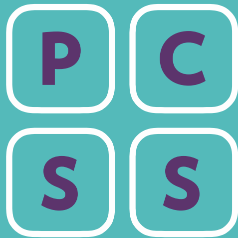

MAT TRAINING

PROVIDERS' CLINICAL SUPPORT SYSTEM
For Medication Assisted Treatment

MAT in the OTP Setting: Integrating the Three Approved Medications (Methadone, Buprenorphine, ER Naltrexone)

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Commercial Disclosers	What Was Received?	For What Role?
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PCSS MAT TRAINING
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System Requirements

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Target Audience

- The overarching goal of PCSS-MAT is to make available the most effective medication-assisted treatments to serve patients in a variety of settings, including primary care, psychiatric care, and pain management settings.

Educational Objectives

- At the conclusion of this activity participants should be able to:
  - Discuss the unique characteristics of Opioid Treatment Programs (OTPs)
  - Identify OTPs as part of the continuum of care
  - Assess the infrastructure available to support medication management in OTPs
  - Review challenges and opportunities in integrating all three medications (methadone, buprenorphine and extended release naloxone) into the OTP setting
  - Discuss the clinical and operational issues related to medication choice in the OTP setting.

What is an OTP?

- An Opioid Treatment Program (OTP) provides:
  - multidisciplinary
  - outpatient-based
  - maintenance care of
  - patients with
  - opioid addiction,
  - utilizing FDA approved medication (typically methadone), and
  - operating under OTP regulations and licenses from the federal and state governments

Why are there OTPs?

- Until 2000, under federal law, patients could only receive scheduled opioid medications for maintenance treatment of opioid addiction via medication ordered and dispensed from an "Opioid Treatment Program" (OTP)

- In an OTP, there is no "prescription" on a pad – medication is ordered and dispensed from the OTP

- The DATA 2000 Act allows for physicians to obtain waivers allowing limited prescribing of approved opioids less than Schedule II (e.g. buprenorphine) in other settings, such as Office Based Opioid Treatment (OBOT)

What is special about OTPs? Federal and State Requirements

- Full bio-psycho-social admission assessment, performed by nursing, counselling and physician staff, including physical examination, drug screens and laboratory work
- Admission only under a physician's order
- Open 6-7 days per week with nurses on site each day
- Patient's medication doses are dispensed and consumed under supervision of nurse/pharmacist (state rules vary)
  - Patients initially must come to clinic to dose daily
- Clinics are licensed by state and federal agencies, and accredited by either CARF or The Joint Commission (prev. JCAHO)

What is special about OTPs? Federal and State Requirements

- Required counselling for substance use disorders (not synonymous with psychotherapy for mental health issues)
- Documented full treatment planning
- Diversion control processes
  - Drugs screens (urine, oral swabs). Drug testing for confirmations if necessary.
  - Urine collections may be observed or unobserved.
  - Call backs for both random urine drug screens (UDS) and to check that any take home medications are accounted for

What is special about OTPs? Federal and State Requirements

Gradual increases in unsupervised (take-home) medication over time, based on:*

(i) Absence of recent abuse of drugs or alcohol
(ii) Regularity of clinic attendance
(iii) Absence of serious behavioral problems at the clinic
(iv) Absence of known recent criminal activity, e.g., drug dealing
(v) Stability of the patient's home environment and social relationships
(vi) Length of time in comprehensive maintenance treatment
(vii) Assurance that take-home medication can be safely stored within the patient's home
(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

The application of these criteria varies by state

*As outlined in Federal Register, 42 CFR Part 8, Part II, 2001

What is special about OTPs? Federal and State Requirements

Often additional state requirements, such as:

- Maximum ratio of patients: counselors and/or patients: physicians
- Use of Prescription Drug Monitoring Programs
- Hepatitis and/or HIV testing
- Only board certified addiction medicine physicians or psychiatrists may be program physicians or medical directors, without a special waver from the state

What is special about OTPs?

- Around 1,200 OTPs operational in the US
- Very few commercial health plans will contract with or pay for OTP services
- Some urban areas have OTPs funded by grants, other direct governmental funding, or Medicaid plans contracting with OTPs for services
- This means that typically OTPs operate on a patient self-pay model (daily or weekly payments)
  - Around $70-130/week with all required services and methadone medication included

What is special about OTPs?

- Methadone is dispensed, not prescribed
- The medication is stored in unrefrigerated safes
- Dose formulation is usually liquid, or 40 mg tablet wafers and/or 5 mg pills
  - 10 mg pills may not be provided by OTPs
  - 10 mg pills found on the street were therefore initially prescribed for pain, not dispensed by OTPs.
  - This has allowed the CDC to state clearly that the vast majority of diverted methadone is not coming from OTPs

What is the "OTP Level of Care"?

The spectrum of addiction treatment:

- Outpatient care traditionally consists of such services as a 50 minute individual therapy session, a 90 minute group therapy session, or a 15 minute medication check by a prescriber. These typically occur 1-2 times per week, per month, or, for fully stable patients, per quarter. (ASAM Level I)

- Intensive outpatient services are approximately 3 hours of service, three times a week and may not include medications (ASAM Level II.1)

- Partial Hospital Programs are 4 hours a day, 5 days a week (ASAM Level II.2)

- Inpatient services range from medically intensive hospitalizations to rehabilitation programs with no medical services included (ASAM Level III-IV)

What is the "OTP Level of Care"?

- "Opioid Maintenance Therapy" (OMT) is considered a specific service that can be provided as part of any level of care
- However, since most "OMT" is provided in "OTPs", an outpatient environment, criteria are provided in the outpatient format
- The patient's need for both high levels of structured therapy and medication to prevent withdrawal separate the OTP from other outpatient levels of care

Historically, OTPs provided Methadone maintenance therapy

- Methadone has been the “Gold Standard” of care for opioid addiction for over 50 years
- Newer FDA approved medications, buprenorphine products (sublingual and buccal) and extended release (ER) naltrexone, may be used outside of the OTP setting
- BUT - OTPs have a unique infrastructure which can be effectively utilized to provide all medication options
- Specific operational and clinical issues must be considered to integrate the full range of pharmacotherapies into the OTP setting

Methadone: Clinical issues

- Methadone is a full mu opioid agonist with a long half life
- Once per day dosing for addiction, but 3-4 times daily dosing for chronic pain management. OTPs can only dose a patient daily without approved exception to split into more frequent daily doses
- Can prolong QTc with risk of Torsades de Pointes
- Meaningful peak and trough blood levels
- Respiratory depression can be a side effect at any dose
  - Large volume of distribution and unpredictable pharmacokinetics makes rapid dose titration dangerous
  - Risk increased significantly if mixed with "The 3 Bs -- benzos/barbs/booze"

Methadone: Clinical issues

- Uncomfortable and objectively obvious opioid withdrawal occurs after missing 1- 2 days of medication
- Requires daily dosing initially in the OTP
- Federal law prohibits patients from taking methadone and utilizing a commercial driver's license
- Patients who travel for work need to either receive take home doses if eligible or obtain dose ("guest dose") at another OTP

Case (Part I)

Johnny is a 34 y/o male; hurt back working in the coal mines and was prescribed opioids; use escalated and he began using multiple oxycodone/APAP 30/500 mg tabs through IV route daily. Meets criteria for Opioid Use Disorder, AST/ALT less than 3x normal.

Tried buprenorphine from a clinic where he saw a doctor and received a prescription: "It didn't work for me. I just stopped taking it and used, and took it some more and then stopped and used. It was too easy to game it. I need more. I don't want that medicine".

What patients may do well with Methadone?

- Long history of opioid addiction
- IV route of illicit drug administration
- Require diversion control procedures
- Respond to high levels of external daily structure
- Benefit from contingency management interventions

Methadone and Buprenorphine Similarities

1. Are daily dosed medication taken via the oral cavity

2. Can be stored in an unrefrigerated safe

3. Act to cover the mu opioid receptor in order to:
   i. Decrease or eliminate cravings
   ii. Control physiological withdrawal
   iii. Prevent euphoria from use of other mu agonists

Methadone and Buprenorphine Similarities

1. Can cause withdrawal upon abrupt cessation
2. Have a range of dosing, which is titrated to the individual patient’s needs
3. Safe and effective discontinuation of medication consists of gradual tapering to zero dose
4. Patients can currently only be admitted to OTPs/ prescribed buprenorphine by physicians

Methadone and Buprenorphine Similarities

1. Are mu receptor agonists (full and partial, respectively), and therefore can be used by people not dosing daily with them for euphoric effect

2. Have significant street value when diverted

3. Can be lethal in overdose (as full agonist, risk with methadone is higher than partial agonist buprenorphine but low threshold for unintentional overdose seen in adults stable on methadone due to long half-life; buprenorphine fatalities have occurred in children or in other people without tolerance)

4. Stigmatized as "still addicted" by many 12 step mutual support groups despite recovery; patients are often advised not to tell others at meetings they are taking these medications

5. Stigmatized by some people in 12 step mutual support groups, criminal justice system, other health care providers that these are "just substituting one drug for another" despite recovery

Buprenorphine Issues in the OTP

Buprenorphine is accessible in 2 ways:

1. Prescribed by an OTP physician under their Data 2000 waiver using OBOT restrictions (30 or 100 patient limit)

OR

2. Ordered and dispensed under OTP rules (full admission work up, daily supervised dosing, medication ordered and dispensed from the OTP, required counselling, drug screens, call backs, etc)

   - EXCEPT: the time in treatment requirement to receive take home medication is not applicable under federal regulations (states vary)

   - As with methadone, there is no limit on the number of patients a physician may have on buprenorphine in an OTP (states vary)

Buprenorphine Issues in the OTP

- OTP vs. OBOT in the clinic: It is either/or but not both for a single patient during an episode of care.
  - Patients being prescribed buprenorphine by their waivered physician may not be dosed at the OTP unless they are first admitted and maintained under OTP rules.

Buprenorphine Issues in the OTP: Available Infrastructure

Although not required for OBOT, the OTPs have the ability to perform a variety of useful services for buprenorphine patients who require additional structure:

- Counseling
- Physical examinations
- Nursing services including observed dosing
- Diversion control processes
  - Drug testing
  - Random call backs
  - Pill/film counts

Buprenorphine Issues in the OTP

1. Buprenorphine does not require as careful an induction because of its ceiling effect on respiratory depression

2. Patients must have their mu opioid receptors adequately "uncovered" from a full mu agonist to begin dosing with the partial agonist buprenorphine, or they will experience opioid withdrawal

3. Because of the slower time to dissolve sublingual buprenorphine vs oral ingestion of methadone, dosing buprenorphine can take significantly more staff time to monitor

Case (Part II)

- Johnny did extremely well with methadone at a maximum dose of 85 mg per day and began a gradual dose reduction. At 3 years he on 70 mg and has been eligible for 27 take homes per 28 days, but opts to get 13 in 14 days (“I don’t trust myself with more. I need to come here to keep myself honest”)

- He has an opportunity to change jobs from underground mining to hauling coal locally, which requires a commercial driver’s license. He is willing to change to buprenorphine, recognizing he is now doing well presenting every 2 weeks to clinic.

What patients may do well with Buprenorphine?

1. Able to maintain treatment plan without daily supportive contacts or structure of OTP clinic

   i. Structure (employed, other)
   ii. Strong recovery support system
   iii. Adequate stress management skills

Or OTP can order and dispense buprenorphine under OTP rules

Overview of Cost Issue

- Direct cost of methadone = <$1 a day
- Direct Cost of buprenorphine (SL) = $ 4 - $30 a day
- Direct Cost of ER naltrexone = $700-1000 per injection (monthly)

Buprenorphine Issues in the OTP: Payment for Medication

- Buprenorphine retails $7-10 for 8 mg dose unit (with or without naloxone).
    - Health plans might or might not cover buprenorphine

- Buprenorphine costs to OTP through a distributer might be < retail
    - But not <$1 per day as with methadone

- OTPs dispensing buprenorphine instead of methadone will need to cover the increased costs by:
    - increasing daily or weekly charges to the patient
    - billing medication costs directly to plans (in some states done by obtaining a pharmacy license, in others billed directly to insurance)

Extended Release Naltrexone

- Full mu opioid antagonist
- Blocks the euphoric effect of mu opioid agonists
- Will precipitate withdrawal if agonists (full or partial) are occupying mu receptors
  - Must be 7-10 days without other opioid use before starting naltrexone
- Monthly dosing improves adherence

How ER Naltrexone differs from Methadone and Buprenorphine

- IM injection into buttocks
- Doses once monthly
- No addiction potential; not a scheduled medication
- Can be prescribed by advanced practice nurses/physician assistants (varies by state)
- Specialty pharmaceutical product
- Medication must be refrigerated and mixed shortly before administration
- Substantially less stigma

ER Naltrexone OD risks

- Fatal overdoses have been reported in patients taking ER naltrexone, especially when:
  - Trying to overcome opioid blockade
  - Using opioids at or near end of 1 month dosing interval
  - Using opioids after missing dose

Patients may not understand that their loss of tolerance when taking ER naltrexone is a danger if they lapse to opioid use.

Case (Part III)

- Johnny made the change from methadone to buprenorphine, stabilized at 12 mg qd for a year and gradually tapered to 4 mg qd. Attempts to lower the dose have failed.
- Continues to choose to present every 2 weeks to clinic, although eligible for monthly visits and has been encouraged to find support outside of clinic
- Local mines have closed, and he has the option for work in another state. Plans to come home once monthly. Will have insurance with new job, and has saved substantial money since he stopped using street opioids and began treatment 6 years ago.

Which patients may do well with ER Naltrexone?

- High motivation
  - Patients needing treatment where drug court judges, professional boards, or others may not allow agonist medication
- Short duration or less severe history of opioid addiction
- Inability to manage opioid use disorder with agonist treatment
- Do not wish to take agonist medication
- Done well with agonist medication and want to change to less intensive medication treatment regimen

How to Choose Medications?

- No evidence-informed guidelines on choosing the three options currently
- Guidelines are being built by ASAM with date of release mid-2015
- In lieu of formal guidelines, physicians must use clinical judgment considering multiple issues

Factors Providers May Face in Choosing Medications

- Severity of opioid use disorder
- Patient history of treatment response
- Co-existing medical and psychiatric conditions
- Other medications and potential for interactions
- Other substance use disorders
- Patient beliefs about specific medications, in collaboration and discussion with family
- Patient's financial ability to obtain
    - Medication itself
    - All services necessary to support treatment that includes a medication

Choosing Medications

- Arbitrary restrictions by professional boards/ employers/ family services or court representatives
- Potential for misuse and diversion
- Patient's access to OTP:
  - geographically
  - time constraints
  - transportation availability and cost

Operational Challenges

Integrating all three medications into OTP setting

- Expanding safe storage for medications
    - Refrigeration required for ER naltrexone
- Managing "patient flow" - different times of day for different medications? Recall longer time to observe buprenorphine administration
- Pricing differences
- Establishing protocols for induction, maintenance, and therapeutic discontinuation with buprenorphine and ER naltrexone in addition to methadone
- Establishing clear criteria and patient communication materials to explain selection of different medications

Operational Challenges

Integrating all three medications into OTP setting

- Relationships with payers and medication distributers
- New patient and family education materials
- New patient informed consent materials
- Education of all staff on all three medications
- Education of community on availability of all three medications
- Obtaining physician resources to lead clinical care with all three medications
- Anticipating likely availability of new buprenorphine formulations in near future

Conclusion

- OTPs offer unique characteristics which can be used to provide care with methadone, buprenorphine, and ER naltrexone
- There are multiple clinical and operational challenges in integrating all medications
- All three FDA approved medications have unique profiles which provide real treatment options for patients

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PCSS-MAT Mentoring Program

- PCSS-MAT Mentor Program is designed to offer general information to clinicians about evidence-based clinical practices in prescribing medications for opioid addiction.
- PCSS-MAT Mentors comprise a national network of trained providers with expertise in **medication-assisted treatment, addictions** and **clinical education**.
- Our 3-tiered mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available, at no cost to providers.

For more information on requesting or becoming a mentor visit:

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PCSSMAT is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA) and American Society of Addiction Medicine (ASAM).

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