

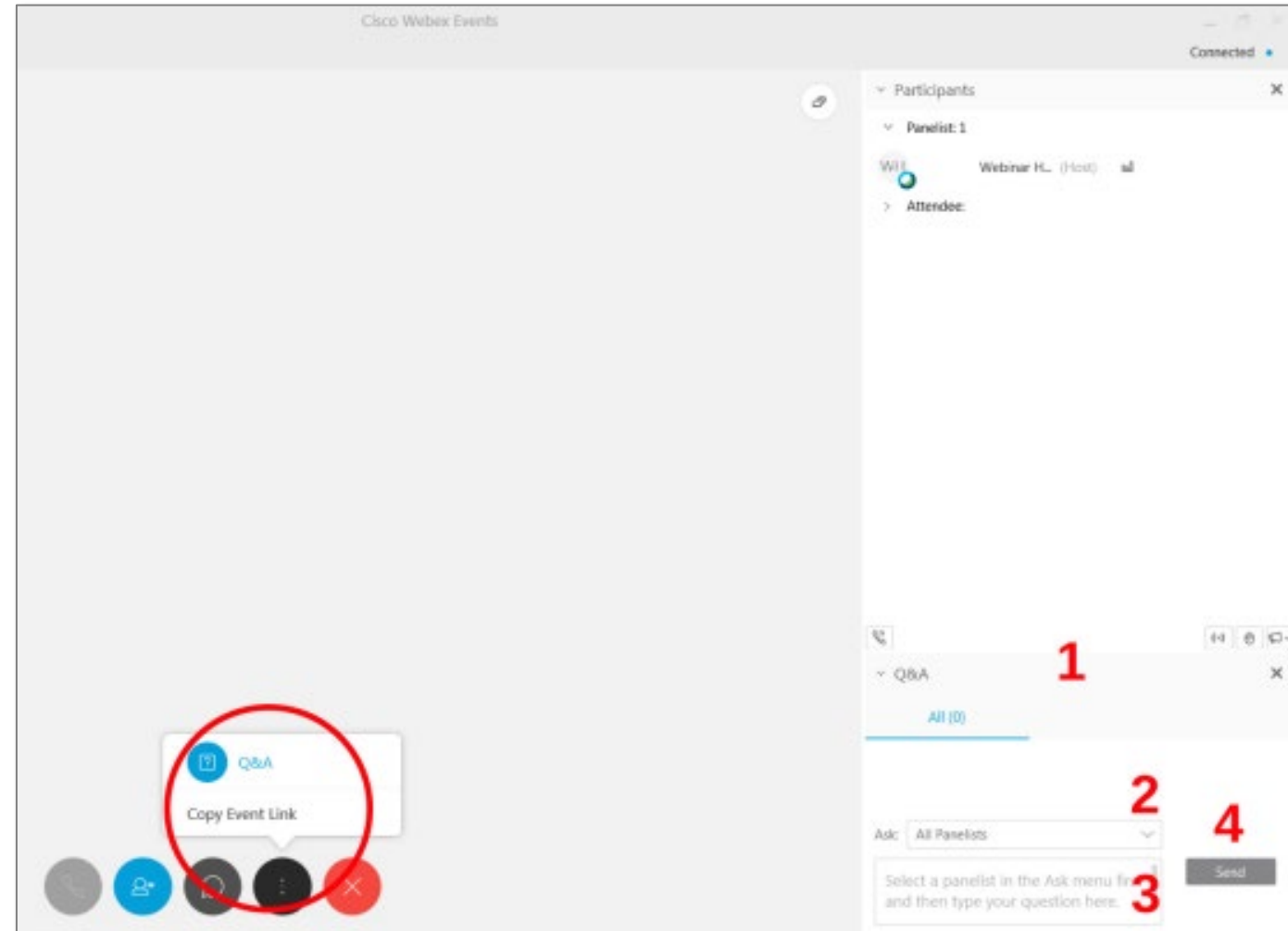
Increased Access to Medications for Opioid Use Disorder during the COVID-19 Epidemic and Beyond

July 23, 2020 | 2:00 – 3:30 PM ET

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- J.D., University of California Irvine School of Law

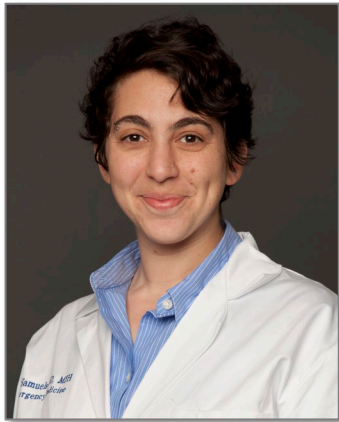
Presenter



Corey Davis, Director, Harm Reduction
Legal Project, Network for Public Health Law

- J.D., Temple University
- M.S.P.H., University of North Carolina at Chapel Hill

Presenter



Elizabeth Samuels, Assistant Professor, Department of Emergency Medicine, Alpert Medical School of Brown University, Consulting Assistant Medical Director, Rhode Island Dept. of Health Drug Overdose Prevention Program

- M.D., Tufts University
- M.P.H., Tufts University
- M.H.S., Yale University School of Medicine

Presenter



Zoe Weinstein, Director, Boston Medical Center's Addiction Consult Service;
Assistant Professor, Boston University
School of Medicine

- M.D., University of California, San Francisco

Presenter



Louise Vincent, Executive Director of NC Survivors Union & Urban Survivors Union

- M.P.H., University of North Carolina at Greensboro and Wake Forest University

Increased Access to Medications for Opioid Use Disorder during the COVID-19 Epidemic and Beyond

Corey Davis

Network for Public Health Law

July 23, 2020

Background

- » **Two concurrent public health emergencies**
 - » Nearly 71,000 overdose deaths in US in 2019
 - Highest number ever, and 2020 looks worse
 - Public Health Emergency declared Oct. 2017

 - » Over 141,000 Covid-19 deaths in US in 2020
 - Public Health Emergency declared January 2020

 - » Both epidemics disproportionately harm disadvantaged groups
 - » Both made worse by lack of access to evidence-based interventions

One big difference!

- » **We don't have good medication treatment for Covid-19**
 - » Hopefully soon?

- » **We do have good medication treatment for OUD**
 - » Opioid agonist treatment with methadone and buprenorphine works
 - Reduces all-cause mortality by ~50%
 - Reduces overdose, risky drug use, relapse
 - Helps people lead the lives they want to lead
 - Treating OUD without OAT “like trying to treat an infection without antibiotics” – HHS Secretary Azar

Law as barrier

» Barriers to buprenorphine

- » Most providers must obtain a federal “waiver” to prescribe buprenorphine for OUD
 - Requires 8 hours for physicians, 24 hours for other prescribers
- » Caps on number of patients waived providers can treat
- » Ryan Haight Act generally requires an initial in-person consultation before issuing controlled substance prescription

- » These limits are structural barriers to evidence-based tx access
 - More than half of rural counties have no waived providers
 - In-person req’t disproportionately impacts people in rural areas, those w/o reliable transportation, and ppl w/ disabilities

Law as barrier

» Barriers to methadone

- » Only federally certified Opioid Treatment Programs (OTPs) may dispense methadone for OAT
- » Only patients w/ certain characteristics are eligible
- » Prospective patients must have an initial in-person visit
- » Initial doses are limited
- » Periodic urinalysis is required
- » All patients required to come to the OTP daily initially; take-homes per federal schedule, not provider expertise or patient characteristics
- » State laws often impose further limitations
 - Limits on number of OTPs, burdensome and unnecessary showing of support from community, etc.
- » Local law often restricts siting, imposes other restrictions

Law as barrier

» These restrictions matter

- » Despite the fact that they *reduce* harm, methadone and buprenorphine for OAT are much more restricted than nearly any other medication – including those same meds when used for pain
- » Only ~4% of US physicians were waived in 2016
- » ~50% of counties have no waived provider
- » Somewhere around 75% of people with OUD received no treatment in the past year
- » Majority white counties more likely to have buprenorphine providers; majority Black counties more likely to have methadone providers

Temporary changes

» Buprenorphine

- » Using statutory authority, HHS Sec'y has waived the Ryan Haight in-person examination req't during Covid PHE
 - Initially limited to real-time, audio-visual communication system, DEA has used its enforcement authority to authorize telephone consults
 - This innovation is key, as Dr. Samuels will describe
- » DEA has waived, in some instances, req't that each provider be registered in the state in which the patient is located
- » HHS OCR will not enforce HIPAA in conjunction w/ good faith effort to provide telehealth

Temporary changes

» **Methadone**

- » SAMHSA permits states to request blanket exemptions to permit
 - 28 day take-homes for stable patients
 - 14 day take-homes for less-stable patients

- » DEA permits some OTPs to provide doses in off-site locations w/o separate registration
- » DEA permits authorized OTP employees, law enforcement, and national guard to deliver methadone to patients (mailing is still forbidden)

These changes will expire when the Covid-19 emergency ends (if not before)

What happens after Covid-19?

» Permanent change is needed

- » Crisis of opioid-related harm existed before Covid-19 and will exist after
- » Covid-19 epidemic almost certainly increasing risk for ppl w/ OUD
- » Some people w/ OUD are at increased risk for Covid-19
- » While not much research yet, all signs point to these changes improving outcomes for ppl w/ OUD

- » Two main ways to permanently remove barrier to OAT:
 - Legislative action
 - Regulatory action and use of regulatory discretion

Increasing access post-Covid

» **Legislative change**

- » Congress can and should make the COVID-related temporary changes permanent
 - TREATS Act good idea but doesn't go far enough
 - Telephonic initiation is important!
- » Barriers to OAT should be systematically identified and removed
 - Most limitations on OAT *reduce* patient and public health

- » Can also take positive steps to increase OAT access, e.g. conditioning funding to states on ensuring OAT is available in all correctional settings

Increasing access post-Covid

» **Regulatory change**

- » HHS can tie Ryan Haight Act waiver to opioid emergency instead of Covid emergency
- » DEA should continue telephone exemption for length of opioid emergency
- » DEA is required to create “special registration” for telemedicine providers but has failed to do so
 - Should quickly promulgate rules permitting Rx of buprenorphine via telehealth
- » DEA can change regulations to permit mobile methadone delivery

What happens after Covid?

» **State and local changes needed as well**

- » Many states have modified telehealth provisions during Covid
- » Others have mandated payment parity for telehealth
- » Some have made positive steps to improve access to harm reduction services
- » To the extent state or local law is more restrictive than federal law, permanent conforming changes should be made

- » Set Medicaid rates at reasonable levels
- » Require all licensed providers obtain waiver
- » Ensure all justice-involved individuals are screened and offered non-coercive OAT if indicated
- » Exchange criminalization for public health approaches

But what about diversion?

» **What about it?**

- » “Diverted” buprenorphine is nearly always used for the purpose for which it was intended
 - to reduce use of other opioids and treat withdrawal
- » Greater frequency of non-prescribed buprenorphine use is significantly associated w/ lower risk of overdose
- » No evidence that current, extremely restrictive methadone regime improves outcomes compared to e.g. pharmacy dosing and longer take-homes
 - Problem is almost always too little OAT, not too much

Conclusions

- » OAT works
- » Everyone who wants it should be able to access it – quickly, affordably, and with dignity
- » Both Covid-19 and the “opioid crisis” exacerbate existing inequalities
- » Need to address stigma, financial barriers, and structural inequities
- » But also: Change the law
- » Federal and state governments can and should identify and remove legal and policy barriers to OAT

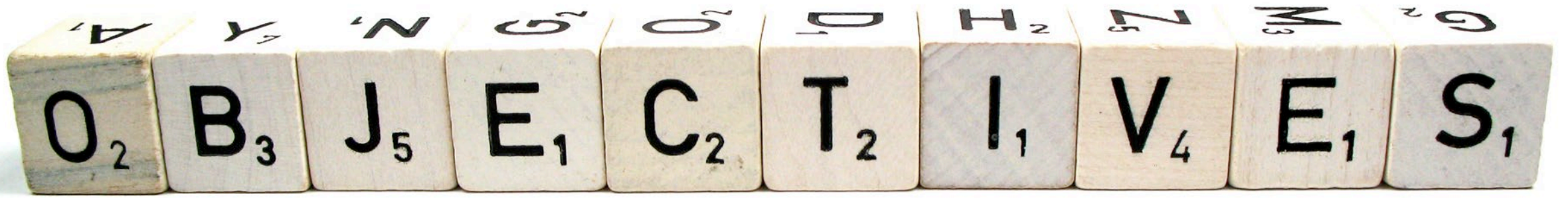
Corey S. Davis, JD, MSPH, EMT
Director, Harm Reduction Legal Project
Network for Public Health Law
cdavis@networkforphl.org

Buprenorphine During COVID-19:

An opportunity to improve access

Elizabeth A. Samuels, MD, MPH, MHS
Brown Emergency Medicine, Alpert Medical School of Brown University
Drug Overdose Prevention Program, Rhode Island Department of Health

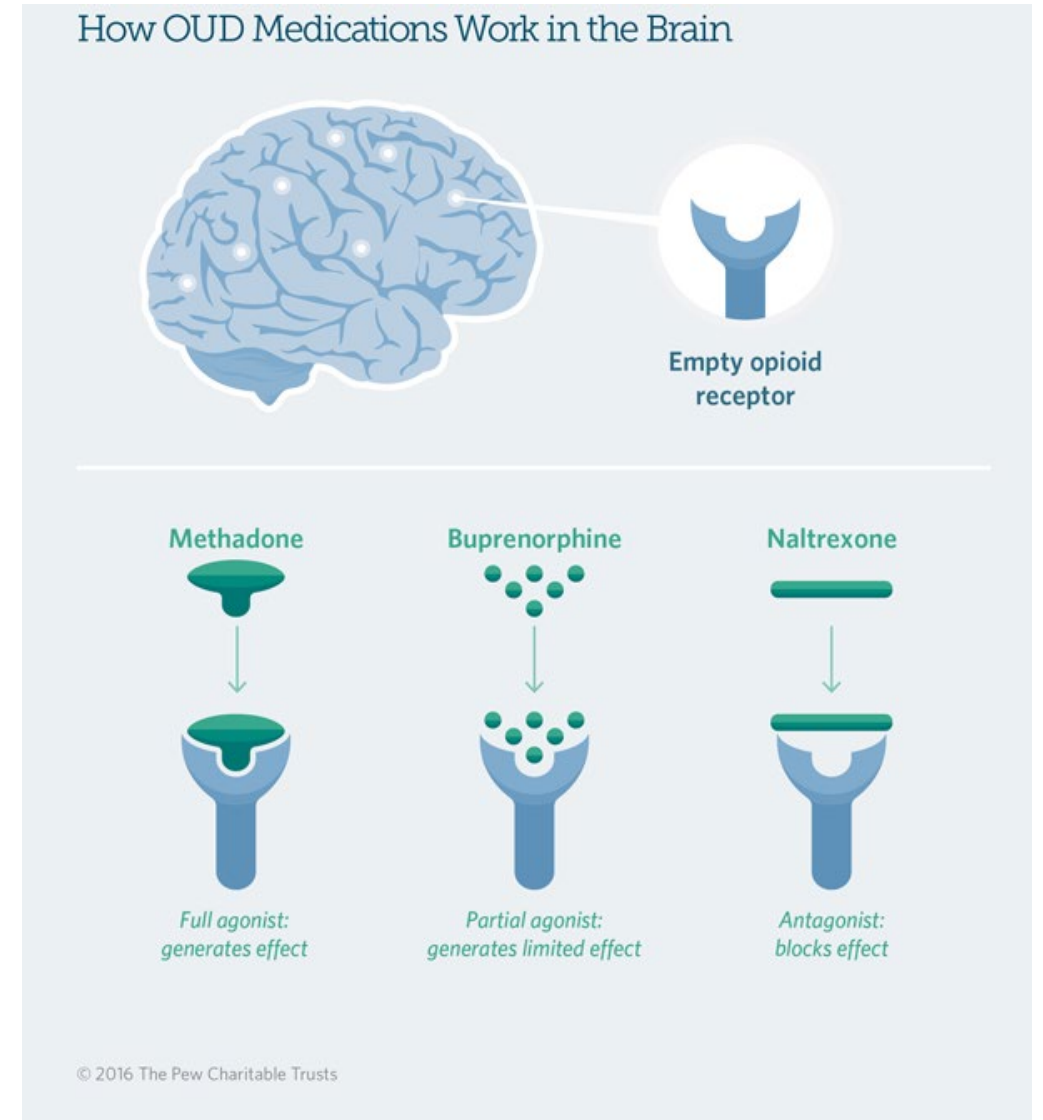
Increased Access to Medications for Opioid Use Disorder During the COVID-19
Epidemic & Beyond
The Network for Public Health Law
July 23, 2020



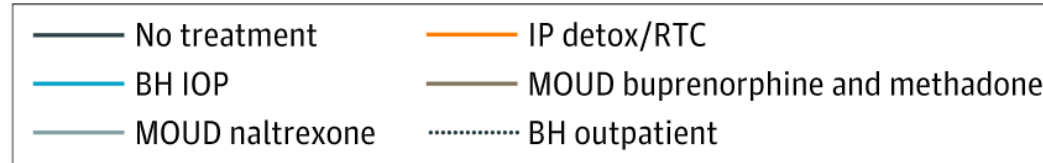
- Buprenorphine overview
- Treatment inequities
- Buprenorphine for telehealth
- Buprenorphine telehealth during COVID
- Rhode Island initiatives: Buprenorphine Hotline & ED Overdose Callbacks
- Future of buprenorphine telehealth

Buprenorphine

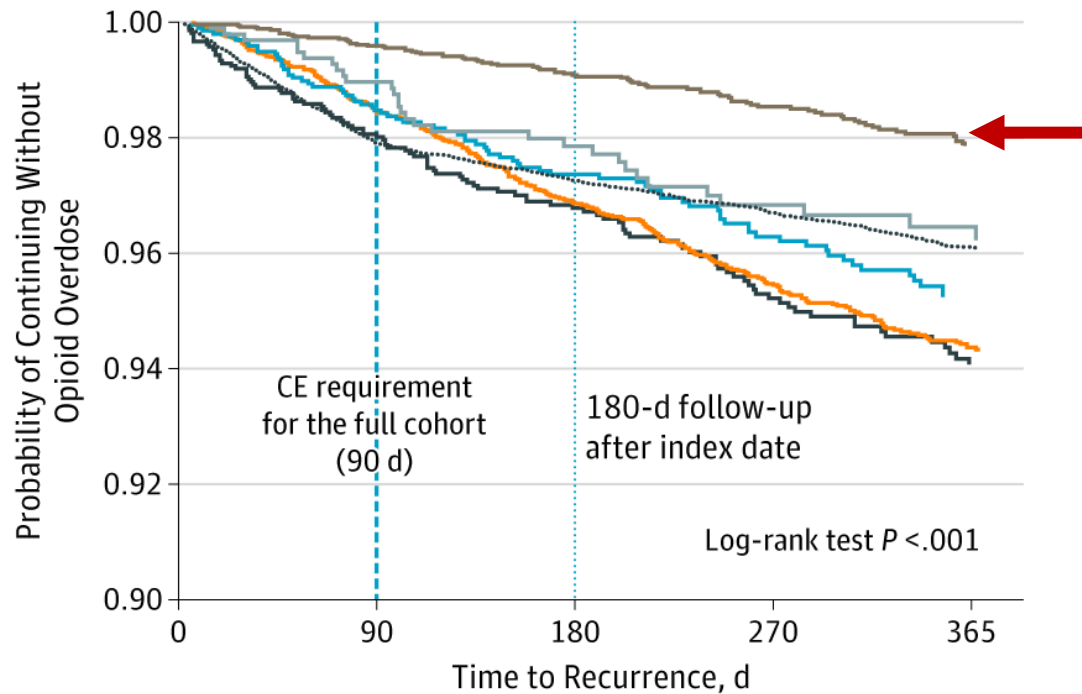
- Partial agonist
 - High affinity for mu opioid receptor
 - Reduces cravings, treats withdrawal
 - Has a “ceiling effect”
- Reduces overdose, death
- Available through office-based provider or opioid treatment program
- Prescriber must be “X-waivered”



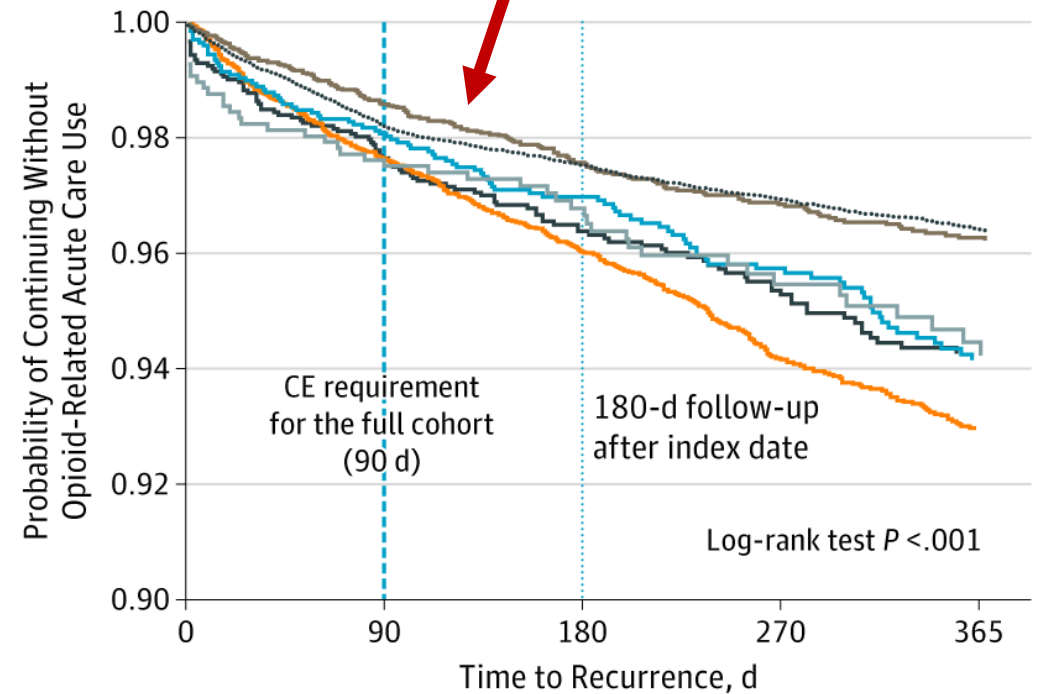
MOUD reduces overdose, acute care use



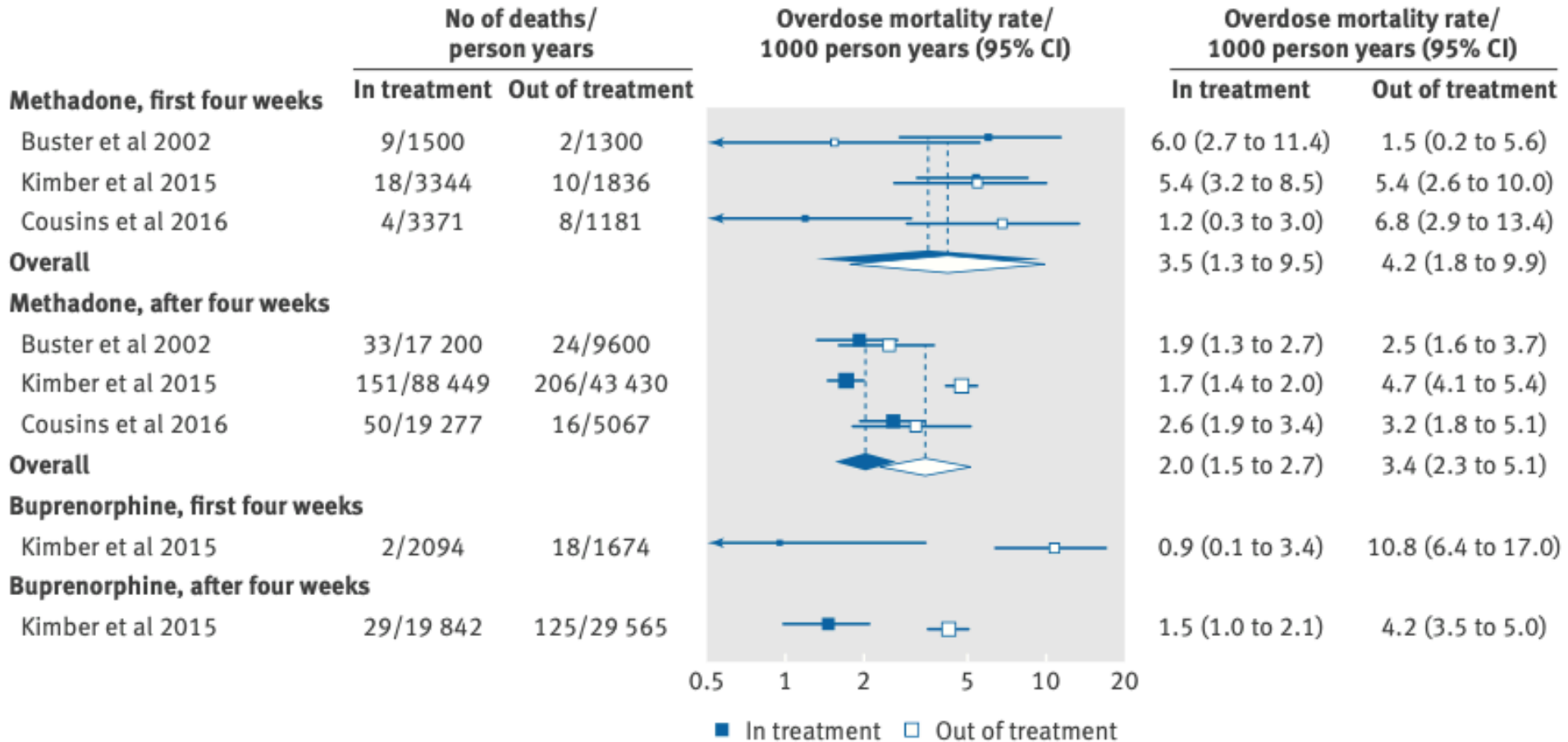
A Opioid overdose at 3 mo



B Acute care use at 3 mo



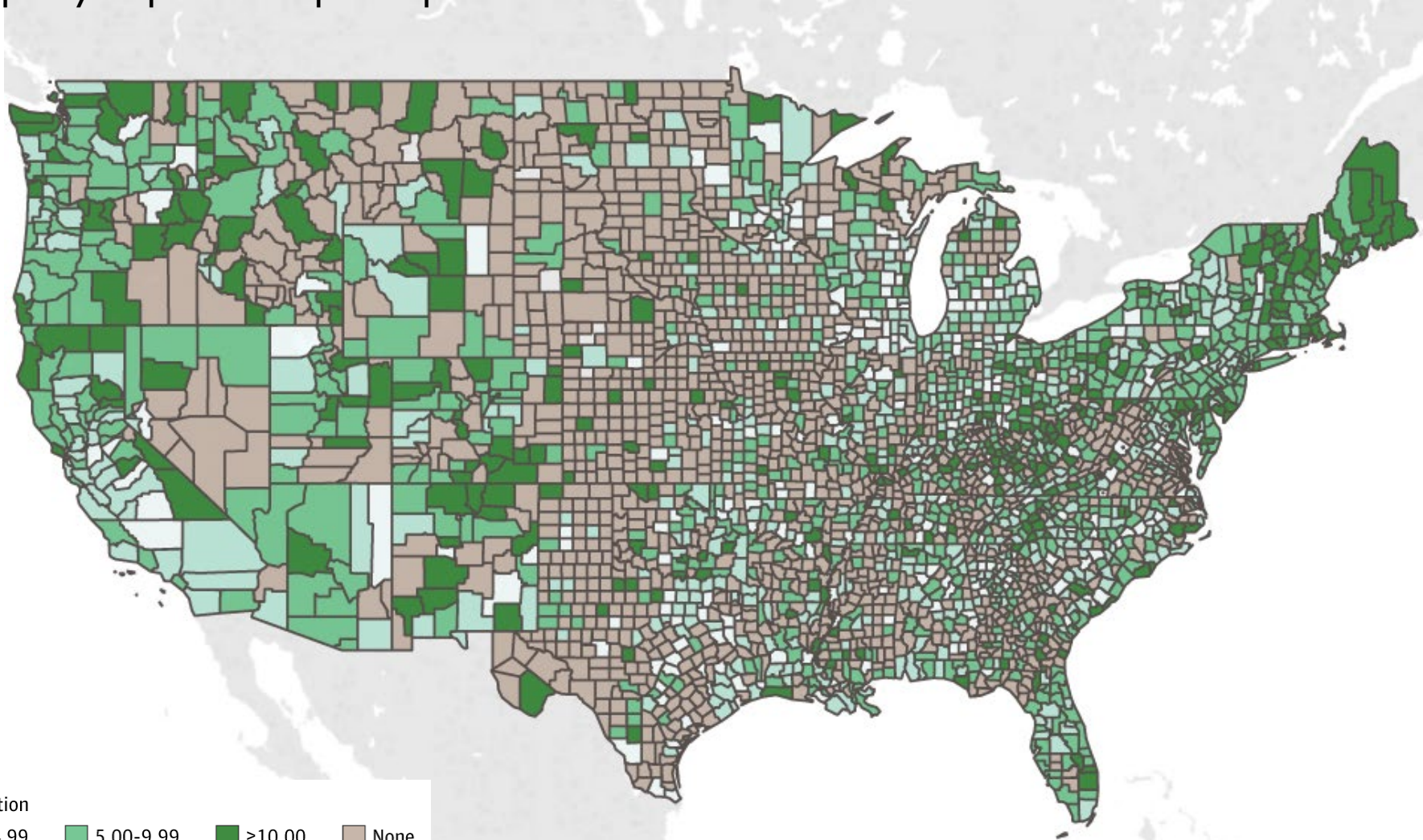
MOUD reduces overdose death



Overdose mortality rates by time interval in and out of opioid substitution treatment with methadone or buprenorphine and pooled overdose mortality rates, 2002-16.

Treatment Inequity- *Geography*

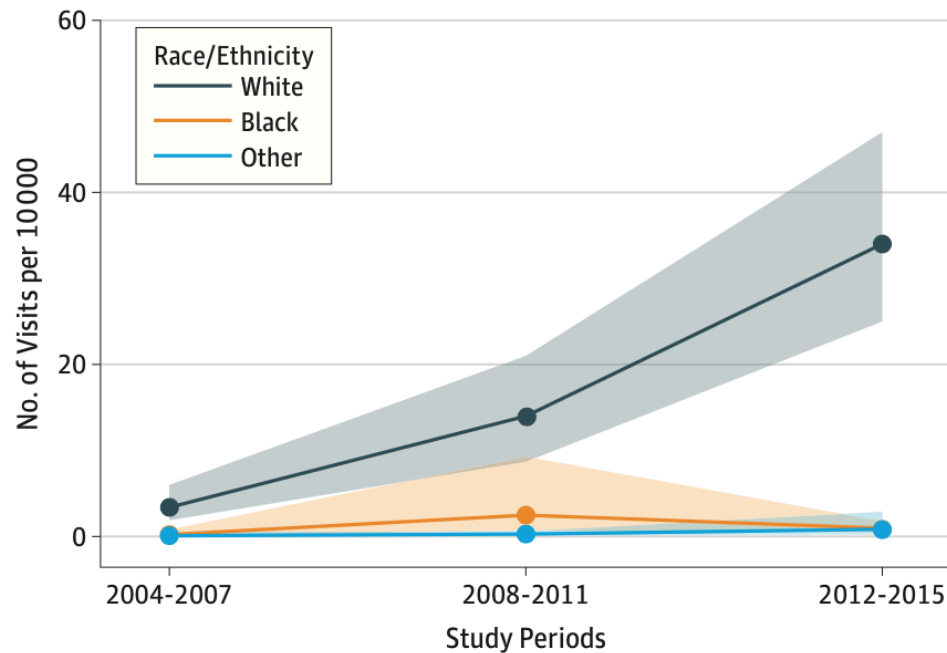
County level capacity to provide buprenorphine



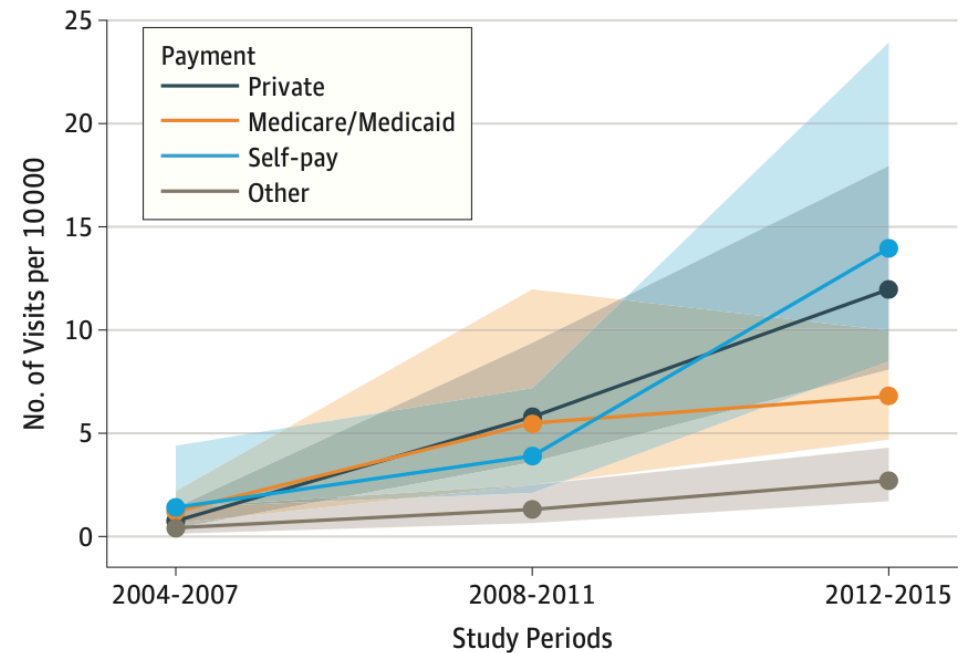
Treatment Inequity- Race & Insurance

Figure. Buprenorphine Visits by Race/Ethnicity and Payment Type, 2004-2015

A Visits by race/ethnicity



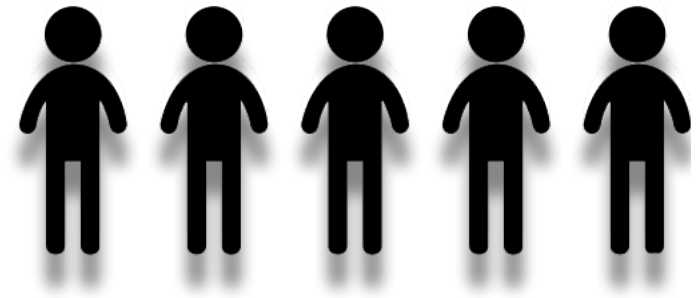
B Visits by payment



Buprenorphine visits (n = 1369) and 95% CIs per 10 000 visits (shaded areas), grouped by year and stratified by race/ethnicity and payment type. Estimates account for complex survey design elements and are nationally representative.

Barriers to treatment

- Cost
- Insurance
- Transportation
- Stigma
- Availability of a waived provider



Buprenorphine telehealth

- Previously used for maintenance treatment
- Comparable:

Patient retention

Medication maintenance

Obstetric outcomes

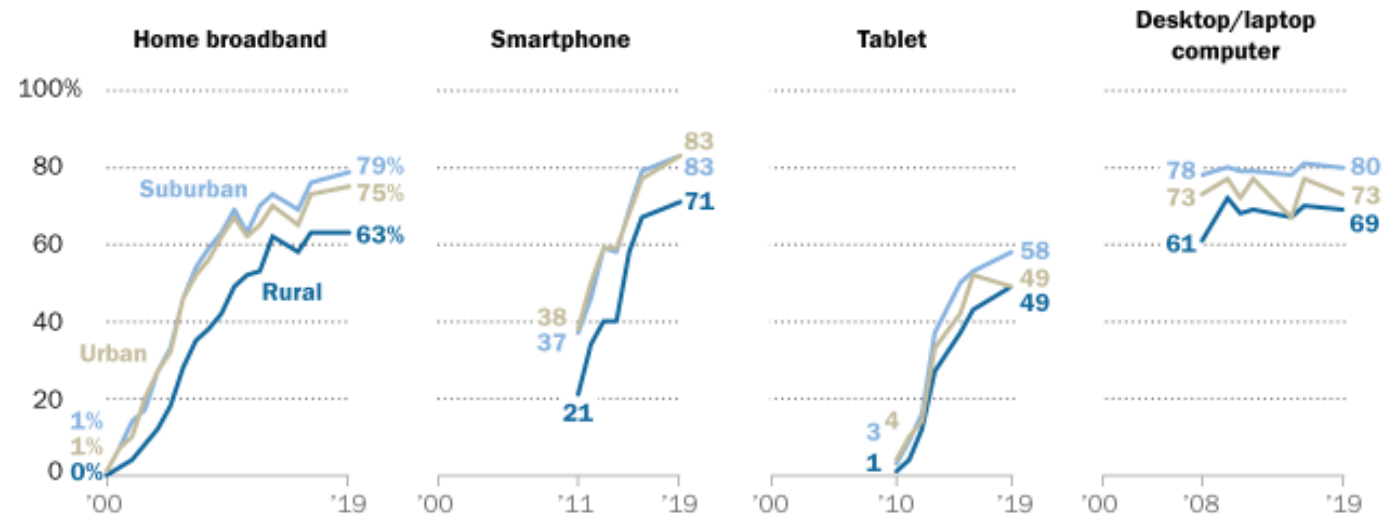


Equity & Buprenorphine telehealth

- Opportunity to decrease inequities due to transportation, geography
- Will exacerbate inequities if video is required
 - Video requires smartphones or internet, inequities by:
 - Income
 - Rurality
 - Age

Rural Americans have consistently lower levels of broadband adoption

% of U.S. adults who say they have ...



Note: Respondents who did not give an answer are not shown.

Source: Survey conducted Jan. 8-Feb. 7, 2019. Trend data from other Pew Research Center surveys.

PEW RESEARCH CENTER

COVID concerns

- Decreased access to harm reduction services & treatment
- Increased risk of overdose death due to:
 - Increased use of opioids alone due to isolation, physical distancing, closure of public spaces
 - Disruptions in drug supply resulting in loss of tolerance
 - Increase in resumed use after period of abstinence related to COVID-19 stressors
 - Increased potency of drug supply

Tele-Buprenorphine During COVID-19



Photos courtesy of Peter Tobia/PhillyRespond

Center for Opioid Recovery and Engagement

Call today to connect to a recovery specialist & access Buprenorphine

Clinic hours (by phone)
Monday-Friday 9AM-5PM
Please call:
(484) 278-1679

CORE will be operating a telehealth buprenorphine service in response to COVID-19.

This program will serve all Philadelphians seeking treatment for Opioid Use Disorder, wishing to begin or continue buprenorphine.

Virtual Buprenorphine Clinic Taking New Patients



Starting **March 25th**, NYC Health + Hospitals will begin operating a virtual buprenorphine (Suboxone) clinic in response to the COVID-19 emergency.

The virtual buprenorphine clinic will serve all New Yorkers seeking opioid addiction treatment for **continuation or initiation** of buprenorphine.

Referrals from all NYC H+H staff are welcome!

Clinic hours (by phone or video conference):
Mon - Fri, 9 AM - 5 PM

For appointments and referrals, call:
212-562-2665

Bellevue Building A Room 235

Rhode Island Tele-Buprenorphine

Buprenorphine Hotline

- 24/7
- Free
- Buprenorphine consultation, treatment initiation, and linkage to treatment

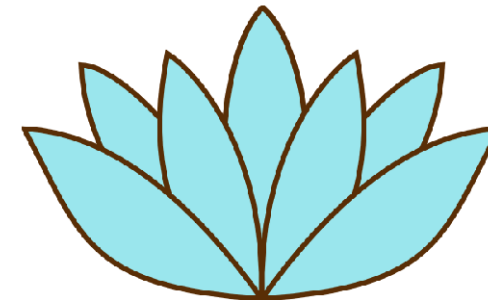
Post-Overdose ED Callbacks

- Post-ED overdose visit follow up calls
- Harm reduction and recovery resource referral
- Consultation with a buprenorphine prescriber

Are you struggling
with Opioid Use?

Call the Buprenorphine Hotline

(401) 606-5456



HELP IS HERE

Call us **24/7** for a **FREE**
Buprenorphine (Suboxone)
consultation

We'll match you with a
healthcare provider that can
start you on medication today
in your path to better living.

Principles & Goals

1. Provide low threshold buprenorphine access
2. Utilize principles of harm reduction to deliver patient-centered care
3. Improve equity in addiction treatment access



Buprenorphine Hotline

- Telephone-based
- 24/7
- Initiate buprenorphine treatment
- Link to a treatment provider

- 6 providers
- Not currently billing



Starting the patient encounter

Patient calls hotline or begins virtual clinic appointment & consents to telehealth encounter

Patient assessment: determining appropriateness for buprenorphine initiation

Does patient have moderate-severe OUD based on DSM-V criteria?

No

Do NOT prescribe buprenorphine

Yes

Is patient taking methadone?

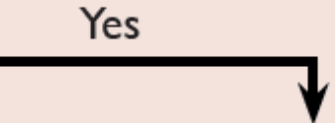
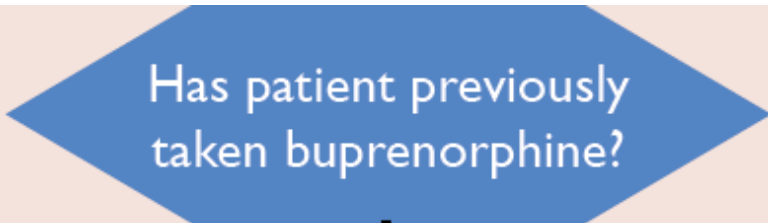
Yes

Comprehensive patient history

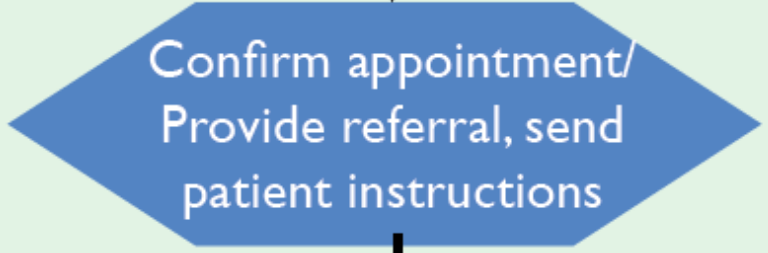
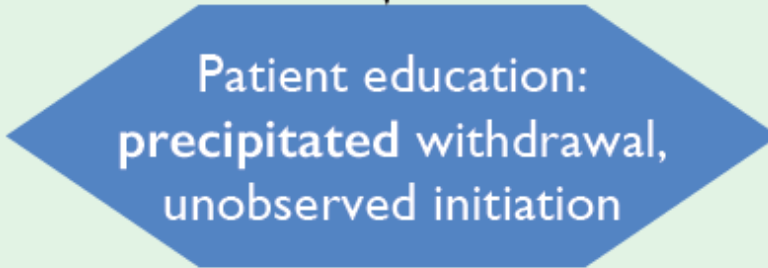
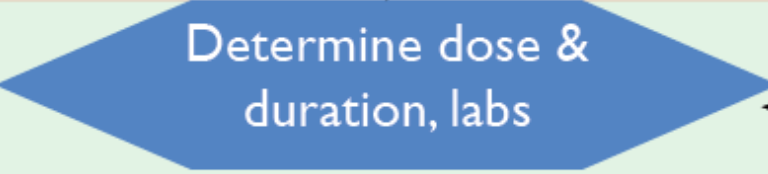
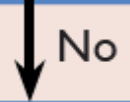
No

Assess current substance use, date of last opioid use, prior treatment history, & opioid use withdrawal using SOWS

Buprenorphine initiation & next steps



Discuss prior experience & address concerns



Prescribe buprenorphine & naloxone

Buprenorphine Hotline, 4/15/20-7/22/20



65 calls



27 new
buprenorphine
prescriptions



66.7% follow up
(12/18 patients)

Post-Overdose Call Backs

- High risk of death after an ED visit for opioid overdose
- Low services provision at time of ED visit

TOXICOLOGY/BRIEF RESEARCH REPORT

One-Year Mortality of Patients After Emergency Department Treatment for Nonfatal Opioid Overdose

Scott G. Weiner, MD, MPH*; Olesya Baker, PhD; Dana Bernson, MPH; Jeremiah D. Schuur, MD, MHS

*Corresponding Author. E-mail: sweiner@bwh.harvard.edu, Twitter: [@scottweinermd](https://twitter.com/scottweinermd).

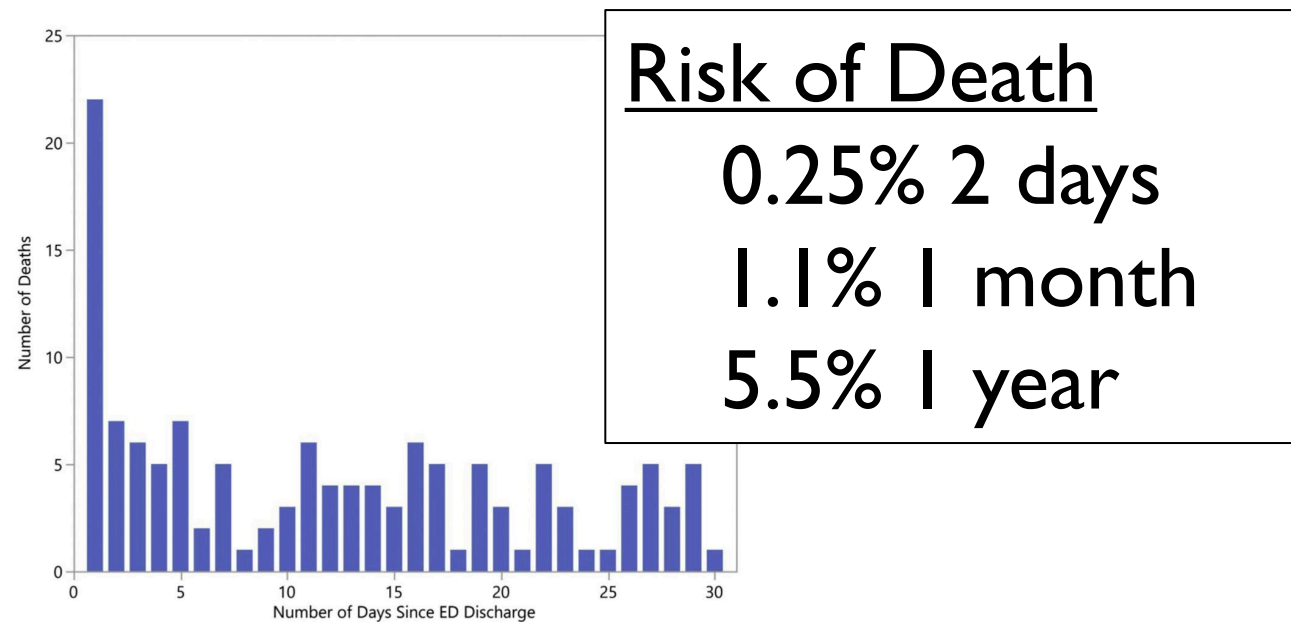
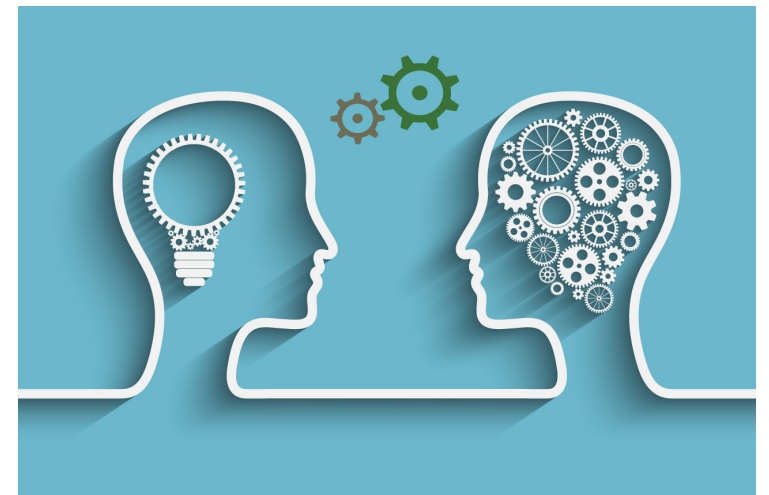


Figure 2. Number of deaths after ED treatment for nonfatal overdose by number of days after discharge in the first month, by day (n=130).

Post-Overdose Call Backs

- Developed script and trained research assistants to call people recently treated in the ED for an opioid overdose
- Provide information & referral to harm reduction, peer recovery, & treatment services
- Offer immediate consultation with a buprenorphine provider



TREATS Act - 2020

Telehealth Response for E- Prescribing Addiction Therapy Services Act

- Would expand telehealth services for SUD treatment
- Provides support to rural areas
- Requires video for initial evaluation

(a) SUBSTANCE USE DISORDER SERVICES FURNISHED THROUGH TELEHEALTH UNDER MEDICARE.— Section 1834(m)(7) of the Social Security Act (42 U.S.C. 1395m(m)(7)) is amended by adding at the end the following: “With respect to telehealth services described in the preceding sentence that are furnished on or after January 1, 2020, nothing shall preclude the furnishing of such services through audio or telephone only technologies in the case where a physician or practitioner has already conducted an in-person medical evaluation or a telehealth evaluation that utilizes both audio and visual capabilities with the eligible telehealth individual.”.

Take home points

- Federal telehealth regulations for buprenorphine during COVID-19 can improve access to treatment, could help address inequities
- Need for audio-only capabilities to maintain equity in access
- Need for ongoing evaluation and research to ensure equity in treatment access, measure outcomes



Thank you!

elizabeth_samuels@brown.edu

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Opportunities and Challenges for Providing Methadone for Opioid Use Disorder during the COVID-19 Pandemic

Zoe M. Weinstein, MD, MS

Assistant Professor of Medicine, BUSM
Associate Director, Grayken Addiction Medicine Fellowship, BMC
Medical Director, Addiction Consult Service, BMC



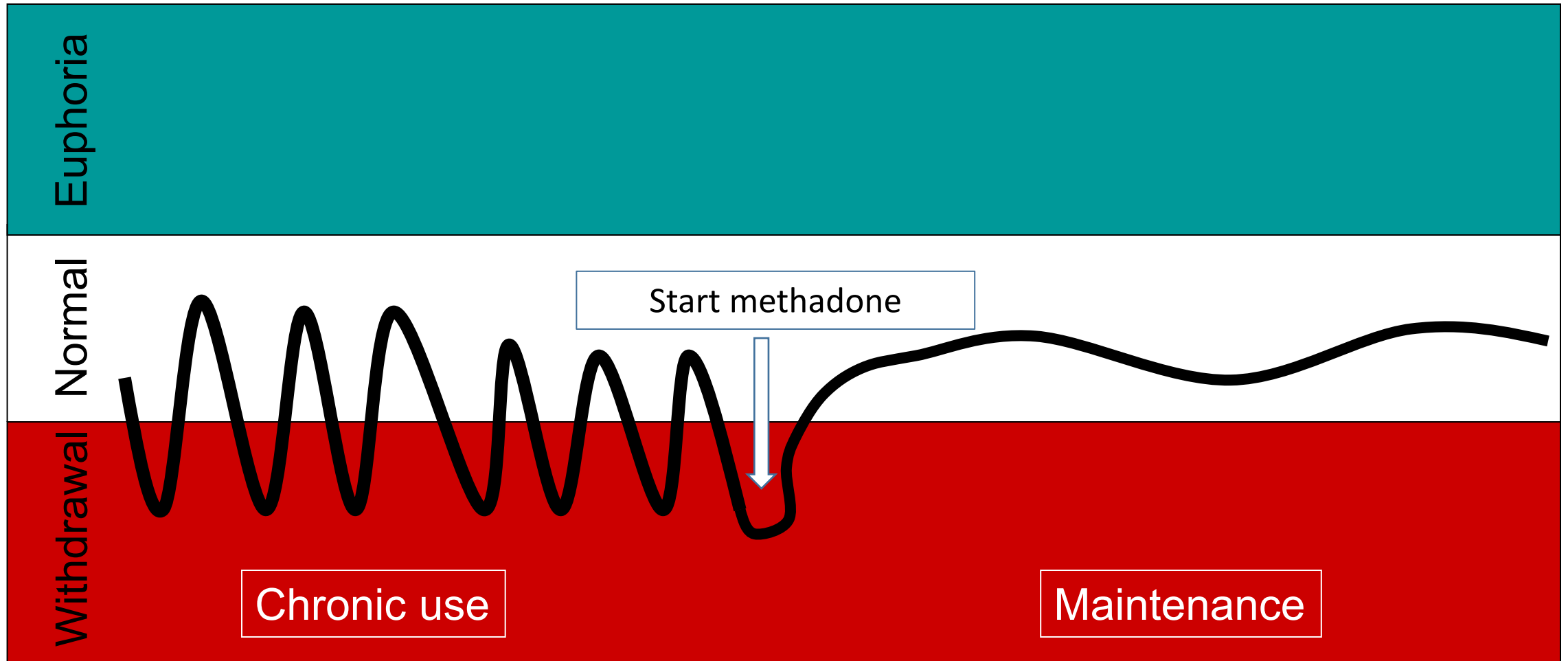
Boston University School of Medicine



No disclosures other than:
OTP disclosures: Zoe Weinstein has been a site physician and/or medical director for various Healthcare Resource Centers OTPs in the Boston area from 2015-Present, leased out by Boston University School of Medicine.



Maintenance Treatment for Severe Opioid Use Disorder



Goals of medication for opioid use disorder

Relief of withdrawal symptoms

- Low dose methadone (30-40mg)

Reduce opioid craving

- High dose methadone (>60mg)

Opioid blockade

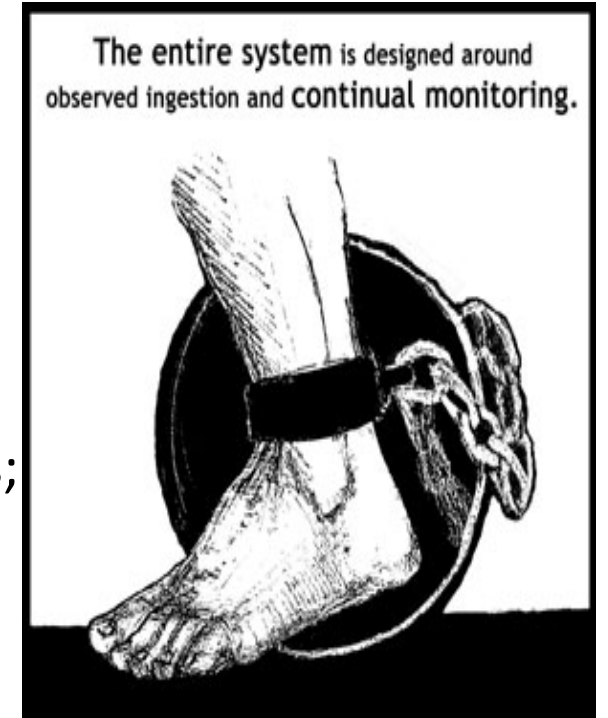
- High dose methadone (60mg-120mg)

Restoration of reward pathway

- Long term (>6 months)

Methadone maintenance is highly structured

- Daily nursing assessment
- Weekly individual and/or group counseling
- Random supervised toxicology screens
- Medical director oversight
- Methadone dosing
 - Observed daily \Rightarrow “Take-homes”
 - Strict criteria to earn TH
- Inconvenient and highly punitive
- Mixes stable and unstable patients
- Lack of privacy
- Separate system not involving primary care
- Limited access: 5 states: 0 clinics; 4 states: < 3 clinics
- Stigma
- No ability to “graduate”



The 8-point criteria = How to earn take homes

1. Absence of recent use of drugs (opioid or nonnarcotic), including alcohol
2. Regularity of clinic attendance
3. Absence of serious behavioral problems at the clinic
4. Absence of known recent criminal activity, e.g., drug dealing
5. Stability of the patient's home environment and social relationships
6. Length of time in comprehensive maintenance treatment
7. Assurance that take-home medication can be safely stored within the patient's home
8. Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion



Pre-COVID take home schedule

- Day 1-90 – take-homes limited to 1 dose each week
- Day 91-180 – 2 doses per week
- Day 181-270 – 3 doses per week
- Day 271-365 – 6 doses per week
- Day 366-730 (Year 2) – 13 doses every 14 days
- Day 731 (year 3) and beyond – 27 doses per 28 days

Most clinics have loss of take homes result in return to the first phase and work their way back through.



An important mechanism for rapid change = Exception requests

- OTP staff can submit requests to state and federal (SAMHSA) regulators to request an exception to take home requirements or other care deviations
- Typically requests are to give any/additional take-homes to patients who do not qualify by regs, but need them due to travel, disability etc. for an individual patient
- Weather emergencies (e.g. snow day), clinic wide request

SAMHSA/CSAT OTP Extranet Log In Page

User Name:
Password:

SIGN IN

[Reset Password/Reactivate Account](#)

You can request a user account at <http://otp-extranet.samhsa.gov/request>.



A crowded space for a contagious virus



Methadone maintenance (OTP) in era of Covid-19

- Initially there was no state or federal guidance about how to adapt care to a setting where the majority of patients come daily
- No clear best practices, as prior emergencies that have impacted methadone care have been both short term and regional (e.g. hurricanes Katrina or Sandy)
- Seattle local clinics and Washington state regulators were leaders in developing practices that were later widely adopted nationally
 - *A great example that in a void – a few small advocates can dictate national policy!*

Changes in take-home at OTPs from SAMHSA

- "The state may request **blanket exceptions** for **all stable patients** in an OTP to receive **28 days** of Take-Home doses of the patient's medication for opioid use disorder."
- "The state may request **up to 14 days** of Take-Home medication for those patients who are **less stable but who the OTP believes can safely handle** this level of Take-Home medication."
- Rapid increase in number of patients currently receiving take homes to dramatically decrease daily census of OTP



MA State OTP Regulatory Changes

Memorandum

Re: Waiver from Certain Regulatory Requirements

To: All BSAS Licensees

On March 10, 2020, Governor Baker declared a State of Emergency in response to the outbreak of Coronavirus Disease 2019 (COVID-19). Substance Use Disorder programs (programs) are considered essential services, and it is therefore imperative that the treatment system remain responsive to the needs of individuals seeking treatment during the public health emergency.

The Department of Public Health (DPH)/Bureau of Addiction Services (BSAS) understands the unique challenges that programs face, however, programs must ensure that operations continue, and that new patients are admitted. Towards this end, the Department is encouraging programs to consider sharing resources, utilizing telehealth whenever appropriate, and evaluating the merits of consolidating programs to maximize resources. It is the responsibility of the programs to ensure that appropriate measures are in place (e.g.; Qualified Service Organization Agreements etc.) to facilitate these changes.

Similarly, the Department continues to explore ways to provide programs additional flexibility, and recognizes the need for relief from certain regulatory requirements at this time.



Additional OTP changes during COVID

- Suspending “annual” visits
- Decreasing the number of annual require drug tests
- Allowing counseling visits and some medical visits to be remote
- However, admissions still must be *in person*



Impact on a single clinic

	February 2020	June 2020
Clinic census	790	771
# Pts Dosing Daily	665	276
# with 28 Take Homes*	2	75
# with 14 Take Homes**	13	205
# with 1-6 Take Homes	87	204

*patients on 28 – were on exception waiver, as in MA max is 14

**patients on 14 grandfathered in from previous clinic



Notes from the field

- Many more patients with TH, most doing well
- Some prior stable TH patients relapsing and struggling without in-person support and larger # of TH
- Many patients continue to use, but are able to safely manage every other day dosing
- Challenges with retaining new patients, when most supports (counseling etc.) is remote



Potential changes to retain post-COVID

- Accelerate timeline for patients to be eligible to earn 1st take-home and time between each subsequent take home
- Create a formal pathway for patients to get even 1 take (or every other day dosing) for patients who do not meet 8-point criteria



Areas for expansion/advocacy beyond current regulations

- Allow for telehealth visits in methadone clinics, including initial visits, like for buprenorphine
- Close clinics at least 1 day per week
- Alternative dosing sites to minimize travel and crowding:
 - Mobile methadone vans or methadone delivery (NYC)
 - Pharmacy-based methadone
 - Primary care-based methadone



RECOVERY

Expectations



Reality



Realistic Expectations!

Addiction is a chronic relapsing condition

Over time treatment works
People get better

Thank you!

Zoe.Weinstein@bmc.org

Travel times- to OTP vs Pharmacy

Table 1. Driving Times to the Closest Opioid Treatment Program and Pharmacy^a

Outcome	One-way driving time, mean (95% CI), min	
	Opioid treatment program	Pharmacy
Primary outcome		
Total US	20.4 (20.3-20.6)	4.5 (4.4-4.5)
Secondary outcomes		
Metropolitan counties		
Large central metro	9.8 (9.8-9.9)	2.8 (2.8-2.8)
Large fringe metro	15.8 (15.6-15.9)	4.2 (4.1-4.2)
Medium metro	15.9 (15.7-16.1)	4.5 (4.4-4.5)
Small metro	24.4 (23.7-25.1)	5.5 (5.4-5.7)
Nonmetropolitan counties		
Micropolitan	48.4 (47.5-49.4)	7.0 (6.7-7.2)
Noncore	60.9 (59.8-62.0)	9.1 (8.8-9.5)

^a Population-weighted mean driving times (95% CIs) were calculated from census tract mean centers of population to the opioid treatment program and pharmacy with the shortest driving time. Census tract population estimates and mean centers of population were obtained from the 2010 US Census. The primary and secondary outcomes were defined a priori as the population-weighted mean driving times. Weighted 1-sample *t* tests on the





Louise Vincent MPH

Methadone Patient

Activist

Drug User

Fatal drug overdoses hit a record high last year. Covid-19 is making the problem worse.

Medication-Assisted Treatment and COVID- 19 Treatment Recommendations

www.ncurbansurvivorsunion.org

- 1) No discharges unless there is violence toward staff or other clients
- 2) No “feetoxing” during COVID-19
- 3) No X-waiver
- 4) Pharmacy Based Delivery
- 5) Take Home Privileges Extended
- 6) Telehealth Replaces in Person for Methadone
- 7) Do away with lock boxes (SAMHSA TIP 43)
- 8) State and Federal Medicaid Dollars to Cover all Take Homes

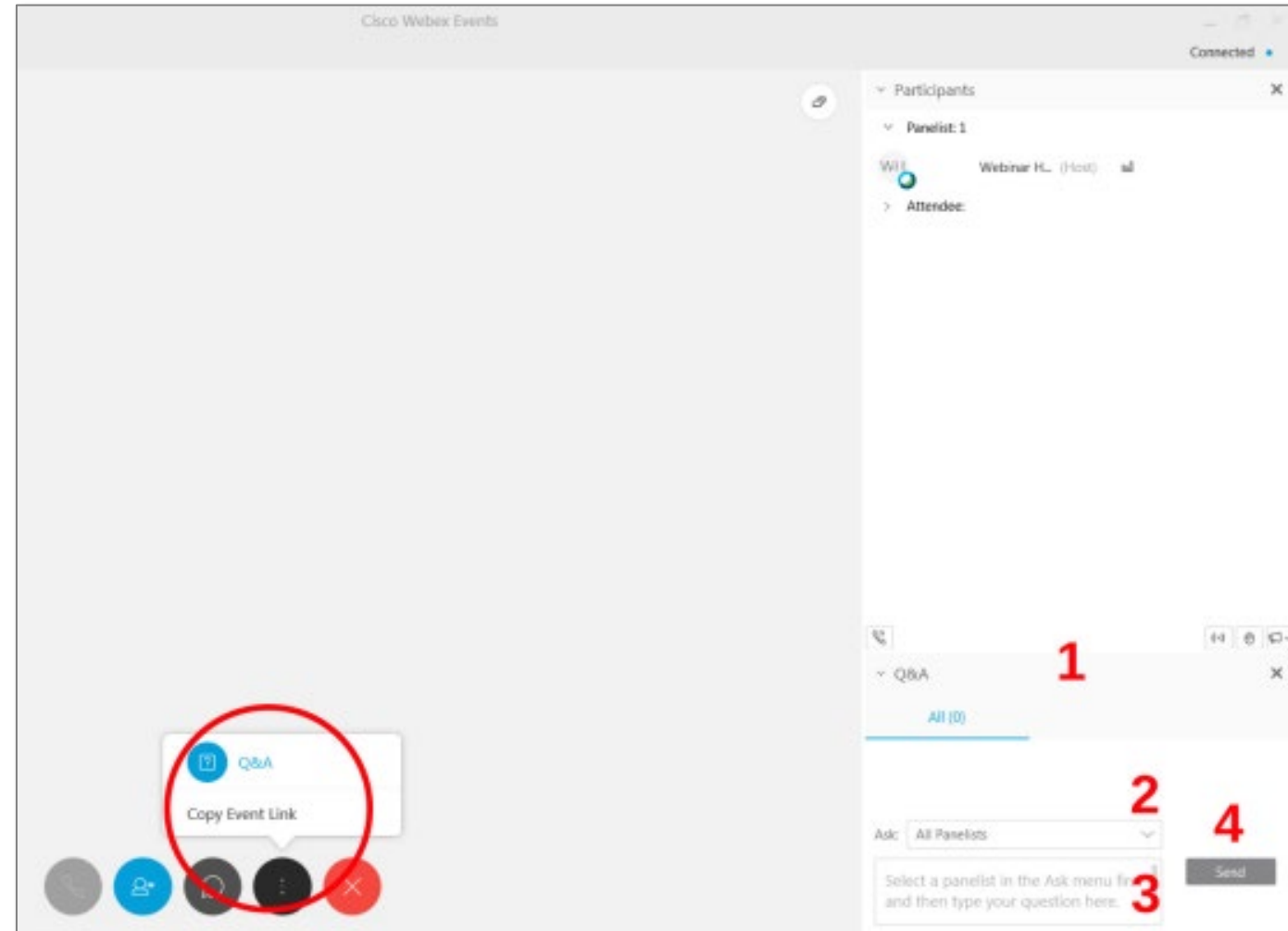
**The evidence is in!
There is no question about what works!
It's a matter of political will.**

Let me tell you a story about methadone:



How to Use WebEx Q & A

1. Open the Q&A panel
2. Select “All Panelists”
3. Type your question
4. Click “Send”



Thank you for attending

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COVID-19 Response and Recovery
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