An Overview of the Opioid Treatment Landscape

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Treatment, Advocacy, and Education Issues
Preliminary ABA Recommendations

Individuals with opioid disorders should have guaranteed access to treatment and recovery programs.
There should to be widespread educational effort about the extent and reasons for the opioid crisis, and the full spectrum of possible treatment options (including available therapeutic drugs). These educational efforts should be directed to the general population, families, and incarcerated individuals.
Educational efforts should provide targeted, immediate next steps for those with acute opioid problems.
Treatment and long-term recovery efforts need to be greatly enhanced, improved, and expanded. These efforts should include expedited review of new treatments, medications, and protocols; review of best practices in chronic pain management; review of existing programs (including 12 Step Programs) and therapeutic treatment; identification of non-pharmaceutical treatment and supports; emergency interventions; and improved methods of program evaluation and effectiveness monitoring.
New and alternative non-opioid based strategies for managing chronic pain are needed, including strategies for adherence to protocols for best-practice prescribing, and discontinuation.
Medication Assisted Treatment

Not Medication As Treatment!
Who Supports MAT?
MAT Reduces Deaths

The graph shows the number of heroin overdoses, buprenorphine patients, and methadone patients from 1995 to 2009. The number of heroin overdoses was highest in the early 2000s and then decreased significantly. The number of buprenorphine patients increased steadily over the years, while the number of methadone patients also increased but fluctuated more than the buprenorphine patients.
MAT Reduces Relapse

![Graph showing relapse rates over treatment episodes in months. The graph compares relapse rates for Buprenorphine, Methadone, and Non-OAT Behavioral Health.]
The Action of MAT Drugs
Figure 1
How OUD Medications Work in the Brain

Empty opioid receptor

Methadone  Buprenorphine  Naltrexone

Full agonist: generates effect  Partial agonist: generates limited effect  Antagonist: blocks effect

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# MAT Options

## Table 1

<table>
<thead>
<tr>
<th>Medication</th>
<th>Mechanism of action</th>
<th>Route of administration</th>
<th>Dosing frequency</th>
<th>Available through</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>Full agonist</td>
<td>Available in pill, liquid, and wafer forms</td>
<td>Daily</td>
<td>Opioid treatment program</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Partial agonist</td>
<td>Pill or film (placed inside the cheek or under the tongue)</td>
<td>Daily</td>
<td>Any prescriber with the appropriate waiver</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implant (inserted beneath the skin)</td>
<td>Every six months</td>
<td></td>
</tr>
<tr>
<td>Naltrexone</td>
<td>Antagonist</td>
<td>Oral formulations</td>
<td>Daily</td>
<td>Any health care provider with prescribing authority</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Extended-release injectable formulation</td>
<td>Monthly</td>
<td></td>
</tr>
</tbody>
</table>

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MAT: Opioid Agonist Drugs

• Agonist therapy
  – Agonists bind to µ-opioid receptors and activate them
  – Most patients feel the opioid effect
  – Magnitude of effect differs with drug and dose
  – Produce physical dependence:
    • Withdrawal syndrome when medication is reduced or stopped
Methadone

• Daily witnessed dosing through Opioid Treatment Programs (OTPs)

• Initial doses must be observed. Take-home doses earned by negative UDS and participation in programming

• Caron does not offer methadone maintenance treatment
  – Candidates for methadone treatment are referred to an appropriate methadone clinic (OTP)
  – Patients on methadone may still receive counseling through Caron outpatient clinics
Buprenorphine

• Available as “mono-product” (Subutex) and combination product (Suboxone)
  – Combination product carries less risk of misuse
• Well tolerated – few adverse reactions
• Few drug interactions
**Buprenorphine Maintenance**

**Induction:**

- **Day 1:**
  
  - Patients should be in moderate withdrawal (12-24 hours after short acting opioid, 36-72 hours after long acting opioids (COWS scale))
  
  - First dose: 4mg sublingual (sl)
  
  - May repeat in 1-2 hours if withdrawal symptoms persist
  
  - Maximum dose first day = 8-12 mg
**Buprenorphine Maintenance**

– Day 2:

• Assess effectiveness of first day’s dose
• Increase, maintain, or decrease dose as needed
• Proper dose achieves 2 goals:
  – Alleviation of withdrawal symptoms
  – Suppression of cravings
• Most patients require 12-16 mg buprenorphine/day
Buprenorphine Maintenance

– Day 3 and onward:
  • If patient still has withdrawal symptoms and/or cravings:
    – Determine if patient is taking medication correctly
    – If they are, increase dose by 2-4 mg increments/day until goal is reached
    – This is the maintenance dose
    – Maximum dose = 32mg/day (rarely necessary)
Buprenorphine Regulations

• To prescribe or dispense buprenorphine, providers must qualify and apply for a waiver under DATA 2000.
  – Physicians, Nurse Practitioners, Physician Assistants
  – Prescribing limits:
    • Year one: 30 patients
    • Year two forward: 100 patients
    • Some providers may qualify for 275 patients
Buprenorphine

• Diversion is a concern
• Duration of treatment is not standardized
• Implantable formulation
  – Probuphine approved May 2016
  – Indicated for patients stable on sublingual buprenorphine
  – 80 mg per 4 implants.
  – Duration of action = 6 months, then remove
  – Can be supplemented with s.l. formulation
Depot Buprenorphine Injection
Approved 11/30/2017

FDA News Release

FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder

Agency encourages safe adoption and more widespread use of FDA-approved treatments to help combat opioid addiction
XR-Naltrexone

- Vivitrol FDA approved 2010 for “the prevention of relapse to opioid dependence following opioid detoxification.”
  - First dose is given no less than 8 days after last dose of agonist opioid
  - Necessitates managed opioid withdrawal
- Monthly IM injection, 380mg dose
- No special training or licensure required
XR–Naltrexone – Adverse Reactions

- Hepatotoxicity – avoid in advanced liver disease
- Injection site reactions
- Depression and suicidality
- Precipitated withdrawal
- Potential opioid overdose risk
- Opioid ineffectiveness
Both Vivitrol and Buprenorphine Reduce Cravings

Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial
Lee, Joshua D et al. Lancet online Nov. 14, 2017
Considerations When Choosing Between MAT Options

1. Physiologic Dependence
   - Means that a patient will have a withdrawal syndrome when the medication is discontinued
   - Often mistaken for “addiction” to the MAT drug
   - Methadone produces high physiologic dependence
   - Buprenorphine produces low–moderate physiologic dependence
   - Vivitrol produces no physiologic dependence
     • Does that make Vivitrol better?
Considerations When Choosing Between MAT Options

2. Patient experience
   – What have they taken previously?
     • How helpful was it?
     • Any adverse effects?
   – What do they prefer?
     • Why?
Considerations When Choosing Between MAT Options

3. Treatment Environment
   – Where are they going after discharge?
     – IOP, extended residential?
     – What will be available in that setting?
     – Need to refer to like-minded providers
Considerations When Choosing Between MAT Options

4. Disease characteristics
   – Multiple substances?
   – Co-occurring medical/psychiatric illness?
   – Will the patient be compliant with treatment?

5. Medication characteristics
   – Physiologic Dependence:
     • Methadone > buprenorphine > Vivitrol
   – Dosing
     • Methadone – daily witnessed dosing
     • Buprenorphine – daily (un)witnessed dosing
     • Vivitrol – monthly witnessed dosing
Considerations When Choosing Between MAT Options

6. Cost of treatment
   – Is the MAT covered by insurance?
   – Does the patient have insurance?
Candidates for MAT with XR-Naltrexone (Vivitrol)

• Patients not interested in or able to be on agonist maintenance
• Those with high degree of motivation for abstinence (active in 12 Step Programs)
• In professions where treatment with agonist is controversial (health care professionals)
• Patients successful on agonist but who want to try abstinence
• Patients who failed prior treatment with agonist
Candidates for MAT with XR-Naltrexone (Vivitrol)

• Patients who are abstinent but at risk for relapse
• Moving to old neighborhood, increased stress, worsening psychiatric problems
• Patients for whom relapse could be disastrous (e.g., physicians, parolees)
• Patients with less severe form of a disorder
  – Short history of use, lower level of use
  – Younger patients
Who Is Likely to Benefit From Naltrexone?

- Highly motivated patients who are committed to abstinence
- Older patients with long history of use and multiple relapses
- Those with longer periods of abstinence between relapses
- Patients who relapsed and returned to treatment
Candidates for MAT with Buprenorphine

- Patients with history of overdoses, particularly following detoxification
- Patients with serious mental illness, disorganized, homeless
- Patients who have been opiate-free but never felt “normal”
- Patients in whom psychiatric illness emerged/worsened after previous detoxes (with or without naltrexone)
Candidates for MAT with Buprenorphine

- Patients with chronic pain requiring chronic opioid treatment
- Patients with severe GI disorders exacerbated by withdrawal/abstinence
- Patients with advanced liver disease
- Patients whose insurance will only pay for buprenorphine
Good, sober is.

Extended Abstinence is Predictive of Sustained Recovery

After 5 years – if you are sober, you probably will stay that way.

It takes a year of abstinence before less than half relapse

Dezuris et al, Eval Rev, 2007
What We Need to Learn

• What is the optimum duration of treatment with MAT drugs?
  Discontinue ASAP ↔ Lifetime

• What is the ideal combination of medication, psychosocial, and 12 Step recovery treatment for our patients?
Medications used in medically assisted detox programs are typically provided on a tapering schedule, lasting weeks.
In November 2017, the FDA granted a new indication to an electronic stimulation device, NSS-2 Bridge, for use in helping reduce opioid withdrawal symptoms.
Summary of MAT

The principal mechanisms are reducing craving for opioids, preventing negative withdrawal symptoms, and blocking euphoric effects if opioids are used. Though patients are still physically dependent on the substitution medication, maintenance treatments result in less time spent on drug-related activities and may allow dependent individuals to transition to abstinence based programs.
The Hard Facts

“The current physician reimbursement structure does not account for all the services that patients with an opioid use disorder need to progress to successful treatment and recovery. While we know that a combination of medication and psychosocial support systems is the evidence-based standard for treatment, we continue to find that patients are not able to access treatment due to limited or non-existent insurance coverage.”

Dr. Shawn Ryan, Chair of the AMA-ASAM APM Working Group and ASAM’s Payer Relations Committee
Of the 2 million Americans with full-blown opioid use disorders, just 20% are getting treatment. Of those getting treatment, only 37% are getting medication, including methadone, buprenorphine, or naltrexone.
The Role Of Medicine in Addiction Treatment

“Imagine seeking assistance from a health care facility and being told that you have a progressively debilitating and potentially fatal medical disorder (one widely recognized in the research community as a brain disease), but then discovering that no physician or other medical personnel will be involved in the assessment, diagnosis, acute treatment, or continued monitoring of your condition . . .
The Role Of Medicine in Addiction Treatment (cont.)

... Imagine that vast majority of organizations specializing in treatment of your condition have no affiliation with a hospital or other primary healthcare facility. Imagine the existence of FDA-approved medication specifically for treatment of your condition, but that you will not be informed about nor have access to these medications as part of your prescribed treatment.”

- William White
Extent of MAT coverage varies state by state. Medicaid, Medicare, private insurance, the local, state, and/or federal government often provide some coverage, but extent and timely access to it varies greatly.
The Current Status of Treatment

About one-third of American addiction programs offer what many experts worldwide see as the standard of care – long-term use of either methadone or buprenorphine. Most programs view medication as a crutch for short-term use and provide only talk therapies. The widespread rejection of proven addiction medications is the single biggest obstacle to ending the overdose epidemic.
Funding isn’t the barrier: outpatient medication treatment is both more effective and significantly cheaper than adding inpatient beds at rehabilitation centers. The problem is an outdated ideology that views needing a medication to function as a form of addiction.
Principles of Effective Treatment

• Addiction is a complex but treatable disease that affects brain function behavior
• No single treatment is right for everyone
• People need to have quick access to treatment
• Effective treatment addresses all of the patient’s needs, not just his or her drug use
• Staying in treatment long enough is critical
Principles of Effective Treatment

• Counseling and other behavioral therapies are the most commonly used forms of treatment

• Medications are often an important part of treatment, especially when combined with behavioral therapies

• Treatment plans must be reviewed often and modified to fit the patient’s changing needs
Principles of Effective Treatment

• Treatment should address other possible mental disorders
• Medically assisted detoxification is only the first stage of treatment
• Treatment doesn’t need to be voluntary to be effective
• Drug use during treatment must be monitored continuously
In 2017, Health and Human Services (HHS) announced five priorities for addressing the opioid crisis:

1. Improving access to treatment and recovery services
2. Promoting use of overdose-reversing drugs
3. Strengthening our understanding of the epidemic through better public health surveillance
4. Providing support for cutting-edge research on pain and addiction
5. Advancing better practices for pain management
Forty-nine states have prescription drug monitoring programs, databases which enable health care providers to curb “doctor shopping” by patients who obtain opioid prescriptions from multiple physicians. Missouri’s program is not yet statewide, but has enacted legislation to authorize it.
The 21st Century Cures Act, passed in 2016, allocated $1 billion over two years in opioid crisis grants to states, providing funding for expanded treatment and prevention programs. In April 2017, Health and Human Services Secretary Tom Price announced the distribution of the first round of $485 million in grants to all 50 states and US territories.
In August 2017, Attorney General Jeff Sessions announced the launch of an Opioid Fraud and Abuse Detection Unit within the Department of Justice. The unit’s mission is to prosecute individuals who commit opioid-related health care fraud. The DOJ is also appointing two US attorneys who will specialize in opioid health care fraud cases as part of a three-year pilot program in 12 jurisdictions nationwide.
State legislatures are also taking action, introducing measures to regulate pain clinics and limit the quantity of opioids that doctors can dispense.
On October 26th, 2017, President Trump declared a national public health emergency to combat the opioid crisis, telling an audience in the East Room of the White House that “we can be the generation that ends this opioid epidemic.”
On February 9th, 2018, a $6 billion boost in funding for prevention and law enforcement in the fight against opioid abuse is included in the budget agreement signed by President Trump, ending an overnight government shutdown.

This strategy outlines the federal government’s first coordinated plan for reducing the burden of chronic pain that affects millions of Americans. A diverse team of experts from around the nation drafted the National Pain Strategy as a roadmap toward achieving a system of care in which all people receive appropriate, high quality, and evidence-based care for pain.
The Opioid Crisis Response Act

“The Senate health committee . . . voted to approve the Opioid Crisis Response Act of 2018, which Chairman Lamar Alexander said will ‘help create an environment for states to succeed in fighting the opioid crisis.’

“What the federal government can do is create an environment so that everyone – judges, mayors, counselors, police officers, DEA agents, doctors, nurses, parents, pharmacists, hospitals – can succeed in fighting the crisis. The legislation we approved today aims to create that environment to help states and communities begin to bring an end to the opioid crisis.
“This legislation includes over 40 different proposals, from 38 different senators of both political parties, including legislation to help stop illegal drugs like fentanyl at the border, accelerate research on non-addictive pain medicines, reduce the number of inappropriately prescribed opioids, and support state intervention for children who have experienced trauma, such as a parent using opioids.”
Treatment Trends

- Integrating MAT into primary care health facilities
- Ongoing development of additional MAT medication and protocols
- Efforts by insurance companies and governmental bodies to reduce geographic and financial barriers to appropriate treatment
• Continued limitations and education regarding opioid prescriptions
• Overdose education and wider availability of Narcan
• Decrease availability of fentanyl
• Address social and environmental issues of individuals in communities with dense level of opioid use
• Increase number of treatment programs utilizing MAT (currently only one-third)

• Visit www.hhs.gov; www.opioids.gov; www.samhsa.gov
Educational Trends

- Use of experts utilizing all communication methods: in-person, web-based, tele-health, community-based, stakeholder conference
- Specific residential programs or tracks for opioid addicts
- Increased psychosocial therapy and assessment in conjunction with MAT
• Increased counseling and linking to existing family support and to community service
• Increased methods, medications, and coping skills to deal with chronic pain (without opioids)
Conclusion
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