Clinical Support for Mentoring for Medication Assisted Treatment (MAT)

National Council for Behavioral Health Conference
Washington DC
May 5, 2014

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Funding for this initiative was made possible (in part) by Providers’ Clinical Support System for Medication Assisted Treatment (1U79TI024697) from SAMHSA.

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Disclosures

Daniel Alford
- No Relevant Financial Relationships with Any Commercial Interests

Colleen LaBelle
- No Relevant Financial Relationships with Any Commercial Interests

Prescription Opioid Abuse
Common Path to Heroin

80% of individuals who reported that they began using heroin in the past year had previously abuse prescription pain medications

Kuehn BM. JAMA 2013; 310:1433
1% of US population has tried heroin, of those ~23% become dependent. Currently ~370,000 with heroin dependence

Natural History of Opioid Dependence

Withdrawal Normal

Euphoria

Tolerance & Physical Dependence

Acute use Chronic use
Conflicting Priorities...

Opioid Detoxification Outcomes

- Low rates of retention in treatment
- High rates of relapse post-treatment
  - < 50% abstinent at 6 months
  - < 15% abstinent at 12 months
  - Increased rates of overdose due to decreased tolerance

O’Connor PG JAMA 2005
Mattick RP, Hall WD. Lancet 1996
Stimmel B et al. JAMA 1977
Reasons for Relapse

• Protracted abstinence syndrome
  • Secondary to derangement of endogenous opioid receptor system
• Symptoms
  • Generalized malaise, fatigue, insomnia
  • Poor tolerance to stress and pain
  • Opioid craving
• Conditioned cues (triggers)
• Priming with small dose of drug

Medication Assisted Treatment

• Goals
  • Alleviate physical withdrawal
  • Opioid blockade
  • Alleviate drug craving
  • Normalized deranged brain changes and physiology
• Some options
  • Naltrexone (opioid antagonist)
  • Methadone (full opioid agonist)
  • Buprenorphine (partial opioid agonist)
Medication Assisted Treatment

- Acute use
- Chronic use

Tolerance & Physical Dependence

Withdrawal

Euphoria

Medication Assisted Treatment

Opioid Potency

<table>
<thead>
<tr>
<th>% Efficacy</th>
<th>Full Agonist Methadone</th>
<th>Partial Agonist Buprenorphine</th>
<th>Full Antagonist Naltrexone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid effect, sedation, respiratory depression</td>
<td>Log Dose of Opioid</td>
<td></td>
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</tbody>
</table>

- Full Agonist
- Partial Agonist
- Full Antagonist
Naltrexone

- Pure opioid antagonist
- Oral naltrexone
  - Well tolerated, safe
  - Duration of action 24-48 hours
  - FDA approved 1984
- Injectable naltrexone (Vivitrol®)
  - IM injection (w/ customized needle) once/month
  - FDA approved 2010
  - Patients must be opioid free for a minimum of 7-10 days before treatment

Oral Naltrexone

- 10 RCTs ~700 participants to naltrexone alone or with psychosocial therapy compared with psychosocial therapy alone or placebo
  - No clear benefit in treatment retention or relapse at follow up

- Benefit in highly motivated patients
  - Impaired physicians > 80% abstinence at 18 months

Cochrane Database of Systematic Reviews 2006
Injectable Naltrexone (XR-NTX)

- Multicenter (13 sites in Russia-OAT unavailable)
- DB RPCT 24 weeks
- N=250 with opioid dependence randomized to XR-NRT vs placebo
- All offered biweekly individual drug counseling
- Funded by pharmaceutical company - Alkermes

<table>
<thead>
<tr>
<th></th>
<th>XR-NTX (n=126)</th>
<th>Placebo (n=124)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary endpoint</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of weeks of confirmed abstinence</td>
<td>90.0% (69.9 to 92.4)</td>
<td>35.0% (11.4 to 63.8)</td>
</tr>
<tr>
<td>Patients with total confirmed abstinence</td>
<td>45 (35-7, 27.4 to 44.1)</td>
<td>28 (22.6, 15.2 to 29.9)</td>
</tr>
<tr>
<td><strong>Secondary endpoint</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of self reported opioid free days over 24 weeks</td>
<td>99.2% (89.1 to 99.4)</td>
<td>50.4% (46.2 to 94.0)</td>
</tr>
<tr>
<td>Craving: mean change in VAS score from baseline</td>
<td>-10.1 (-12.3 to -7.8)</td>
<td>-0.7 (-3.1 to 4.4)</td>
</tr>
<tr>
<td>Number of days of retention</td>
<td>&gt;1681</td>
<td>96 (63 to 105)</td>
</tr>
</tbody>
</table>


Methadone Hydrochloride

- Full opioid agonist
- PO onset of action 30-60 minutes
- Duration of action
  - 24-36 hours to treat opioid addiction
  - 6-8 hours to treat pain
- Proper dosing for opioid addiction
  - 20-40 mg for acute withdrawal
  - > 80 mg for craving, “narcotic blockade”
Methadone Maintenance
Still controversial...

Methadone Maintenance Treatment
Highly Structured

- Daily nursing assessment
- Weekly individual and/or group counseling
- Random supervised toxicology screens
- Psychiatric services
- Medical services
- Methadone dosing
  - Observed daily ⇒ “Take homes”
In a Comprehensive Rehabilitation Program...

- Increases overall survival
- Increases treatment retention
- Decreases illicit opioid use
- Decreases hepatitis and HIV seroconversion
- Decreases criminal activity
- Increases employment
- Improves birth outcomes

Methadone Treatment Marks 40 Years

FORTY YEARS AND COUNTLESS POLITICAL FIRESTORMS AFTER IT WAS FIRST INTRODUCED, METHADONE MAINTENANCE FOR THE TREATMENT OF OPIOID ADDICTION REMAINS A STANDARD THERAPY IN THE FIELD OF ADDICTION TREATMENT.

The publication on August 23, 1965, of positive results from a small clinical trial of methadone as a treatment for heroin addiction in JAMA marked a sea change in the treatment of addiction (Dole and Nyswender. JAMA. 1965. 193:696-697). The study, conducted at Rockfeller University in New York City by Vincent P. Dole, MD, and the late Marie E. Nyswender, MD, suggested that a medication could be used to control the cravings and withdrawal that often lead to relapse in individuals with opioid addiction who attempt to quit.

The work, along with subsequent research by Dole, an endocrinologist, Nyswender, a psychiatrist, and colleagues established the concept of opioid addiction as a chronic disease, similar in nature to other chronic diseases treated with medications.

The new head of the Laboratory of the Biology of Addictive Diseases at Rockfeller University, explained that work conducted by the group in 1966 established that methadone blocked the effects of heroin and stabilized patients, who prior to treatment oscillated between feeling good on the high of heroin and sick on the low of withdrawal.

Methadone maintenance therapy is a program that helps people with opioid addiction to reduce or stop their drug use. It is a method of treatment that involves taking a medication called methadone, which is an opioid that produces effects similar to those of heroin.

The Methadone Maintenance Program was established under the Narcotic Addict Treatment Act of 1974 (NATTRA), which created a separate system of care for opioid addiction that was not part of the traditional medical system.

The program has been criticized for being highly regulated, with strict rules and regulations that can make it difficult for people to enroll or stay in the program. Despite these limitations, the program has been successful in helping many people overcome opioid addiction and live healthy lives.

Methadone Maintenance Limitations

- Highly regulated - Narcotic Addict Treatment Act 1974
  - Created methadone clinics (Opioid Treatment Programs)
  - Separate system not involving primary care or pharmacists
- Limited access
- Inconvenient and highly punitive
- Mixes stable and unstable patients
- Lack of privacy
- No ability to “graduate” from program
- Stigma
DATA 2000 and Buprenorphine

2000: Drug Addiction Treatment Act (DATA) 2000

- Allows qualified physician to prescribe scheduled III - V narcotic FDA approved for opioid maintenance or detoxification treatment limit 30 patients per practice

2002: Suboxone and Subutex FDA approved

2005: Limit to 30 patients per physician

2007: Limit to 100 patients per physician after 1 year

Buprenorphine

- Buprenorphine (Subutex or generic) “mono”
- Buprenorphine + naloxone (Suboxone)“combo”
  - Schedule III
  - Sublingual tablets, film
  - Treatment of opioid dependence
  - High receptor affinity
  - Slow dissociation
  - Ceiling effect for respiratory depression
Buprenorphine Efficacy

• Studies (RCT) show buprenorphine more effective than placebo and equally effective to moderate doses (80 mg) of methadone on primary outcomes of:
  • Abstinence from illicit opioid use
  • Retention in treatment
  • Decreased opioid craving

Johnson et al. NEJM 2000
Fudala PJ et al. NEJM 2003

Provider Clinical Support System for Medication Assisted Treatment PCSS-MAT

• National training and mentoring project developed in response to:
  • prescription opioid misuse epidemic
  • underutilization of medications for opioid use disorders
• The goal is increase availability of MAT in a variety of settings, including primary care, psychiatric care, and pain management settings.
• Funded by SAMHSA
PCSS-MAT Goals & Objectives

- **Develop**...a comprehensive electronic repository of training materials and educational resources to support evidence-based treatment of opioid dependence

- **Create**...a mentoring program to provide guidance, direction and advice to help prescribers and key health professionals who are new to the field of Medication Assisted Treatment

- **Continue**...to offer waiver training for physicians interested in providing buprenorphine treatment under the DATA 2000.

PCSS-MAT Team

- **Lead Organization**
  - American Academy of Addiction Psychiatry (AAAP)

- **Partner Organizations**
  - American Osteopathic Academy of Addiction Medicine (AOAAM)
  - American Psychiatric Association (APA)
  - American Society of Addiction Medicine (ASAM)

- **Affiliate Partner**
  - Association for Medical Education and Research in Substance Abuse (AMERSA)
Clinical Expert Panel

- AAAP Chair: Maria Sullivan, MD, PhD
- AOAAM: Steven Wyatt, DO
- APA: John Renner, Jr., MD
- ASAM: Daniel Alford, MD, MPH
- AMERSA: Colleen LaBelle, BSN,RN-BC

Training Formats

- Clinical Online Modules
- Webinars
- Case Vignettes
- Half and Half Buprenorphine Training
- Live Buprenorphine Training
- Listserv
- Clinical tools for practicing clinicians
- Mentoring
Mentoring Program

- Mentoring aimed at improving providers confidence in use of MAT to treat opioid use disorders
- Does NOT include clinical supervision of individual patients

- Adam Bisaga, M.D., Chair
  - AAAP—Andrew Saxon, M.D.
  - APA-----John Renner, M.D.
  - ASAM---Edwin Salsitz, M.D., Dawn Howell
  - AOAAM-William Morrone, D.O.
  - AMERSA-Erik Gunderson, M.D.

Mentoring Levels

Level 1: Ask a Question
Level 2: Ad-Hoc Mentoring
Level 3: In-Depth Mentoring
Level 1 Mentoring

- Ask a Question
  - Prompt Response to a “Simple” Question
  - FAQs will often provide answer—will be directed to site by admin.
  - Listserve for mentors and mentees—to be utilized if information not available on FAQs
  - MOC—Mentor On Call. One month rotation by organization. Monitor the listserve, and respond promptly. Admin. Monitoring
  - Website Referrals

Level 2 Mentoring

- Brief Mentoring
  - Provide individualized guidance to discuss specific questions related to more complex clinical situations e.g. logistics of practice, pregnant patient, pain issue
  - Involves a number of interactions; phone, email
  - Mentoring relationship may be maintained over long time period
  - After Admin. matches, mentor expected to contact mentee within 3 business days
  - M & M fill out mentoring and confidentiality agreement
  - F/U to confirm if advice was helpful.
Level 3 Mentoring

• In-Depth Mentoring
  ▪ Expected to last at least 6 months, with regularly scheduled interactions. e.g., expand practice to patients with mental illness, institute IM NTX., HepC
  ▪ M & M agree to statement of confidentiality
  ▪ M & M complete mentoring agreement
  ▪ At least monthly contacts
  ▪ F/u to verify if goals achieved

PCSS-MAT Mentoring Program

Mentors

• Live Mentor Training Shelved for Now
• Web Based Trainings May Become Available
• Potential Mentor Fills Out Application Form on PCSS-MAT website.
• Hopefully the mentors will be a diverse group
• Mentor supplies Brief Bio. And Photo for Website
• Availability: 2-3 hours/month
PCSS-MAT Mentoring Program
Mentees

- Apply on Website
- Specialty, Organization, Level of Mentoring Requested, Areas of Interest
- Admin is “Matchmaker”
- Mentee Can Choose Mentor
- Mentor Can Decline (Politely)

Executive Committee

Mission: improve health and well-being through interdisciplinary leadership in substance use education, research, clinical care and policy

Founded in 1976 by members of the Career Teachers Program, a multidisciplinary health professional faculty development program supported by NIAAA and NIDA

Over 300 members representing physicians, nurses, social workers, psychologists, pharmacologists, dentists, and other professionals
AMERSA’s Scope of Work

- Online Modules with Case Vignettes
- Workshops and Symposium
- Mentoring
- Outreach and Promotion

AMERSA’s Online Module Topics

1) Overdose Prevention and Narcan Administration
2) Counseling and MAT better outcomes with integrated care
3) Role of Office based Opioid Treatment (OBOT) in Federally Qualified Community Health Centers (FQHCs)
4) Models of Induction
AMERSA’s Mentoring Program

- Develop a plan to include professionals who are non prescribers in the mentoring plan—both as mentors and mentees.
  - Health professionals of diverse disciplines
- Members mentor other health professionals interested in becoming teachers, researchers and clinicians in addiction field
- Multidisciplinary with primary care focus

Clinical Online Modules

- Enhance professionals’ knowledge, skills and attitudes regarding safe and effective use of MAT
- Increase the flexibility of approaches for providers working in traditional treatment models to allow implementation of the medical model of addiction management, recognizing the importance of pharmacotherapy as the most effective strategy to prevent relapse to opioid dependence

New Free Online Module with 1 AMA PRA Category 1 credit™
• ASAM is a professional society representing over 3,000 physicians and associated professionals dedicated to
• increasing access and improving the quality of addiction treatment;
• educating physicians, other medical professionals and the public;
• supporting research and prevention; and
• promoting the appropriate role of physicians in the care of patients with addictions.

ASAM’s Scope of Work

• Content focus targeted to Primary Care and Ob/Gyn
• Online Modules with Case Vignettes (10/year)
• Buprenorphine Trainings
  ▪ One 8 hour live training
  ▪ Four ½ and ½ trainings
• Workshops and Symposium
  ▪ One per year at national meetings
• Mentoring
• Outreach and Promotion
PCSS-MAT
ASAM Year 1 Online Module Topics

1) Managing co-occurring addictions
2) MAT in the OTP Settings
3) Challenges of working with payers
4) Billing and coding for MAT
5) MAT during pregnancy
6) Substance use screening education and counseling in OB
7) Fetal/neonatal issues with MAT
8) Stigma issues in methadone maintenance
9) Acute and chronic pain in patients maintained on bup
10) Urine drug testing in office-based settings

PCSS-MAT Website

Home Page:

Mentoring Page:
How to Connect to PCSS-MAT

- View Online Modules
- Find or Become a Mentor
  - [http://pcssmat.org/mentoring/](http://pcssmat.org/mentoring/)
- Attend or Watch a Webinar
  - [http://pcssmat.org/education-training/webinars/](http://pcssmat.org/education-training/webinars/)
- Stay in the Loop – sign up for current news
  - [http://pcssmat.org/resources/whats-new/](http://pcssmat.org/resources/whats-new/)
- Browse Resources

Questions?

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