INTEGRATING AN OPIOID DETOXIFICATION PROGRAM INTO A MEDICAL PRACTICE

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Disclaimer: this presentation is intended to promote interest and provide resources for establishing an opioid detoxification treatment program in a medical practice. It does not substitute for full training on this topic.
Target Audience:

Primary Care:
- Family Medicine
- Emergency Medicine
- Internal Medicine
- Pediatrics
- Obstetrics/Gynecology
- Psychiatry

Specialist:

There is a need to understand opioid detoxification treatments and/or establishing a referral network (warm hand off)
Learning Objectives:

Review the current trends in the national opioid crisis

Understanding Opioid Use Disorder (OUD)

Review Medications for Opioid Use Disorder (MOUD). Term Medication-assisted Treatment (MAT) is also used for general substance use treatments.

Review the training and resources for getting providers started or updated on MOUD

Discussing barriers to initiating and maintaining a MOUD treatment program in a medical practice

Setting patient goals and support for success

Considerations when starting a MOUD treatment program
Current Trends in the National Opioid Crisis

In 2019 opioid related deaths averaged 130 per day
In 2020 that number had increased to 223 per day
More than 90,000 people died in 2020 according to data from the CDC from opioid abuse. The highest opioid death rate occurs between the age of 25 and 54.

The US faces an opioid overdose epidemic that has prematurely ended thousands of Americans lives. The CDC report that overdose deaths have increased 26.8 percent ending in August 2020 compared to the previous 12 months.

The COVID-19 pandemic has had a negative impact on the nation’s health and wellbeing. All substances of abuse have increased due to the pandemic. OUD is currently an epidemic during a pandemic!

Prescription Opioids are not driving the current overdose epidemic!
Opioid prescriptions have decreased 44% nationwide since 2011 but drug overdoses have tripled since that time. Illicitly manufactured fentanyl is driving the current overdose epidemic.
We are the public’s medical experts!

The U.S. Surgeon General has asked that 2.3 million providers and health care leaders address the opioid crisis by educating ourselves and screening patients for Opioid Use Disorder and treat opioid addiction as a chronic illness.

Our patients, family, and friends will come to us for help with problems of substance abuse because of our medical expertise. It is not going to matter what specialty you currently practice as this crisis effects everyone and is in every region of our country.

How will you respond when asked what you can do to help? A delay in intervention could mean the difference in life or death even in the next 24 hours. “Even one pill can kill !”

Every healthcare provider should understand addiction and substance abuse in OUD and a planned response when the question first arises. Have a treatment plan or a number you can call (warm hand off).

This presentation will focus on Opioid Use Disorder (OUD) with the understanding that Substance Use Disorder (SUD) can be polysubstance abuse. MOUD has been shown to be an effective part of the response to OUD crisis.
Opioid Use Disorder (OUD)

Opioids refer to a natural and synthetic substances that act at one of the three main opioid brain receptors mu, kappa, and delta. They have analgesic and central nervous system depressant effects as well as the potential to cause euphoria. They are addicting and produce withdrawal symptoms which are barriers to stopping their use.

DSM-5 defines Opioid Use Disorder as a craving or strong desire to use opioids which can result in failure to fulfill major role obligations at home, school or work. This pattern of use leads to clinically significant impairment and distress. It is a chronic medical condition.
## DSM-5 Criteria for Diagnosis of Opioid Use Disorder

**Diagnostic Criteria**

These criteria are intended to identify those individuals taking opioids solely under appropriate medical supervision.

Check all that apply:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tbody>
<tr>
<td>Opioids are often taken in larger amounts or over a longer period of time than intended.</td>
<td></td>
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<tr>
<td>There is a persistent desire or unsuccessful efforts to cut down or control opioid use.</td>
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<td>A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.</td>
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<tr>
<td>Craving, or a strong desire to use opioids.</td>
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<td>Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.</td>
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<td>Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.</td>
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<td>Important social, occupational or recreational activities are given up or reduced because of opioid use.</td>
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<tr>
<td>Recurrent opioid use in situations in which it is physically hazardous.</td>
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<tr>
<td>Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.</td>
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<tr>
<td><em>Tolerance, as defined by either of the following:</em></td>
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<td>(a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect</td>
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<tr>
<td>(b) markedly diminished effect with continued use of the same amount of an opioid</td>
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<td><em>Withdrawal, as manifested by either of the following:</em></td>
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<tr>
<td>(a) the characteristic opioid withdrawal syndrome</td>
<td></td>
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<tr>
<td>(b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms</td>
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</tbody>
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**Total Number Boxes Checked: ____________________**

**Severity:** Mild: 2-3 symptoms. Moderate: 4-5 symptoms. Severe: 6 or more symptoms

*Criteria from American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Washington, DC. American Psychiatric Association page 541. For use outside of CIT MAT/ITs Colorado, please contact 719-471-0576@ColoradoHealthLink.org.*
Opioid Use Disorder (OUD)

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DSM-5 defines Opioid Use Disorder as a craving or strong desire to use opioids which can result in failure to fulfill major role obligations at home, school or work. This pattern of use leads to clinically significant impairment and distress. It is a chronic medical condition.

Opioid use disorder has become the leading cause of accidental death in the United States even though there are several effective treatment Medications for Opioid Use Disorder (MOUD) that can help. Unfortunately, up to 80% with OUD do not receive these needed treatments.

Primary care physicians are most likely to prescribe opioid prescriptions and should monitor opioid use to identify patients at risk for OUD.
Medications for Opioid Use Disorder (MOUD)

The Drug Addiction Treatment Act of 2000 (DATA 2000) amended the Controlled Substance Act and was passed in order to improve medical access for the detoxification treatment of OUD.

Detoxification refers to a set of interventions aimed at managing acute intoxication and withdrawals. It involves the clearing of toxins from the body which is dependent on a substance of abuse.

Allows qualified practitioners to prescribe approved buprenorphine for OUD treatment in settings other than opioid treatment programs (OTP) without holding a separate registration for this purpose. It requires completion of specialized training and DEA X-wavier.

MOUD with opioid agonist medications has been found to reduce morbidity and mortality, decrease overdose deaths, reduce transmission of infectious disease, improve social functioning, and reduce criminal activity.

The medications most often used for MOUD are methadone, naltrexone, and buprenorphine.
Medications for Opioid Use Disorder (MOUD)

Methadone:

A long-acting agonist at the mu receptor and can offset other opioids from that receptor (heroin, morphine, Fentanyl, carfentanil). It can reduce craving and reduce withdrawal symptoms and is an effective MOUD. It is a potent medication and can cause sedation and death. It must be dispensed by a certified Opioid Treatment Program (OTP).

Has a long half life and dosing must be monitored in a regulated licensed certified clinic. Opioid Treatment Programs (OTP) must be certified, accredited, licensed in the state they operate in, and registered with the DEA.

Must be prescribed by a physician at a Substance Abuse and Mental Health Services (SAMHSA) certified OTP clinic.
Medications for Opioid Use Disorder (MOUD)  
Naltrexone:

It is not an opioid and is not addictive. It blocks the euphoric and sedative effects of opioids like heroin, morphine, and codeine. It binds and blocks opioid receptors and blocks opioid cravings and sedation.

Approved for OUD and Alcohol Use Disorder (AUD). It comes in oral and a long-acting intramuscular formulation. It maybe prescribed by any licensed practitioner. It is not a controlled medication.

A Risk Evaluation and Mitigation Strategy (REMS) is required for the long term injectable when using for MOUD to select the appropriate patient and to review the risks and benefits of this treatment.

Patients must wait 7 days after their use of short-acting opioids and 7-10 days after using long-acting opioids to reduce the risk of side effects and withdrawal.

Serious side effects can occur if started too soon after opioid removal or if the patient restarts opioids. If patients attempt to restart opioids at the previous dose, they risk increased sensitivity from the naltrexone which can lead to potential overdose and death.
Medications for Opioid Use Disorder (MOUD)

Buprenorphine:

It is a partial mu receptor opioid agonist. It is used in MOUD as approved in 2000 by Congress in DATA2000 statutes. It requires training and a DEA X-waiver for use as a MOUD in the United States.

It is a schedule III-controlled substance and is available in sublingual films/tablets, transdermal, and injection dosing. It is used in the United States for OUD and analgesic pain treatment.

It has a great affinity for the mu receptor and displaces other opioids off the receptor rapidly even heroin. Induction of its use as a MOUD requires training and understanding dosing which can be safely performed in a medical office or home induction with physician supervision.

An advantage is its safety and ease of use over other MOUDs. Because of its partial receptor affinity, it has much less respiratory suppression with increasing doses unlike Methadone. It also does not require dispensing from an OTP clinic.
Medications for Opioid Use Disorder (MOUD)

**Buprenorphine:**

When combined with naloxone (Suboxone, Zubsolv), it reduces the risks of altering the dose and diversion over plain buprenorphine alone (Subutex). Combining it with naloxone at a 4 to 1 ratio does not affect the bioavailability when taken sublingually. It does affect the bioavailability if the tablet/film is altered and then injected.

Buprenorphine with naloxone has become the treatment of choice but access is currently limited due to the low number of practitioners trained and qualified to prescribe it. Many physicians that are qualified to use buprenorphine are not currently participating with MOUD or have low enrollment numbers.

Injectable buprenorphine (Sublocade) is given once monthly and requires Risk Evaluation and Mitigation Strategy (REMS) training. It must be administered by a healthcare provider in a certified healthcare setting.
Practitioner training and registration can be found through the Substance Abuse and Mental Health Services Administration (SAMHSA) samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner.

To acquire a practitioner wavier to administer, dispense, and prescribe buprenorphine and buprenorphine/naloxone for OUD, practitioners notify and apply through SAMHSA’s Center for Substance Abuse (CSAT) with their notice of intent (NOI) to practice with this type of MOUD. A buprenorphine wavier application must be submitted and approved before initial dispensing or prescribing.

Qualified practitioners that can apply include physicians, nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetist, and certified nurse midwives. Qualified includes having a current licensure to practice and an active DEA registration number with Schedule III controlled substance authorization.
The DEA requires an additional provider waiver number that will be your current DEA number except it will begin with the letter X in place of your current DEA first letter. This has become known as the X-Waiver. You retain your current DEA number for controlled substances but have the DEA X-Waiver number to use when dispensing and prescribing buprenorphine for OUD.

To qualify for a X-Waiver, a practitioner needs to satisfy certain requirements related to training (8-hour course), counseling, and other ancillary services that are coded under 21 U.S.C. 823 and DATA 2000 statutes.

The Secretary of Health and Human Services determined in 2021 that these requirements of training, counseling, and ancillary services represent a barrier to OUD treatment with buprenorphine. After discussion with the DEA and other regulatory agencies, the Secretary of HHS created exemptions of the certification requirements under 21 U.S.C. 823. A practitioner otherwise qualified to practice and has a current active DEA registration may apply to treat OUD with buprenorphine up to 30 patients at one time and can be exempt from training, counseling, or other ancillary services when applying for a waiver to treat OUD.
Unless Congress changes the current law, a DEA X-waiver number is still required when dispensing or prescribing buprenorphine for OUD even with the 30-patient limit exemption.

Under this exemption, PA’s, NP’s, CNS’s, CRNA’s, and CNM’s are required to be supervised by a X-waivered registered physician when prescribing buprenorphine for OUD. These groups may submit a notice of intent (NOI) to treat without direct physician supervision through SAMHSA after completing a 24-hour training course.

Physicians who wish to manage and treat more than 30 patients at a time may do so by completing the 8-hour training requirements currently under 21 U.S.C. 823 and can treat up to 100 patients after meeting additional conditions for a “quality practice setting”. After 1 year at the 100-patient limit, a physician can apply for a “275 waiver” to increase the limit to 275 patients at a time.

While training, counseling, and ancillary services are exempt to OUD treatment with up to 30 patients, the Department of HHS recommends utilizing their Buprenorphine Quick Start Guide.
Training and resources for Medications for OUD Treatment

The Substance Abuse and Mental Health Services Administration (SAMHSA.gov) has the information and application process to get started and the resources to assist with OUD treatments. The SAMHSA website has information on practitioner training and programs. The Provider Clinical Support System (pcssnow.org) has free provider training modules that meet the 8-hour training requirement, provides CME, and other important OUD treatment information. There is also a Mentor assistance program for physicians on the website.

MOUD treatments should include patient informed consents and treatment agreements. Counseling and behavioral treatment improve success and effectiveness but should not delay induction of treatment if they are not available initially.

When staring treatment for OUD with buprenorphine, understanding its induction for each patient situation is important. Training and quick reference guides can assist with treatment induction and stabilization to minimize opioid withdrawals. There are multiple treatment induction schemes including in office and at home inductions. It’s important to note that the patient should be in opioid withdrawal when starting an induction treatment. Withdrawal symptoms can be assessed with the Clinical Withdrawal Opioid Scale (COWS).
## Clinical Opiate Withdrawal Scale (COWS)

**Wesson & Ling, J Psychoactive Drugs. 2003 Apr-Jun;35(2):253-9.**

**Resting Pulse Rate:**
- 0: Pulse rate 90 or below
- 1: Pulse rate 91-100
- 2: Pulse rate 101-120
- 4: Pulse rate greater than 120

**GI Upset:**
- 0: no GI symptoms
- 1: Stomach cramps
- 2: Nausea or loose stool
- 3: Vomiting or diarrhea
- 5: Multiple episodes of diarrhea or vomiting

**Sweating:**
- 0: No report of chills or flushing
- 1: Subjective report of chills or flushing
- 2: Flushed or observable moistness on face
- 3: Beads of sweat on face or brow
- 4: Sweat streaming off face

**Tremor observation of outstretched hands:**
- 0: No tremor
- 1: Tremor can be felt, but not observed
- 2: Slight tremor observable
- 4: Gross tremor or muscle twitching

**Resistents Observation during assessment:**
- 0: able to sit still
- 1: Reports difficulty sitting still, but is able to do so
- 3: Frequent shifting or extraneous movements of legs/arms
- 5: Unable to sit still for more than a few seconds

**Yawning Observation during assessment:**
- 0: No yawning
- 1: Yawning once or twice during assessment
- 2: Yawning three or more times during assessment
- 4: Yawning several times/minute

**Pupil size:**
- 0: Pupil pinned or normal size for room light
- 1: Pupils possibly larger than normal for room light
- 2: Pupils moderately dilated
- 5: Pupils so dilated that only the rim of the iris is visible

**Anxiety or irritability:**
- 0: None
- 1: Patient reports increasing irritability or anxiety
- 2: Patient obviously irritable
- 4: Patient to irritable or anxious that participation in the assessment is difficult

**Bone or joint aches:**
- 0: Not present
- 1: Mild diffuse discomfort
- 2: Patient reports severe diffuse aching of joints/muscles
- 4: Patient is rubbing joints or muscles and is unable to sit still because of discomfort

**Gooseflesh skin:**
- 0: Skin is smooth
- 1: Pilocereation of skin can be felt or hairs standing up on arms
- 5: Prominent pilocereation

**Runny nose or tearing:**
- 0: Not present
- 1: Nasal stuffiness or unusually moist eyes
- 2: Nose running or tearing
- 4: Nose constantly running or tears streaming down cheeks

**Score:**
- 5-12 mild; 13-24 moderate; 25-36 moderately severe; more than 36 = severe withdrawal
Training and resources for Medications for OUD Treatment

Physician close monitoring at induction and stabilization can promote the physician-patient relationship and reduce treatment failures. Limiting quantity on early prescriptions and urine drug screens help reduce prescription diversion and with patient compliance. Prescribing buprenorphine/naloxone has been shown to reduce medication altering and diversion.

Longer term maintenance treatment with buprenorphine is more effective than short term treatment with early medication tapering. Even with counseling, tapering in 12 weeks was shown to have a high relapse rate. Opioid Use Disorder is a chronic disease and treatment may take years.

National Clinician Consultation Center has a substance use warmline at (855)300-3595 for healthcare providers.

Project ECHO for OUD from Beacon Health uses virtual and telemedicine platforms with “grand round meetings” for provider support and training. Patient can be found at Beaconhealthoptions.com

SAMHSA also has a National Helpline 1-800-662-4357, Substance Use Treatment Locator at FindTreatment.samhsa.gov, and a Buprenorphine Practitioner Locator on its website.
Reducing Barriers to OUD Treatments

On one survey, 80% of family physicians felt they regularly saw patients addicted to opioids. The majority surveyed (70%) felt as family physicians they bore responsibility for treating opioid addiction.

They cited reasons for barriers to starting MOUD included inadequately trained staff (83%), insufficient time (80%), inadequate office space (49%), and cumbersome regulations (47%).

Other barriers listed include limited physician education and understanding of OUD treatments, insurance reimbursement, requiring prescription prior authorizations for treatment, and the stigma of the population being treated as being “difficult patients”.

Policy makers and healthcare leaders need to push for increased access for mandated insurance treatment coverage for OUD without prior authorizations for MOUDs, increased addiction medicine education, and promote interdisciplinary care team platforms for OUD(SUD).
Patient support Programs

Support programs can keep the patient engaged for success and set ongoing goals.
Narcotics Anonymous at NA.org
Project Echo for OUD at beacohealthoptions.com
Behavioral Health Treatment Services Locator at findtreatment.SAMHSA.gov
Team Patient at teampatient.com

Care teams available both by local and online formats can help keep MOUD treated patients engaged in recovery. There are many existing “HUB and SPOKE “support programs that organize the care teams for patient support. An example of a program one of my patients participates in called “Team Patient” (teampatient.com)
Each team is organized around the patient, based on their ability to help patient goals.

Teams are organized in groups, to share information, communications, appointments and work tasks.

Team members can include ......

As needed at each stage of the continuum of care
“At risk” stage

Exclusive “in-app” access

- Periodic testing
- Review provider choices **
- Connect to insurance
MOUD Treatment Considerations

The ability to get practitioner training and support online and reach the patients through telemedicine should increase access to OUD patients in need of detoxification and stabilization. We need to reach that 80% with Opioid Use Disorder that are untreated!

To better understand MOUD, use mentors and colleagues to help you plan out your treatment program details. ECHO at beaconhealthoptions.com and Providers Clinical Support System PCSSnow.org

There are existing MOUD treatment programs developed already for primary care offices, urgent care clinics, inpatient and outpatient clinics, and emergency departments. The FOMA website is adding information on Opioid Use Disorder programs and resources as part of its provider benefits under the physician’s toolbox. Please share ways your practice has been successful with OUD treatments with us.

It is ok to start low and go slow. What is important is that you START!
Thank you

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