AETC AIDS Education & Training Center Program Mountain West

Telemedicine and Opioid Use Disorder Part II: Clinical Tips

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Disclosures

No conflicts of interest or relationships to disclose.

Outline

- Briefly review regulatory changes and evidence for telemedicine delivery of OUD care
- Breaking news updates on the DEA X waiver
- Discuss risk/benefit decisions re: in-person visits for OUD in the age of COVID
- Some specific telemedicine strategies (new patient visits, remote adherence monitoring, and responding to relapse)

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REVIEW: Regulatory Changes

1) Public Health Emergency Exception to Ryan Haight Act

OK to prescribe controlled substances to new or existing patient after telehealth evaluation. For bup, also OK after telephone evaluation.

2) HIPAA Changes

No penalties for nonadherence with regulatory requirements.

3) 42-CFR Part II Changes

HPI Restrictions don't apply in situations of a medical emergency.

4) CMS Reimbursement

Removal of geographic and originating site restrictions (beneficiary can be in their home). Reimbursement same as in-person FFS rate. Phone visit rates increased. Expanded payable service codes.

5) DEA exception to separate state registration requirements

Providers don't need to obtain additional registration with DEA in the additional state(s) where the prescribing/administering occurs.

See Resources Slide for citations or Telemedicine and OUD Part I

REVIEW: Evidence for Telemedicine in OUD

- **2 randomized studies** focused on telemedicine for psychotherapy (for patients on methadone maintenance)
  - No difference in number of sessions attended, percent drug positive urines, provider/patient rated degree of therapeutic alliance.
- **3 retrospective, non-randomized studies** of medication management (methadone and buprenorphine).
  - Patient was at remote or rural clinic, and treating physician at distant site. Other components of care included urine toxicology screens and (often intensive) counseling.
  - No worsened retention in care, difference in time to abstinence.
- No studies have examined telehealth delivery of OUD care to a patient home with attendant reduction in Urine drug monitoring and other supports.

Lin et al., 2019. King et al., 2009; King et al., 2014., Eibl et al., 2017; Zheng et al., 2017; Weintraub et al,. 2018.

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BREAKING NEWS: DATA 2000 Waiver Exemption

- On 1/14/2021, HHS issued Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder
  - A physician licensed under state law with a DEA license is exempt from DATA-2000 requirements.
    - i.e. can prescribe buprenorphine for OUD without a waiver
  - Limited to no more than 30 patients at one time (patient limit does not apply to hospital based or ED physicians)
  - "Physicians utilizing this exemption shall place an "X" on the prescription and clearly identify that the prescription is being written for opioid use disorder"
  - You can still obtain (or use) your waiver

Disclaimer: As of January 20, 2021, this regulatory change is on hold. Until further notice, all medical providers will need to adhere to the full DATA 2000 waiver requirements.

https://www.hhs.gov/sites/default/files/mat-physician-practice-guidelines.pdf

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More BREAKING NEWS (sort of): Overdose epidemic is worsening

- CDC has released provisional overdose data as part of a Health Alert Network report: For the 12 months ending in May 2020, overdose deaths have increased over 18% to a total of over 81,000 deaths
- Some big trends emerged in the report
  - Biggest increase in OD deaths occurred from March-May 2020, suggesting contribution from the pandemic and the societal response
  - Psychostimulants (methamphetamine) playing a larger role
  - Fentanyl has moved West

CDC Health Alert Network: Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic: https://emergency.cdc.gov/han/2020/han00438.asp

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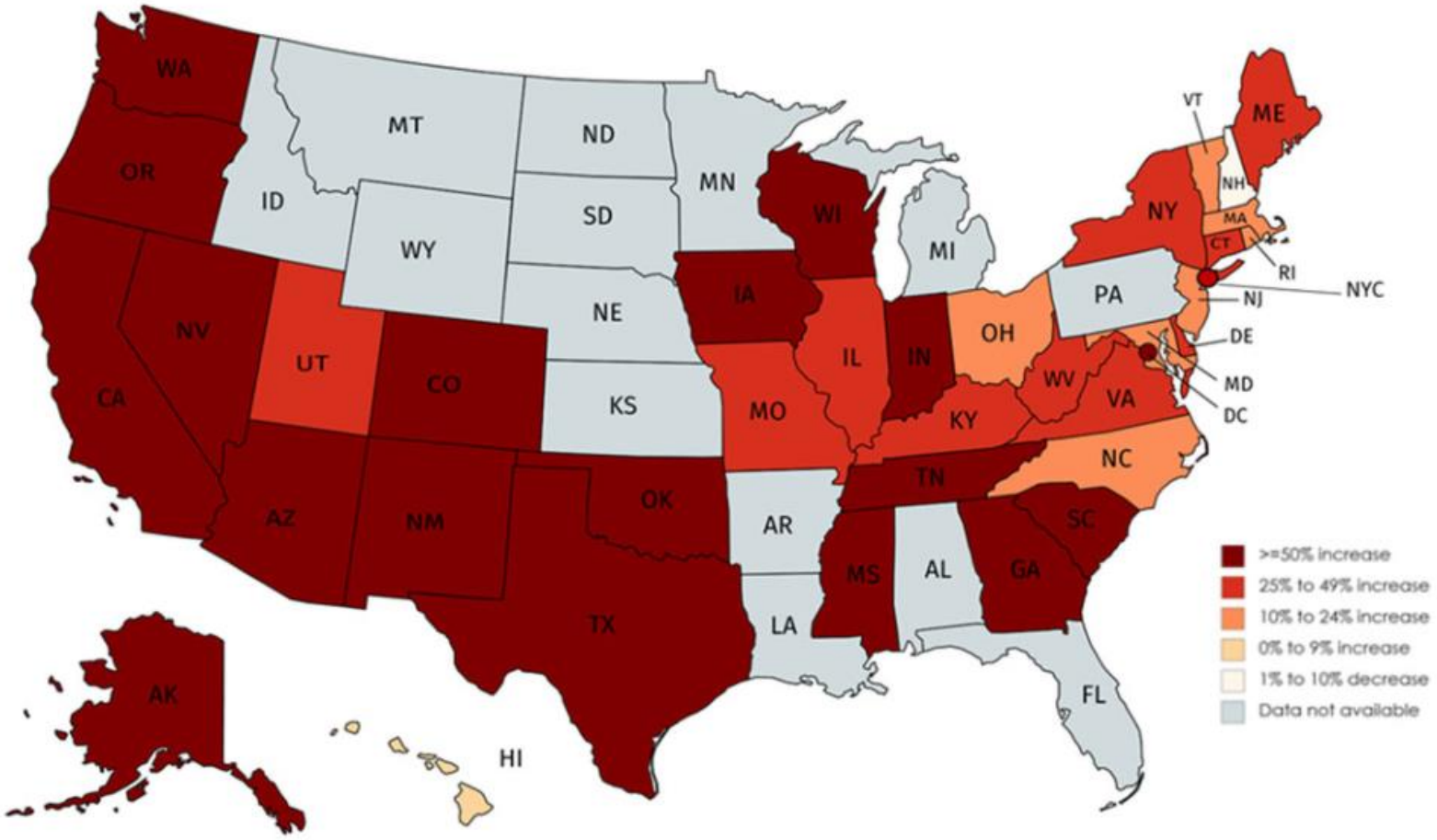
Increase in Fatal Fentanyl Overdoses

Figure 3: Percentage change in 12-months ending provisional[a] count of fatal overdoses involving synthetic opioids[b], 36 states, the District of Columbia, and New York City[c]: Deaths from 12-months ending in June 2019 to 12-months ending in May 2020[d]



Soapbox Summary of Breaking News

- Never has it been so crucial to provide evidence-based treatment for Opioid Use Disorder, and never has the regulatory environment been so conducive to doing so.

Clinical Tips

Rethinking risk/benefits

Risk factors for COVID-19 complications

Risk factors for complications of unmonitored OUD treatment

- While adherence monitoring and screening for ongoing drug use (via urine drug screening) is the standard of care, we don't know the utility or the optimum frequency of testing
- The risk/benefit calculation has been altered by COVID
- There are no best practices for Telemedicine delivery of OUD care

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COVID-related risk factors:

- Higher risk of acquisition or transmission
  - Live in congregate setting (shelter, AFH)
  - Live with or care for vulnerable family member
  - Frontline worker
- Higher risk of complicated or severe disease:
  - Older age (particularly >65yo), Cancer, Chronic kidney disease, COPD, Down Syndrome, Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies), Immunocompromised state from solid organ transplant, Obesity, Pregnancy, Sickle cell disease, Smoking, Type 2 diabetes mellitus
- Degree of COVID-19 transmission in the community
- Vaccination status

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Drug use-related risks: Individual's risk factors

- History of overdose
- Use by IV route
- History of impairment in clinic; ED visits for impairment/intoxication
- Polysubstance use, multiple co-occurring substance use disorders
- History of known or suspected medication diversion
- Significantly unstable opioid and/or other substance use disorder (particularly benzodiazepines and/or alcohol)
- New to treatment; newly discharged/disengaged from treatment
- Recent release from jail, prison or abstinence-based residential treatment program
- Co-occurring mood or thought disorder
- Active or past suicidality
- Ability to safely store medication

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Drug use-related risks: Community risk factors

- Circulation of high-potency synthetic opioids in community
- Availability of harm reduction services (syringe service programs, naloxone)
- Availability of treatment options in the community

How about risks *to* the COMMUNITY

- Buprenorphine is a highly diverted drug
- Numerous studies demonstrate that illicit use of buprenorphine is primarily for therapeutic purposes (treatment of withdrawal symptoms, reduction in use of other opioids), often in the setting of poor access to treatment.[1]
- Studies suggest prior exposure to illicit buprenorphine correlates with retention in office based opioid treatment.[2]
- Overdoses involving buprenorphine are very rare. Retrospective structured interview study suggests use of illicit buprenorphine reduces non-fatal overdoses (with dose-response relationship).[3]

1. Cicero et al, 2018; 2. Cunningham et al, 2013; 3. Carlson, et al. 2020;

OUD: Psychotherapy

COVID risk

Drug-related risk

= Reduced frequency of in-person monitoring/intervention

OUD: Psychotherapy

Drug-related risk

COVID risk

= Increased frequency of in-person monitoring/intervention

OUD: Psychotherapy

COVID risk

Drug-related risk

= The Gray Zone

Initial Visit

- Telehealth visits for buprenorphine induction are untested. Is a remote initial visit appropriate for this patient? (Patients entirely new to treatment, diagnostic dilemmas, complicated polysubstance use may benefit from in-person evaluation)
- SAMHSA and PCSS recommend considering buprenorphine (over methadone) as the treatment modality of choice for patients new to treatment during the pandemic.
- H+P, substance use history etc. conducted in similar fashion to in-person.
- Can you gather some objective findings from prior hospitalizations, clinic or ED visits. Prior labs or urine drug screens? Review of PDMP.
- Physical Exam: Can document presence or absence of sclerotic veins. Can appreciate signs of withdrawal (pupillary size, tremor, yawning, lacrimation etc.). Mental Status Exam.

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Initial Visit

- For inductions (or initiations) of buprenorphine, consider counseling the patient on a self-start (out-of-office induction)
- SOWS score can be used by patient to grade withdrawal (Score of ≥ 17 c/w moderate withdrawal)

SOWS

Item	Symptom	Not at all	A little	Moderately	Quite a bit	Extremely
1	I feel anxious	0	1	2	3	4
2	I feel like yawning	0	1	2	3	4
3	I am perspiring	0	1	2	3	4
4	My eyes are teary	0	1	2	3	4
5	My nose is running	0	1	2	3	4
6	I have goosebumps	0	1	2	3	4
7	I am shaking	0	1	2	3	4
8	I have hot flushes	0	1	2	3	4
9	I have cold flushes	0	1	2	3	4
10	My bones and muscles ache	0	1	2	3	4
11	I feel restless	0	1	2	3	4
12	I feel nauseous	0	1	2	3	4
13	I feel like vomiting	0	1	2	3	4
14	My muscles twitch	0	1	2	3	4
15	I have stomach cramps	0	1	2	3	4
16	I feel like using now	0	1	2	3	4

Total Score: _____

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Increasing support (response to ongoing opioid use, non-opioid illicits)

- Increased frequency of telemedicine visits. Dose re-evaluation.
- Decrease length of prescriptions (though patient will have to make more frequent visits to pharmacy. Discuss curbside pharmacy pick-ups.)
- Conversion to in-person visit (with appropriate infection control precautions.)
- Refer to telemedicine-delivered counseling.
- Refer to virtual community supports.
- Refer to higher level of care (residential treatment), if available in community.

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Increasing structure (response to adherence concerns)

- Increased frequency of telemedicine visits.
- Decrease length of prescriptions (though patient will have to make more frequent visits to pharmacy. Discuss curbside pharmacy pick-ups.)
- Conversion to in-person visit (with appropriate infection control precautions.)
- Expectation of dose observation during telehealth visit.
- Virtual pill count during telehealth visit.
- Video DOT.
- Injectable buprenorphine.
- Home POC drug monitoring (oral swabs self-administered by patient during telehealth visit.)

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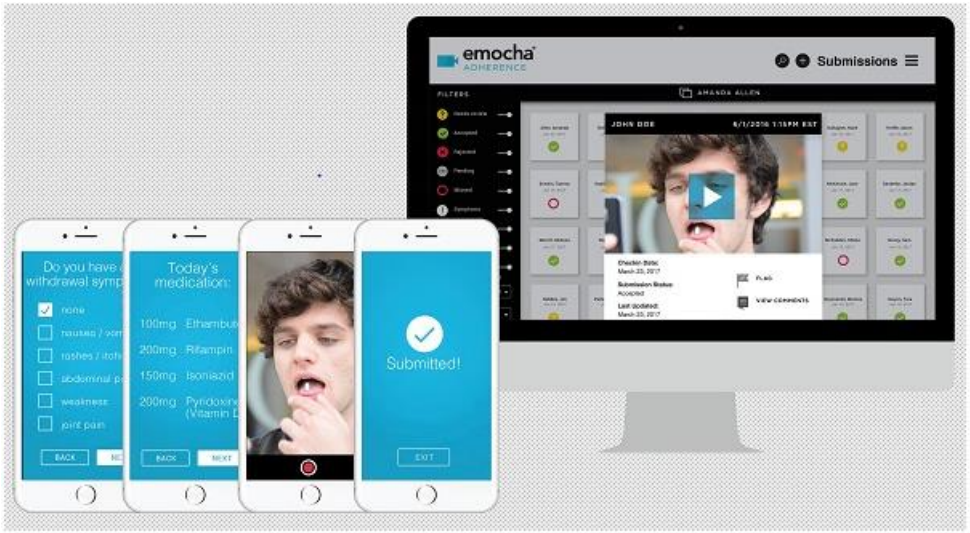
VIDEO DOT

- A pilot study among 14 patients
- On average, daily videos were submitted by participants 72% of the time
- Most participants reported being "very satisfied" with the application
- Participants reported liking the accountability and structure of the application provided and its ease of use
- Randomized, controlled, multisite trial underway (TAAB study)



Godersky, 2020

Take Home points

- Never has it been so crucial to provide evidence-based treatment for Opioid Use Disorder, and never has the regulatory environment been so conducive to doing so.
- Best practices are not codified, but the risks of unmonitored treatment must be weighed against the risk of disease transmission.
- Remote options exist for patients requiring additional supports or adherence monitoring.
- You no longer need an X-waiver to prescribe buprenorphine (once published in Federal Register)!

  Disclaimer: As of January 20, 2021, this regulatory change is on hold. Until further notice, all medical providers will need to adhere to the full DATA 2000 waiver requirements.

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Resources

- Pcssnow.org: Modules on Telehealth
- ASAM COVID-19 Task Force Recommendations
  - Supporting Access to Telehealth for Addiction Services
  - Access to Buprenorphine in Office-Based settings
  - Adjusting Drug Testing Protocols.
- SAMHSA COVID-19: https://www.samhsa.gov/coronavirus Drug Enforcement
- DEA COVID-19 Information Page: https://www.deadiversion.usdoj.gov/coronavirus.html

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