Medication Assisted Treatments for Opioid Dependence & Barriers to Implementation

9th Annual Midwest Conference on Problem Gambling and Substance Abuse

Erin L. Winstanley, Ph.D.

University of Cincinnati College of Medicine, Department of Psychiatry & Behavioral Neuroscience & the Ohio Valley Node of the NIDA Clinical Trials Network
NIDA CTN

Goals:
1. Bridge the gap between research and practice
2. Conduct clinical trials
3. Disseminating evidenced-based treatment to community treatment programs

- 13 Nodes across the country
- 6 active studies
- Enrolled 14,647 study participants
OVN NIDA CTN

Ohio Valley Node

NIDA CTN

Community Treatment Programs

15 States
23 Programs

States having Ohio Valley Node CTPs (N=15)

Ohio Valley Node RRTC

Ohio Valley Node CTP (N=23)
“The CTN has done a remarkable job translating our research and involving and integrating scientists from multiple backgrounds. It is flexible so as to engage the right people and facilitate their working together to hone research-based treatments and get our best science out to the field.”

—NIDA Director Nora Volkow, M.D. (address to NIDA Council, Feb. 2010)
**Figure 5. Percentage of prescription drugs used most often, by drug type and age group: United States, 2007–2008**

<table>
<thead>
<tr>
<th>Age group and drug type</th>
<th>0-11</th>
<th>12-19</th>
<th>20-59</th>
<th>60 and over</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children aged 0–11</td>
<td>3.7</td>
<td>3.9</td>
<td>5.7</td>
<td></td>
</tr>
<tr>
<td>Penicillins (treat infections)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leukotriene modifiers (asthma, allergies)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bronchodilators (asthma)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adolescents aged 12–19</td>
<td>4.8</td>
<td>5.4</td>
<td>8.4</td>
<td>19.9</td>
</tr>
<tr>
<td>Antidepressants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bronchodilators (asthma)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CNS stimulants (attention deficit disorder)</td>
<td>6.1</td>
<td></td>
<td></td>
<td>26.4</td>
</tr>
<tr>
<td>Adults aged 20–59</td>
<td></td>
<td></td>
<td></td>
<td>44.9</td>
</tr>
<tr>
<td>Cholesterol lowering drugs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analgesics (pain relief)</td>
<td>10.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antidepressants</td>
<td>10.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Older adults aged 60 and over</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diuretics (high blood pressure, heart disease)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ß-blockers (high blood pressure, heart disease)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol lowering drugs</td>
<td>19.9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTES:** Primary indication for the use of the drug class is in parentheses. CNS is central nervous system. SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.
Prescription Drugs of Abuse

1. Opioids (for pain)
   a) Hydrocodone (Vicodin®)
   b) Oxycodone (OxyContin®)
   c) Propoxyphene (Darvon®)
   d) Hydromorphone (Dilaudid®)
   e) Meperidine (Demerol®)
   f) Diphenoxylate (Lomotil®)

2. Central nervous system depressants (for anxiety and sleep disorders)
   a) Pentobarbital sodium (Nembutal®)
   b) Diazepam (Valium®)
   c) Alprazolam (Xanax®)

3. Stimulants (for ADHD and narcolepsy)
   a) Dextroamphetamine (Dexedrine®)
   b) Methylphenidate (Ritalin® and Concerta®)
   c) Amphetamines (Adderall®)

SOURCE: NIDA Research Report, NIH Pub. #05-4881
**National Data**

**Prevalence**
- 20% (28 mil.) persons reported lifetime use
- 2.8% (7 mil.) persons reported past month use
- From 2002 to 2009, there was an increase (5.5% to 6.3%) among young adults aged 18 to 25 reports of current use

**Source of Drugs**
- Over half get their drugs from a friend or relative for FREE
- 17.6% report getting the drugs as a prescription from a doctor
- 4.8% got the drugs from a dealer or stranger

**SOURCE:** SAMHSA, NSDUH 2009 & NIDA Research Report, NIH Pub. #05-4881
Consequences

• Medical
• Psychiatric
• Social
• Family
• Criminal

41 People die every day pain pill overdose

Source: CDC Policy Impact Prescription Drug Overdoses, 2011
Defining Addiction

American Society of Addiction Medicine (ASAM)’s Definition:

Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry.

Addiction is characterized by:

- Inability to consistently abstain;
- Impairment in behavioral control;
- Craving; or increased “hunger” for drugs or rewarding experiences;
- Diminished recognition of significant problems with one’s behaviors and interpersonal relationships; and
- A dysfunctional emotional response.

Source: www.asam.org
Pharmacotherapy should be a standard component of treatment for SUD when effective drugs exist

- American Medical Association (AMA)
- American Psychiatric Association
- National Institute on Drug Abuse (NIDA)
- National Quality Forum
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- Veteran’s Administration

SUD= substance use disorders
EBPs for Opioid Dependence?

**Medication (detox):**
- Methadone
- Clonidine
- Benzodiazepines
- Buprenorphine (Suboxone)

**Medication (maintenance):**
- Methadone
- Buprenorphine
- Naltrexone (ReVia/Vivitrol)

**Psychosocial:**
- Cognitive Behavioral Therapy
- Contingency Management
- Brief Medication Management
- Individual & group counseling

Detox Meds + Maint. Meds + Psychosocial
Medications can be used to/for:

- Detoxification
- Decrease withdrawal symptoms/cravings
- Decrease reinforcing effects of drugs
- Prevent relapse
- Treat co-occurring psychiatric disorders
Methadone

- Mu opioid agonist with long half-life, prevents withdrawal, craving, and high

- Dose: Typically 60 – 120 mg, highly regulated and only provided by licensed narcotic treatment programs

- Side effects: sedation, constipation, sweating, arrhythmia; can cause QTc interval prolongation

- Results: Highly effective – reduces illicit opioid use, criminal activity, spread of HIV, death due to overdose
Naltrexone

- Mu-opioid antagonist prevents high

- Dosing: 100 mg on Monday and Wednesday and 150 on Friday orally or 380 mg IM

- Side effects: nausea, anxiety, dysphoria, insomnia, sedative effects, can have hepatic effects (increased LFTs); used with caution in patients with liver disease, contraindicated for acute hepatitis or liver failure

- Effectiveness: Decreases opioid use in compliant patients, reduces craving (Vivitrol study)
High affinity partial mu opioid agonist and kappa-opioid antagonist prevents withdrawal, high, reduces craving; advantage: very low risk from overdose.

Dose: Typically 12-16 mg/day, initiated while patient is in mild to moderate withdrawal, prescribed by physicians who have completed a certification process.

Formulations: Buprenorphine only (Subutex), combined with naloxone (4:1; Suboxone).

Side effects: Constipation, drowsiness, headache.

Results: Very effective in reducing illicit opioid use.
NIDA CTN: POATS

- Multi-site, two-phase adaptive, sequential treatment design
- 10 Community-based treatment programs
- Prescription opioid dependence, excluded prominent heroin use
- Included subjects with chronic pain
- Psychiatrically stable
- All subjects received bup/nx (8mg-32mg)

**Online First**
Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence
A 2-Phase Randomized Controlled Trial
Naloxone Hydrochloride

- Reverses: respiratory depression, sedation & hypotension
- Dose 1 mg/ml, onset within 2 minutes
- Injectable & intranasal formulation
- Limited access
Sublingual formulations of buprenorphine have been associated with diversion

A subcutaneous implant that delivers buprenorphine for 6 months, reduces risk of diversion, improves compliance, and reduces buprenorphine dose; maintains opioid tolerance, protects against inadvertent opioid overdose for 6 months

Phase-III trial revealed probuphine, relative to placebo, significantly improved treatment retention and reduced opioid use, craving, and withdrawal

Implant procedure generally well tolerated and the adverse events were similar to placebo
Why Provide MAT?

- Better outcomes
  - Less substance use, less criminal problems, less health problems, better employment & reduced mortality
- Cost-effective
- Evidence-based practice
- Provision of MAT as a quality indicator

Giving patients access to all of the tools that may improve the probability of recovery
MAT in Iowa

- 125 Substance abuse treatment facilities, 36.8% provide medications:
  - 29.6% provide meds for psychiatric disorders
  - 15.2% nicotine replacement
  - 16.8% Campral
  - 16.8% Anatabuse
  - 12% Naltrexone
  - 10.4% Buprenorphine
  - 4% Methadone

- 27 Physicians certified to provide buprenorphine

Source: SAMHSA's 2010 National Survey of Substance Abuse Treatment Services (N-SSATS)
MAT in Kansas

• 211 Substance abuse treatment facilities, 34.6% provide medications:
  • 26.5% provide meds for psychiatric disorders
  • 12.3% nicotine replacement
  • 17.1% Campral
  • 13.3% Anatabuse
  • 13.3% Naltrexone
  • 10.9% Buprenorphine
  • 3.3% Methadone

• 67 Physicians certified to provide buprenorphine

Source: SAMHSA’s 2010 National Survey of Substance Abuse Treatment Services (N-SSATS)
MAT in Nebraska

- 115 Substance abuse treatment facilities, 37.4% provide medications:
  - 29.6% provide meds for psychiatric disorders
  - 18.3% nicotine replacement
  - 13.9% Campral
  - 11.3% Anatabuse
  - 11.3% Naltrexone
  - 10.4% Buprenorphine
  - 6.1% Methadone

- 28 Physicians certified to provide buprenorphine

Source: SAMHSA’s 2010 National Survey of Substance Abuse Treatment Services (N-SSATS)
MAT in Missouri

- 264 Substance abuse treatment facilities, 40.2% provide medications:
  - 29.9% provide meds for psychiatric disorders
  - 7.6% nicotine replacement
  - 11.7% Campral
  - 6.4% Anatabuse
  - 17.4% Naltrexone
  - 10.6% Buprenorphine
  - 6.1% Methadone

- 134 Physicians certified to provide buprenorphine

Source: SAMHSA’s 2010 National Survey of Substance Abuse Treatment Services (N-SSATS)
MAT in Oklahoma

• 191 Substance abuse treatment facilities, 31.9% provide medications:
  • 21.5% provide meds for psychiatric disorders
  • 14.1% nicotine replacement
  • 7.9% Campral
  • 4.7% Anatabuse
  • 7.3% Naltrexone
  • 5.8% Buprenorphine
  • 8.4% Methadone

• 87 Physicians certified to provide buprenorphine

Source: SAMHSA’s 2010 National Survey of Substance Abuse Treatment Services (N-SSATS)
Barriers to Implementing MAT
Medications for MI

Safe
Effective
Patient-Centered
Timely
Efficient
Equitable
FIGURE 2. Number (N = 188) and location of local drug overdose prevention programs providing naloxone in 2010 and age-adjusted rates of drug overdose deaths in 2008 — United States

* Not shown in states with fewer than three local programs.
† Per 100,000 population.

SOURCE: MMWR 2/12/12, Vol. 61, Num.6
Barriers to MAT

Environmental
Organizational
Clinician
Client
Environmental Barriers

- **Regulatory**
  - Medication not on the Medicaid formulary
  - Training requirements & prescribing limitations for buprenorphine
  - Methadone facilities

- **Requires buy-in at the:**
  - State
  - Community-level
  - Political
  - Police

- **Geographic distance to treatment facility & pharmacy**
“Although not for everyone, it is an essential part of the comprehensive array of services available to people struggling with addiction to alcohol or other drugs. A paradox in our field is that although we recognize addiction as a chronic, relapsing disease, some substance abuse counselors and administrators have been reluctant to embrace new technologies for its treatment.”

-- Mark G. Stringer, Director
Organizational Barriers

- Organizational size
- Staffing
- Hospital affiliation
- Organizational leadership buy-in
- Urine drug screening
- Profit status
- Modalities offered
- Cost
- Participation in NIDA CTN & other pilot studies

Sources: Knudsen et al. (2009) *JSAT*; Ducharme & Roman (2009) *JSAT*
Clinician & Patient Barriers

**Clinician**
- MAT educational opportunities
- Fear of diversion & liability
- Experience treating patients with SUD

**Patient**
- Health insurance
- Income

- Knowledge & attitudes about medication
- Experience with medication

*Sources: Knudsen et al. (2009) The American Journal on Addictions*
Clinician & Patient Barriers

Attitudes + social norms/expectations = Intentions to use MAT

Source: Rieckmann et al. (2007) JSAT
Philosophical Barriers

“Cultural belief ..... That medications are not effective when interjected into therapy, in spite of the preponderance of evidence-based practice to the contrary”

---Anonymous SSA

- Drug addiction should not be treated with a drug
- Abstinence –only approach
- Inconsistent with 12-Step facilitation
MAT as a Barrier

- Patient compliance with medication (e.g., antabuse & oral naltrexone)
- Buprenorphine & Vivitrol induction process
- Sufficient dose
- Diversion
- Drug availability

“I think the dosage needs adjusting. I'm not nearly as happy as the people in the ads.”
Overcoming Barriers

Medications at a reduced cost
  • Partner with FQHC or 24B clinicians
  • Become an FQHC look-alike
  • Add addiction medications to state Medicaid formularies

Access to medical personnel
  • Coordinate with medical providers in your area
Overcoming Barriers

Medication compliance ➔
• switch medications or formulation (Vivitrol)
• use psychosocial treatment approaches or contingency management to improve compliance

Philosophical differences ➔
• Medication saves lives
• Provision of MAT as a quality indicator
• Adoption of evidence-based practices for addiction
• Reconcile use of medication as a treatment towards the ultimate goal of recovery from ADDICTION
Overcoming Barriers

Education

- Participate in clinical training on how to use medications
- Educate patients & the community regarding the benefits of medications
- Learn from clinicians & patients with medication experience
- Physicians can use the PCSS-B online course to receive training on buprenorphine
- ATTC provide 6-hour training on buprenorphine for clinicians
Overcoming Barriers

Participate in a medication study ➔
- Gain experience with a medication as part of a study

Try new modalities ➔
- Buprenorphine induction centers
- Coordinate services with an inpatient detoxification center

Adopt policies to address diversion ➔
- Implement urine drug screening
Need to improve tx for alcohol, tobacco, or opiate dependent patients

Buy-in at the stakeholder level

Funding mechanism

Quality Indicator

Adoption of EBP

Address Fears

Recovery

Psychosocial Staff

Medical Staff

Diversion

Liability

Educational Opportunities

First-hand experience

Supervision

IMPROVING OUTCOMES FOR PATIENTS

Philosophy

Organizational Structure
Re-invention to improve access

2.6 billion people around the globe do not have access to toilets, which accounts for as many as half of the hospital admissions in some countries.

..... If they can re-invent the toilet, we can re-invent the addiction specialty treatment system.

Take Home Messages

• Prescription drug taking has increased substantially over the past decade
• Abuse of prescription painkillers has increased substantially nationally
• Rapid increase in overdose deaths
• Expanding access to medications is needed to prevent overdose deaths and improve rates of long-term recovery

*Drug abuse is a public health problem, not a criminal problem or a moral problem*
Additional Resources

http://ctndisseminationlibrary.org/

PCSS-B Webinars

http://buprenorphine.samhsa.gov/bwns_locator/
THANK YOU!

Erin L. Winstanley, Ph.D, 513-487-7809 winstanley@carc.uc.edu

AODtxWorks Ohio Valley Node of the NIDA CTN