PCSS 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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System Requirements

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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
  - Understand the infrastructure available to support medication management in OTPs
  - Understand 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.

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.

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 government

Why are there OTPs?

- Under federal law, patients may be treated with scheduled narcotics for maintenance treatment of opioid addiction only via medication ordered and dispensed from an “Opioid Treatment Program” (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 narcotics less than Schedule II 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 methadone doses are dispensed and consumed under supervision of nurse/pharmacist (state rules vary)
  - Patients initially must come to clinic to dose daily
- Clinics licensed by state and feds, and accredited by either CARF or The Joint Commission (prev. JCAHO)

What is special about OTPs? Federal and State Requirements

- Required counselling for substance abuse (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 meds are accounted for

What is special about OTPs? Federal and State Requirements

Gradual increase in take- home privileges

After several weeks / months (varies by state) of:

- Passed drug screens
- Perfect attendance
- Full adherence to treatment plan

Then patients may, under a physician's order:

- Take home one fully labeled dose of methadone per week

What is special about OTPs? Federal and State Requirements

- Earned number of days per week of take home medications increase gradually by SAMHSA and state-specific guidelines
- The maximum a patient may have under federal guidelines is a 27 days supply per 28 days; may be earned after a minimum of 2 years in treatment

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. Relapse rates are high when treatment with medication is discontinued
- 4. Patients can currently only be admitted to OTPs/ prescribed buprenorphine by physicians

What is special about OTPs?

- Around 1200 OTPs in the US
- Very few commercial health plans will contract with/ pay for OTP services
- Some urban areas have OTPs funded by block grants, other direct governmental funding, or Medicaid plans contracting with OTPs for services
- Meaning that typically OTPs operate on a patient self-pay model (daily or weekly payments)
  - Around $70-130/week, all required services and methadone medication included

What is special about OTPs?

- Methadone is dispensed, not prescribed
- Liquid, 40 mg wafers and/or 5 mg pills
  - 10 mg pills may not be provided to/used 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
- Stored in unrefrigerated safes

What is the “OTP Level of Care”?

- 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 prescribing (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” is a considered a specific service that can be provided under 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 structures therapy and medication to prevent withdrawal separate the OTP from 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 (SL and buccal) and ER naltrexone, may be used outside of the OTP setting
- BUT - OTPs have a unique infrastructure which can be effectively utilized to provide all these mediation modalities
- 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 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 qd without state exception to split into 2 doses
- Prolongs QTc with risk of Torsades de Pointes
- Meaningful peak and trough blood levels
- No ceiling effect on respiratory depression
  - Dangerous to titrate up quickly
  - Dangerous mixed with “The 3 Bs” - benzos/barbs/booze

Methadone: Clinical issues

- Uncomfortable and objectively obvious withdrawal occurs after missing 1- 2 days of dose
- Requires daily dosing initially in the OTP
- Patient are not allowed to be in methadone treatment and utilize a commercial driver's license
- Patients who travel for work will need to either earn take homes or guest dose at other facilities

Case (Part I)

Johnny is a 34 yo male; hurt back working in the coal mines and was rxed opioids; use escalated and he began using multiple oxycodone with APAP 30/500 mg tabs through IV route daily. Meets criteria for Opioid Dependence, LFTs 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 treatment?

- Long hx 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 techniques of the take home / phase system

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 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. The endpoint of an episode of care consists of gradual tapering to medication discontinuation
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 to get high

2. Have significant street value when diverted

3. Can be lethal in overdose (low threshold for unintentional overdose seen in adults due to long half-life and no respiratory depression ceiling; buprenorphine fatalities have occurred in children or in other people without tolerance)

4. Are seen as “using” by many 12 step groups; patients are often advised not to tell others at meetings they are taking these medications

5. Stigma by some people in 12 step groups, criminal justice system, other health care providers that these are “just substituting one drug for another’

Buprenorphine Issues in the OTP

- Buprenorphine may be obtained in 2 ways:

1. Prescribed by an OTP physician under their Data 2000 waver using OBOT restrictions (30/100 pt limit)

Or

2. Ordered and dispensed under methadone 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 earn take home phases is not applicable under federal regs (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 wavered 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 screens/tests
  - Random call backs
  - Pill/film counts

Buprenorphine Issues in the OTP

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

2. Patients must have their mu receptors adequately "uncovered" by full mu agonist in order to begin dosing the partial agonist of buprenorphine, or they will be thrown into withdrawal

3. Because of the slow to absorb time SL vs. oral injestion of methadone, dosing SL buprenorphine can take significantly more staff time to monitor and ensure no diversion.

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 2 weeks to clinic.

What patients may do well with Buprenorphine?

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

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

Or OTP can order and dispense buprenorphine under methadone rules

Overview of $ 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 (with or without naloxone).
  - Health plans might/ 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/weekly charges to the patient
  - billing medication costs directly to plans (such as by obtaining a pharmacy license)

Extended Release Naltrexone

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

How ER naltrexone differs from methadone and buprenorphine

- IM injection into buttocks
- Doses once monthly
- No abuse potential; not a scheduled narcotic
- Can be prescribed by advanced practice nurses/physician assistants (varies by state)
- Specialty pharma 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 their loss of tolerance when taking ER naltrexone is a danger when they lapse.

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 present q 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 for abstinence
  - Patients needing treatment where drug court judges, professional boards, others may not allow agonist tx

- Short/less severe hx of opioid addiction
- Failed agonist treatment
- Do not wish to use agonist tx
- Succeeded in agonist tx 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

Choosing Medications

- Patient history of tx response/failure
- Family history of tx response/failure
- Patient's / family's beliefs about specific medications
- Patient's financial ability to obtain
  - Medication itself
  - all services necessary to support a medication treatment

Choosing Medications

- Restrictions due to professional boards/ employers/ family services or court representatives
- Potential for abuse/diversion
- Potential for drug interactions
- medical contraindication (relative or absolute)
- 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 for ER naltrexone
- “patient flow” - different times of day for different medications? Recall slower buprenorphine SL dosing flow
- Pricing new services
- Establish protocols for induction, maintenance, and therapeutic discontinuation with buprenorphine and ER naltrexone

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 modalities
- Education of community on availability of all three modalities
- Obtaining physician resources to lead clinical care in all modalities
- Probable availability of new buprenorphine formulations in near future

Conclusion

- OTPs offer a 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 modalities
- 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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