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Opioid Use Disorder:

Expanding Access to Medication

Learning Objectives

The goal of this activity is to enable effective collaboration between members of the professional teams who care for patients with OUD. After participating in this educational activity, participants should be better able to:

- Examine the need to expand the use of medications to treat opioid use disorder and evaluate existing strategies to achieve that goal
- Describe the process to safely initiate a patient on XR-Naltrexone
- Summarize the findings from the X:BOT study and implications for practice

Faculty

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What Does OUD Encompass?

- DSM-5 (Diagnostic and Statistical Manual 5th Edition): a rethinking of the DSM IV terminology of opioid dependence or abuse
- A problematic pattern of opioid use leading to clinically significant impairment or distress as manifested by at least two criteria occurring within a 12-month period. The severity is based on the number of symptoms.

TABLE 1 Summarized DSM-5 diagnostic categories and criteria for opioid use disorder

Category	Criteria
Impaired control	• Opioids used in larger amounts or for longer than intended • Unsuccessful efforts or desire to cut back or control opioid use • Excessive amount of time spent obtaining, using, or recovering from opioids • Craving to use opioids
Social impairment	• Failure to fulfill major role obligations at work, school, or home as a result of recurrent opioid use • Persistent or recurrent social or interpersonal problems that are exacerbated by opioids or continued use of opioids despite these problems • Reduced or given up important social, occupational, or recreational activities because of opioid use
Risky use	• Opioid use in physically hazardous situations • Continued opioid use despite knowledge of persistent physical or psychological problem that is likely caused by opioid use
Pharmacological properties	• Tolerance as demonstrated by increased amounts of opioids needed to achieve desired effect; diminished effect with continued use of the same amount • Withdrawal as demonstrated by symptoms of opioid withdrawal syndrome; opioids taken to relieve or avoid withdrawal

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Treatment Options

- Medication
  - The most effective treatment
  - Use one of the FDA-approved medications to treat, control, and improve opioid use disorder
    - Buprenorphine
    - Extended release-naltrexone (XR-naltrexone)
    - Methadone (clinics)
- Rehabilitation graduating to outpatient follow-up
- Counseling

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Methadone, Buprenorphine, and Naltrexone

Methadone	Buprenorphine	XR-Naltrexone
• Opiate • Stabilizes the opiate system and blocks effects of other opiates	• Opiate • Stabilizes the opiate system and blocks effects of other opiates • In combination with naloxone • Maintenance approach	• Opiate antagonist/blocker • Patient preserves an opiate-free state • Patient must be opiate free before beginning treatment
Dosage: Once daily (ongoing); Only available at methadone clinic	Dosage: Once daily; sublingual	Dosage: Injectable; Every 30 days
Clinic settings; Primary care physicians cannot prescribe	Schedule III; Medical providers can prescribe with x-waiver	Primary care physicians can prescribe

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Assessing Readiness for XR-Naltrexone

- Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: published by the Substance Abuse and Mental Health Services Administration (SAMHSA)
- Appropriate for patients who have been detoxified from opioids: An opioid-free interval is recommended. The interval should be guided by the type of opioid that the patient had been taking previously.
- Health care providers should always be prepared to manage withdrawal symptomatically.
- Part of a comprehensive management program that includes psychosocial support.
- Other good candidates include persons with a short or less severe addiction history or those who demonstrate to professional licensing boards or criminal justice officials that their risk of opioid use is low.

Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder. Substance Abuse and Mental Health Services Administration (SAMHSA) 2015. Available at https://store.samhsa.gov/shin/content/SMA14-4892R/SMA14-4892R.pdf

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X:BOT Study

- 570 participants
- 24 week, open-label, randomized controlled, comparative effectiveness trial of XR-naltrexone (XR-NTX) or buprenorphine / naloxone (BUP-NX)
- XR-NTX was associated with substantial induction hurdle: fewer participants successfully initiated XR-NTX than BUP-NX (72% vs 94% respectively p<0·0001)
- **Among participants successfully inducted, 24 week relapse events were similar across study groups (p=0·44)**
- Self-reported opioid craving was initially less with XR-NTX than with BUP-NX (p=0·0012), then converged by week 24 (p=0·20)
- Treatment-emergent adverse events including overdose did not differ between treatment groups

Lee ID et al. Lancet. 2018. 391 (10118): 309-318

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Primary Care Models to Expand Access to Medications

- The treatment of OUD can be successfully integrated into general office practices by physicians and healthcare providers who are not addiction specialists
- **Practice-based model** (Physician needs to apply for the X-waiver if prescribing buprenorphine)
- **Nurse or team-based model**
  - Prescriber in-house
  - Day-to-day management of patients handled by trained nurse practitioners and physician assistants
  - Cost effective; treat a lot of patients
- **Hub and Spoke model**
  - Efficiently deploys OUD expertise and helps expand access to medication for OUD to the state of Vermont
  - 9 Regional Hubs for daily support to patients with complex addictions
  - > 75 local Spokes, mostly primary care practices, with doctors, nurses, and counselors for ongoing treatment fully integrated with general healthcare and wellness services

State of Vermont. Blueprint for health. Hub and Spoke. http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke

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In Summary

- OUD is a public health crisis that can be easily addressed with greater use of medications
- Some medications are easy to prescribe and accessible to PCP (buprenorphine and XR-naltrexone)
- Expanding access to medication can be made possible by developing primary care models
  - Treatment would become available in remote areas, including rural areas
- Need to educate clinicians regarding OUD management and requirements for prescription (eg. x-waiver)