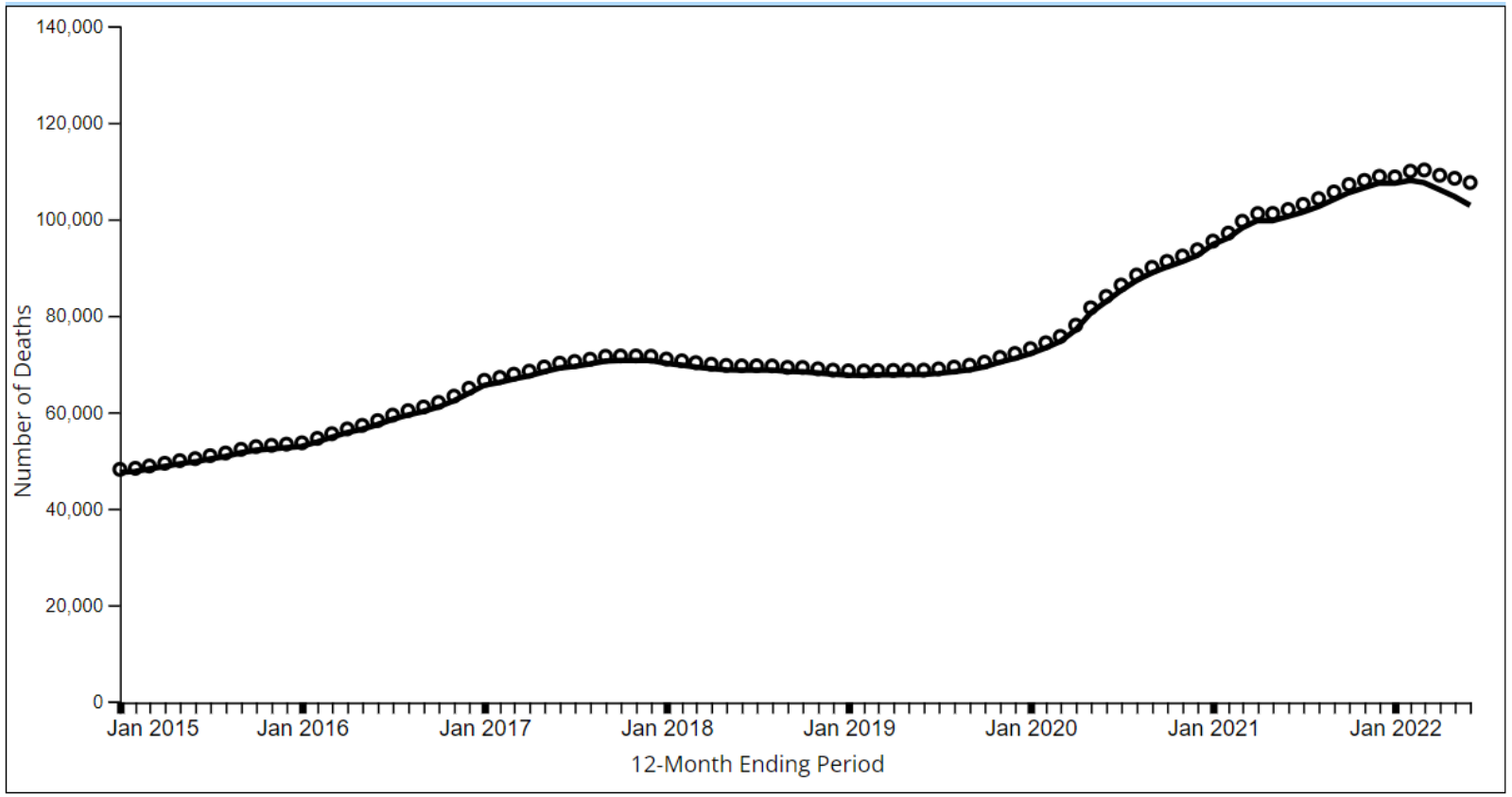
Please Chat In…

- Who is on the webinar with us today,
  - What organization you are with,
  - Where are you located, and
  - What is your role within your organization?

Today's Facilitator

Marghie Giuliano, RPh
Medication Safety Pharmacist
Healthcentric Advisors

Opioids: Provision Counts Overdose Deaths US



Select Jurisdiction

United States

Predicted Value

Reported Value

5.5%

06/21-06/22

Update 11/06: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

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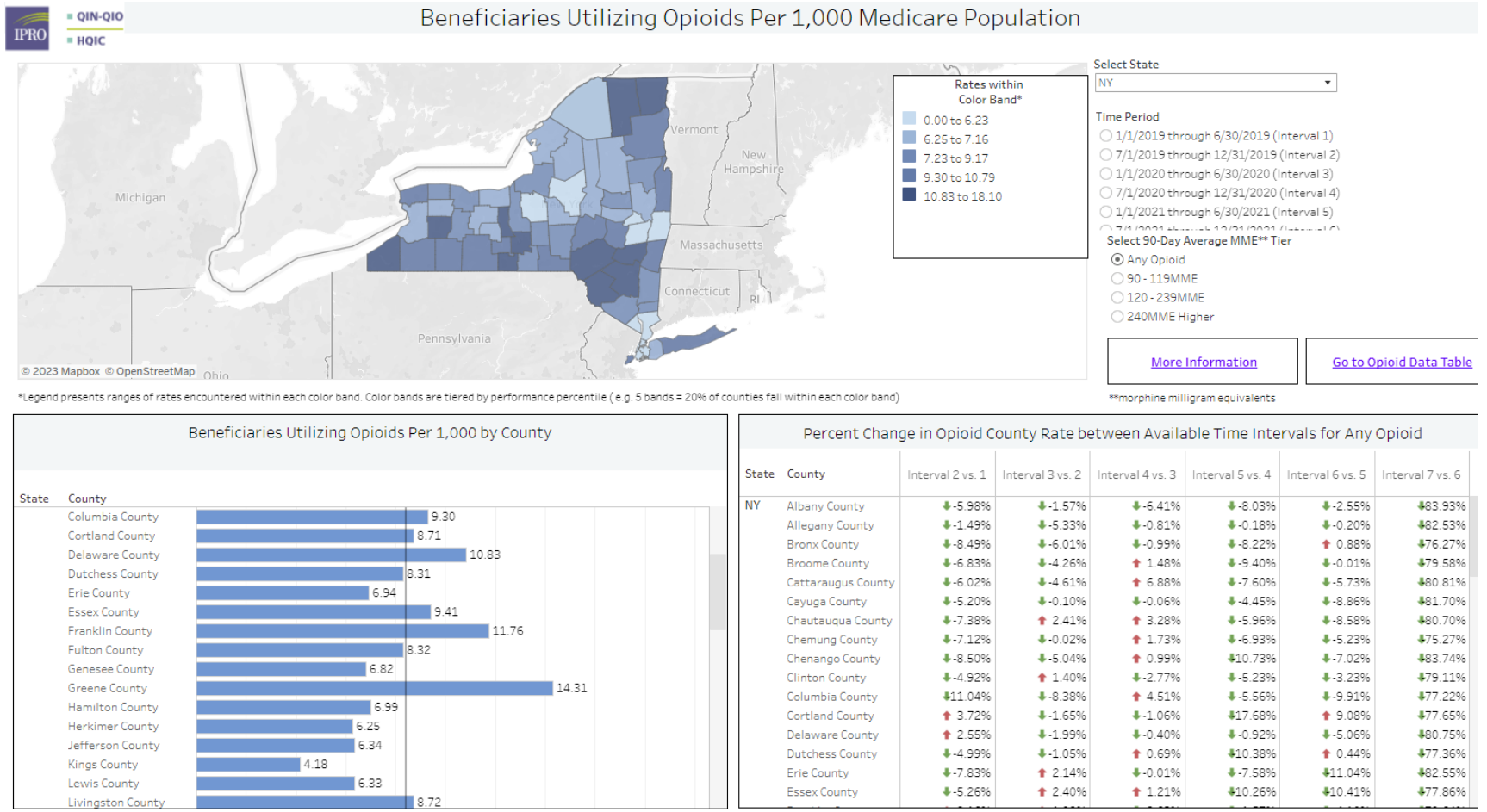
Opioid Utilization Dashboard



https://qi-library.ipro.org/2023/01/12/ipro-qin-qio-opioid-utilization-dashboard/

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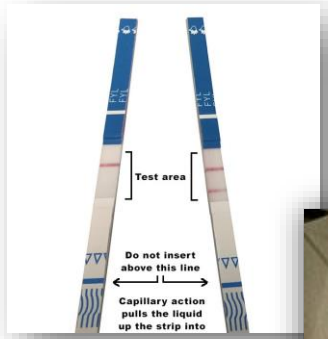
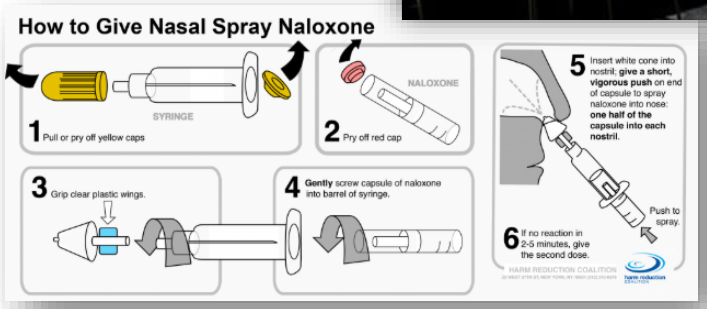
Harm Reduction Strategies

- Fentanyl Test Strips
- Safe Injection Sites
- Access to Naloxone
  - FDA approve to move naloxone to OTC





Medications for Opioid Use Disorder

FDA-approved medications for opioid addiction, overdose, and withdrawal work in various ways.

Opioid Receptor Agonist

Medications attach to opioid receptors in the brain to block withdrawal symptoms and cravings.

Opioid Receptor Partial Agonist

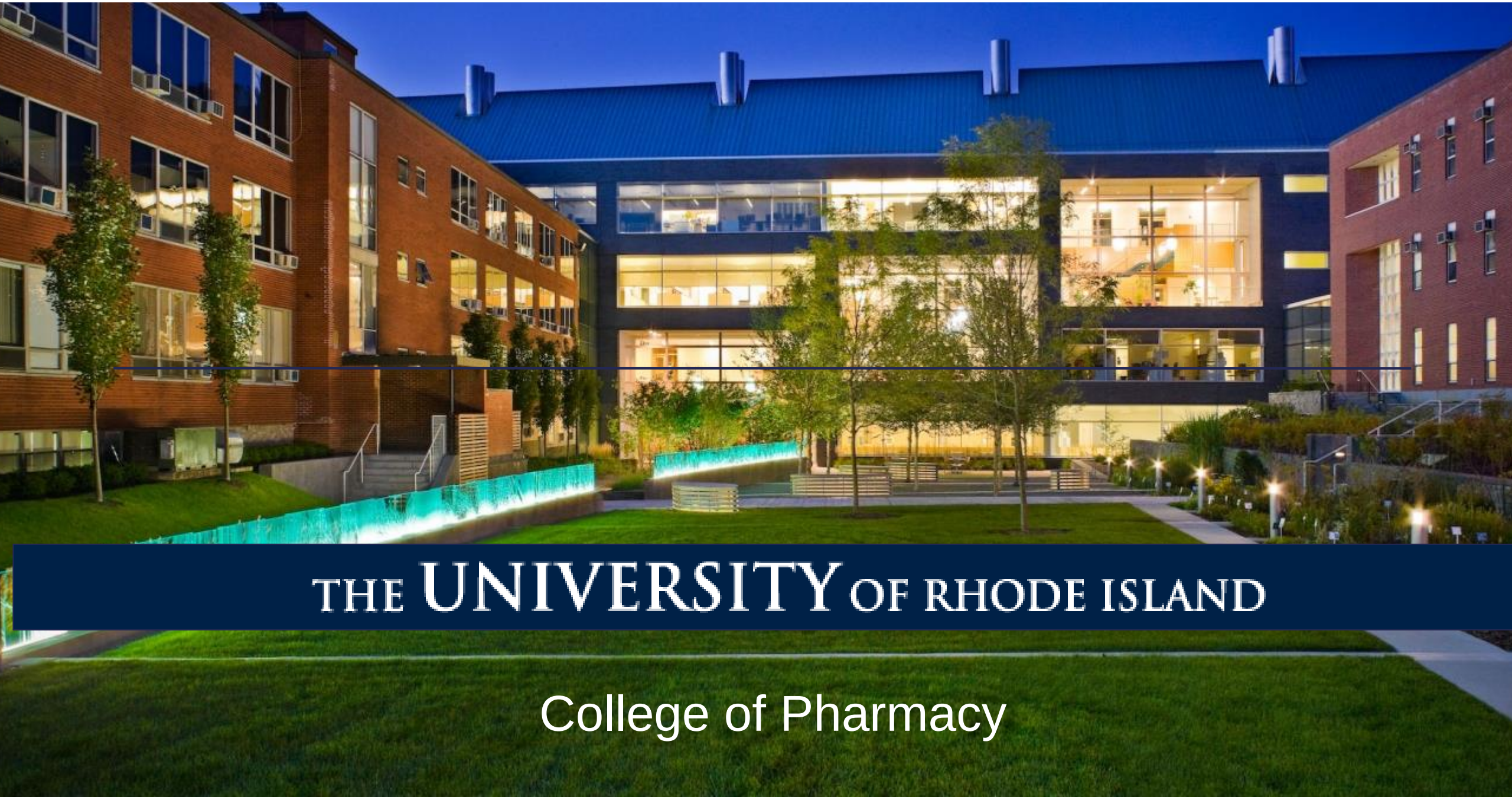
Medications attach to and partially activate opioid receptors in the brain to ease withdrawal symptoms and cravings.

Opioid Receptor Antagonist

Medications block activity of opioid receptors in the brain to prevent euphoric effects (the high) of opioids and alcohol and help reduce cravings.

Today's Speaker

Jeffrey Bratberg, PharmD, FAPhA
Clinical Professor of Pharmacy Practice
University of Rhode Island
College of Pharmacy


THE UNIVERSITY OF RHODE ISLAND
College of Pharmacy

The University of Rhode Island Land Acknowledgement

The University of Rhode Island occupies the traditional homelands of the Narragansett Nation. What is now the state of Rhode Island occupies the traditional homelands and waterways of the Narragansett Nation and the Niantic, Wampanoag and Nipmuc Peoples. We honor and respect the enduring and continuing relationship between these nations and this land by teaching and learning more about their histories and present-day communities, and by becoming stewards of the land we too inhabit. In addition, let us acknowledge the violence of conquest, war, land dispossession and of enslavement endured by Black and Indigenous communities in what is now the United States. Their contemporary efforts to endure in the face of colonialism must be acknowledged, respected and supported.

https://web.uri.edu/artsci/diversity/

A PHARMACY-BASED APPROACH TO CARING FOR INDIVIDUALS WITH OPIOID-USE DISORDER

March 2023

Jeffrey Bratberg, PharmD, FAPhA
Clinical Professor of Pharmacy Practice and Clinical Research
University of Rhode Island College of Pharmacy
Kingston, RI

Learning Objectives

- Recognize the urgent need for barrier-free models of buprenorphine access.
- Explain the key elements of a novel collaborative model of pharmacy-based buprenorphine induction.
- Describe the characteristics of the participants in the model.

Question 1

Which of the following has been documented as a barrier to accessing buprenorphine in the US?

A. Manufacturer drug shortages

B. Lack of 3rd party prior authorization

C. Drug-drug interactions

D. Patient's skin color

Question 2

Which of the following was the key element of a Rhode Island collaborative practice agreement (CPA) that permitted initiation of buprenorphine in the pharmacy?

A. State pharmacist DEA registration

B. Provider status permitting payment for services

C. Patient-initiated saliva toxicology testing

D. Public health emergency audio-only induction

Question 3

Which of the following groups were DISPROPORTIONATELY represented in the buprenorphine induction population as compared to the 2020 RI census?

A. BIPOC

B. Hispanic

C. White

D. Asian

Stateline

Addiction Treatment May Be Coming to a Pharmacy Near You

STATELINE ARTICLE | February 24, 2023 | By: Christine Vestal | Read time: 5 min

Genoa Pharmacist Andrew Terranova, URI PharmD:

"My experience with patients," Terranova said, "showed me that many people seeking treatment face **homelessness, stigma, judgment and economic barriers** every day. So, coming into a pharmacy and being greeted by a pharmacist who wants to sit down with you and talk about being healthy was very much appreciated."

Overall, Terranova said he and the other pharmacists at his pharmacy found the Brown University program rewarding. **"The improvement we saw and our interactions with patients, and to feel their gratefulness for getting help in a way and manner they weren't used to, was extremely rewarding,"** he said.

"I'd be more than willing to jump in and keep helping addiction patients if the program were to ramp up," he said. **"We'd all be willing to participate again and continue what we started."**

https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2023/02/24/addiction-treatment-may-be-coming-to-a-pharmacy-near-you

Stateline

Addiction Treatment May Be Coming to a Pharmacy Near You

STATELINE ARTICLE | February 24, 2023 | By: Christine Vestal | Read time: 5 min

Study Investigator Jody Rich, MD:

"What we have in this epidemic is a workforce issue," Rich said. "We don't have enough bodies prescribing buprenorphine. **Physicians have had more than 20 years to go ahead and prescribe it for their patients with opioid use disorder and the vast majority have said, 'No thank you.'"**

"Pharmacists are the most highly trained and **underappreciated health professionals** we have, and they are in the trenches," Rich said. "They see what's going on out there. We need them now and apparently, they're up for the task."

https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2023/02/24/addiction-treatment-may-be-coming-to-a-pharmacy-near-you

Pharmacist's Oath (6/2021-)

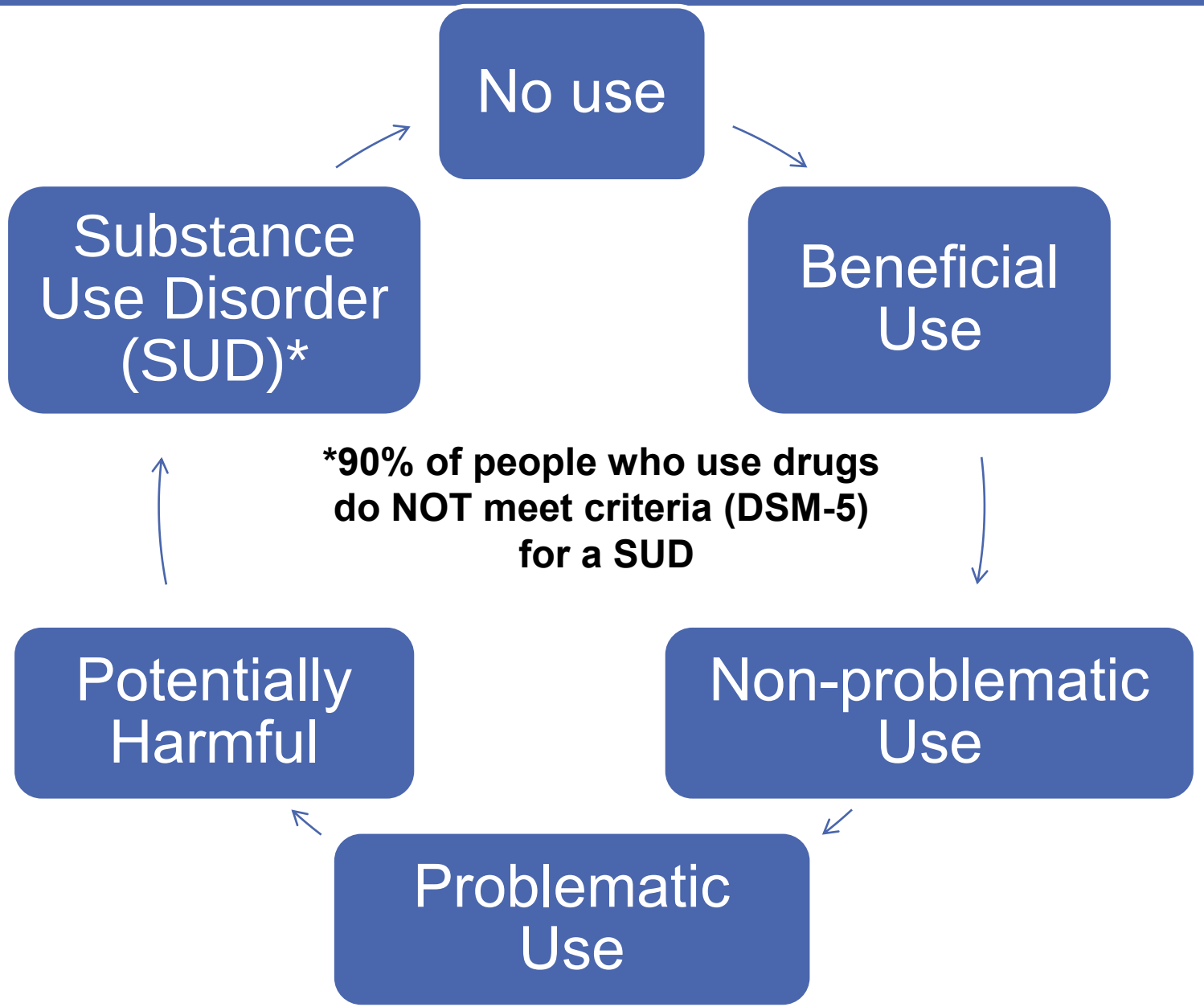
I will apply my knowledge and experience to advance health equity to assure optimal outcomes for all patients.

I will accept the responsibility to improve my professional knowledge, expertise, and self-awareness.

I will champion diversity and inclusion, respect the perspectives of others, and mitigate my personal biases.

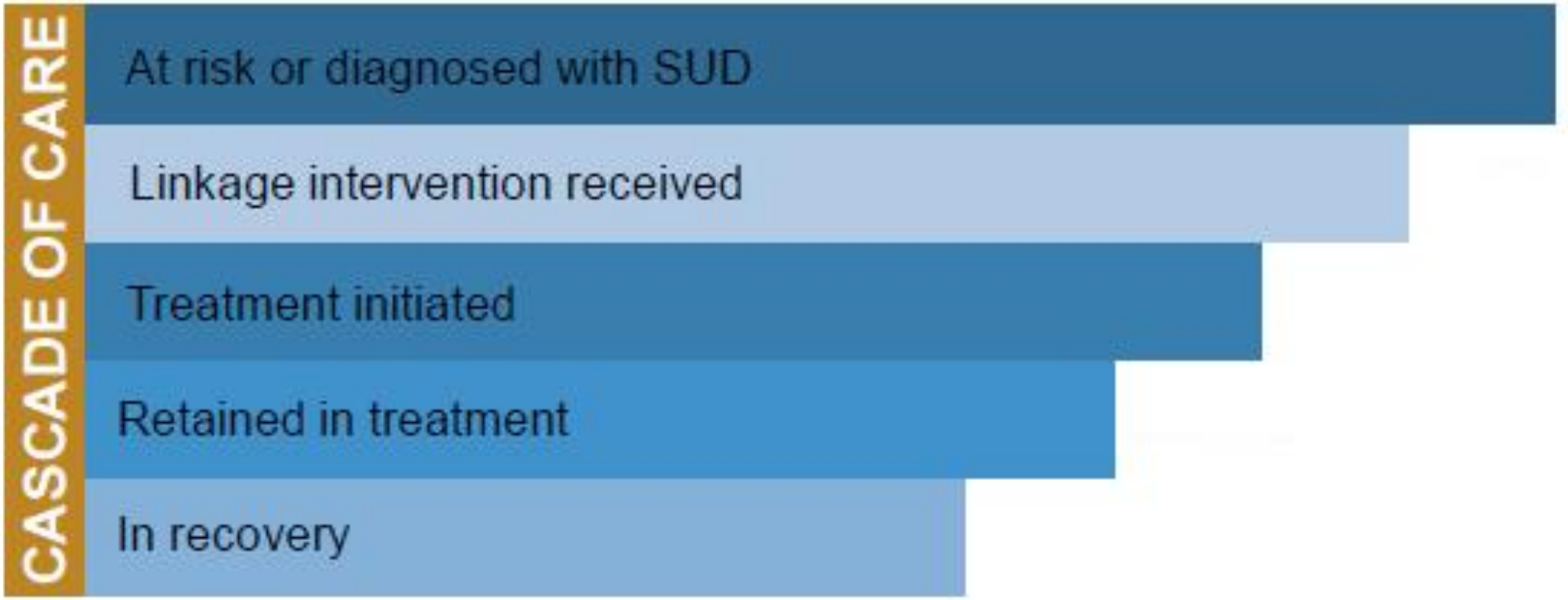
https://www.pharmacist.com/Publications/Transitions/oath-of-a-pharmacist-changing-times#:~:text=Oath%20of%20a%20Pharmacist%3A%20Final%20revised%20draft%20Revised%3A,service%20to%20others%20through%20the%20profession%20of%20pharmacy.

Continuum of Substance Use



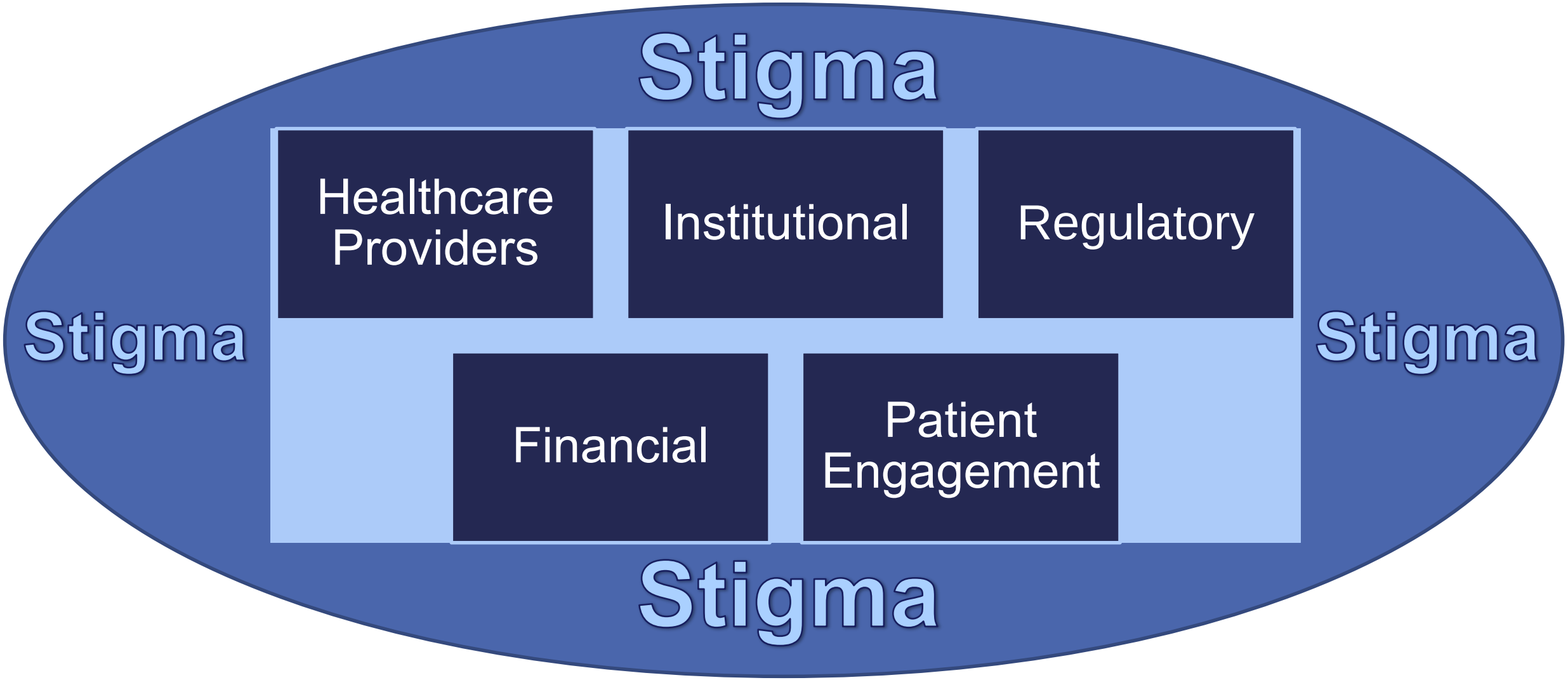
Modified from School Mental Health Ontario
https://smho-smso.ca/educators-and-student-support-staff/substance-use-and-addiction/

Figure 1. Cascade of SUD Care (adapted from NIDA)



The Cascade of Care Can Help Tailor Substance Use Disorder Interventions
https://www.hsrd.research.va.gov/publications/forum/spring20/default.cfm?ForumMenu=spring20-2

Barriers to SUD Care



How Stigmatizing Language Impacts Treatment

How do you feel about two people actively using drugs and alcohol?

"Substance Abuser"

"Having a substance use disorder"

- ↑ benefit from punishment
- ↓ benefit from treatment
- ↑ socially threatening
- ↑ blame for substance-related difficulties
- ↑ able to control substance use without help

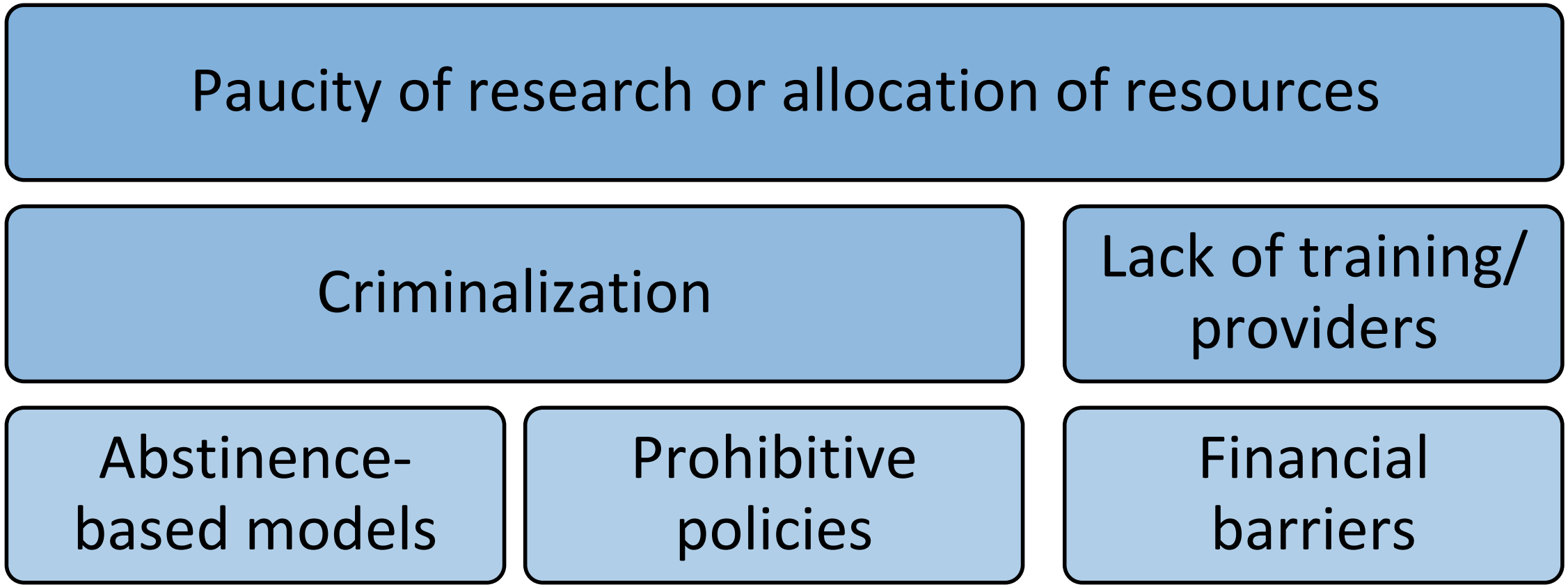
less likely to receive treatment

more likely to be isolated

at higher risk of adverse outcomes

Kelly JF, Westerhoff CM. Does it matter how we refer to individuals with substance-related conditions? A randomized study of two commonly used terms. Int J Drug Policy. 2010;21(3):202-207.

Barriers Beyond Stigma



OAT limitations

Only 1/3 of people with OUD receive ANY form of treatment

- Fewest receive medication for OUD treatment **~1 out of 9 (13%)**
- Pharmacists cannot dispense methadone for OUD in US*
- Pharmacists not permitted to prescribe buprenorphine via waiver without state DEA authority outside of CPA

Barriers and Inequities

- Geography (e.g., Rural)
- Insurance (e.g., Medicaid)
- Structural and systemic racism
- Social distancing

COVID-19 – More Overdoses

- Decreases access to opioids
- Unsafe supply
- Substance co-use
- Less tolerance
- Less nonprescribed buprenorphine access

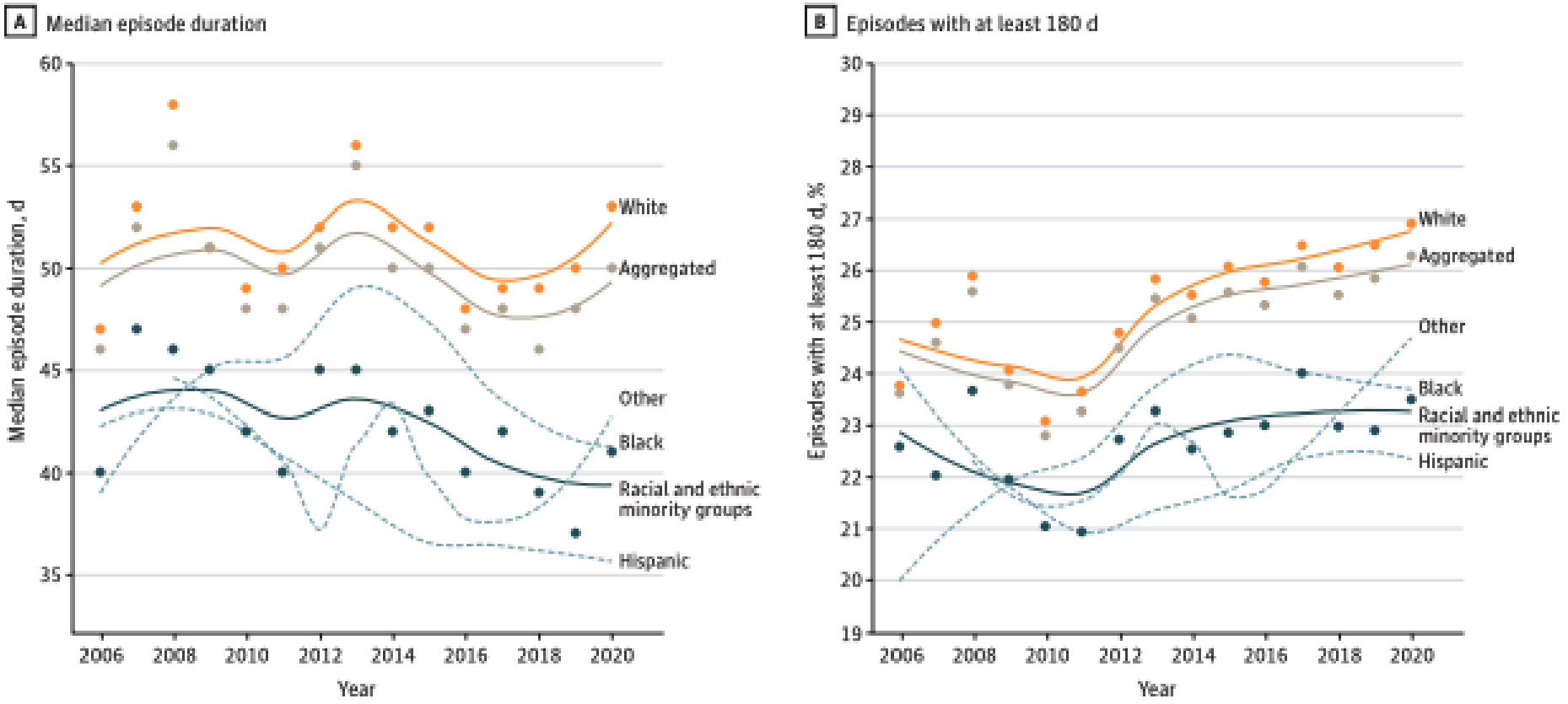
Black people face barriers in **every step** of care cascade

- Initiation
  - Clinician visit prescriptions less likely[1]
  - Emergency department administration or prescription less often[2]
  - Black pregnant people 37% less likely to receive MOUD than White people[3]
- Maintenance
  - Medicaid-covered patients with OUD – 42% less prescribed than White[4]
  - COVID-19 decreased access for Black people and not White[5]

Lagisetty PA, Ross R, Bohnert A, Clay M, Maust DT. Buprenorphine Treatment Divide by Race/Ethnicity and Payment. *JAMA Psychiatry*. 2019;76(9):979. doi:10.1001/jamapsychiatry.2019.0876 2. Holland WC, Li F, Nath B, et al. Racial and Ethnic Disparities in Emergency Department-Initiated Buprenorphine Across 5 Healthcare Systems. *Academic Emergency Medicine*. n/a(n/a). doi:10.1111/acem.14668 3. Schiff DM, Nielsen T, Hoeppner BB, et al. Assessment of Racial and Ethnic Disparities in the Use of Medication to Treat Opioid Use Disorder Among Pregnant Women in Massachusetts. *JAMA Netw Open*. 2020;3(5). doi:10.1001/jamanetworkopen.2020.5734 4.Dunphy CC, Zhang K, Xu L, Guy GP. Racial–Ethnic Disparities of Buprenorphine and Vivitrol Receipt in Medicaid. *American Journal of Preventive Medicine*. 2022;63(5):717-725. doi:10.1016/j.amepre.2022.05.006 5. Nguyen T, Ziedan E, Simon K, et al. Racial and Ethnic Disparities in Buprenorphine and Extended-Release Naltrexone Filled Prescriptions During the COVID-19 Pandemic. *JAMA Netw Open*. 2022;5(6):e2214765. doi:10.1001/jamanetworkopen.2022.14765

Black people face barriers in **every step** of care cascade Retention

Figure. Trends in Buprenorphine Episode Duration in the US From 2006 to 2020, Aggregated and Stratified by Racial and Ethnic Groups



Dong H, Stringfellow EJ, Russell WA, Jalali MS. Racial and Ethnic Disparities in Buprenorphine Treatment Duration in the US. *JAMA Psychiatry*. Published online 2022. doi:10.1001/jamapsychiatry.2022.3673

Dismantling racism against Black, Indigenous, and people of color across the substance use continuum: A position statement of the association for multidisciplinary education and research in substance use and addiction

Holly N. Hagle, PhD[a], Marlene Martin, MD[b], Rachel Winograd, PhD[c], Jessica Merlin, MD, PhD, MBA[d], Deborah S. Finnell, DNS, RN, CARN-AP, FAAN[e], Jeffrey P. Bratberg, PharmD, FAPhA[f], Adam J. Gordon, MD, MPH[g,h], Cheyenne Johnson, MPH, RN, CCRP[i], Sharon Levy, MD, MPH[j], Doreen MacLane-Baeder, BA[k], Rebecca Northup, MAT, MA[k], Zoe Weinstein, MD, MS[l], and Paula J. Lum, MD MPH[m]

"We insist that **all persons who use drugs** be treated with *compassion and lifesaving services* driven by antiracist and anti-oppressive principles—whether they seek **effective drug treatment options** or the tools and resources to **reduce the harms of ongoing drug use**. We cannot afford to continue to ignore the structural racism that underlies substance use treatment and harm reduction services for persons who use drugs."

Hagle HN, Martin M, Winograd R, et al. Dismantling racism against Black, Indigenous, and people of color across the substance use continuum: A position statement of the association for multidisciplinary education and research in substance use and addiction. *Subst Abus*. 2021;42(1):5-12. doi:10.1080/08897077.2020.1867288

Public Attitude Survey on Behavioral Health Issues in RI: 2019-20

PharmacyBridge

Taking you as far as you want to go today

- 90% agree that addiction can be a chronic, life-threatening condition like high blood pressure or heart disease.
- 86% agree that people who suffer from substance use issues should have access to long term and repeated treatments.
- **Only 60% believe medication is appropriate for someone with a substance use disorder.**

Buprenorphine WORKS

Benefits	Primary Evidence
↓ risks of both all-cause and overdose-related mortality (> 50%)	Degenhardt, 2014, Pierce, 2016, Sordo, 2017, Larochelle, 2017, Ma, 2018
↓ rates of other opioid use (including injection) and cravings	Kakko, 2003, Fudala, 2003, Mattick, 2014, Thomas, 2014, Woody, 2014
↓ risk of HIV and hepatitis C infection	MacArthur, 2012
↑ **access = ↓ opioid overdose deaths**	**Schwartz, 2013**
↑ **social functioning**	**Bart, 2012**
↑ **QoL compared to those not in treatment**	**Ponizovsky, 2007**
↑ **maternal and fetal outcomes**	**Thomas, 2014**
Rarely found in overdose death toxicology	Wightman 2020

Perspective

Transforming Management of Opioid Use Disorder with Universal Treatment

Rahul Gupta, M.D., M.P.H., M.B.A., Rachel L. Levine, M.D., Javier A. Cepeda, Ph.D., M.P.H., and David R. Holtgrave, Ph.D.

Education
Increase MOUD access
Preserve telemedicine access
Access for incarcerated patients
Address SDOH to increase retention and recovery

Gupta R, Levine RL, Cepeda JA, Holtgrave DR. Transforming Management of Opioid Use Disorder with Universal Treatment. *New England Journal of Medicine*. 2022;0(0):null. doi:10.1056/NEJMp2210121

MOUD Access Barriers - Pharmacy

- Several state studies document lack of naloxone and/or buprenorphine availability (PA, IN, TX, CA).
- One recent national study of 921 pharmacies shows 20%, or 1 in 5, unable to dispense buprenorphine
  - Higher in independents >> chains (25% > 15%)
  - Higher in South >> other regions (26% >> 11-18%)
  - If available, quantities and formulations sufficient
- Limits
  - DEA caps / wholesaler limitations
  - Stock cost / customer demand
  - Opioid prescribing stigma

Kazerouni NJ, Irwin AN, Levander XA, et al. Pharmacy-related buprenorphine access barriers: An audit of pharmacies in counties with a high opioid overdose burden. *Drug and Alcohol Dependence*. 2021;224:108729. doi:10.1016/j.drugalcdep.2021.108729

“Red Flags” & “Red Tape” –

Telehealth and pharmacy-level barriers to buprenorphine

- Treat all opioids the same
- Troublemaker vs Legitimate
- Geographic and bureaucratic hurdles to in-person and tele-health
- Business outcomes >>> patient and community outcomes
- Fear-based messaging and action
- Suspicion, control, abandonment, punishment
  - Medical gatekeeping
  - Legal gatekeeping
  - Avoidance

Textor L, Ventricelli D, Aronowitz SV. ‘Red Flags’ and ‘Red Tape’: Telehealth and pharmacy-level barriers to buprenorphine in the United States. *International Journal of Drug Policy*. 2022;105:103703. doi:10.1016/j.drugpo.2022.103703

Federal and State Pharmacy Regulations and Dispensing Barriers to Buprenorphine Access at Retail Pharmacies in the US

Goals	Actions	Responsible agencies
Protect distributors, pharmacies, and pharmacists from DEA liability and litigation for buprenorphine diversion	-Suspend BUP-related pharmacy DEA audits/litigation -Exempt BUP from corresponding responsibility -Exempt BUP from federal monitoring and reporting	DEA SAMHSA **State Pharmacy Boards** State Public Health
Ensure buprenorphine availability at community pharmacies	-Require minimum BUP stocking -Require wholesalers to ship BUP orders without delay to pharmacies	DEA SAMHSA **State Pharmacy Boards** Public Health
Prevent pharmacies from declining to dispense BUP Rx	-Pass state legislation to fill all valid BUP for OUD -Implement corresponding responsibility specific for MOUD	**State Pharmacy Boards** Public Health State policy officials DEA, CMS, SAMHSA

Qato DM, Watanabe JH, Clark KJ. Federal and State Pharmacy Regulations and Dispensing Barriers to Buprenorphine Access at Retail Pharmacies in the US. *JAMA Health Forum*. 2022;3(8):e222839. doi:10.1001/jamahealthforum.2022.2839

American Pharmacists Assoc. (APhA) House of Delegates Actions

2020

1. APhA supports the use of evidence-based **medicine** as **first-line treatment for opioid use disorder** for patients, including healthcare professionals, in and out of the workplace, **for as long as needed to treat their disease.**

2. APhA encourages pharmacies to maintain an inventory of medications used in treatment of opioid use disorder**, to ensure access for patients.**

3. APhA encourages pharmacists and payers to ensure patients have **equitable access to, and coverage for, at least one medication from each class of medications** used in the treatment of opioid use disorder.

2022

APhA advocates for pharmacists' **independent prescriptive authority** of medications indicated for opioid use disorders (MOUDs) and other substance use disorders to expand patient access to treatment.

Buprenorphine – Pharmacist Roles

Inpatient	Outpatient Clinics	Community
• Educate staff • Develop inpatient protocols for initiation (traditional, low-dose) • Develop protocol to ensure medication access through the Emergency Department • Develop protocol to ensure naloxone co-prescribing and patient education • Identify currently hospitalized buprenorphine candidates and ensure access to treatment • Ensure continuation of buprenorphine during hospitalization • Develop protocols for medication continuation in unique situations, such as surgery • Bedside delivery of medication • Discharge planning and pt. education	• Educate office staff • Encourage prescribers to obtain DATA waiver • Advocate for / support removal of ~~DATA waiver~~ • ~~Interim: Advocate for pharmacist inclusion as DATA waiver eligible provider~~ • Leverage telehealth / preserve COVID regulations • Administer long-acting buprenorphine • Co-provide intranasal naloxone • Develop medication take-home education pamphlets	• Increase product education and proper use • Advocate for / support removal or loosening of wholesaler medication ordering limits by DEA • Maintain adequate stock for demand • On-demand initiation / starter kits • Ensure connection to care in the community • Troubleshoot reimbursement barriers • Advocate for /support easier third-party billing, or allowance of verbal authorization / web-based signatures for refills • Co-provide intranasal naloxone in compliance with local law • Co-provide safe injection supplies in compliance with local law

Peckham AM, Ball J, Colvard MD, et al. Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic. *Am J Health Syst Pharm*. 2021;78(7):613-618. doi:10.1093/ajhp/zxab003

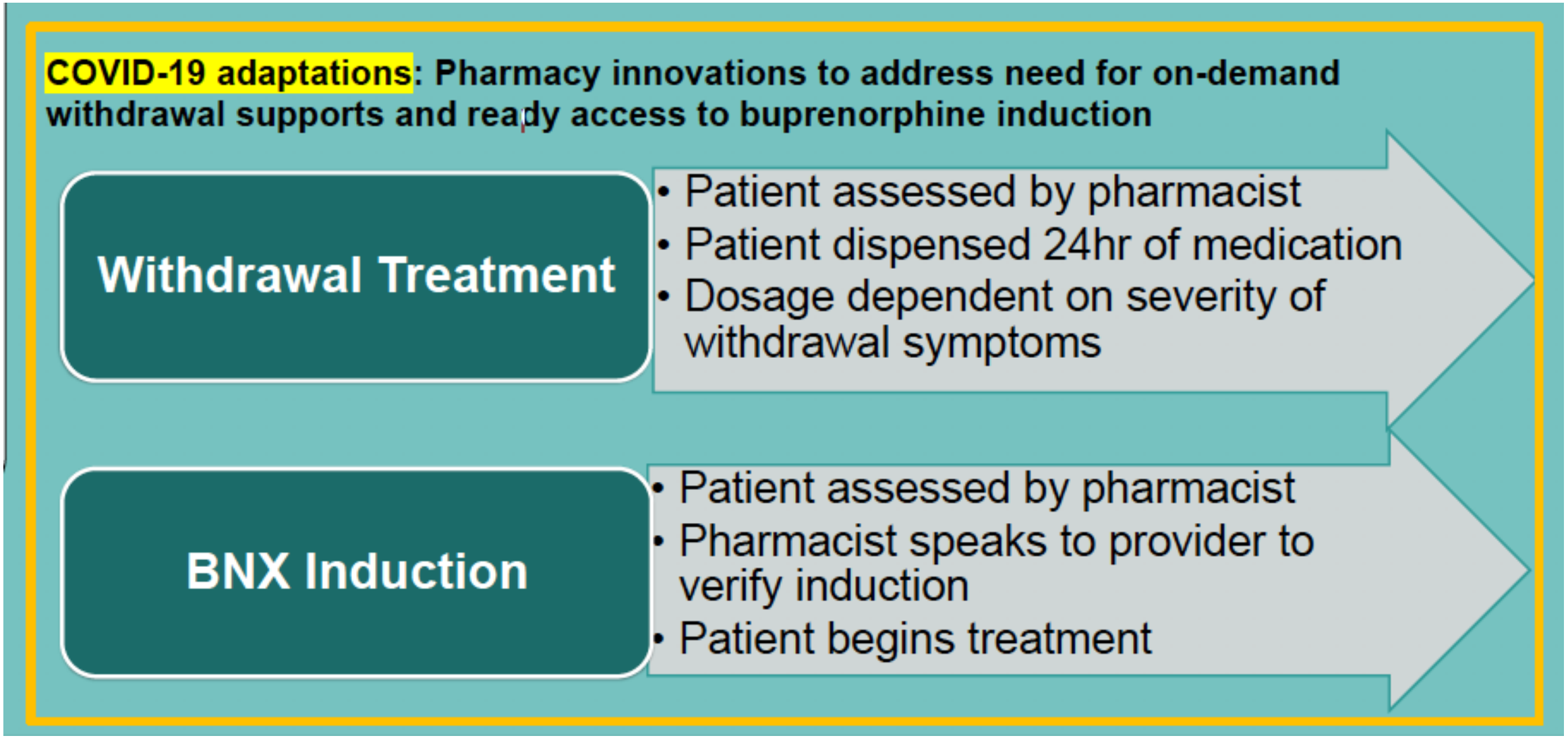
Low-Barrier Buprenorphine is Successful

"Provide care that is **evidence-based, emphasizes harm reduction, has a low barrier to entry, and is longitudinal.**

When we shift our focus to providing individualized care that incorporates patient-centered outcomes, we can better help our patients with OUD achieve **remission and lead improved lives."**

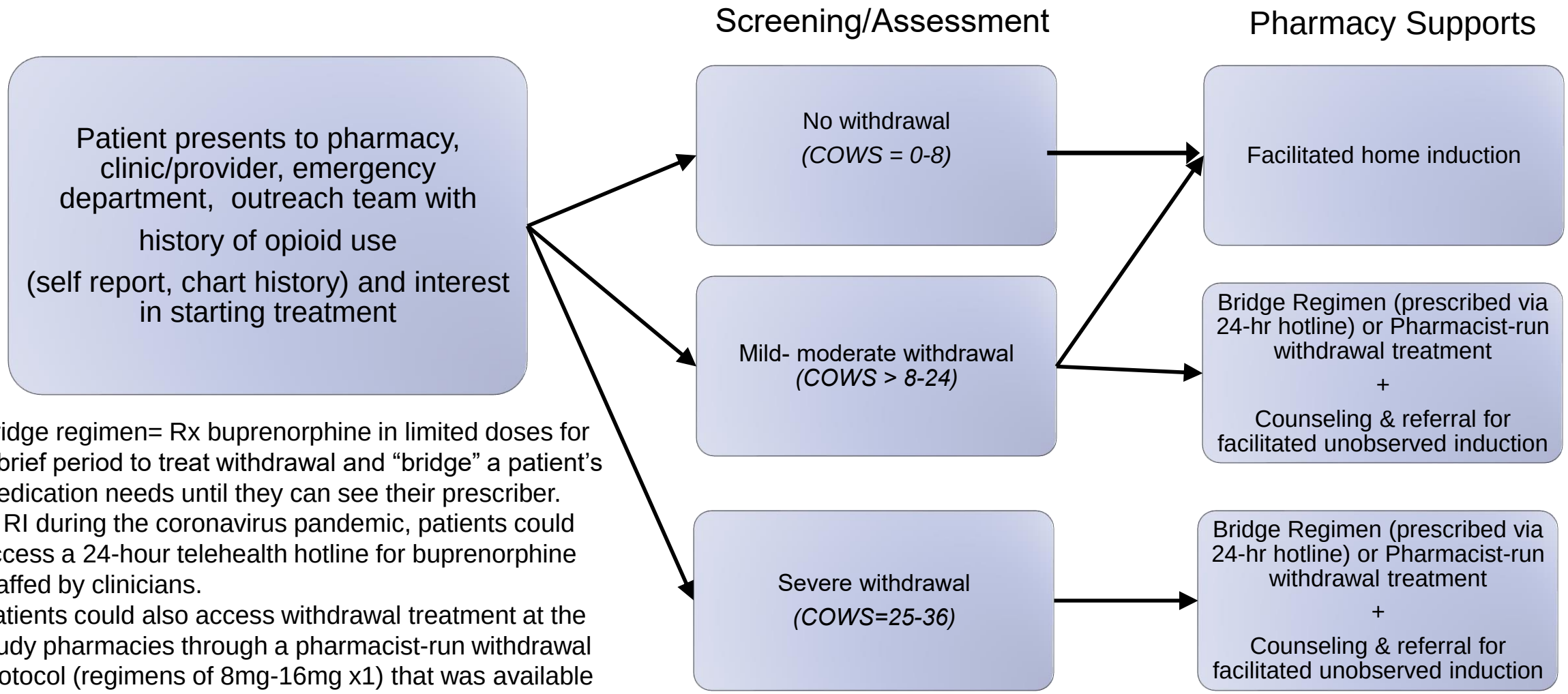
Martin SA, Chiodo LM, Bosse JD, Wilson A. The Next Stage of Buprenorphine Care for Opioid Use Disorder. Ann Intern Med 2018;169(9):628–35.

MATPharm Adaptations during COVID-19 Pandemic



Green T, McKenzie M, Serafinski R, Clark S, Langdon K, Rich J, Bratberg J. Pharmacy-based care model for the treatment of opioid use disorder: Pilot findings and novel care adaptations during COVID-19. Addiction Health Services Research Conference [Virtual] October 2020. October 2020.

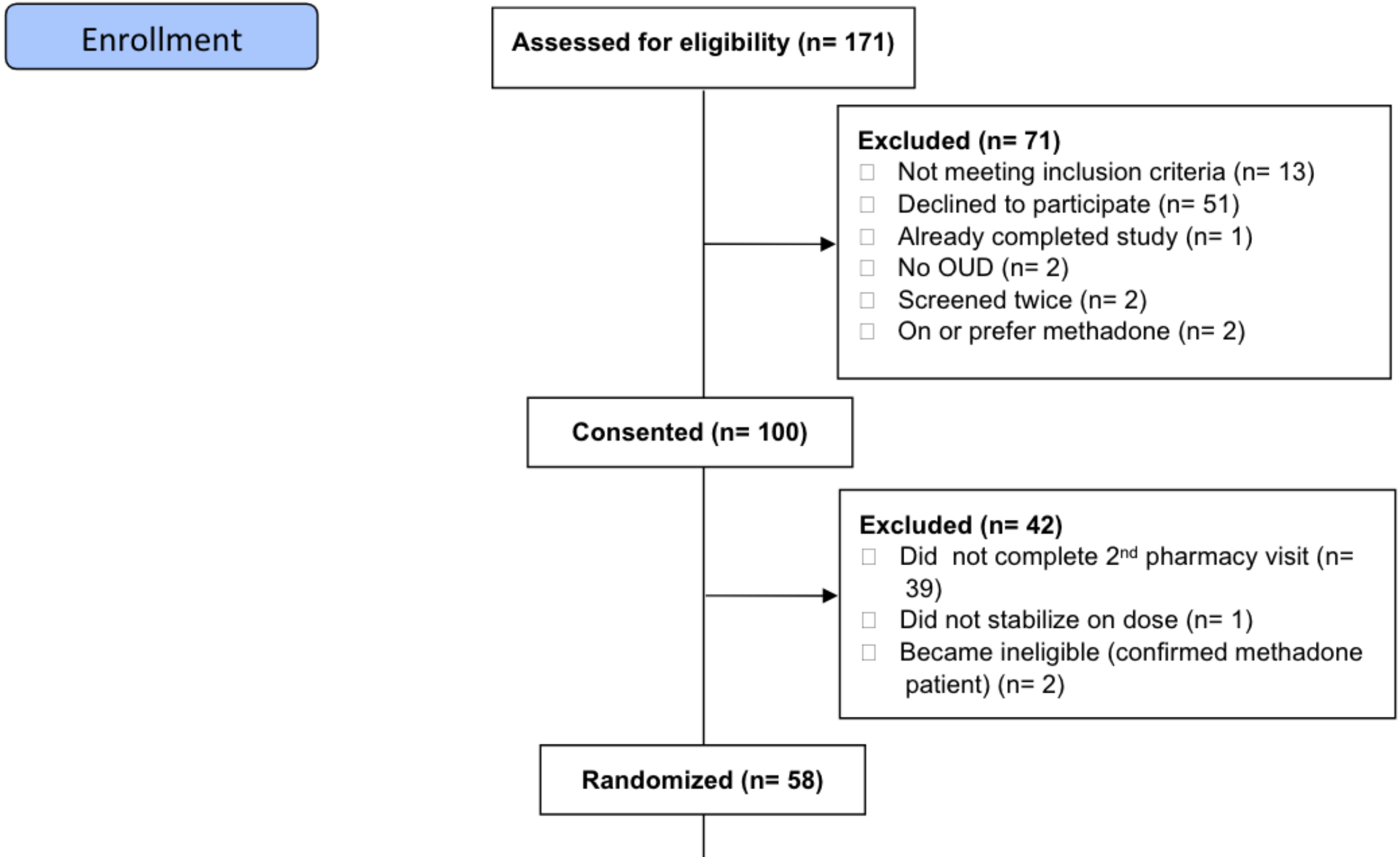
MATPharm Eligible: Any Opioid Hx,18+ years old, On treatment or Interest in MOUD

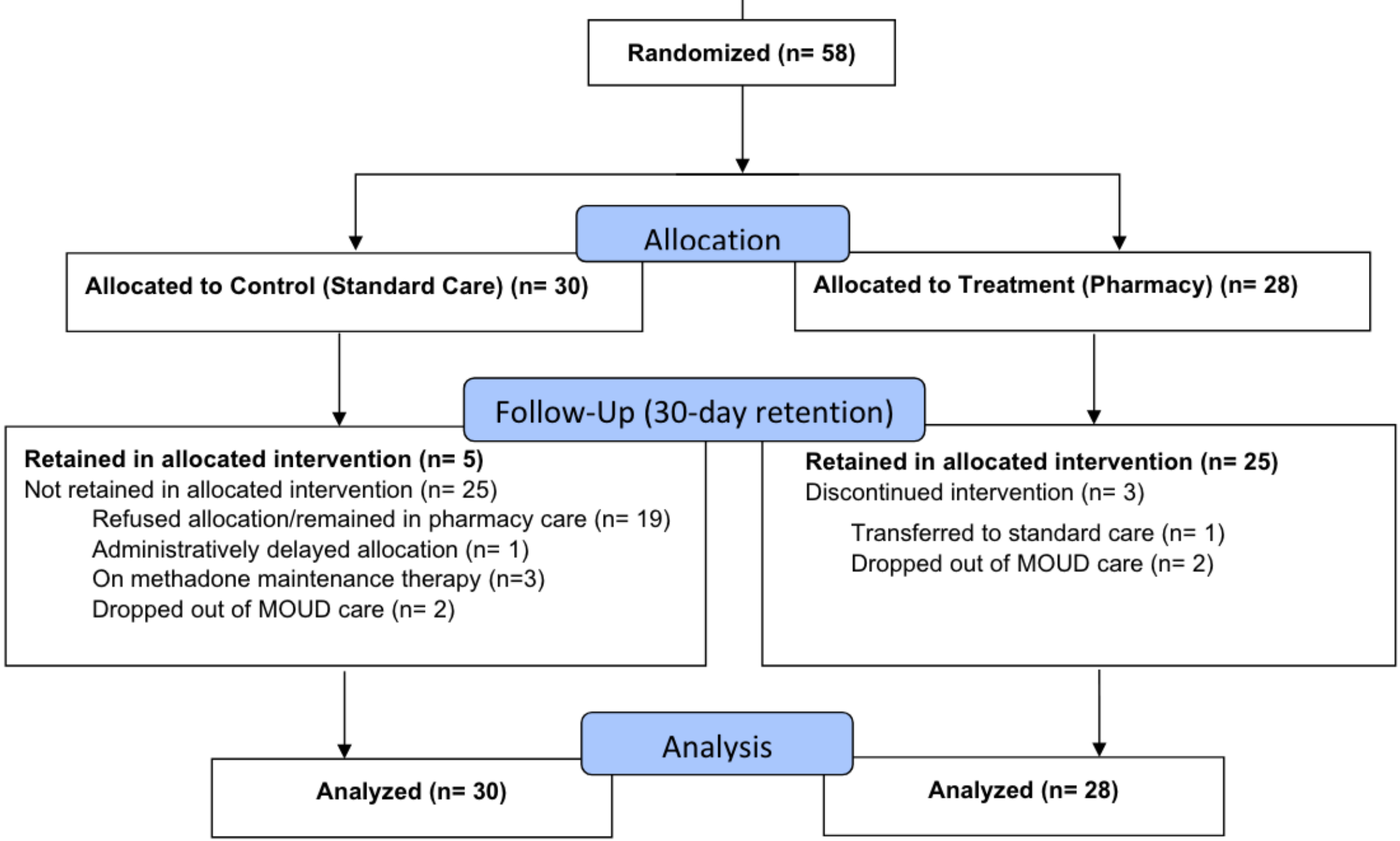


Bridge regimen= Rx buprenorphine in limited doses for a brief period to treat withdrawal and "bridge" a patient's medication needs until they can see their prescriber.
In RI during the coronavirus pandemic, patients could access a 24-hour telehealth hotline for buprenorphine staffed by clinicians.
Patients could also access withdrawal treatment at the study pharmacies through a pharmacist-run withdrawal protocol (regimens of 8mg-16mg x1) that was available as part of the induction care model in the present study.

COWS: Clinical opiate withdrawal scale (scores 0 to 36)
Treatment=medication treatment with Rx buprenorphine

Figure S2: CONSORT Diagram




Randomized (n= 58)
Allocation
Allocated to Control (Standard Care) (n= 30)
Allocated to Treatment (Pharmacy) (n= 28)
Follow-Up (30-day retention)
Retained in allocated intervention (n= 5)
Not retained in allocated intervention (n= 25)
Refused allocation/remained in pharmacy care (n= 19)
Administratively delayed allocation (n= 1)
On methadone maintenance therapy (n=3)
Dropped out of MOUD care (n= 2)
Retained in allocated intervention (n= 25)
Discontinued intervention (n= 3)
Transferred to standard care (n= 1)
Dropped out of MOUD care (n= 2)
Analysis
Analyzed (n= 30)
Analyzed (n= 28)

MATPharm: Pharmacy care has high induction rate, engagement comparable to usual care, less drop-out, no safety concerns

Induction success rate: **58%** stabilized (≥2 pharmacy visits)

Primary outcomes: Initial engagement with community MAT (≥1 visit in first 30 days post stabilization)

- 89% pharmacy care, 17% usual care

Drop out of care*

- 6 pharmacy care (10%), 16 usual care (27%)

Treatment crossovers*

- 7 Pharmacy Inducted patients randomized to usual care refused to leave pharmacy care
- 5 Pharmacy Inducted patients randomized to usual care took 4-8 weeks to transfer to usual care provider

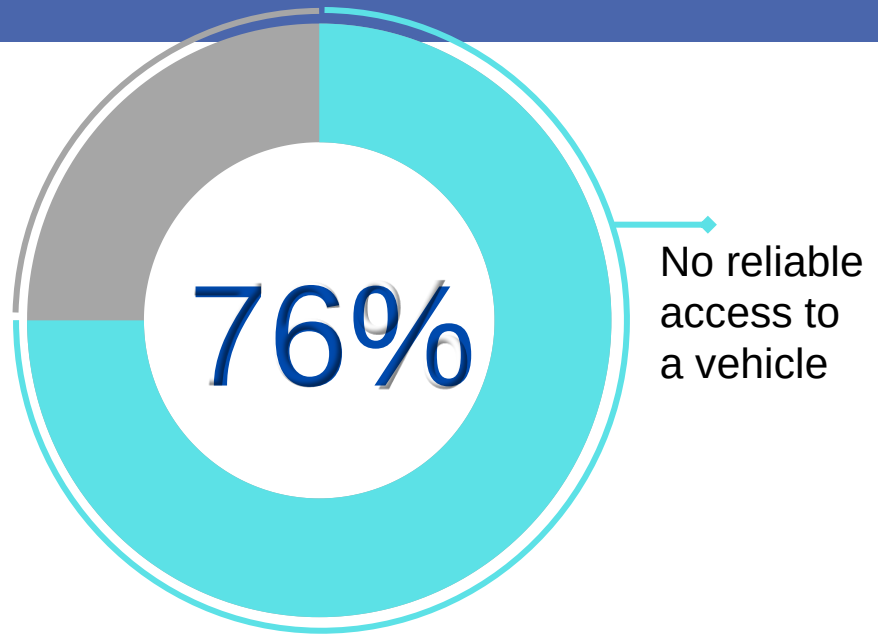
***Safety concerns*:** 0 deaths, 0 unanticipated severe adverse events, +33 dispensed naloxone

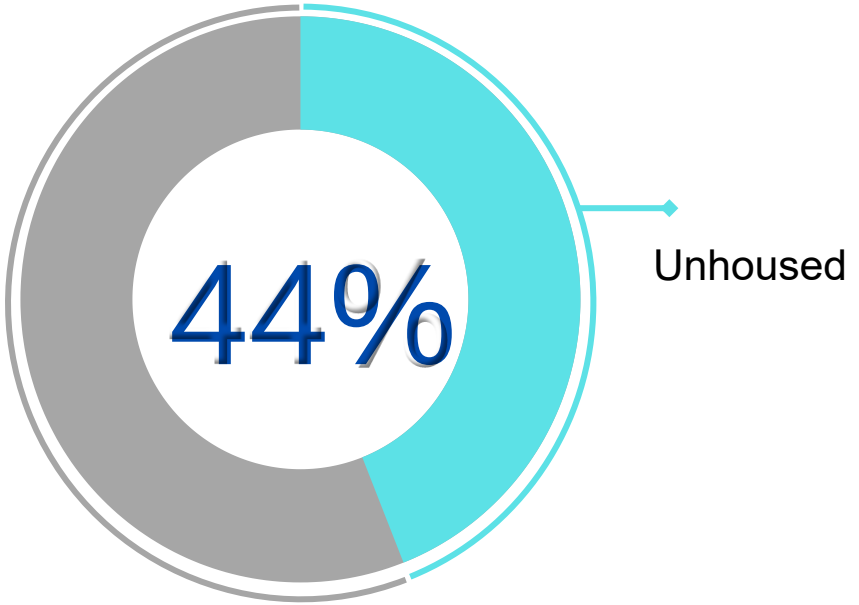
*active, ongoing follow up

Green T, Serafinski R, Rich J, Clark S, Bratberg J. et al. 'Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies." New Eng J Med. (in revision)

Pharmacy induction promotes racial and economic equity and access to care

Rhode Island state	Induction patients
White: 80.5%	**White: 66%**
19.5% BIPOC: Black or African American: 6.77% Other race: 5.47% Asian: 3.40% Two or more races: 3.33% Native American: 0.50% Native Hawaiian or Pacific Islander: 0.08%	**34% BIPOC:** Black or African American: 12% Other race: 11% Asian: 0%, Two or more races: 8%, Native American: 3%, Native Hawaiian or Pacific Islander: 0%
15% Hispanic	**15% Hispanic**





Green T, Serafinski R, Rich J, Clark S, Bratberg J. et al. 'Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies." New Eng J Med. (in revision)

Conclusions: Induction

Patients inducted in the pharmacy attain stabilization comparable to community-based usual care.

Transitions imposed by studies, systems, and stigma disrupt engagement in care. Patients started in the pharmacy should maintain care in the pharmacy.

Pharmacy based induction promotes racial and economic equity in medication treatment access.

Research is needed to identify the **combination and level of peer, social, and material supports needed** to optimize rates of induction to maintenance for pharmacy and other novel care models.

Green T, Serafinski R, Rich J, Clark S, Bratberg J. et al. 'Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies." New Eng J Med. (in revision)

EDITORIAL

Preserving dignity through expanded and sustained access to buprenorphine

Pharmacists, prescribing clinicians, and other treatment advocates are called to act by implementation solutions that directly improve and sustain access to **high quality [behavioral healthcare]**, including:

-Education
-Regulatory changes
-Scope of practice expansion
-Payment reform

"Medication first" advocates need to go beyond hurdles to stocking, dispensing, insurance limitations, and communication **and implement solutions that directly expand equitable access to addiction care.**

All pharmacists should advocate for permanent changes to their state collaborative practice and telehealth policies to permit collaborative controlled substance initiation and maintenance…

Bratberg JP, Falleni A. Preserving dignity through expanded and sustained access to buprenorphine. *Journal of the American Pharmacists Association*. 2023;63(1):220-223. doi:10.1016/j.japh.2022.12.026

Learning Objectives

- Recognize the urgent need for barrier-free models of buprenorphine access.
- Explain the key elements of a novel collaborative model of pharmacy-based buprenorphine induction.
- Describe the characteristics of the participants in the model.

Question 1

Which of the following has been documented as a barrier to accessing buprenorphine in the US?

A. Manufacturer drug shortages

B. Lack of 3rd party prior authorization

C. Drug-drug interactions

D. Patient's skin color

Question 2

Which of the following was the key element of a Rhode Island collaborative practice agreement (CPA) that permitted initiation of buprenorphine in the pharmacy?

A. State pharmacist DEA registration

B. Provider status permitting payment for services

C. Patient-initiated saliva toxicology testing

D. Public health emergency audio-only induction

Question 3

Which of the following groups were DISPROPORTIONATELY represented in the buprenorphine induction population as compared to the 2020 RI census?

A. BIPOC

B. Hispanic

C. White

D. Asian

Withdrawal vs. Facilitated Induction Protocol

PharmacyBridge
Taking you as far as you want to go today

Withdrawal Protocol (4/2019)

- NOT part of MATPharm study
- No need to call prescriber
- 1-2 buprenorphine 8 mg doses
- COWS 8-36
- Standing Order always valid

Facilitated Induction CPA (7/2020)

- Patient must enroll in MATPharm
- Must contact CPA prescriber, research team
- Up to 14 x 8 mg doses dispensed
- COWS 0-24
  - Self-treating OUD using nonprescribed buprenorphine
  - May/will lose access to medications
  - Mild-Moderate withdrawal
- COWS 25-36 severe withdrawal
  - ← ONLY use withdrawal protocol
- Only valid if SAMHSA telemedicine & DEA controlled substance prescribing regulations remain relaxed for induction
  - No in-person assessment
  - No video requirement

Pharmacist Training and Communications

American Society for Addiction Medicine (ASAM) Treatment of Opioid Use Disorder Course, ***adapted for pharmacists***

Clinical documentation

Urine/oral swab testing and test interpretation

Motivational interviewing

- Harm reduction, *considerations for post-release from incarceration*

Stigma reduction / communications

7 pharmacists trained May 2018 **9 pharmacists trained Nov 2018** **5 pharmacists trained 2019-2021**

Ongoing supports & detailing

- Weekly phone-based meetings, clinician check-ins
- Academic detailing of sites by lead pharmacist
- Emailed newsletters

Steps for Home Induction

PharmacyBridge

Taking you as far as you want to go today

1

Patient: Seeks buprenorphine for induction or withdrawal.

Pharmacist: Offers induction treatment as part of study (free medication, $$ incentives).

2

If patient presents/agrees to induction, contact research staff.

3

While waiting for call-backs, perform COWS assessment.

25+ : Offer withdrawal protocol or call Bupe Hotline 401-606-5456 for non-study induction; patient can come back for study induction later.

< 25 : Text/call CPA prescribers, or the Bupe Hotline for callback to prescribe.

4

Pharmacist: Issue patient forms, review PMP, OTP record, prescription system for buprenorphine; *enter patient information if new patient.*

Patient: Complete forms (CPA consent, 42 CFR induction, privacy practices, ROI).

“It’s ok to share my info w/ research team & Lifespan Recovery Center (LRC).”

Steps for Home Induction continued

5

Pharmacist/Patient: Interview

- Pregnant
- Allergies
- Insurance
- Employed
- Last opioids/other drugs used
- Last opioid overdose / naloxone
- History of seizure
- Past treatment
- Permission to contact PCP/other providers and contact info

6

- **Pharmacist:**
- ____ Enter patient into ProScript (get insurance card, other ID) / Review Genoa pharmacy records.
- ____ Check Prescription drug medication program (PDMP).
- **Consult with Dr. Clark/Dr. Rich/Bupe hotline and issue CPA prescription.**
  - Up to #14 X 8 mg buprenorphine/naloxone strips or pills
  - Up to #14 X 8 mg buprenorphine pills

Patient (optional) speak to Dr. Clark/Rich/Bupe hotline.

Steps for Home Induction continued

PharmacyBridge

Taking you as far as you want to go today

7

- **Pharmacist: Evaluate SDOH/Peer Support Needs.**

- **Do you have any needs regarding the following (especially in the next 7 days)?**
  - Food
  - Phone/communication
  - Safe Medication storage
  - Insurance coverage
  - COVID-19 Testing
  - Housing
  - Naloxone
  - Sterile syringes

Do you participate in any of the following:

- **Counseling appointments?** If Yes, list_____

- **Peer support meeting attendance?** If Yes, list_____

When to start

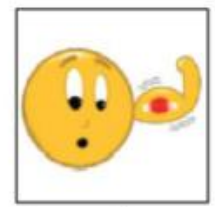
✔ Check below. Start "Bupe" when you have **5** ☑☑☑☑☑

MUST have **at least 1** ☑ **from this group**

☐ 
I feel like yawning

☐ 
My nose is running

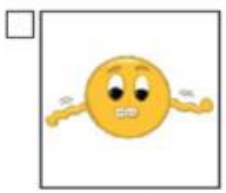
☐ 
I have goose bumps

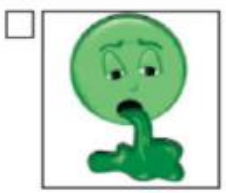
☐ 
My muscles twitch

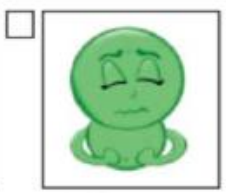
☐ 
My bones & muscles ache

☐ 
I am sweating

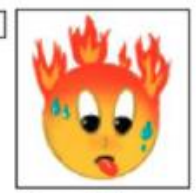
☐ 
I cannot sit still

☐ 
I am shaking

☐ 
I am vomiting

☐ 
I feel like vomiting

☐ 
I have cramps in my stomach

☐ 
I have hot flashes

How to take?

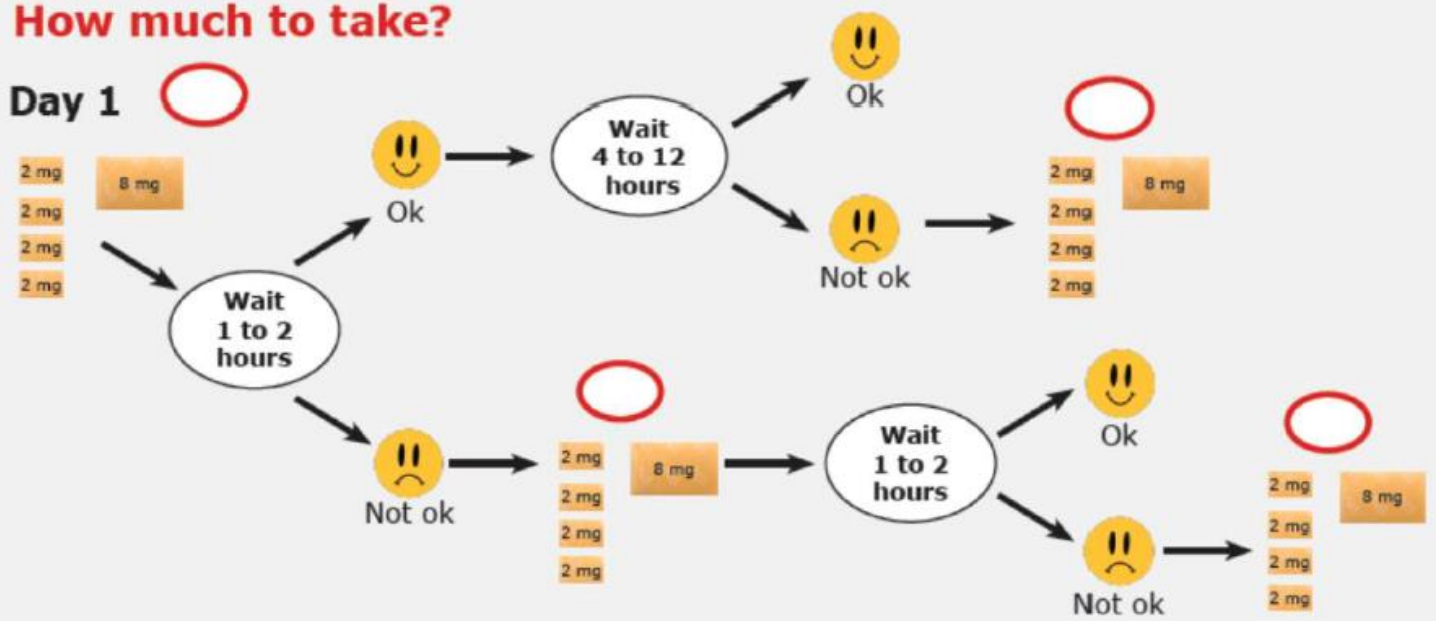
1. Before you start, drink water if your mouth is dry

2. Cut the strip into 4 equal pieces

3. Put "Bupe" under your tongue

- Let the medication dissolve completely
- For best results, **DO NOT** swallow or spit for at least 5 minutes

How much to take?



Patient Instructions and Medication Guide

Day 1

Cut one strip or pill in half (4 mg), and place under tongue to dissolve completely, followed by second ½ strip or ½ pill as needed for unresolved withdrawal symptoms in one hour.

Repeat preparing and taking ½ strip or ½ pill every 6 hours up to maximum 3 pills or 3 strips (24 mg)

Days 2-7

Take the total amount you needed on day one as a single dose in the morning under your tongue until it dissolves completely.

1 strip/pill (2 halves) is 8 mg

2 strips/pills (4 halves) = 16 mg

3 strips/pills (6 halves)= 24 mg

If you're too sleepy, take 4 mg less the next day (1/2 pill or ½ strip less).

***Day 5* – Contact pharmacist by phone or in-person for next refill dose, quantity, and delivery method.**

Home Induction Protocol Modified from: The California Bridge Treatment Model https://www.bridgetotreatment.org/cabridgeprogram

Med Guide modified from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020732s006s007mg.pdf

MATPHARM MEDICATION GUIDE - BUPRENORPHINE

What is BUPRENORPHINE?

BUPRENORPHINE is a prescription medicine used to treat adults who use opioid drugs (either prescription or illegal).

Keep your BUPRENORPHINE in a safe place, away from children, at room temperature. Never give your BUPRENORPHINE to anyone else; it can cause death or harm them.

Who should not take BUPRENORPHINE?

Do not take BUPRENORPHINE if you are allergic to buprenorphine. Allergic reactions may include rash, hives, swelling of the face, trouble breathing, or fainting. Call a doctor or pharmacist or get emergency help right away by calling 911.

How should I take BUPRENORPHINE?

Always take BUPRENORPHINE exactly as your doctor or pharmacist tells you. Your doctor or pharmacist may change your dose after seeing how it affects you. Do not change your dose unless your doctor or pharmacist tells you to change it.

Put the tablets or strips under your tongue. Let them dissolve completely. While BUPRENORPHINE is dissolving, do not chew or swallow the tablet or strips because the medicine will not work as well.

If you miss a dose of BUPRENORPHINE, take your medicine when you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take 2 doses at the same time unless your doctor or pharmacist tells you to. If you are not sure about your dosing, call your doctor or pharmacist.

Do not stop taking BUPRENORPHINE suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine.

If you take too much BUPRENORPHINE or overdose, call Poison Control at 1-800-222-1222 and get emergency medical help right away by calling 911.

Steps for Home Induction continued

PharmacyBridge

Taking you as far as you want to go today

8

Patient: speak to research team to make appointment for baseline.

- **Personal phone**
- **Study phone (issued from pharmacist)**

9

- Pharmacy team: Fill and dispense medication in name of CPA provider.
- Pharmacist: Counsel on home induction steps and expectations.

Open Forum

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QIN–QIO
Quality Innovation Network - Quality Improvement Organizations
CENTERS FOR MEDICARE & MEDICAID SERVICES
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