MAT in the Primary Care Setting

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BACKGROUND

- History of opioid use
- Prevalence & Impact of OUD
- Physiology of opioid use
- MAT for OUD
- Goals of Research
HISTORY OF OPIOID USE

- 1804: Morphine developed in Germany
- 1895: Bayer company markets diacetylmorphine as OTC “heroin”
- 1903: US facing massive heroin crisis
- 1914: Harrison Narcotics Tax Act
- 1924: Heroin Act
- 1990s: Increased lobbying to increase the use of opioids for all pain types
- 2001: Joint Commission “Pain as the 5th vital sign”
- 2017: Opioid Crisis declared a National Public Health Emergency
PREVALENCE & IMPACT OF OUD

- Roughly 1 in 3 U.S. adults reported recent use of Rx opioids in the 2015 National Survey on Drug Use and Health
- Economic Burden of Opioid Crisis: $78.5 billion
- > 115 Americans die daily from opioid overdose
- From 2009 WHO data, USA is 5.1% of the world’s population, but:
  - Consumes 81% of the global oxycodone supply, and
  - Consumes 99% of global hydrocodone supply.

- National Public Health Emergency Status
Opioids defined as “natural and synthetic substances that act at one of the three main opioid receptor systems: μ, κ, and δ”

- **μ (Mu):** reward pathway, analgesia, withdrawal, respiratory depression, euphoria, miosis
  - Secondary messengers (cAMP) acutely decreased with opioid use
  - Chronically upregulated with chronic use
  - Results in tolerance and increased dose needed to achieve similar effect
    - Leads to dependence/OUD
- **κ (Kappa) and δ (Delta):** fewer side effects
  - Research ongoing to find new drugs to work on these receptors
**OPIOID USE DISORDER (OUD)**

- “A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by >2 of the following, occurring in 12-month period”:
  - Opioids taken in *larger amounts* or over a longer period than was intended;
  - A persistent desire or unsuccessful efforts to *cut down or control* opioid use;
  - A great deal of *time is spent* in activities necessary to obtain the opioid, use the opioid, or recover from its effects;
  - *Craving*, or a strong desire or urge to use opioids;
  - Recurrent opioid use resulting in a *failure to fulfill major role obligations* at work, school, or home;
  - Continued opioid use despite having persistent or *recurrent social or interpersonal problems* caused or exacerbated by the effects of opioids;
  - Important social, occupational, or recreational *activities are given up* or reduced because of opioid use;
  - Recurrent opioid use in situations in which it is *physically hazardous*;
  - Continued opioid use *despite knowledge* of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance;
  - *Tolerance*
  - *Withdrawal*
MAT FOR OUD

● Methadone:
  ○ **Full opioid agonist**, used since 1960s
  ○ Also used for severe chronic pain
  ○ May only be dispensed through SAMHSA certified OTP, often dispensed daily
  ○ Risk of hyperalgesia and cardiac arrhythmias

● Buprenorphine:
  ○ **Partial opioid agonist**, used for pain since 1980s and OUD since 2002
  ○ Requires waiver to prescribe
  ○ Different formulations, w/ or w/o naloxone
    ■ If injected (abused), naloxone will induce immediate withdrawal
  ○ Safer and more accessible than methadone

● Naltrexone
  ○ **Full antagonist**, used since 1984
  ○ Not DEA scheduled
  ○ Also used for alcohol use disorder and weight loss
  ○ Long- and short-term formulations
  ○ Recommended for “highly-motivated” patients
GOALS OF RESEARCH

● How can MAT with buprenorphine be better incorporated into the primary care setting?
● What barriers exist in better incorporating MAT into the primary care setting?
● Evaluating strengths and weaknesses of primary care clinics with MAT in the Chapel Hill and surrounding community
● Developing a program plan for a primary care clinic that would like to incorporate MAT
METHODS

- Literature Review
- Key Informant Interviews
- Intervention Mapping
LITERATURE REVIEW

● Searched:
  ○ PubMed, Google Scholar, Cochrane Library, and EmBase

● Purpose:
  ○ Foundational knowledge regarding the pathophysiology, epidemiology, and treatment options of OUD and utilization of MAT
  ○ Examined different implementation models

● 2 systematic reviews:
  ○ Amato et al, 2011:
    ■ Evaluate effectiveness of psychotherapy plus agonist maintenance treatment vs. standard treatment for opioid dependence
  ○ Gowing et al, 2017
    ■ Analyzed differences in treatment outcomes of buprenorphine vs. methadone

■ Also reviewed an AHRQ and multiple treatment protocols
KEY INFORMANT INTERVIEWS

- 6 key informants
  - Interview 1: Clinic 1 - MAT physician, case worker
  - Interview 2: Clinic 2 - MAT Provider
  - Interview 3: Internal Medicine Physician
  - Surveys: 2 Family Medicine providers

- Interview Formats (see Appendix for questions)
  - In-person interviews
  - Surveys

- Primary Care Clinics
  - UNC Aycock Family Medicine
  - Piedmont Health Chapel Hill Community Health Clinic
  - Piedmont Health Prospect Hill Community Health Clinic

- 5 key themes
INTERVENTION MAPPING

- Bartholomew et al:
  - “planning approach based on using theory and evidence as foundations for taking an ecological approach to assessing and intervening in health problems and engendering community participation”
  - 6 Steps
    - Logic model of problem & change
    - Program design, production, implementation and evaluation
RESULTS

- Literature Review Findings
- Key Informant Interview Themes
- Program Plan
LITERATURE REVIEW FINDINGS

- Implementation Models per AHRQ review:
  - See Appendix for remaining models

| Office-Based Opioid Treatment (OBOT) Model | Buprenorphine prescribed by PCPs who complete DATA 2000 waiver training |
LITERATURE REVIEW FINDINGS (continued)

- Systematic Reviews
  - Amato et al, 2011:
    - No statistically significant difference between MAT w/o or w/o psychotherapy
  - Gowing et al, 2017
    - Similar treatment results between buprenorphine and methadone

- AMSTAR Bias Tool used
KEY INFORMANT INTERVIEW THEMES

- Provider awareness and motivation
- Stigma
- Appropriate Patients and Referral Structures
- Adequate Support Staff
- Institutional Buy-In and Cost
PROVIDER AWARENESS & MOTIVATION

- Lack of general awareness regarding MAT
- Time constraints for training
- Fear of negative patient outcomes
- Lack of motivation

Proposed Solutions
- Colleague mentorship
- UNC ECHO
STIGMA

- Stigma against patient population
- “Difficult patients”
- Misinformation regarding addiction
- Proposed Solution
  - Staff training
  - Reframing addiction as a brain disease
APPROPRIATE PATIENTS & REFERRAL STRUCTURES

- Discerning appropriate patients
- Managing complex patients
- Proposed Solutions:
  - Defining scope of MAT practice
  - Defining “appropriate patients”
  - Next level care referrals
Adequate Support Staff

- Potential for larger patient load
- Support to manage new patients
- Proposed Solutions:
  - Development of protocols
  - Educating existing staff
  - Behavioral health resources
  - In-house social worker
INSTITUTIONAL BUY-IN & COST

- Buy-In at all levels
- Fiscal sustainability
- Proposed Solution
  - Financial model development
  - Grants
Step 1: Logic Model of OUD

**Personal determinants:**
- Mental health
- Physical pain/health
- Genetic/physiologic reactions
- Prescription access
- Education
- Employment
- Health insurance
- Religiosity
- Negative life events

**Behavioral factors:**
- Substance use
- Unemployment
- Physical inactivity
- Gang involvement

**Environmental Factors:**
- Relationship-level:
  - Intimate partner
  - Parents/family
  - Household
  - Peers
- Community-level:
  - Living arrangement
  - Workplace
  - School
  - Community norms
- Societal-level:
  - Discrimination
  - Social media
  - Socioeconomic status

**Health Problem:** Opioid Use Disorder
PROGRAM PLAN

Step 2: Plan Objectives

- **Primary goal:**
  - Incorporate MAT into primary care practice

- **Secondary outcomes:**
  - Increasing the number of patients with OUD in remission
  - See Appendix for full list of outcomes

- **Performance objectives:**
  - What needs to be done for outcomes to be met
  - Broken down by ecological level
  - Personal, interpersonal, organizational, community, societal
PROGRAM PLAN

Step 2: Logic Model of the Change

**Change objectives:**
- Treatment of mental health conditions
- Treatment of physical health conditions/chronic pain
- Consideration of genetic/physiologic differences
- Prescription monitoring/appropriate prescribing
- Education
- Gainful employment
- Health insurance coverage
- Encouragement of spiritual fulfillment
- Consideration of negative-life events/trauma-informed care

**Behavioral change outcomes:**
- Prevention/abstinence from substance use
- Gainful employment
- Engagement in physical activity
- Avoidance of gang involvement

**Health Problem Outcome:**
Remission of OUD

**Environmental change outcomes:**
- Healthier, drug-free relationships
- Community-level:
  - Safe living arrangements
  - Drug-free workplace
  - Drug-free schools
  - Involvement in a drug-free community (e.g. AA, NA)
- Societal-level:
  - No discrimination
  - Higher socioeconomic status
PROGRAM PLAN  Step 3 & 4: Design & Production Considerations

- **Potential users:**
  - Primary care practices treating adults w/ OUD
  - >1 provider will offer MAT

- **Model of care:**
  - Recommend Office Based Treatment Model
  - Tailor tx to unique clinic/patient needs

- **Plan addresses clinic issues of implementing MAT**
  - Does not address induction, maintenance or monitoring methods
    - Clinic must decide which induction/monitoring methods
**Step 1**: Develop a **financial model** describing:
1). How a practice will absorb the costs of MAT for financially burdened patients
2). How all aspects of care will be paid for without any sunken costs

**Step 2**:  
1). Hire in-house social worker or psychologist  
OR  
2). Develop relationship with local **behavioral health professional** such that patients can obtain services in a timely manner.

**Step 3**: Host **in-house information session for providers** discussing MAT and OUD

**Step 4**: Host **in-house buprenorphine DATA 2000 waiver training** session for interested providers
### PROGRAM PLAN

#### Step 5: Implementation Plan (continued)

<table>
<thead>
<tr>
<th>Step 5</th>
<th>Potential MAT providers <strong>review current patients</strong> and determine which may benefit from MAT</th>
</tr>
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<tbody>
<tr>
<td>Step 6</td>
<td>Practice/providers <strong>determine if new patients will be accepted</strong> for MAT treatment. If so: 1). Develop screening process for determining which patients will be accepted. 2). Determine who will conduct screening (behavioral health provider or MAT provider)</td>
</tr>
<tr>
<td>Step 7</td>
<td>Host <strong>in-house informational session for support staff</strong> discussing OUD, MAT and potential changes in clinic functioning</td>
</tr>
<tr>
<td>Step 8</td>
<td>1). Providers <strong>begin to offer MAT</strong> to current patients deemed appropriate AND 2). Begin accepting new patients for MAT, at clinic/provider discretion</td>
</tr>
<tr>
<td>Step 9</td>
<td>Clinic <strong>periodically evaluates effectiveness</strong> of its MAT program and makes adjustments to workflow as necessary</td>
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Program Plan Step 6: Program Evaluation Methods

- Annually
- All providers/staff involved complete a survey addressing following indicators:
  - # patients receiving MAT
  - Patient success
    - See Appendix for full list of success indicators
  - Provider effectiveness, success and barriers
  - Staff perception of success and barriers
- Practice should also evaluate economic health of the program, make changes as necessary
SUMMARY & IMPLICATIONS

- Potential Barriers
- Implications for Patients & Practice
- Future Research
POTENTIAL BARRIERS

- **Economic Barriers**
  - Insurance Reimbursement
  - Internal Clinic Cost
  - In-House Behavioral Medicine
  - Patient Costs (uninsured, underinsured)

- **Lack of Awareness**
  - Patient
  - Provider

- **Insufficient nursing support**
- **Insufficient office support**
- **Lack of Institutional support**
- **Pharmacy issues**
- **Low demand**
- **Office staff stigma**
- **Limited Access to Facilities**
IMPLICATIONS FOR PATIENTS & PRACTICE

● Implications for patients
  ○ Remission of OUD
  ○ Increased interaction w/ healthcare system
    ■ Preventative health measures and chronic issues addressed

● Implications for practice
  ○ Clinic needs to decide induction method (home vs. in-clinic) and monitoring protocols
  ○ Diversion of prescribed medication
    ■ An issue anytime prescribing narcotics
    ■ Needs further research
      • Methadone tx includes diversion control plans
  ○ Increased psychiatric care in primary care setting
    ■ Some providers may not be comfortable with this
FUTURE RESEARCH

- Telemedicine for MAT maintenance visits
- Comparison of Patient Outcomes among MAT models
- Management of Patients with OUD and Concomitant Chronic Pain Disorders
- Efficacy of Longer-Term Medication Formulations
  - Implantable and Injectable Buprenorphine
- Economic models
- Quality Improvement/ Evaluation Models for MAT
- Cultural barriers and variations
- Maternal OUD MAT
SPECIAL THANKS!

All of our Key Informants!

- Our first reader: Paul Chelminski, MD, MPH
- Our second reader: Sara Koenig, MD, MBA
- Kim Faurot, PA-C, PhD, MPH
- Janelle Bludorn, PA-C
QUESTIONS?
<table>
<thead>
<tr>
<th>Clinic Perspective</th>
<th>Interview Questions</th>
</tr>
</thead>
</table>
| Has implemented MAT     | 1. How and when was MAT implemented at this clinic?  
|                         | 2. What models did this clinic consider in the early stages?  
|                         | 3. What model does this clinic follow?  
|                         | 4. What were the barriers to implementing MAT at this clinic?  
|                         | 5. How did the clinic overcome these barriers (if able)?  
|                         | 6. What were some factors that contributed to the clinic’s success?  
|                         | 7. In addition to the SAMHSA DATA 2000 waiver requirement to be able to prescribe buprenorphine, are there any additional requirements to prescribe at this clinic?  
|                         | 8. Have there been any barriers to providers becoming licensed to prescribe buprenorphine?  
|                         | 9. What do you think is the biggest reason providers choose to/not to become licensed?  
|                         | 10. Have you noticed stigma around MAT (among providers, staff or other patients) to be an issue at the clinic?  
|                         | 11. What is the biggest strategic barrier to incorporating MAT patients into this clinic?  
|                         | 12. How is insurance coverage for these services?  
|                         | 13. What have the results been like for patients at this clinic?  
|                         | 14. Are there restrictions on the types of patients accepted by the clinic (e.g. no psychiatric comorbidities, only OUD, etc.)?  
|                         | 15. What feedback have you received from providers regarding implementing MAT at the clinic?  
|                         | 16. What behavioral health resources are a part of this clinic’s program?  
|                         | 17. What role does social work/care management play in this clinic’s program?  
|                         | 18. Is there an educational/outreach component (among patients, providers, and/or staff) to the program? |

| Has not yet implemented MAT | 1. What barriers do you anticipate facing in incorporating MAT into practice?  
|                           | 2. How do you plan to overcome the aforementioned barriers?  
|                           | 3. What factors do you anticipate will contribute to the clinic’s success?  
|                           | 4. What model of MAT is the clinic considering?  
|                           | 5. Have any providers completed the training to prescribe buprenorphine as of yet, or do any plan on becoming waivered within the next 6 months?  
|                           | 6. What do you think is the biggest reason providers choose to/not to become licensed to prescribe buprenorphine?  
|                           | 7. Does the clinic plan on placing restrictions on the types of patients it will accept (e.g. no psychiatric comorbidities, only OUD, etc.)?  
|                           | 8. What feedback have you gotten from providers regarding plans to implement MAT at the clinic?  
|                           | 9. What behavioral health resources will be incorporated into the program?  
|                           | 10. What role will social work/care management play in the program?  
|                           | 11. Do you anticipate there being an educational/outreach component (among patients, providers, and/or staff) to the program? |
**IMPLEMENTATION MODELS PER AHRQ REVIEW**

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Office-Based Opioid Treatment (OBOT) Model</strong></td>
<td>Buprenorphine prescribed by PCPs who complete DATA 2000 waiver training</td>
</tr>
<tr>
<td><strong>Massachusetts Nurse Care Manager Model</strong></td>
<td>Primary care–based model in which nurse care managers perform initial screening, intake, education, observed/supports induction, follow-up, maintenance, stabilization, and medical management with provider</td>
</tr>
<tr>
<td><strong>Hub and Spokes Model</strong></td>
<td>Centralized intake and initial management (buprenorphine induction) at “hub”; patients then connected to “spokes” in community for ongoing management</td>
</tr>
<tr>
<td><strong>ED Initiation of OBOT</strong></td>
<td>ED identification of OUD; buprenorphine–naloxone induction initiated in ED; coordination with OBOT, nurse with expertise in buprenorphine working in collaboration with PCP</td>
</tr>
</tbody>
</table>
## Patient Suitability for Office-based Opioid Treatment Versus Opioid Treatment Program*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>OBOT**</th>
<th>OTP*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can an office-based setting provide needed resources?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Patient’s psychosocial supports</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Co-occurring psychiatric disorders</td>
<td>Stable</td>
<td>Unstable</td>
</tr>
<tr>
<td>Dependence on CNS depressants</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Previous failed treatment attempts w/ opioid agonists</td>
<td>None/Few</td>
<td>Many</td>
</tr>
<tr>
<td>Response to sublingual buprenorphine in the past</td>
<td>Good</td>
<td>Poor</td>
</tr>
<tr>
<td>Expected to be reasonably compliant in treatment</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Co-occurring serious pain syndromes (especially those requiring opioids)</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Opioid Treatment Program (OTP): methadone and buprenorphine
**Office-based Opioid Treatment (OBOT): buprenorphine

# PROGRAM PLAN

## Step 2: Plan Objectives

<table>
<thead>
<tr>
<th>Ecological Level</th>
<th>Expected Outcomes</th>
<th>Performance Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal behavioral</td>
<td>Patients...[Abstain from recreational substance use]</td>
<td>Patients...[Make the decision to seek treatment for substance use disorder]</td>
</tr>
<tr>
<td></td>
<td><em>Engage in behaviors that promote their sobriety</em> (e.g., individual/group therapy, 12-step program, etc...)</td>
<td><em>Have transportation/access to treatment center and pharmacy</em></td>
</tr>
<tr>
<td></td>
<td><em>Take buprenorphine at prescribed dose and frequency</em></td>
<td><em>Have the financial means/insurance to afford treatment</em></td>
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<tr>
<td></td>
<td></td>
<td><em>Avoid places, people and triggers that may lead them to engage in substance use</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Have a support system that assists them in maintaining sobriety</em></td>
</tr>
<tr>
<td>Interpersonal environmental</td>
<td><em>Intimate partners/family members support patients in abstaining from substance use and in adhering to buprenorphine treatment</em></td>
<td><em>Intimate partners/family members/peers do not use recreational substances</em></td>
</tr>
<tr>
<td></td>
<td><em>Peers do not encourage substance use</em></td>
<td></td>
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<table>
<thead>
<tr>
<th>Organizational environmental</th>
<th>At healthcare facilities...</th>
<th>At healthcare facilities...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Policies, programs, and facilities exist to assist substance-dependent people in achieving and maintaining sobriety</em></td>
<td><em>MAT is offered at primary care clinics</em></td>
</tr>
<tr>
<td></td>
<td><em>Providers have been waiver-trained to provide buprenorphine treatment</em></td>
<td><em>Providers have been waiver-trained to provide buprenorphine treatment</em></td>
</tr>
<tr>
<td></td>
<td><em>A behavioral medicine specialist (e.g., social worker, psychologist, etc...) is available as needed (e.g., at the clinic, by referral, etc...)</em></td>
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</tr>
<tr>
<td></td>
<td><em>Staff has been trained to assist substance-dependent patients</em></td>
<td><em>Staff has been trained to assist substance-dependent patients</em></td>
</tr>
<tr>
<td></td>
<td><em>Policies and procedures have been developed specifically for MAT at the clinic</em></td>
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</tr>
</tbody>
</table>

| Community environmental     | *Care for substance use disorder is easily accessible to patients*                | *MAT is available at primary care clinics, as opposed to solely by specialty practitioners* |
|                             | *Health ordnances encourage treatment of substance use disorders*               |                                           |
|                             | *Community groups exist that encourage sobriety (e.g. group therapy, 12-step groups)* |                                           |
|                             | *Substance use disorder is not stigmatized, but instead viewed as a treatable illness* |                                           |

| Societal environmental      | *Legislation, law enforcement and regulations encourage rehabilitation and treatment of substance use disorders* | *Funding is available for clinics offering MAT*                                       |
|                             | *Resources are allocated for rehabilitation and treatment*                      |                                           |
|                             | *Policies, programs, and facilities exist to assist substance-dependent people in achieving and maintaining sobriety* |                                           |
Step 6: Program Evaluation Methods

**Patient success indicators**
- Abstinence from opioid use, as measured by urine drug screen
- Compliance with buprenorphine treatment, as measured by urine drug screen
- Involvement in treatment, as measured by attendance rate for medication-management appointments and for behavioral health appointments
- Patient well-being, measured by provider perception, patient self-report, patient employment status

**Provider effectiveness, success and barriers indicators**
- Number of MAT visits per evaluation period
- Estimated or calculated length of average MAT visit
- Provider perception of success
- Provider report of barriers faced

**Staff perception of success and barriers**
WORK CITED

- Opioid overdose crisis, Revised March 18. Available at: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis
WORK CITED (continued)

● UpToDate. Available at: https://www.uptodate.com/contents/pharmacotherapy-for-opioid-use-disorder?search=methadone%20to%20suboxone&source=search_result&selectedTitle=1~123&usage_type=default&display_rank=1. Accessed April 8, 2018.


● Primary Care. Available at: https://www.aafp.org/about/policies/all/primary-care.html. Accessed April 8, 2018.


WORK CITED (continued)


