



Vermont  
Medical  
Society

2020-2021

THIRD THURSDAY  
WEBINAR SERIES

*12:00 pm to 1:00 pm*



## **THIRD THURSDAY WEBINAR SERIES**

Date: September 17, 2020

Title: MOUD Modifications in a COVID-19 World

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# VMS Third Thursday Webinar Series: MOUD Modifications in a COVID-19 World

**Speakers:** Tony Folland, VT State Opioid Treatment Authority (SOTA)

**Planning Committee Members:**

Jessa Barnard, ESQ, Catherine Schneider, MD, Stephanie Winters & Elizabeth Alessi

**Purpose Statement/Goal of This Activity:** MOUD is almost universally identified as a lifesaving intervention however COVID-19 has required practitioners to reconsider how to initiate care, monitor treatment responses, and modify treatment plans while minimizing face to face contact. We will discuss the regulatory and clinical opportunities and challenges, and lessons learned to date.

**Learning Objectives:**

- Attendees will understand the regulatory changes made in response to the State and Federal declaration of disaster
- Participants will be introduced to various telemonitoring techniques to mitigate patient risk
- Presenter will introduce setting specific modifications recommended and implemented during the pandemic (Hubs and Spokes)

**Disclosures:**

Is there anything to Disclose? Yes  No

Did this activity receive any commercial support? Yes  No

*(The CMIE staff do not have any possible conflicts)*



UNIVERSITY OF VERMONT  
VERMONT MEDICAL SOCIETY

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# Clinical and Regulatory Modifications To MAT: Living in a COVID-19 World

# Objectives for Today

- 1. Identify State and Federal regulatory changes during the COVID-19 state of emergency
- 2. Increase understanding of current clinical practices to ensure access to high quality MAT while mitigating community disease transmission risks
- 3. Differentiate between Hub vs Spoke specific regulatory and clinical modifications

# What is MAT

- Medication-assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders. Medications used in MAT are approved by the Food and Drug Administration (FDA) and MAT programs are clinically driven and tailored to meet each patient’s needs. (SAMHSA)

# Why Prescribe MAT

- The ultimate goal of MAT is full recovery, including the ability to live a self-directed life.
- This treatment approach has been shown to:
  - Improve patient survival
  - Increase retention in treatment
  - Decrease illicit opiate use and other criminal activity among people with substance use disorders
  - Increase patients' ability to gain and maintain employment
  - Improve birth outcomes among women who have substance use disorders and are pregnant
  - Can contribute to lowering a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse.

# FDA Approved MAT medications

## Alcohol

- ❑ Disulfiram/Antabuse
- ❑ Naltrexone (oral/IM)
- ❑ Acamprosate/  
Campral

## Opioids

- ❑ Naltrexone (Oral/IM)
- ❑ Buprenorphine
- ❑ Methadone

# Pandemic Response Considerations

## □ Regulatory Considerations:

- What could we do?
- What did we control?
- What waivers/agreements/workarounds were needed? And could we get these?

## ■ Clinical Considerations:

- Risk stratification of patients COVID and OUD
- Ensuring continued access to care as OUD is lethal too... potentially more lethal
- Balancing risk of community disease transmission in a high risk population vs. medication adherence, “close monitoring”/structure and accountability which are the hallmarks of good OUD care

# Considerations Continued

- Maintaining access to care:
  - ▣ Could we realistically? If so, how?
  - ▣ What about COVID +/- Quarantined patients in need of meds?
  - ▣ PPE needs and considerations?
  - ▣ Individuals exiting institutional settings needing community access?
  - ▣ Telemed in a rural state? Could we really....

# The Regulatory considerations.. 2 settings, 2 regulatory structures..

## Hubs

- Governed by 42 cfr part 8
- Highly regulated (DEA, SAMHSA, SOV, Medicaid, Accreditation)
- Serve as both medical practice and pharmacy
- 7/8 clinical criteria for take home medication eligibility (7 for buprenorphine, 8 for methadone including time in treatment)
- High risk patients for disease transmission likely highest need for treatment structure as well

## Spokes

- Data 2000 waived prescribers
- VT MAT Rules
- DEA and Licensing Specialty Board
- Medicaid/Insurance Requirements
- Overall lower regulatory hurdles to be considered and more control at state/provider level.. Other than DEA face to face visit

# Spoke Federal Regulatory Modifications

## □ Pre-COVID

- Ryan Haight DEA rule: face to face initial visit unless (a) in DEA licensed facility or (b) in presence of a DEA licensed practitioner
- Telemedicine required HIPAA compliant equipment and secure connection

## □ Declaration of Disaster:

- Waived: allowed for telemedicine initial visit with subsequent DEA expansion to telephone initiation of buprenorphine
- HHS Office of Civil Rights “HIPAA-covered healthcare providers may, in good faith, provide telehealth services to patients using remote communication technologies... for telehealth services even if the application does not fully comply with HIPAA

# State Spoke Regulatory Modifications

- BC (Before COVID-19)
  - Initial face to face/physical exam
  - Medicaid Buprenorphine Rx 2 week max
  - Wholesalers monitor/limit narcotics supplies to pharmacies
  - Telehealth “visual” counseling reimbursed
- Current
  - Waived
  - Extended Rx to 30 days
  - Worked with DEA and medication supply distribution chain to increase availability of Buprenorphine
  - Waived all state requirements to mirror DEA changes
  - Allowed reimbursement for telephone only counseling and reduced hours for IOP counseling

# Spoke Clinical Modifications

- ❑ Convert admissions and clinical services to Telehealth for majority of patients
- ❑ Extend Rx consistent with risk stratification
- ❑ For face to face patient consideration, balance risk of disease transmission (provider, other patients and community) vs. risk of sentinel event related to OUD. Include transportation and virtual connectivity as a clinical considerations.
- ❑ Primary goal is medication ingestion, 8-fold decrease in OD risk and significant decreases in all cause mortality
- ❑ High risk patients, consider telemonitoring when possible, either tele-dosing or POCT testing and increase telehealth visit frequency
- ❑ ASAM guidance to decrease or suspend toxicology testing...
- ❑ Utilize Spoke staffing to support patients, because they have no face-to-face billing requirement
- ❑ Masks/distancing/sanitization/etc
- ❑ Monthly spoke calls and tailored trainings to feedback in the ever evolving field

# Hub Federal Regulatory Changes

## □ BC

- Required 7/8 factor stability for take home doses unless individual exemption requested (3000+ patients currently)
- Limited maximum # of take home doses by time in treatment
- Medication only dispensed direct to patient or medical provider to medical provider
- Face to face physical exam
- Minimal allowance for cascading orders
- Minimum 8 urine screens annually

## □ Current

- Because Gov. Scott order in place, SAMHSA allowed Vermont to approve clinic/system level waivers
- Allowed up to federal maximum 31 day take home medications for “stable” patients irrespective of tot
- Allowed non-medical clinic staff to deliver medications/allowed for proxy pick-up with CoC agreements
- Waived in-person physical exam for Buprenorphine but not methadone
- Tightened requirement that dose changes done in clinic only
- Urine screen requirement not waived

# Hub Take Home Requirements

- Exhibit no recent drug use
- Attend a clinic regularly
- Exhibit no serious behavioral problems
- Engage in no criminal activity
- Demonstrate a stable home environment and good social relationships
- Meet length of time in treatment requirements
- Provide assurance that take-home medication will be safely stored
- Show that the rehabilitative benefit outweighs the risk of diversion

## ☐ Time in Tx. for Methadone

- ☐ 1-90 days: 1 take home
- ☐ 91-180 days: 2 take homes
- ☐ 181-270 days: 3 take homes
- ☐ 271-365: 6 take homes
- ☐ After 1 year: Max 14 take homes
- ☐ After 2 years: Max 31 take homes

For Buprenorphine time in treatment is not required

# State Hub Regulatory Requirements

## BC

- ❑ Open 7 days a week
- ❑ Check VPMS consistent with VPMS rules

## Current

- ❑ Authorized Sunday closures
- ❑ Stayed unchanged

# Hub Clinical Modifications

- Hub Medical and clinic directors agreed to consistent approach to services and access
- Reducing average daily census to reduce disease transmission while managing high risk OUD patients was the target
- Elongated take home doses for stable patients (on avg. double BC take home doses)
- Unstable patients: developed 2 cohorts of every other day dosing to reduce daily census but balance need for monitoring/structure.. Unstable patients with no more than 2 days ever in take home doses
- Sunday closures for cleaning/staff self-care (other than WestRidge)
- Virtual counseling and support services
- Reduction/discontinuation of urine screens/breathalyzers
- Weekly sort/stratification of effectiveness and adjustments to take home schedules
- Masks/temp checks/social distancing

# Modifications Continued

- Weekly Hub Medical Director's call
- Weekly Hub Clinic Director calls
- Weekly call check-in with each Hub
  
- Tapered to currently Q 2 weeks still to assess and identify hot spot needs, shared learning and monitoring risks and trends in the community

# Risk Stratification

## □ COVID-19 risks vs OUD stability and lethality risks..

Roughly 100+/- overdoses per year in Vermont involving opioids (130 in 2018, 111 in 2019)

Active substance use correlates to disease transmission, greater community movement, higher risk tolerance

Supply chains likely to be disrupted and ever increasing fentanyl and its analogs

Morbidity associated with cardiovascular issues (cocaine) and ID's with IVDU

Effects of loneliness, comorbidities and decreased social monitoring

# Utilizing the Tools we have...

- TNQ: usually for placement (Hub vs Spoke) but designed in using a Risk Stratification framework
- OSI: Ability to target ongoing areas of instability such that specific interventions can be designed
- Telemonitoring of toxicology results or observational dosing... build into a visit remote or in-person
- Power of the relationship.. Virtual or not!!

# The UVM Licensed Treatment Needs Questionnaire

- Brooklyn and Sigmon
- Research informed and commonly used to stratify Spoke vs Hub initial treatment placement
- Mostly static items but built on a risk stratification methodology

# TEATMENT NEED QUESTIONNAIRE ©

	YES	NO
Have you ever used a drug intravenously?	2	0
If you have ever been on medication-assisted treatment (e.g. methadone, buprenorphine) before, were you successful?	0	2
Do you have any legal issues (e.g. charges pending, probation/parole, etc)?	1	0
Are you currently on probation?	1	0
Have you ever been charged (not necessarily convicted) with drug dealing?	1	0
Do you have a chronic pain issue that needs treatment?	2	0
Do you have any significant medical problems (e.g. hepatitis, HIV, diabetes)?	1	0
Do you have any psychiatric problems (e.g. major depression, bipolar, severe anxiety, PTSD, schizophrenia, personality subtype of antisocial, borderline, or sociopathy)?	1	0
Do you ever use cocaine, even occasionally?	2	0
Do you ever use benzodiazepines, even occasionally?	2	0
Do you have a problem with alcohol, have you ever been told that you have a problem with alcohol or have you ever gotten a DWI/DUI?	2	0

# TREATMENT NEED QUESTIONNAIRE ©

	YES	NO
Are you motivated for treatment?	0	1
Are you currently going to any counseling, AA or NA?	0	1
Do you have 2 or more close friends or family members who do not use alcohol or drugs?	0	1
Do you have a partner that uses drugs or alcohol?	1	0
Are you a parent of a child under age 18? If so, does your child live with you?	0	1
Is your housing stable?	0	1
Do you have a reliable phone number?	0	1
Are you employed?	0	1
Do you have access to reliable transportation?	0	1
Did you receive a high school diploma or equivalent ( complete 12 yrs of education)	0	1

# Validity

- Many of the items have been shown to be predictive of stability in treatment
- These items were given scores of a 2
  - ▣ Intravenous drug use
  - ▣ Cocaine use
  - ▣ Benzodiazepine use
  - ▣ Alcohol use
  - ▣ Chronic pain
  - ▣ Previous success in medication assisted treatment program

# Validity

- Rest of the items added to look at issues that will impact decisions on treatment location and were given scores of 1
  - Employment and education
  - Psychological issues
  - Medical issues
  - Family and social supports
  - Legal issues, especially drug dealing
  - Travel and access issues
  - Motivation

# OBOT Stability Index

- ❑ Developed By Ben Nordstrom, MD et al at Dartmouth Medical School
- ❑ Designed to assess for ONGOING stability in the SPOKES
- ❑ Provides common language of “stability” across providers
- ❑ Can be used by MAT team and used to decide if more services are needed in the SPOKE or a referral to the HUB is needed
- ❑ Consistent with ASAM recommendations for toxicology testing frequencies. Weekly if less stable, monthly when stabilized
- ❑ Reminder: New to treatment with you, doesn't mean new to treatment and recommendations for screening frequencies should be adjusted..
- ❑ Cannabis?!?! Remember up to 30 day detection window and research has pretty consistently suggested that cannabis use does not equate to opioid relapse rates nor suggest higher diversion rates..

*OBOT Stability Index*

1) Was the patient's previous urine drug screen positive for illicit substances? Yes No
2) If YES to #1 or if the patient was recently started on buprenorphine, does the patient have fewer than four consecutive weekly drug-free urine drug screens? Yes No
3) Is the patient using sedative-hypnotic drugs (e.g. benzodiazepines) or admitting to alcohol use? Yes No
4) Does the patient report drug craving that is difficult to control? Yes No
5) Does the patient endorse having used illicit substances in the past month? Yes No
6) Does the query of the Vermont Prescription Monitoring System (VPMS) show evidence of the unexplained, unadmitted, or otherwise concerning provision of controlled substances? Yes No
7) Did the patient report their last prescription as being lost or stolen? Yes No
8) Did the patient run out of medication early from his/ her last prescription? Yes No

**SCORING:**

If NO to all, the patient is "stable" can be seen monthly for prescriptions and urine drug screens.

If YES to any of the above, the patient is "unstable" and needs to be seen weekly for prescriptions and urine drug screens.

Additionally, if YES to 1-6, the patient should be referred for addiction services.

# Data and Results

- ❑ Limited due to pandemic response... but...
- ❑ No Hubs or Specialty Addiction Treatment programs closed to new admissions
- ❑ Overall MAT utilization INCREASED during the COVID period
- ❑ Most providers reported rapidly adjusting to telehealth with patients, reserving in-person visits for highest acuity OUD patients
- ❑ Decreased utilization of toxicology testing required differential means of assessing overall stability
- ❑ Providers continued to admit rapidly from institutional settings with limited notice
- ❑ Residential providers continued to admit while decreasing census to ensure safe distancing

# Data and Results continued..

- Emergency Department providers utilized this time to obtain DATA 2000 Waivers and several hospitals finalized ED Buprenorphine induction protocols
- Several addiction specialty providers (“Super Spokes”) added weekend telehealth coverage for new admissions to increase access and reduce potential ED utilization
- **But....**
- Fatal opioid overdoses increased (82 thru July vs 60ish last year thru July)
- 61 OD 3/20-7/20 vs 50 in same period 2019
- Some increased reports of diversion (Methadone particularly) though limited sentinel events associated

# Lessons Learned...

- Relationships matter.... Provider, payer, regulator
- Telemedicine can be very effective for some patients
- Payment structures allow for enhanced supportive care
- Vermont medical providers are a pretty amazing group of people.. We receive great medical leadership from the field!
- Despite our best efforts, fatal OD rates increased during the pandemic... we have more work to do!
- Even in the midst of COVID-19, we continue to grow the care options for the future for Vermonters with OUD.
- I am lucky to live in Vermont.. Thank you all for what you do day in and day out...