



UMP - Vietnam - HIV





TC International Technology Transfer Center
A program of the International Consortium of Universities
for Drug Demand Reduction

Methadone clinics management strategies in the context of COVID-19: International experiences

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Objectives

- Evaluate the link between substance use disorders and COVID-19 risk
- Judge how addiction medicine balances between the risk of COVID-19 and risk of opioid overdose
- 3. Explain the impact of COVID-19 related regulatory changes on methadone outcome



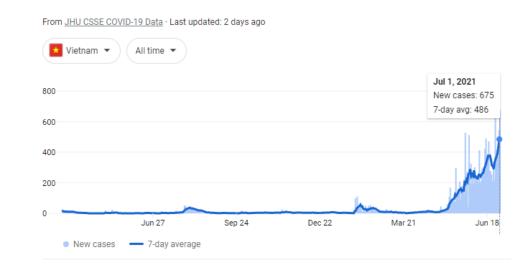
Disclosures

- I receive grant funding from
 - National Institute on Drug Abuse
 - National Institute of Diabetes and Digestive and Kidney Diseases
- I have been compensated as a contractor for work funded by the US Substance Abuse and Mental Health Services Administration and the US Department of State



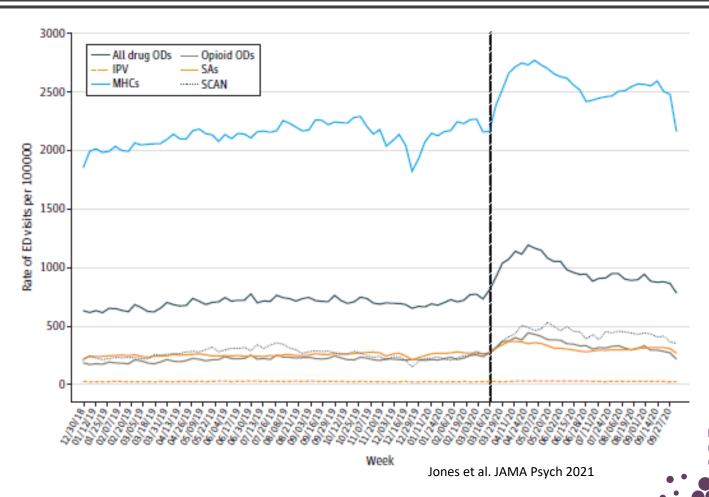
Vietnam has been a Covid-19 success

- Limited group activities
- Early quarantine
- Border protection
- Delta variant may be surging
- Prevention is key, but
 - Not all settings can close
 - Access to healthcare is critical





The pandemic has made things worse





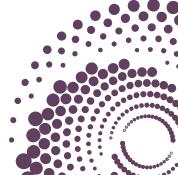
COVID-19 and mental health diagnoses

- 62 million adults analyzed
- 1.3 million with recent psych dx
- 15,000 COVID-19 positive
- 3,430 with recent psych and COVID
- Adjust analyses for demographics and medical comorbidity

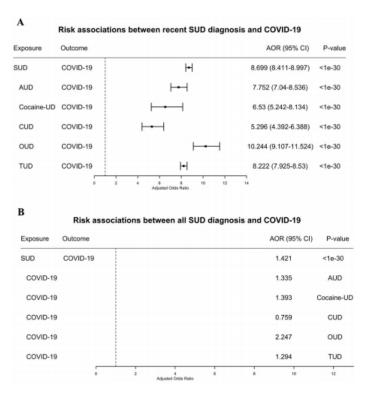
Exposure	Outcome		AOR (95% CI)	р
ADHD	COVID-19	ı÷l	5.82 (5.46-6.20)	<0.001
Bipolar disorder	COVID-19	H	5.72 (5.35-6.10)	<0.001
Depression	COVID-19	н	7.64 (7.45-7.83)	<0.001
Schizophrenia	COVID-19	ŀ • ·I	7.34 (6.65-8.10)	<0.001
	0	2 4 6 8 10 12 14 16 Adjusted odds ratio (AOR)		

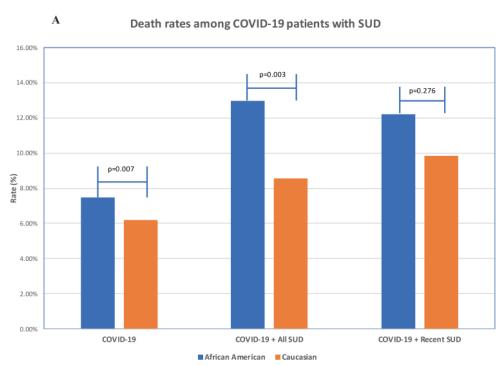
Wang et al. 2020





COVID-19 and Substance Use Disorders





Wang et al. 2020





Hennepin Healthcare Addiction Medicine

- Licensed Opioid Treatment Program
 - SAMHSA CSAT
 - DEA
 - DHS "Rule 245G"
 - Joint Commission
- Staffing
 - Practice manager
 - 2 Supervisors
 - 5 nurses
 - 15 LADC
 - 3 specimen technicians
 - 3 front desk
 - 1 intake coordinator

Census February 3, 2021	576
Cis-male	50.0%
Average age (range)	49 y (19-100)
Black	23%
American Indian	15%
Asian	8%
White	45%
Latinx	2%
Other/unknown	5%
Average dose (range)	74 mg (1-295)



Methadone is an essential medication

- Reduces all-cause and overdose mortality after non-fatal overdose by ~ 50%
- Reduces all-cause mortality >60% while on methadone
- Reduces risk of HIV infection >50%
- Reduces annualized healthcare costs by 50%
- Reduces violent and non-violent crime ~34% while on methadone
- Aspirin reduction in post-MI mortality 23%

Larochelle et al. 2018; Sordo et al. 2017; MacArthur et a. 2012; McCarty et al. 2010; Russolillo et al. 2018; ISIS-2 1988



Federal rule for methadone take out dosing

- Absence of recent abuse of drugs as seen in negative UA screens, including alcohol
- 2. Regular clinic attendance without absences.
- 3. Absence of serious behavioral problems at clinic.
- 4. Absence of known recent criminal activity.
- 5. Stable home environment and relationships.
- 6. Length of time in comprehensive maintenance treatment.
- 7. Assurances that take-home medication can be safely stored.
- 8. Whether the reduction in attendance will assist the patient in reaching their treatment goals

- First 90 days (0-3 months): 6 days/week
- Second 90 days (3–6 months): 4 days/week
- Third 90 days (6-9 months): 3 days/week
- Months 9-12: 1 day/week
- After one year: a maximum of a 2-week supply
- After two years: a maximum of a 1-month supply



42 CFR 8.12



y

@MayorFrey I goto a methadone clinic on university ave, in Minneapolis and for weeks now.. I've been stuck going in 6 days a week, every morning, while I watch other clinics follow the new guidelines and get people out. This place has refused to do so, what so ever.. help?



8:56 AM · Mar 28, 2020

TEB News

People on Methadone Have a Dangerous Choice: Risk Relapsing, or Expose Themselves to Coronavirus

"It's getting to the point where it's safer to go back to using street drugs. I won't have to be packed into rooms full of people."



By <u>Trey Strange</u>



By Gabrielle Caplan

Vice News April 3, 2020





Federal rule for methadone take out dosing COVID-19



5600 Fishers Lane • Rockville, MD 20857 www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)



3/16/2020 (Updated 3/19/2020)

Opioid Treatment Program (OTP) Guidance

SAMHSA recognizes the evolving issues surrounding COVID-19 and the emerging needs OTPs continue to face.

SAMHSA affirms its commitment to supporting OTPs in any way possible during this time. As such, we are expanding our previous guidance to provide increased flexibility.

FOR ALL STATES

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 scale-up to promote social distancing

- March 3: expand take-outs as allowed
- March 11: cancel group activities
- March 16: further expand takeouts*
- Review all patients for risk:
 - Overdose
 - Drug diversion
 - Mental health medical complexity
 - COVID-19

	Number of patients seen in 2020					
Visit	March 1	April 6	February 3			
frequency						
6x/week	157	0	57			
5x/week	45	0	92			
4x/week	37	0	23			
3x/week	27	143	62			
2x/week	47	25	32			
1x/week	83	79	89			
2x/month	105	91	73			
Every 21	37	9	7			
days						
1x/month	6	189	141			



^{*}first week of change resulted in dispensing 630,000 mg more methadone than usual



COVID-19 related changes at Hennepin Healthcare Addiction Medicine Program

- Suspend all group activities
- Disperse staff into exam rooms for officing
- Counseling moved to telephone
- No patients enter clinic March-June
 - Threshold dosing
 - Back stoop dosing if symptomatic
 - Methadone delivery if outbreak
- Screen all patients everyday
- Suspend all drug screening March-June





Clinical protections during pandemic



- Screen staff and patients daily
- Clean surfaces before opening and after each patient
 - Anything a patient or staff touches
 - Anything that touches a patient or staff
- Face masks and eye protection
- Socially distance staff
- Remove lobby chairs from clinic
- Limit number of patients in clinic at any one time
- Place floor markers and directional arrows

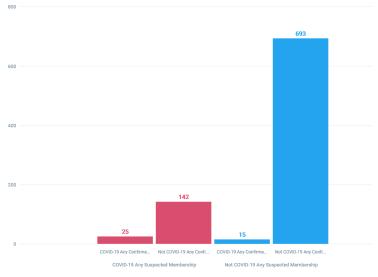
COVID-19

- While OUD increases odds of COVID-10 ten-fold there are no data on methadone
- Hennepin Healthcare Addiction Medicine COVID-19 deaths ~5
- Suspected COVID-19
 - HHS adults 23.3%
 - HHS addiction medicine 23.4%
- COVID-19 confirmed
 - HHS adults 7.4%
 - HHS addiction medicine 5.6%

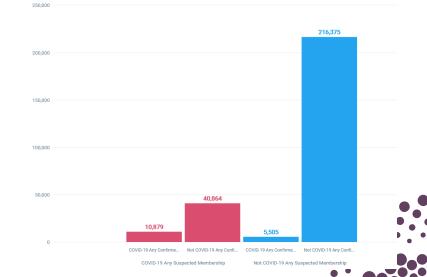
Epic SlicerDicer 2/3/21

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Addiction Medicine Patients by COVID-19 Membership



HHS Adult Patients by COVID-19 Membership



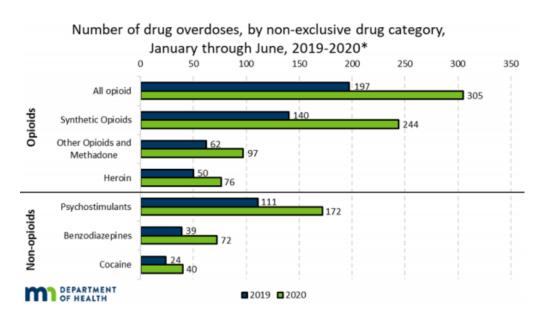
In crisis there is opportunity

- What is the impact of the pandemic on treatment demand and access?
- What is the impact of OTP regulatory change on outcomes?
 - Overdose
 - Methadone diversion
 - COVID-19
 - Drug use
- Can changes during the pandemic inform post-pandemic care?
 - Relaxed take home schedule
 - Methadone delivery
 - Medication units
 - Mobile methadone services



Overdose and diversion

- Too early to tell about overdose
 - Anecdotal reports
 - Adjudication is complicated
- Diversion
 - To help a friend
 - To raise money
 - Not clear if there is an increase



MN MDH 2020; Figgatt et al. 2020; HIDTA personal communication 2020





Did federal rule change lead to more drug use?

- All urine drug tests
 - July 2020
 - July 2019
- Take home schedule
 - 1-2/week
 - 3-5/week
 - 6/week
 - > 6/week
- Age and gender

- Outcomes of interest
 - Primary: opioid positive drug test
 - Secondary: non-opioid positive
- Generalized linear mixed-effects model
 - Random effect: person
 - Fixed effects:
 - Year
 - Take-out schedule
 - Year x take-out schedule interaction
 - Age
 - Gender
 - Remove main effect of year while keeping year x take-out schedule interaction



Drug use before and during COVID-19

	7/2010	7/2020
	7/2019	7/2020
Variable N(%)	N = 568	N = 602
Methadone*		
NEG	11 (1.9%)	24 (4.0%)
POS	557 (98%)	578 (96%)
Opiates*		
NEG	486 (86%)	467 (78%)
POS	78 (13%)	135 (22%)
RX	4 (0.7%)	0
Amphetamine*		
NEG	508 (89%)	508 (84%)
POS	58 (10%)	94 (16%)
RX	2 (0.4%)	0
Benzodiazepine*		
NEG	509 (90%)	528 (88%)
POS	36 (6.3%)	68 (11%)
RX	23 (4.0%)	6 (1.0%)
Cocaine		
NEG	508 (89%)	529 (88%)
POS	60 (11%)	73 (12%)
Oxycodone		
NEG	545 (96%)	581 (97%)
POS	15 (2.6%)	19 (3.2%)
RX	8 (1.4%)	2 (0.3%)





^{*} p<0.001 for 2020 versus 2019

Did regulatory changes cause more drug use?

- More opioid and non-opioid positive tests in 2020 than 2019
- Opioid and non-opioid positive tests decrease across all phases in 2019 but not 2020
- Significant effect of take-outs on opioid and non-opioid positive (p<0.001, each)
- Significant year x take-out interaction opioid and non-opioid (p<0.01, each)

Take-out doses	2019				2020	
	Fitted	Fitted		Fitted	Fitted	
Opioids	(with year)	(without year)	Actual	(with year)	(without year)	Actual
1-2/week	0.277	0.435	0.303	0.344	0.202	0.364
3-5/week	0.096	0.187	0.129	0.366	0.226	0.381
6/week	0.028	0.060	0.044	0.228	0.121	0.260
>6/week	0.012	0.027	0.020	0.075	0.036	0.107

Non-opioid drugs						
1-2/week	0.426	0.587	0.437	0.561	0.398	0.551
3-5/week	0.106	0.187	0.140	0.529	0.377	0.524
6/week	0.062	0.119	0.089	0.270	0.161	0.302
>6/week	0.023	0.049	0.041	0.081	0.040	0.119

Bart, Wastvedt, Hodges, Rosenthal, under revision





Interpretation

- Absolute percent of positives increased after federal rule change
- Increase cannot be fully attributed to changing in take-out schedule
- Unidentified differences between 2019 and 2020 other than take out change contribute to increased positive drug tests
 - COVID-19 stress
 - Social isolation
 - Economic downturn
 - Social unrest (e.g., killing of George Floyd)
 - Political divisions
- Overall, effect of COVID-19 rule change on drug use is confounded by a complicated 2020





Conclusion

- Opioid crisis has intensified during pandemic
 - Increased overdose
 - Decreased treatment availability
- Opioid use disorder associated with increased COVID-19 infection
- Drug use may be increasing during pandemic
 - Economy
 - Social/racial injustice
 - Local/national political climate
- Full impact of regulatory change is unknown, 2020 was complicated





Thank you

- Rebecca Rosenthal, MS LADC RN
- Fred Ohlerking, LP LAc LADC
- Addiction Medicine staff

- James Hodges, PhD
- Solvejg Wastvedt



Stopping EFV and starting DTG

- EFV induces methadone metabolism
 - Upregulation of gene transcription
 - Improved enzyme efficiency
- Clinical impact of EFV
 - Can cause withdrawal and need to increase methadone dose to compensate
 - COWS ≥ 5 in 20% of those on EFV versus 2% those not on ART
 - Average methadone dose 154 mg for EFV versus 67 mg for those not on ART
 - Methadone half-life reduced to ~ 20 hours if on EFV
- No impact of DTG on methadone
 - UGT 1A1 metabolic pathway
 - No effect on methadone plasma levels
 - No subjective effects on methadone

Bart et al. 2021 in press; Song et al. 2013





Stopping EFV

- Gradual increase in methadone plasma levels and halflife
 - Not an overdose risk although some sedation may be noticed
 - Tolerance develops to rising levels
 - Need for split dosing will disappear
- Should methadone dose be lowered when stopping EFV?
 - Not preventatively
 - Not automatically
 - Individualize based on sedation
- Conceptually this is similar to
 - Stopping rifampicin
 - Post-partum



