NC Opioid and Prescription Drug Abuse Advisory Committee (OPDAAC)

Coordinating Workgroup Meeting
February 8, 2018
Welcome! and Introductions of Attendees

• Welcome!
  – Susan Kansagra
  – Steve Mange

• Introductions of Attendees
  – Your name
  – Your organization/affiliation
OPIOID USE DISORDER AND MEDICATION-ASSISTED TREATMENT

Jana Burson M.D.
Board-certified in Addiction Medicine and Internal Medicine
Medical Director, Wilkesboro Comprehensive Treatment Center
North Wilkesboro, NC
Three medications approved to treat opioid use disorder – this is MAT

- Methadone
- Buprenorphine
  - Combination products – contains buprenorphine and naloxone
    - Suboxone, Zubsolv, Bunavail
    - Generic products
  - Mono-product – contains only buprenorphine
    - Generic products for sublingual use
    - Depot implants – Probuphine
    - Depo subcutaneous - Sublocade
- Naltrexone
  - Tablet form – daily dosing
  - Depot monthly injection
    - Vivitrol
Opioid use disorder

• Acute withdrawal
  • Miserable: body aches, sneezing, runny nose, nausea & vomiting, diarrhea, chills & sweats, fever, elevated blood pressure and heart rate
  • Not fatal in most healthy adults
• Post acute withdrawal
  • Theorized to occur due to the changes in the body seen when opioids are used for long time period (over three months)
  • Prolonged opioid use changes the structure and function of the brain
  • Leaves a “drug hunger”
  • Low-grade fatigue, depression, anxiety, poor appetite, aches, cravings for opioids
  • Lasts weeks to months
  • Conceived as a metabolic disease; body’s own opioid (endorphins) production stops
  • Will the patient ever return to normal?
  • Many do, if they can remain abstinent from opioids for long enough
Opioid agonists: methadone and buprenorphine

- Replace the opioids to which the brain has become accustomed
- Very long-acting: give steady blood levels
  - This pharmacologic property makes both medications ideal for once-daily dosing
- At proper dose, patients feels normal
- Can function normally
- Relieves “drug hunger”
Methadone stabilizes opioid blood level, allows normal functioning through the day, due to its unique pharmacology, compared to short-acting opioids most commonly used for intoxication.

http://international.drugabuse.gov
Methadone

• Highly regulated by federal/state/local entities
• It is illegal for physicians to prescribed from an office for the purpose of treating addiction
• Only approved opioid treatment programs (OTPs) can legally prescribe and dose methadone for the treatment of opioid use disorder
• These centers have oversight by Drug Enforcement Administration (DEA), state’s department of health and human services, state’s department of facility services, also by state’s opioid treatment authority, usually inspected by CARF
• Most highly regulated area of medicine
• Patients must dose daily under observation for months, until stable enough for take home doses
• Frequent and observed drug screens
Methadone

- Counseling is built into the system at an opioid treatment program
- Focus on counseling regarding patient’s individual issues
  - Identify & address co-occurring substance use – random drug screens (monthly or more often as needed)
  - Individual and group counseling
    - Minimum set by state is two sessions per month
    - Some OTPs have Intensive Outpatient Groups
  - Identifying relapse triggers
  - Change of lifestyle
    - Avoid criminal activities
    - Gain social skills
    - Gain coping skills
    - Find positive activities
  - Address untreated physical/mental health issues
  - Family counseling when possible/if needed
Scientific literature shows patients on methadone have

- Marked reduction in illicit opioid use
- Reduction in use of other illicit drugs
- Improved physical health
- Improved mental health
- Higher rates of employment
- Marked reduction in criminal activity
- Reduced commercial sex work
- Reduced needle sharing
- Reduce risk for both HIV and Hep C
- Is cost effective: each dollar spent saves around $4-$11 in incarceration costs, hospitalization costs
- Marked reduction in death
  - Patients who leave methadone treatment have 8-fold increase in risk of death
Characteristics of good opioid treatment programs

- Well-educated staff with low turnover and frequent trainings
- Good communication between medical staff, counseling staff, and administrators
- Use evidence-based dosing – no arbitrary limits on dosing, patients encouraged to raise their dose high enough to curb withdrawal and cravings
- Many services under one roof
  - More intense counseling programs available
    - Substance abuse comprehensive outpatient treatment: usually 16 hours per week
    - Substance abuse intensive outpatient program: usually 9 hours per week
  - Primary care
  - Psychiatric care
  - Vocational rehabilitation
- Good therapeutic relationship between staff and patients
Buprenorphine

- Is a unique opioid, man-made
- Long half-life – average of 36 hours
- Fewer medication interactions than methadone
- Still can be fatal if mixed with sedatives like benzodiazepines and alcohol
- Partial opioid agonist
  - Acts on the opioid mu receptors just as morphine, oxycodone, methadone, but it has a weaker action
  - Can still cause euphoria & sedation in an opioid-naïve patient
- It has a high affinity to the receptors
  - It sticks to them vigorously
  - It will kick other opioids off the opioid receptors
  - It will block the action of other opioids given after it
Why buprenorphine is safer than methadone

**Partial vs Full Opiate Mu Agonist**

- **Opiate Effect**
  - Full Agonist (e.g., methadone)
  - Partial Agonist (e.g., buprenorphine)

**Dose of Opiate**
Buprenorphine can be prescribed in two settings:

- Office-based practice (OBOT) under the DATA 2000 act
  - Much less restrictive than care at an opioid treatment program
  - Intended to provide an alternative to the more restrictive opioid treatment program
  - Usually these practices don’t do observed dosing
  - Prescriptions are written, taken to pharmacies to be filled
  - Physician has to have an “X” DEA number
  - Little oversight by other agencies – at present
  - Prescribing physician can require as much counseling or drug screening as they see fit
Buprenorphine prescribed at an opioid treatment program

- Patients are much more closely monitored
- Patients have to follow same restrictive rules as if they were on methadone
- Must do daily observed dosing until patient shows stability
- Counseling and drug screening is built into the system, mandated minimum number of sessions and screens
- Physician doesn’t need an “X” number because it’s dosed under the OTPs DEA number
- No limit on the number of patients that may be treated in this setting, except prescribed limits on ratio of patient:counselor
Advantages of buprenorphine

• Much safer
  • Far less potential to overdose
• Patients report feeling more normal on buprenorphine compared to methadone, less “medicated”
• Stable patients can be treated in an office setting, like patients with any other ailment
  • More flexibility with treatment, can individualize care
• Somewhat less stigma against it than methadone
• Easier to taper off of than methadone for most people
Disadvantages of buprenorphine

• Lower retention in treatment, possibly because the withdrawal is less severe than other opioids
• Expensive
• In some areas, office-based buprenorphine physicians are hard to find
• Not strong enough for all patients with opioid use disorder since its only a partial opioid
• Tricky to start the medication – patient must be in at least moderate opioid withdrawal or they will be put into withdrawal by this medication
• Diversion onto black market has been a growing problem, causing increased stigma in communities
Advantages of medication-assisted treatment with methadone/buprenorphine

• It works... reduces the risk of death from overdose
• Attractive to patients with opioid use disorder because they start to feel better right away
• Can be done as an outpatient
• Cheaper than other treatment in the short term; may end up being more expensive depending on length of treatment
• Patients can pay as they go; no big upfront payment is needed
Should a patient doing well on methadone (or buprenorphine) ever be tapered off this medication?

- Relapse rates for patients who leave medication-assisted treatments are high
  - Multiple studies show rates of 80% and higher relapse to opioids within one year
- Risk of death increases after taper off medication-assisted treatment of opioid use disorder
  - Mortality rates of opioid addicts not on medication-assisted treatments found to be double that of opioid addicts enrolled in MAT (Cornish et. al. BMJ, 2010)
  - Patients who remained on methadone had death rate of 1% per year; those who left methadone treatment had death rate of 8.2% per year. (Zanis et. al., 1997)
  - Twenty percent of patients enrolled in taper arm of buprenorphine study died within in year, compared to none in the maintenance arm of study. (Kakko et. al., Lancet, 2003)
Scientific literature shows that patients who taper off methadone:

- Have higher rates of death due to overdose
- Have higher rates of death from other medical illnesses
- Overall worse physical health and mental health
- Increased risk for suicide
- Increased risk for illicit drug use
- Bottom line: beginning a taper off medication assisted treatment with methadone or buprenorphine should not be done lightly, patient must feel ready, relapse prevention work should be done
When/if to taper off methadone/buprenorphine?

- This is a difficult issue
- Most patients want to taper off this medication due to time, expense, and stigma
- Many patients experience considerable pressure from friends & family to “get off that stuff” even while they are doing well
- “Dead addicts don’t recover”
- Better outcomes with delay of taper until patient
  - Has had “enough” counseling
  - Has had physical and mental health issues addressed
  - Physical pain issues addressed
  - Has received relapse prevention counseling
  - Done the work of recovery
Opioid antagonist treatment of opioid use disorder

- Medications that attach to opioid receptors but do not activate them
  - Have a high affinity for receptors
  - Kick full opioids and partial opioids off the receptor
- Antagonists do not cause euphoria
- Antagonists do not cause addiction
- Any physician can prescribe these, no special training needed
- Have to be started after acute withdrawal is over
Opioid antagonist treatment of opioid use disorder

- Naloxone – active ingredient of Narcan – reverse opioid overdose
- Naltrexone
  - Once daily pill form
  - Depot injectable given monthly
    - Better compliance than daily pill
    - Approved by FDA for opioid use disorder AND alcohol use disorder

![Image of Naltrexone tablets and Vivitrol packaging](image-url)
Naltrexone

• No clear evidence to show naltrexone reduces cravings
  • There is some debate about this
• Less evidence to support efficacy than other MAT
• Not always an easy medication to take
• Side effects include low-grade fatigue, muscle aches, nausea, and depression
• Patients should be started on daily pill form to ensure the patient can tolerate this medication prior to receiving month-long depot form –
  • Pills cost $30-$150/month
  • Vivitrol – costs around $1500 per month
• Covered by Medicaid in NC
Naltrexone

• Biggest limitation - patient must be all the way through acute opioid withdrawal prior to first dose
• Since this medication is not a controlled substance, can be prescribed by any physician, no special licensing or DEA oversight
• Best settings for use:
  • Just prior to release from detoxification unit
  • Just prior to release from incarceration
Feel free to contact me with questions

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• Email: bjana@halfmoonmed.com
• Blog: http://janaburson.wordpress.com
MAT Delivery in NC, OTP Oversight, MAT Access

Smith Worth, Amy Morris, Dede Severino
Smith Worth, SOTA Administrator
Amy Morris, SOTA Field Coordinator
DeDe Severino, Chief

Addictions and Management Operations
Division of MH/DD/SA Services

February 8, 2018
OPDAAC Coordinating Meeting
State Opioid Treatment Authority (SOTA)

Role of the SOTA

• Approval and Disapproval of Programs
• Program monitoring to ensure federal and state regulations are being met
• Quality of Care Standards
• Monitoring of quality of patient assessment, placement, treatment planning
• Ensuring program staffing, services, and operations are adequate
• Adopting and communicating ethical standards
• Working with providers to ensure compliance with relevant agency standards and quality of service delivery
Opioid Treatment Program (OTP)

Office-Based Opioid Treatment (OBOT)

Settings for Outpatient Medication Assisted Treatment (MAT)
NC Office Based Opioid Treatment (OBOT) Prescriber Capacity

OBOT Map 122017

SAMHSA DATA Waivers Counties
Number Patients Certified Per: Total
- 30 - 30
- 30 - 100
- 100 - 305
- 305 - 1,070
- 1,150 - 8,530

12/2017 SAMHSA Data Request
65 OTP
Opioid Treatment Programs/Clinics
• 9 Pending Licensure
• Approximately 18,000 patients in treatment

873 Physicians with OBOT/DATA Waivers
• NC only
• (not including out of state registrations)
OTP Oversight

- 5 Oversight Agencies
- 4 Inspections per year (average)
- 6 State/Federal Laws Regulations
- 1 Federal Guideline
Required Substance Use Disorder Counseling
Required Random Monthly Urine Drug Screens
Required Staff Training and Credentialing
Required Screening for Infectious Disease
Required daily dosing for 90 days and patient is stable

Opioid Treatment Program Standards
Safety

2002, buprenorphine, a partial agonist with an improved safety profile, was approved for limited office use by specially qualified physicians.

Private Physicians may prescribe and dispense buprenorphine in office

Integration

Foundation of OBOT is the concept that OUD is a chronic medical condition, similar to other chronic conditions.

Integrates treatment with the general medical and psychiatric care of the patient.
- Less stigma
- Fewer regulations, more flexibility providing care

Access

Expands availability and access to care

Adds another option in the continuum of care

Purpose of DATA 2000 (OBOT)

Allows a **waivered Prescriber** (DEA “X” number) to **prescribe** an opioid (Buprenorphine) to a patient with an opioid use disorder.

Prescriber Qualifications
- Certified Addiction Medicine or Psychiatry, or
- 8 hours of training by AMA, AAAP, ASAM, AOA, APA
OBOT Inspections

3 Oversight Agencies

0 Routine Inspections per year (for cause)

2 State/Federal Laws

1 ASAM Practice Guideline
NC Opioid Treatment Programs
NC Office Based Opioid Treatment (OBOT) Prescriber Capacity

OBOT Map 12/2017

Samhsa DATA Waivers
 Counties
Number Patients Certified Per County: Total
30 - 30
30 - 100
100 - 305
305 - 1,070
1,070 - 5,930

12/2017 SAMHSA Data Request
## Cost Comparison – Methadone and Buprenorphine/Naloxone

<table>
<thead>
<tr>
<th>Medication</th>
<th>Cost</th>
<th>Average Daily Dose Range</th>
<th>Average Daily Dose</th>
<th>Average Daily/Weekly Cost</th>
<th>Annual Cost Range</th>
<th>Annual Cost Average</th>
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</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>.04 /mg</td>
<td>80 – 120 mgs</td>
<td>100 mgs</td>
<td>$4 per day/$28 per week</td>
<td>$1,164 - $1,747</td>
<td>$1,456</td>
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<tr>
<td>Buprenorphine/Naloxone sublingual tablet</td>
<td>$7/8 mg tablet</td>
<td>8 – 24 mgs</td>
<td>16 mgs</td>
<td>$14 per day/$98 per week</td>
<td>$2,548 - $7,644</td>
<td>$5,096</td>
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</tbody>
</table>
It should be noted that this is an example of a course of treatment. This does not include costs for detox or other clinical treatment codes that could be billed, including other often billed codes such as E&M codes billed by OTP physicians, as well as any type of supported living or recovery housing. Not all individuals will require the enhanced service depicted in months 1 – 3. This example also assumes the same average dose of medication over the course of treatment.

<table>
<thead>
<tr>
<th>Months 1 - 3</th>
<th>Months 4 - 6</th>
<th>Months 7 - 9</th>
<th>Months 10 - 12</th>
<th>Months 13 - 18</th>
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<tbody>
<tr>
<td>H0020 (7 days/ wk x 3 mos.) = $1,494</td>
<td>H0020 (5 days/ wk x 3 mos.) = $1,079</td>
<td>H0020 (4 days/ wk x 3 mos.) = $863</td>
<td>H0020 (3 days/ wk x 3 mos.) = $647</td>
<td>H002 (2 days/ wk x 6 mos.) = $863</td>
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<tr>
<td>H0015 = $4,736</td>
<td>90837 (4/mo. x 3 mos.) = $895</td>
<td>90837 (2/mo. x 3 mos.) = $447</td>
<td>90837 (1/mo. x 3 mos.) = $224</td>
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<tr>
<td></td>
<td>90853 (4/mo. x 3 mos.) = $230</td>
<td>90853 (4/mo. x 3 mos.) = $230</td>
<td>90853 (2/mo. x 3 mos.) = $115</td>
<td>90853 (2/mo. x 6 mos.) = $230</td>
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<tr>
<td>Total Cost = $6,230</td>
<td>Total Cost = $2,204</td>
<td>Total Cost = $1,540</td>
<td>Total Cost = $986</td>
<td>Total Cost = $1,093</td>
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</table>

Grand Total 18 months = $12,053

Grand Total + Methadone ($2,184) = $14,237

Grand Total + Buprenorphine/Naloxone Combo ( $7,644) = $19,697
Thoughts from an OTP Provider

Scott Luetgenau, SouthLight Healthcare
OPIOID TREATMENT PROGRAMS
BACKGROUND ON THE MODEL

SCOTT LUETGENAU, MSW, LCSWA, LCASA
“JUST REMEMBER,
WE’RE ALL IN THIS ALONE…”
BRIAN COON
TREATMENT?
Enter the Criminal Justice System
HEROIN & SYNTHETIC OPIATES KILL ONE AMERICAN EVERY 16 MINUTES
Heroin Use Spikes As Drug Deaths Are Expected To Top 70,000 This Year
trib.al/wGggl4k
My son was KILLED! IN VIETNAM. WHAT FOR? America.
SEVEN DAYS OF HEROIN
18 DEATHS

AT LEAST 180 OVERDOSES

MORE THAN 200 HEROIN USERS IN JAIL

15 BABIES BORN WITH HEROIN RELATED MEDICAL PROBLEMS
In a quarter of US counties, opioid prescriptions exceed one per person

Prescriptions per 100 persons, by county (2015)

Source: Centers for Disease Control and Prevention
© FT graphic Alan Smith, Federica Cocco
OPIOIDS ARE SO POWERFUL...
THEY CHANGE OUR BRAIN CHEMISTRY...
IMPACT OF TREATMENT FOR OPIOID DEPENDENCE ON FATAL DRUG-RELATED POISONING: A NATIONAL COHORT STUDY IN ENGLAND
"If we were to compare people who start a medication to those who don’t, the people who don’t are actually at twice the risk of dying within a year from their opioid use disorder."

Source: HarvardX/OpioidX: The Opioid Crisis in America
RECOVERY

a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential. Recovery is built on access to evidence-based clinical treatment and recovery support services for all populations.

FOUR MAJOR DIMENSIONS OF RECOVERY

• Health
• Home
• Purpose
• Community

Source: Substance Abuse and Mental Health Services Administration
stigma

/stɪmə/

noun

1. a mark of disgrace associated with a particular circumstance, quality, or person.
   "the stigma of having gone to prison will always be with me"

synonyms: shame, disgrace, dishonor, ignominy, opprobrium, humiliation, (bad) reputation
   "the stigma of bankruptcy"
“THE ONLY PERSON WHO IS EDUCATED IS THE ONE WHO HAS LEARNED HOW TO LEARN AND CHANGE.”

CARL ROGERS
OPIOID USE DISORDER

Diagnostic Criteria

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire of unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recovery from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school or home.
6. Continued opioid use despite persistent or recurrent social or interpersonal problems.
7. Important social, occupational, or recreational activities are given up or reduced because of use.
8. Recurrent opioid use in situation in which it is physically hazardous.
9. Continued use despite knowledge of having a persistent physiological or psychological problem.
10. Tolerance, as defined by a need for increased amounts of opioids to achieve the desired effect.
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<th>Level 2</th>
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<th>Level 4</th>
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<td>4TH</td>
<td>5TH</td>
<td>6TH</td>
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<td>180 days</td>
<td>12 months</td>
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***Noncompliance with any of these above areas may result in loss or reduction of take home medication***
SOUTHLIGHT OTP
CLIENT SURVEYS

WHAT ARE WE DOING WELL?
WHAT ARE WE DOING HORRIBLY?
HOW MIGHT WE BEST CHANGE TO SUPPORT YOUR RECOVERY?
TO A MAN WITH A HAMMER
EVERYTHING LOOKS LIKE A NAIL
MARK TWAIN
SOUTHLIGHT OTP
THRESHOLD FOR ENGAGEMENT
ANIMAL THERAPY

ACCEPTANCE & COMMITMENT THERAPY

MEDICATION IN RECOVERY

WOMEN'S PARENTING IN RECOVERY

COPING IN RECOVERY

MEN'S & WOMEN'S GROUPS

READY TO RENT

TIME OF EMPOWERMENT
Wrapping medication-assisted treatment within a dynamic, person/family-centered recovery culture that is supportive of global health and quality of life in long-term recovery...
Questions and Group Discussion

Anna Stein
Wrap up, THANK YOU!, and What’s next

• Next OPDAAC Coordinating Meetings
  – April 12 at NC Healthcare Association
  – May 10
  – August 9
  – October 9
  – November 8

• Next Full OPDAAC Meeting
  – March 16, 2018 at NC State McKimmon’s Center