Buprenorphine Treatment for Opioid Use Disorder in the COVID-19 Era

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Assistant Professor of Medicine
Objectives

• Understand epidemiology of opioid-involved overdose deaths in the COVID-19 era
• Review evidence for buprenorphine treatment of opioid use disorder
• Understand telehealth integration for buprenorphine treatment during the COVID-19 era
Three waves in the rise in opioid overdose deaths
Synthetic opioid overdose – fentanyl

• Illegally made, powder form; many fentanyl analogues
  – Not IV, transdermal, or lozenge meds prescribed for pain
• Extremely potent (50-100x morphine, 30-50x heroin)
• Highly lipophilic, rapid onset of action
  – “Fast in, fast out” when crossing the blood-brain barrier
• Overdose can happen very quickly
• Often used unintentionally
  – Cut into the other drugs, e.g. heroin, cocaine, meth, MDMA, etc
Overdose deaths worsened during the COVID-19 pandemic

Figure 2: Percentage change in 12-months ending provisional\textsuperscript{a} data on all fatal drug overdoses\textsuperscript{b}, 50 states, the District of Columbia, and New York City: Overdose deaths from 12-months ending in June 2019 to 12-months ending in May 2020\textsuperscript{c}

Source: CDC Health Advisory Dec 17, 2020 (CDC HAN-00438)
Unintentional Drug Poisoning (Overdose) Deaths
Quarters 1-3, 2020, New York City
April 2021

503 overdose deaths confirmed during the third quarter of 2020

Deaths in 2019 and 2020 still pending final determinations; more recent quarters subject to larger increases

Number of confirmed overdose deaths
Bronx and Harlem neighborhoods have highest rates of overdose death

October 1, 2019 – September 30, 2020

Rate of unintentional drug poisoning (overdose) death, per 100,000 residents
October 1, 2019 – September 30, 2020

- 0.0 - 10.1
- 10.1 - 20.0
- 20.1 - 30.0
- 30.1 - 40.0
- 40.1 - 70.0
Objectives

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Natural history of opioid use disorder

- Acute use $\rightarrow$ pain relief, pleasurable effects (euphoria)
- Chronic use $\rightarrow$ tolerance and physical dependence
- Use continues to avoid opioid withdrawal
  - Opioid withdrawal symptoms: abdominal cramps, nausea, vomiting, diarrhea, muscles/joint pain, anxiety, sweating, palpitations
How does opioid use disorder develop?

- No accurate way to predict who will develop opioid use disorder
- The younger the age of initiating substance use, the greater the risk of developing a substance use disorder
What is opioid use disorder?

- Chronic neurobiological disease with no cure
- Loss of control and continued opioid use despite negative consequences
- **DSM-V Diagnostic Criteria:**

<table>
<thead>
<tr>
<th>Loss of control</th>
<th>Negative consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tolerance*</td>
<td>Unable to fulfill roles (work, parenting)</td>
</tr>
<tr>
<td>Withdrawal symptoms*</td>
<td>Negative impact on relationships</td>
</tr>
<tr>
<td>Cravings</td>
<td>Hazardous conditions (DUI)</td>
</tr>
<tr>
<td>Unsuccessful attempts to stop or cut down</td>
<td>Negative physical or psychosocial consequences</td>
</tr>
<tr>
<td>Using longer/larger amount than intended</td>
<td>Social/recreational activities given up</td>
</tr>
<tr>
<td>Large amount of time/effort obtaining or</td>
<td></td>
</tr>
<tr>
<td>recovering from opioids</td>
<td></td>
</tr>
</tbody>
</table>

  - 2-3 = Mild
  - 4-5 = Moderate
  - >6 = Severe

*Not used as diagnostic criteria when taking prescribed opioids*
Treatment of opioid use disorder

• Pharmacologic treatment
  – Medications:
    • Opioid agonist: methadone & buprenorphine
    • Opioid antagonist: naltrexone
  – Robust data regarding effectiveness of maintenance treatment (not detox/taper)

• Non-pharmacologic treatment
  – Rehab program, residential treatment, outpatient treatment, self-help groups, etc
  – Limited data regarding effectiveness
    • Must be tailored to the individual’s needs
Effectiveness of medication treatment for opioid use disorder

↑ Retention in treatment
↓ Opioid withdrawal and cravings
↓ Opioid relapse by 50%
↓ Opioid overdose deaths by ~50%
↓ Health complications (HIV, Hepatitis C)
↓ Criminal legal costs

## Key differences in medications

<table>
<thead>
<tr>
<th></th>
<th>Methadone</th>
<th>Buprenorphine</th>
<th>Naltrexone</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA approval</td>
<td>1972</td>
<td>2002</td>
<td>2010</td>
</tr>
<tr>
<td>Mechanism</td>
<td>FULL agonist</td>
<td>PARTIAL agonist</td>
<td>Antagonist</td>
</tr>
<tr>
<td>Receptors</td>
<td>µ opioid receptor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receptor affinity</td>
<td>Moderate</td>
<td>VERY HIGH</td>
<td>VERY HIGH</td>
</tr>
<tr>
<td>Administration</td>
<td>Oral liquid</td>
<td>Sublingual tab/film (injection, implant)</td>
<td>Injection (oral)</td>
</tr>
<tr>
<td>Co-formulation</td>
<td>--</td>
<td>NALOXONE</td>
<td>--</td>
</tr>
<tr>
<td>Duration of effect</td>
<td>24-36 hrs</td>
<td>Sublingual: 24-36 hrs (injection: 28 days) (implant: 6 months)</td>
<td>Injection: 28 days (oral 24-48 hrs)</td>
</tr>
</tbody>
</table>
Key differences in medication properties

- **Full agonist** (methadone)
- **Partial agonist** (buprenorphine)
- **Antagonist** (naltrexone)
### Key differences in treatment delivery

<table>
<thead>
<tr>
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<th>Buprenorphine</th>
<th>Naltrexone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulations</td>
<td>Highly regulated</td>
<td>Minimally regulated</td>
<td>None</td>
</tr>
<tr>
<td>Location</td>
<td>Licensed MMTP</td>
<td>Anywhere</td>
<td>Anywhere</td>
</tr>
<tr>
<td>Provider</td>
<td>MD/DO at MMTP</td>
<td>MD, DO, NP, PA 8-24 hrs training Special DEA#</td>
<td>Any prescriber</td>
</tr>
<tr>
<td>Counseling</td>
<td>Regulated</td>
<td>Ability to refer</td>
<td>--</td>
</tr>
<tr>
<td>Visits</td>
<td>Regulated</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Urine drug tests</td>
<td>Regulated</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Dosing</td>
<td>Regulated</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Dispensing</td>
<td>At MMTP</td>
<td>Pharmacy</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Prescriptions</td>
<td>Regulated</td>
<td>30-days w/ refills</td>
<td>--</td>
</tr>
<tr>
<td>Treatment slots</td>
<td>Regulated</td>
<td>30→100→275 per MD</td>
<td>--</td>
</tr>
</tbody>
</table>
Substantial Gap in Treatment of Opioid Use Disorder

~2.1 million people with opioid use disorder in US

Received treatment, 21%

Did not receive treatment, 79%

Source: 2016 National Survey on Drug Use and Health
Buprenorphine treatment capacity is concentrated in high-income, non-minority neighborhoods.

Buprenorphine treatment is accessed mostly by white, privately insured patients.

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

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.

Lagisetty et al, JAMA Psychiatry 2019
Expanding buprenorphine treatment through primary care is necessary

Number of people receiving buprenorphine treatment in the United States, by prescriber group, 2010–18

Source: Authors’ analysis of IQVIA Real World Longitudinal Prescription Data for 2010–18.

Ofson et al, Health Affairs 2020
Objectives

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Montefiore Buprenorphine Treatment Network
• Established in 2005
• 6 primary care clinics with integrated OUD treatment
• >1000 patients ever treated
• ~400 patients active in care

Opioid treatment programs
• Established in 1969
• 5 opioid treatment programs with integrated primary care
• >15,000 patients ever treated
• ~3900 patients active in care

>80% patients in OUD treatment are Black or Latinx, and publicly insured
COVID-19 Surge in New York City by March 2020
Rapidly Adapting Opioid Use Disorder Treatment During COVID-19 Surge

• Team approach
  • Redeployment of providers and staff to hospital
  • Monthly → weekly team meetings

• Constant reassessment
  • Changes in regulations & health system operations
  • What is MOST important = Harm Reduction

• Clinical provider support
  • Project ECHO: monthly → every 2 weeks
  • Open to any clinician across New York State
Key regulatory exemptions for OUD treatment during COVID-19

- All treatment
  - HIPAA violations waived for use of non-HIPAA compliant platforms to conduct telehealth visits
  - Telehealth visits with expanded reimbursement
- Buprenorphine
  - No face-to-face visit required prior to initiating treatment
- Methadone
  - Reduction in pick-up schedule requirements
General Guidance for Buprenorphine Treatment

- Because of changing policies occurring at Montefiore around COVID-19, in consultation with Montefiore Medical Group (MMG) leadership and in compliance with federal regulations, we will provide **ONLY telemedicine visits** for buprenorphine treatment (for new and established patients). No in-person visits will be conducted at our sites until further notice.

- **We will continue to evaluate new patients seeking buprenorphine treatment. Please direct ALL new patient referrals to bupe@montefiore.org or 718-405-8227.** Our staff are informed about which clinics are accepting new patients and will handle screening and scheduling telephonic visits for buprenorphine treatment.

- Patients receiving buprenorphine treatment at MMG clinics should be prescribed at least **one month’s worth of buprenorphine medication** at each telemedicine visit (refills can be provided depending on clinical judgement). Providers should use their clinical judgment about how frequently follow-up telephonic visits should occur. In general, telemedicine visits for stable patients should occur less frequently than typically.

- **Urine drug testing should not be required to receive a buprenorphine prescription until we return to in-person visits.** Providers should use their clinical judgement to refer patients for urine drug testing and other laboratory tests when benefits of testing greatly outweigh the risks of COVID-19 exposure. Currently, urine and blood tests are offered at only a few MMG sites and require appointments.
# Buprenorphine Treatment Roadmap during COVID-19 pandemic (Mar-Aug 2020)

<table>
<thead>
<tr>
<th></th>
<th>Medical Visits</th>
<th>Prescriptions</th>
<th>Urine Toxicology</th>
<th>Naloxone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before COVID</strong></td>
<td>In-person visits required for all patients</td>
<td>Prescription duration typically 7-14 days for new and unstable patient</td>
<td>Urine drug screen required at initial visit and at all follow-up visits</td>
<td>Naloxone kits dispensed at initial visit and as needed at follow-up visits</td>
</tr>
</tbody>
</table>
| **During COVID Surge** | In-person visits suspended  
Telephonic visits conducted for all patients; video whenever possible | Prescription duration of 30 days +/- refills for all patients  
Deliveries through mail-order if needed | Urine drug screens halted completely  
Focused on self-report of medication adherence and substance use | Naloxone kits prescribed to local pharmacies or mailed to patients |
### Buprenorphine treatment referrals before vs during COVID-19 pandemic*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Before COVID-19 N= 72, n (%)</th>
<th>During COVID-19 N=35, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age</td>
<td>45.4 ± 14.1</td>
<td>46.9 ± 14.1</td>
</tr>
<tr>
<td>Female</td>
<td>23 (32)</td>
<td>12 (34%)</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>36 (50)</td>
<td>20 (57)</td>
</tr>
<tr>
<td>Black</td>
<td>15 (21)</td>
<td>6 (17)</td>
</tr>
<tr>
<td>White</td>
<td>14 (19)</td>
<td>5 (14)</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>7 (10)</td>
<td>4 (11)</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public or Uninsured</td>
<td>62 (86)</td>
<td>24 (67)</td>
</tr>
<tr>
<td>Private</td>
<td><strong>10 (14)</strong></td>
<td><strong>11 (31)</strong></td>
</tr>
</tbody>
</table>

*Before COVID = 6 months (3/1/19-8/31/19); During COVID = 6 months (3/7/20-8/31/20)
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<table>
<thead>
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<th>Characteristic</th>
<th>Before COVID-19 N= 72, n (%)</th>
<th>During COVID-19 N=35, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opioid used prior to initiating treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heroin</td>
<td>38 (53)</td>
<td>25 (71)</td>
</tr>
<tr>
<td>Other Opioids/Not Heroin</td>
<td>34 (47)</td>
<td>10 (29)</td>
</tr>
<tr>
<td><strong>Medication treatment status at time of referral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not using any medication for OUD</td>
<td>33 (46)</td>
<td>17 (49)</td>
</tr>
<tr>
<td>Has buprenorphine prescription</td>
<td>35 (49)</td>
<td>15 (43)</td>
</tr>
<tr>
<td>In methadone treatment</td>
<td>4 (5)</td>
<td>3 (8)</td>
</tr>
<tr>
<td><strong>Referral source</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital or emergency department</td>
<td>14 (19)</td>
<td>13 (37)</td>
</tr>
<tr>
<td>Outpatient locations (including clinic, community organization, self-referral)</td>
<td>58 (81)</td>
<td>22 (63)</td>
</tr>
</tbody>
</table>

*Before COVID = 6 months (3/1/19-8/31/19); During COVID = 6 months (3/7/20-8/31/20)
Buprenorphine treatment “cascade of care” before vs during COVID-19 pandemic*

*Before COVID = 6 months (3/1/19-8/31/19); During COVID = 6 months (3/7/20-8/31/20)
Lessons learned about buprenorphine treatment during the COVID-19 era

• Quickly changing the OUD treatment paradigm is feasible
  – Team-based approach and focus on harm reduction
  – Comparable “cascade of care” before and during pandemic

• Telehealth equity
  – One size does not fit all!! Multiple structural barriers, including no device, no internet/data, no privacy, low digital literacy

• Future directions
  – Flexibility in treatment to continue as long as possible
    • Current model at Montefiore is a “hybrid” - offer telehealth intake visits +/- same-day buprenorphine treatment initiation for all patients, arrange for in-person visits within 4 weeks of buprenorphine treatment initiation
  – Full evaluation to follow
NYS Clinical Guidelines for Substance Use Treatment

Treatment of Opioid Use Disorder

*Lead Author: Chinazo O. Cunningham, MD, MS, with the Substance Use Guideline Committee, updated January 2021*

Guidance: Opioid Use Disorder Treatment During COVID-19

*Lead author: Tiffany Lu, MD, MS*
Clinical Provider Support

- Montefiore Project ECHO for Opioid Use Disorder Treatment
  - Meet 1st Wednesday from 4-5pm
  - Virtual didactics, case conferences
  - CME credit offered
  - Email ProjectEcho@montefiore.org
Clinical Tools & Resources

Clinical Tools
• Buprenorphine Intake Assessment
• Buprenorphine Treatment Agreement
• Buprenorphine Home Induction Patient Instructions
• Urine Drug Testing Guide

Clinical Protocols
• Policies & Procedures Manual
• Patient Selection Criteria
• Peri-Operative Management
• Microdosing for Buprenorphine Initiation

visit: bit.ly/montefiorebupe
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- Chrystal Campbell, RN
- Tanya Williams, RN
- Angela Giovanniello, PharmD
- Matthew Carrion, CHW

Patients & Funders

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