Addressing Pain and Opioid Use Disorder

Ilene Robeck, MD

Director of Virtual Pain Care, Richmond VAMC

Co chair – Pact Pain Champions Initiative

Disclosures

- Dr. Robeck has nothing to disclose

Learning Objectives

- To understand the history of how the current opioid crisis evolved
- To understand pain care options for patients at high risk for an opioid related adverse event
- To understand opioid risk mitigation strategies for patients with chronic pain on long term opioid therapy
- To understand treatment options for patients with opioid use disorder and chronic pain.

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Reducing the Risks of Relief — The CDC Opioid-Prescribing Guideline

Thomas R. Frieden, M.D., M.P.H., and Debra Houry, M.D., M.P.H.

N Engl J Med 2016; 374:1501-1504 | April 21, 2016 | DOI: 10.1056/NEJMp1515917

"We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."

- **"1 in every 550 patients** started on opioid therapy died… a median of 2.6 years after the first opioid prescription"
- "as high as **1 in 32** among patients receiving doses of 200 MME"

MME = Morphine Milligram Equivalent dosage per day

Frieden and Houry 2016

Déjà Vu All Over Again
Opioid Timeline

- Sixteenth century- first reports about addiction to opium throughout Europe, India and China
- Early 1800s, the chemist Seturner was able to isolate and identify the active ingredient in opium, which he named Morphine after the Greek god Morpheus. This was touted as the solution to Opium Addiction
- Throughout the early and mid-1800s, morphine was used during surgical procedures as a general anesthetic and as relief for chronic pain. By the end of the century there were just as many individuals addicted to morphine as there were to opium
- Late 1800s- medical profession's creation of so many morphine addicts led to experiments with cocaine as a potential antidote
- Chemists believed they discovered a non-addictive form of opiate around the turn of the nineteenth century –Heroin. The Bayer Company started the production of heroin in 1898

Markel, Howard (2011). An Anatomy of Addiction: Sigmund Freud, William Halsted, and the Miracle Drug Cocaine

A Brief History of Opioid Addiction

- Late nineteenth century Laudanum (a tincture of raw opium in 50 percent alcohol) was prescribed to women complaining of "female problems"
- Epidemiological studies conducted in Michigan, Iowa, and Chicago between 1878 and 1885 reported that at least 60 percent of the morphine or opium addicts living there were women
- Large numbers of men and children complaining of ailments ranging from acute pain to colic, heart disease, earaches, cholera, whooping cough, hemorrhoids, hysteria, and mumps were prescribed morphine and opium

Markel, Howard (2011). An Anatomy of Addiction: Sigmund Freud, William Halsted, and the Miracle Drug Cocaine


MRS. WINSLOW'S
SOOTHING
SYRUP
MRS WINSLOW'S
Soothing
Syrup
FOR
CHILDREN
TEETHING.
FOR CHILDREN TEETHING

A Brief History Opioid Addiction

- A survey of Boston's drugstores published in an 1888 issue of Popular Science Monthly -of 10,200 prescriptions reviewed, 1,481, or 14.5 percent, contained an opiate
- During this period (1880-1900) in the United States and abroad, the abuse of addictive drugs such as opium, morphine, and, soon after it was introduced to the public, cocaine constituted a **major public health problem**

Markel, Howard (2011). An Anatomy of Addiction: Sigmund Freud, William Halsted, and the Miracle Drug Cocaine

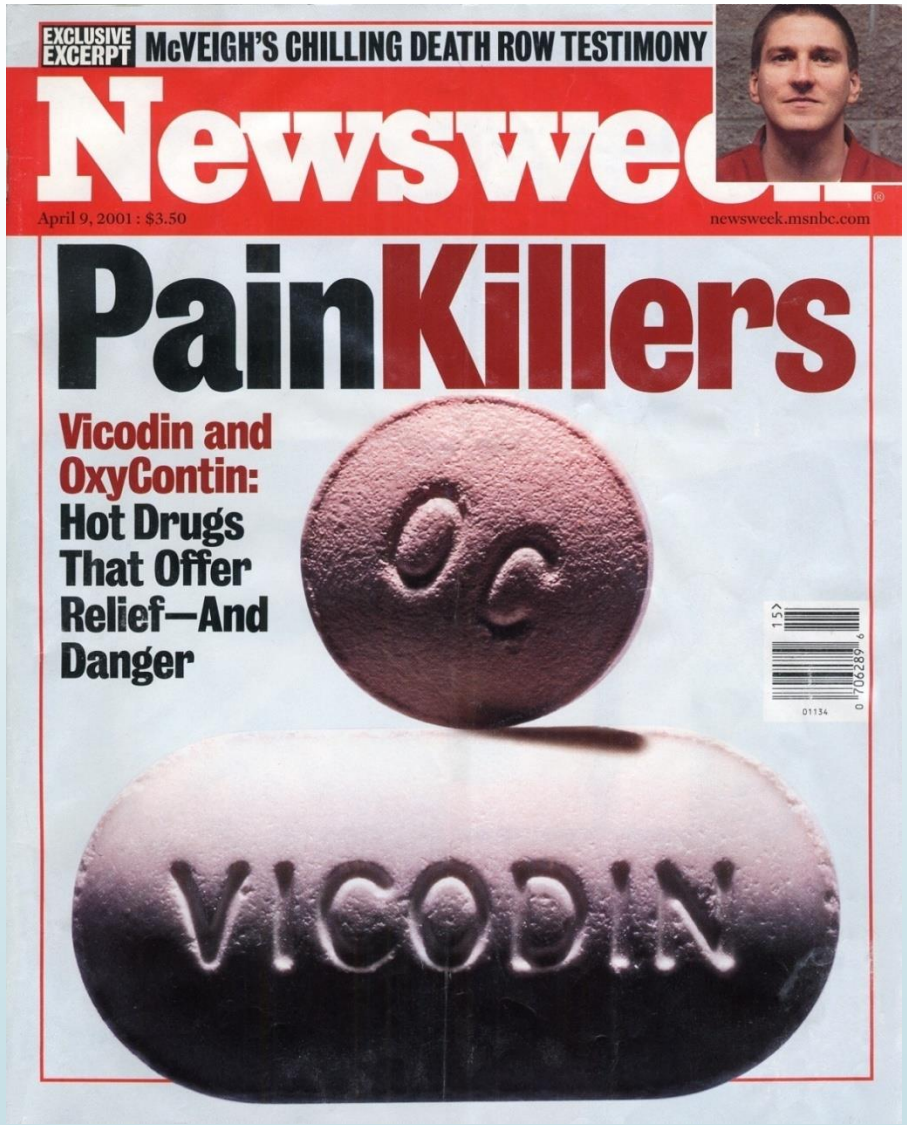
Opioid Timeline

- 1980: The New England Journal of Medicine publishes letter to editor that becomes known as Porter and Jick
- Early 1980s: First Xalisco migrants set up heroin trafficking businesses in the San Fernando Valley of Los Angeles
- 1984: Purdue releases MS Contin, a timed-release morphine painkiller marketed to cancer patients
- 1986: Drs. Kathleen Foley and Russell Portenoy publish paper in the journal Pain, opening a debate about use of opiate painkillers for wider variety of pain

Quinones, Dreamland

Opioid Timeline

- Early 1990-2 Xalisco Boys heroin cells begin expanding beyond San Fernando Valley to cities across western United States. Their pizza-delivery-style system evolves.
- 1996: Purdue releases Oxycontin, timed-released oxycodone, marketed largely for chronic-pain patients
- Aggressive marketing dramatically increases use of Oxycontin in primary care and pain clinics
- 1996: President of American Pain Society urges doctors to treat pain as a vital sign.
- 1996 AAPM issued a consensus statement supporting LTOT Stating that the risk for de novo addiction was low, respiratory depression induced by opioids was short lived and was antagonized by pain, tolerance was not common and efforts to control diversion should not limit opioid prescribing


EXCLUSIVE EXCERPT
McVEIGH'S CHILLING DEATH ROW TESTIMONY
Newsweek
April 9, 2001 : $3.50
newsweek.msnbc.com
PainKillers
Vicodin and OxyContin: Hot Drugs That Offer Relief—And Danger
VICODIN

April 2001

Opioid Timeline

- Late 1990s: Xalisco Boys heroin cells begin to spread to numerous cities and suburbs east of the Mississippi River.
- 1998– 99: Veterans Administration and JCAHO adopt idea of pain as fifth vital sign.
- 2004: Washington State Department of Labor & Industries Drs. Gary Franklin and Jaymie Mai publish findings on deaths of injured workers due to overdoses on opiate painkillers

Opioid Timeline

- Mid-2000s: Xalisco black tar heroin cells are now in at least seventeen states. Portsmouth, Ohio, has more pill mills per capita than any U.S. town. Florida's lax regulations make it another center of illicit pill supply
- 2007: Purdue and three executives plead guilty to misdemeanor charges of false branding of Oxycontin; fined $ 634 million.
- 2008: Drug overdoses, mostly from opiates, surpass auto fatalities as leading cause of accidental death in the United States.
- 2010: NEJM Flood of Opioids, Rising Tide of Deaths NEJM
- 2011: Ohio passes House Bill 93, regulating pain clinics.

The Perfect Storm - 1986-2010

- Pain as the Fifth Vital Sign
- Pharmaceutical Company development of newer opioids with touted less risk along with pharmaceutical company money for provider education
- Managed Care with
  - The shrinking of primary care reimbursement and time spent per patient
  - Lack of funding for substance abuse treatment
  - Lack of funding for a biopsychosocial approach to pain with limitations on PT, CBT and care coordination
- Minimal training of health care providers in pain and addiction
- The transition from the information age to the age of too much information – desensitizing patients and clinicians to risks

Current Situation – 2017

- 2015 Data – Opioids killed more than 33,000 people. Nearly half of all deaths were related to prescription opioids and 75% of illicit opioid users had been on or continued to take prescription opioids
- 2016 data currently predicted to have been over 65,000 overdose deaths with most due to opioids
- Fentanyl is now increasingly being mixed with almost all illicit drugs
  - 50 to 100 times more potent than morphine
  - 25 to 50 times more potent than heroin
- Car fentanyl
  - 10,000 times stronger than morphine
  - 100 times stronger than fentanyl
  - Overdose may occur in seconds or minutes. Response to usual Naloxone dose may be inadequate. Potency of Carfentayl is high enough to negatively impact first responders.

CDC

Potential Risks for All Patients – Even Those Perceived to be at Low Risk

- Endocrinopathies – Hypogonadism, Alterations in Growth Hormone
- Hyperalgesia
- Sleep Apnea
- Constipation
- Decline in Cognition
- Immunosuppression
- Respiratory Depression
- Increased risk of symptoms of depression, PTSD, anxiety
- Decline in functional Improvement
- Increased risk of falls
- Increased risk for accidents
- Chronic Dry Mouth with Increased Risk of Dental Disease
- Osteoporosis

But do they work?

- The literature review conducted for the VA/DoD and CDC Clinical Practice Guidelines identified no studies evaluating the effectiveness of LOT for outcomes lasting longer than 16 weeks
- Multiple studies demonstrate poorer functional outcomes in chronic pain when opioids are used vs non opioid therapies for pain

2017 VA/DoD Guidelines

For the Treatment of Chronic Pain

- **We recommend:**
- Alternatives to opioid therapy (OT) such as self-management strategies, other non-pharmacological treatments, and, when pharmacologic therapies are used, non-opioids over opioids
- **We recommend against:**
- Initiating long-term opioid therapy (LOT) for chronic pain
- LOT, particularly in the following patient populations due to increased risk of adverse events with OT: untreated substance use disorder (SUD), concurrent benzodiazepine use, less than 30 years of age

If initiating OT for chronic pain

- **We recommend:**
- A short duration (consideration of OT ≥90 days requires re-evaluation and discussion with patient)
- The lowest dose indicated, as there is no safe dose and risk increases with dose
- Informed consent discussion of risks and benefits of OT and alternative therapies upon initiation
- Ongoing risk mitigation, including random urine drug testing (and appropriate confirmatory testing),checking state prescription drug monitoring programs, monitoring for overdose potential and suicidality, providing overdose education, prescribing of naloxone rescue and accompanying education, and suicide risk assessment (and intervening if necessary)

If initiating OT for chronic pain

- **We recommend:**
- Evaluation of risks and benefits at least every three months and more frequently as dose increases
- Tapering OT to reduced dose or to discontinuation when risks of LOT outweigh benefits (avoid abrupt discontinuation unless required for immediate safety concerns; individualize tapering)
- Interdisciplinary care (addressing pain, SUD, and/or mental health problems) for patients presenting with high risk and/or aberrant behavior

If initiating OT for chronic pain

- **We recommend against:**
- Doses >90 mg morphine equivalent daily dose (MEDD) for treating chronic pain
- Prescribing long-acting opioids for acute pain, as an as-needed medication, or on initiation of LOT

If continuing OT for chronic pain

- **We recommend:**
- Ongoing risk mitigation, assessment for opioid use disorder (OUD) and suicide, and consideration for tapering
- For patients with evidence of untreated SUD, close monitoring, SUD treatment, and tapering
- For patients with concurrent use of OT and benzodiazepines, tapering one or both medications
- For patients taking >90 mg MEDD, evaluation for tapering to reduced dose or to discontinuation
- **For patients with chronic pain and OUD, medication assisted treatment of OUD**

For acute pain

- **We recommend:**
- Alternatives to opioids for mild-to-moderate acute pain
- If opioids are prescribed, immediate-release opioids at lowest effective dose with reassessment no later than 3-5 days to determine if adjustments or continuation of OT is indicated

- **We suggest:**
- Use of multimodal pain care when opioids are used (should also offer patient education about opioid risks and alternatives to OT)

OUD DSM-5 diagnostic criteria

- A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the symptoms listed below occurring within a 12-month period.
- Tolerance and withdrawal are not criteria for OUD when taking opioid pain medicine **as prescribed.**

DSM V: Opioid Use Disorder

- Taking more or for longer than intended
- Spending a lot of time obtaining, using, or recovering from use
- Giving up or reducing important social, occupational, or recreational activities
- Persistent desire for or being unable to cut down
- Craving, or a strong desire to use (new)
- Failure to fulfill major role obligations at work, school, or home
- Continued use despite social or interpersonal problems related to use
- Continued use in physically hazardous situations
- Continued use despite knowledge of physical or psychological problems related to use
- Tolerance - need more to achieve same effect or less effect from a given amount*
- Withdrawal, or use to avoid withdrawal*

2-3= mild, 4-5=moderate, 6+ severe

*not considered met if taking opioid medication as prescribed

Opioid withdrawal syndrome

- Dysphoric mood
- Piloerection
- Nausea or vomiting
- Diarrhea
- Muscle aches/cramps
- Yawning
- Lacrimation
- Mild fever
- Rhinorrhea
- Insomnia
- Pupillary dilation
- Craving
- Sweating
- Distress/irritability

Protracted Withdrawal

- The presence of substance-specific signs and symptoms common to acute withdrawal but persisting beyond the generally expected acute withdrawal time frames.
- Chronic substance use causes molecular, cellular, and neurocircuitry changes to the brain that affect emotions and behavior and that persist after acute withdrawal has ended
- Adaptive changes in the central nervous system may lead to affective changes that persist for many weeks or longer beyond acute withdrawal
- Repeated use of a substance causes the brain to respond more readily to its effects but less readily to naturally rewarding activities.
- In one study signs and symptoms of protracted withdrawal lasted the duration of a year-long study of people recovering from alcohol use disorders

SAMHSA

Opioids – Protracted Withdrawal

- Anxiety, depression, fatigue, dysphoria, and irritability and sleep disturbances can last for weeks or months following withdrawal from opioids
- Subjects who had been abstinent from opioids for a prolonged period showed decreased ability to focus on a task compared with subjects who had never used opioids
- People in recovery from heroin dependence also show deficits in executive control functions that may persist for months beyond the period of acute withdrawal

Opioid Use Disorder and Prescription Opioids

- Using electronic records from a large US health care system, we identified outpatients receiving five or more prescription orders for opioid therapy in the past 12 months for noncancer pain In 2008, we completed diagnostic interviews with 705 of these patients using the DSM-4 criteria. In the current study, we reassessed these results using the final DSM-5 criteria.
- **Lifetime prevalence of "any" prescription opioid-use disorder in this cohort was 41.3%**
- The best predictors were age less than 65 years, current pain impairment, trouble sleeping, suicidal thoughts, anxiety disorders, illicit drug use, and history of substance abuse treatment.

Boscarino et al
Substance Abuse and Rehabilitation 2015:6 83–91

Opioid Prescribing and OUD

- Patients with CNCP prescribed opioids had significantly higher rates of OUDs compared to those not prescribed opioids. Effects varied by average daily dose and days supply:
  - low dose, acute OR=3.03
  - low dose, chronic OR=14.92
  - medium dose, acute OR =2.80
  - medium dose, chronic OR=28.69
  - high dose, acute OR=3.10
  - high dose, chronic OR=122.45
- Among individuals with a new CNCP episode, prescription opioid exposure was a strong risk factor for incident OUDs; magnitudes of effects were large. Duration of opioid therapy was more important than daily dose in determining OUD risk.

Edlund et al *Clin J Pain*. 2014 July ; 30(7): 557–564.

OUD Checklist

- **Criteria 1: Opioids are often taken in larger amounts or over a longer period than was intended.**
- Have you ever taken more opioid medication than you were prescribed?
- (Yes = 1 point)
- (if patient answers no to this but has requests for early refills, udt positive for unprescribed opioids or pdmp requests for opioids from more than one prescriber add one point)
- **Criteria 2: There is a persistent desire or unsuccessful efforts to cut down or control opioid use.**
- Have you had difficulty with symptoms other than pain when opioid doses are lowered?
- (Yes = 1 point)

OUD Checklist

- **Criteria 3: A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.**
- Do you spend time during the day thinking about getting your next dose of opioid?
- After you take your medication are you unable to engage in your daily activities for a period of time?
- Do you spend time recovering from you medication?
- (Yes to any of the above questions = 1 point)
- **Criteria 4: Craving, or a strong desire or urge to use opioids.**
- Do you ever have a desire to take the medication in between doses?
- Do you feel like you need to take more medication when the dose is lowered?
- Do you have a hard time imagining what your life would be like without the medication?
- (yes to any of the above questions = 1 point)

OUD Checklist

- **Criteria 5: Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.**
- **Criteria 6: Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.**
- **Criteria 7: Important social, occupational, or recreational activities are given up or reduced because of opioid use.**
- Have you experienced worsening function at work, school or home since starting on opioid therapy?
- (yes= 1 point)
- Are there important activities in your life that you have stopped due to the medication or the medication effects?
- (yes= 1 point)
- Do you feel like the need to take the medication is more important than your social, work, home, or recreational activities?
- (yes = 1 point)

OUD Checklist

Criteria 8: **Recurrent opioid use in situations in which it is physically hazardous.**

- Have you ever had a serious problem such as difficulty breathing, difficulty thinking, or a fall that was related to your prescribed opioid medication?
- 8a. If yes… Do you think it would be difficult to lower the dose or discontinue the opioid medication?
- (yes to 8a = 1 point)

Criteria 9: **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.**

- Have you ever been told that your current opioid therapy is detrimental to your health?
- 9a. If yes…Do you feel like you need to continue the medication despite that?
- (yes to 9a = 1 point)

OUD Check list

- **Criteria 10: Tolerance, as defined by either of the following:**
- **A need for markedly increased amounts of opioids to achieve intoxication or desired effect.**
- **A markedly diminished effect with continued use of the same amount of an opioid.**
- Do you find that the dose needed to help with your pain has increased over time?
- (yes = 1 point)
- **Criteria 11: Withdrawal, as manifested by either of the following:**
- **The characteristic opioid withdrawal syndrome**
- **Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.**
- Do you have any of the following symptoms in between doses or when you try to lower your dose? Anxiety, depression, fatigue, irritability, gi upset and sleep disturbances
- (yes = 1 point)

Dependence vs Addiction
A distinction without a difference

- Dependence on opioid pain treatment is not, as we once believed, easily reversible
- It is a complex physical and psychological state that may require therapy similar to addiction treatment, consisting of structure, monitoring, and counseling
- Whether or not it is called addiction, complex persistent opioid dependence is a serious consequence of long-term pain treatment that requires consideration when deciding whether to embark on long-term opioid pain therapy as well as during the course of such therapy.

Ballantyne et al ARCH INTERN MED/VOL 172 (NO. 17), SEP 24, 2012

Comorbidities Associated with OUD – Cause and Effect

- Infectious Diseases
  - HIV, Hepatitis C, Osteomyelitis
- Mental Health
  - Depression, PTSD, Anxiety Disorder
- SUD
- Pain

High Mortality Among Patients With Opioid Use Disorder in a Large Healthcare System.

Conclusions: **Patients with OUD in a general healthcare system demonstrated alarmingly high morbidity and mortality, which challenges healthcare systems to find innovative ways to identify and treat patients with substance use disorder.**

Mortality was 10X higher for patients with OUD

Mortality rate of 48.6 per 1000 person-years and standardized mortality ratio of 10.3

Drug overdose and disorder (19.8%), cardiovascular diseases (17.4%), cancer (16.8%), and infectious diseases (13.5%, were the leading causes of death.

Hser et al. J Addict Med. 2017 Jul/Aug;11(4):315-319

Mortality among older adults with opioid use disorders in the Veteran's Health Administration

- Compare mortality in older (≥ 50 years of age) adults with OUD to that in younger (<50 years) adults with OUD and older adults with no history of OUD
- Older adults with OUD were more likely to die from any cause than younger adults with OUD.
- The drug-related mortality rate did not decline with age. HIV-related and liver-related deaths were higher among older OUD compared to same-age peers without OUD.

Larney et al *Drug Alcohol Depend*. 2015 February 1; 147: 32–37

The Role of Science in Addressing the Opioid Crisis
Volkow and Collins NEJM 5/2017

- Abundant research has shown that sustained treatment over years or even a lifetime is often necessary to achieve and maintain long-term recovery.
- Currently, there are only three medications approved for treating OUD: methadone, buprenorphine, and extended-release naltrexone.
- These medications coupled with psychosocial support are the current standard of care for reducing illicit opioid use, relapse risk, and overdoses, while improving social function

Volkow ND, Frieden TR, Hyde PS, Cha SS. Medication-assisted therapies — tackling the opioid-overdose epidemic. N Engl J Med 2014; 370: 2063-6.

	Buprenorphine/Naloxone**	Methadone
Treatment setting	Office-based	Specially licensed OTP
Mechanism of action	Partial opioid agonist	Opioid agonist
FDA approved for OUD	Yes	Yes
Reduces cravings	Yes	Yes
Best for mild, moderate, or severe OUD?	Mild—Moderate	Mild, Moderate, and Severe
Candidates and history of failed treatment attempts	None/few failed attempts	Many failed attempts
Recommended for OUD candidates with pain conditions requiring ongoing short-acting opioids?	No	Yes
Psychosocial intervention recommendations	Addiction-focused MM	Individual counseling and/or contingency management

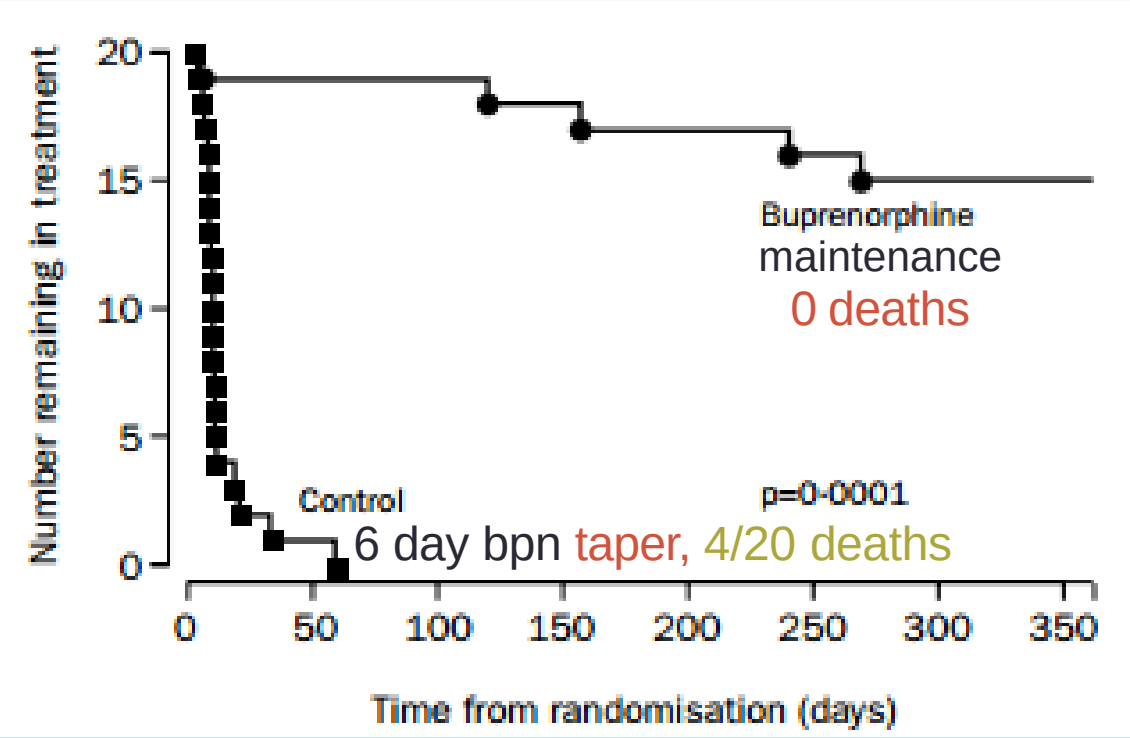
Adapted from VA Academic Detailing

EXTENDED-RELEASE INJECTABLE NALTREXONE

- FDA-approved for the prevention of relapse in adult patients with OUD following complete detoxification from opioids
- Recommended for patients unable/unwilling to take OAT and have not used an opioid in the past week
- Consider Naltrexone IM in patients with comorbid OUD and Alcohol Use Disorder

Medications for OUD: Overview

BPN 16mg daily vs 6day “detox”



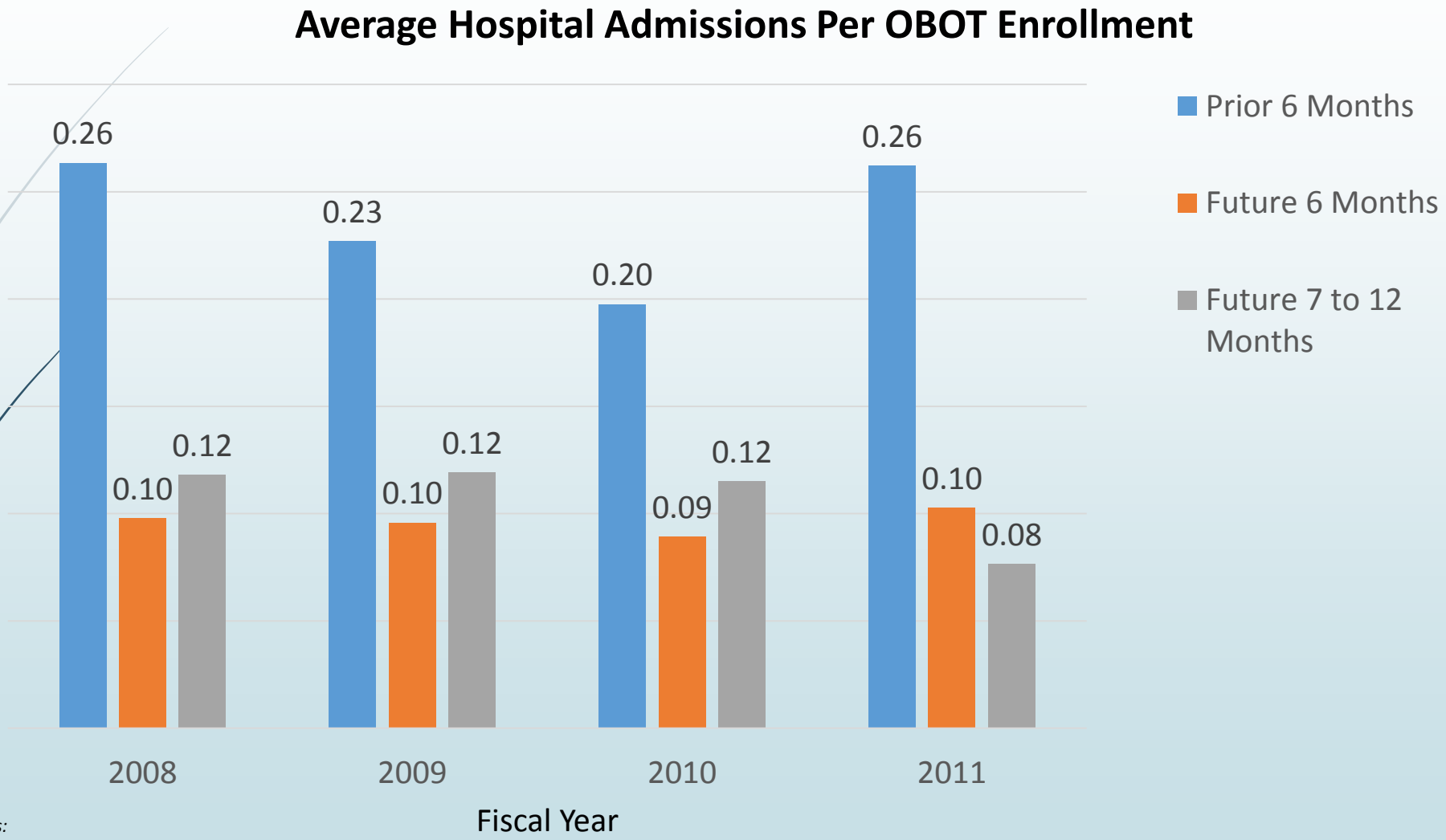
75% of urine screens were negative for illicit drugs among those retained in treatment

1. McCance-Katz, Review of Opioids & Treatment of Opioid Dependence, PCSS-O, Presentation 2012
4. Kakko et al. Lancet. 2003;361(9358):66 (graph)

Data from Nurse Case Manager Model of OUD Treatment in Primary Care

Boston, Massachusetts

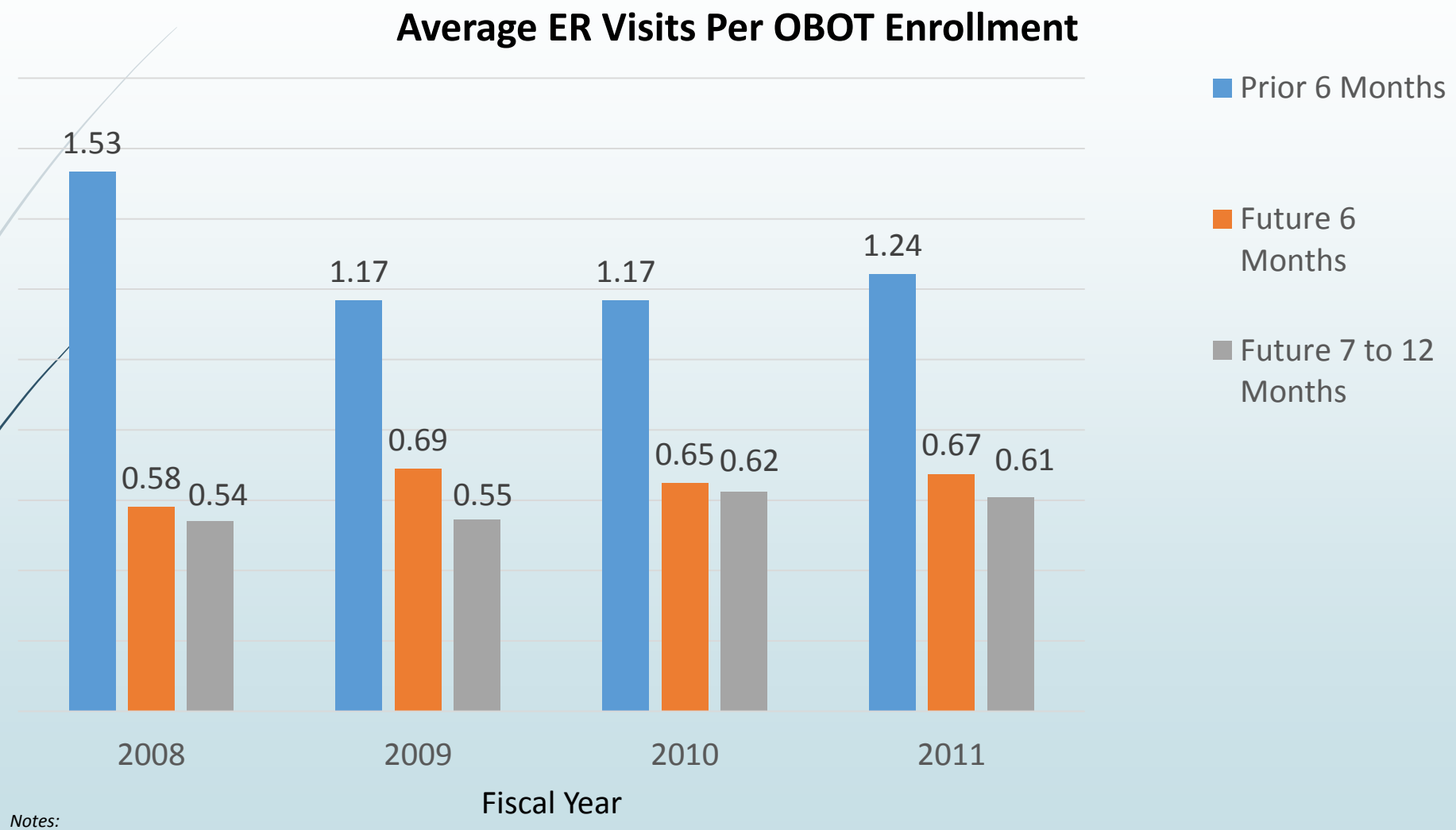
Hospital Admissions



Notes:

- *Hospital data is only available through 9/30/2012*
- *Enrollments must have lasted at least 12 months*
- *Paid amounts are calculated using hospital specific pay to charge ratios*

ER Visits



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Mortality Risk During and After Opioid Substitution Treatment

- Retention in methadone and buprenorphine treatment is associated with substantial reductions in the risk for all cause and overdose mortality in people dependent on opioids.
- Pooled all cause mortality rates were 11.3 and 36.1 per 1000 person years in and out of methadone treatment (unadjusted out-to-in rate ratio 3.20)
- Pooled all cause mortality rates were 4.3 and 9.5 in and out of buprenorphine treatment (2.20)
- The induction phase onto methadone treatment and the time immediately after leaving treatment with both drugs are periods of particularly increased mortality risk, which should be dealt with by both public health and clinical strategies to mitigate such risk.

Sordo et al. BMJ. 2017 Apr 26;357

Association of Mental Health Disorders With Prescription Opioids

- A total of 15 676 veterans were prescribed opioids within 1 year of their initial pain diagnosis.
- Compared with 6.5% of veterans without mental health disorders, 17.8% of veterans with PTSD and 11.7% with other mental health diagnoses but without PTSD were significantly more likely to receive opioids for pain diagnoses.
- Of those who were prescribed opioids, veterans with PTSD were more likely than those without mental health disorders to receive higher-dose opioids (22.7% vs 15.9%), receive 2 or more opioids concurrently (19.8% vs 10.7%), receive sedative hypnotics concurrently (40.7% vs 7.6%),or obtain early opioid refills (33.8% vs 20.4%;).
- Receiving prescription opioids (vs not) was associated with an increased risk of adverse clinical outcomes for all veterans (9.5% vs 4.1%), which was most pronounced in veterans with PTSD.

Seal et al JAMA, March 7, 2012—Vol 307, No. 9

PTSD, Pain and OUD

- Retrospective Analysis of Veterans With PTSD, OUD and Pain
- Retrospective Cohort of 382 OIF/OEF veterans with pain, ptsd, and OUD
- Comparisons made in PTSD Symptoms when buprenorphine was used to treat oud
- Twice as many veterans in the buprenorphine group (23.7%) compared to those in the opioid therapy group (11.7%) experienced improvement in PTSD symptoms
- Compared to veterans in the opioid therapy group, veterans receiving buprenorphine showed significant improvement in PTSD symptoms after 8 months, with increasing improvement up to 24 months.
- There were no differences in the longitudinal course of pain ratings between groups.

Seal et al J Clin Psychiatry. 2016 Mar 1

MAT Models in Primary Care

Agency for Healthcare Research and Quality

Technical Brief No. 28

MAT for OUD in Primary Care

- The majority of medication treatment for opioid use disorder (OUD) is provided in primary care settings.
- Effective and innovative models of care for medication-assisted treatment (MAT) in primary care settings (including rural or other underserved settings) could facilitate implementation and enhance provision and uptake of agonist and antagonist pharmacotherapy in conjunction with psychosocial services for more effective treatment of OUDs.
- In 2014, approximately 1.9 million Americans 12 years or older were estimated to have OUD due to prescription drugs and nearly 600,000 due to heroin use. OUD is associated with decreased quality of life and increased morbidity and mortality.

Hub and Spoke Model

- The system-based Hub and Spoke model was developed in Vermont
- The model consists of two levels of care, with the patient's needs determining the appropriate level
- In this model, "hubs" are OTPs that serve as regional specialty treatment centers (currently numbering 6) that provide traditional treatment for OUD and also have the capacity to either directly provide or to organize comprehensive care and continuity of services in a home health model
- "Spokes" are clinics in the community that provide MAT and comprehensive care for less clinically complex patients

Hub and Spoke Model

- Patients are screened to determine whether they are appropriate for initial stabilization and management in a hub or spoke.
- The hubs provide care for clinically complex patients, support tapering off MAT, dispense methadone if needed, and provide consultative services to the spokes.
- Following stabilization, patients initially managed at a hub who do not require ongoing management at the hub may have their management transferred to a spoke; conversely, patients managed in a "spoke" who require a higher level of care may be transferred to a hub.

Collaborative Opioid Prescribing Mode

- The system-based Collaborative Opioid Prescribing (Co-OP) model was developed in Baltimore
- Initial intake, induction with buprenorphine/naloxone, and stabilization is performed at a center
- Patients are shifted to primary care clinics for ongoing MAT after stabilization on medication
- Unlike the Hub and Spoke model, in the Co-OP model psychosocial services are generally provided concurrently on an ongoing basis by the OTP, rather than at the primary care site

Office-Based Opioid Treatment

- Physicians who complete 8 hours of training and receive a DEA waiver number may prescribe buprenorphine/naloxone in the context of primary care
- While many providers offer OBOT without staff assistance, some practices designate a clinic staff member, or "glue person" (often a nurse or social worker) who works in collaboration with a primary care clinician to coordinate services
- Psychosocial services include regular brief counseling provided by the physician and glue person or other staff; other psychosocial services vary but can include integrated cognitive behavioral therapy or motivational enhancement therapy

Massachusetts Nurse Care Manager Model

- This system-based model was developed in Massachusetts, where Medicaid reimburses Federally Qualified Health Center nurses for OUD care management
- This model is similar to the OBOT model in that a key aspect is the use of a nonphysician to coordinate and manage much of the care.
- Unlike the OBOT model, the Massachusetts model specifically uses nurse care managers who team with primary care physicians to provide MAT

Massachusetts Nurse Care Manager Model

- The nurse care manager performs initial screening, intake, and education, often with assistance from a medical assistant.
- The nurse care manager also provides ongoing management of OUD and other medical issues, including drop-in or same day visits, management of acute issues, coordination of prior authorization requests, communication with pharmacists, and perioperative care coordination.
- The diagnosis of OUD and appropriateness of MAT are confirmed by the prescribing physician, who comanages the patient with the nurse care manager.

Project Extension for Community Healthcare Outcomes

- The University of New Mexico developed a module for supporting rural primary care providers in MAT management. It emphasizes nurse practitioner- or physician assistant-based screening with referral to a collaborating physician prior to initiation of MAT and for ongoing treatment, typically with buprenorphine/naloxone
- Counseling and behavioral therapies are offered from all ECHO team members.
- Complex patients can be referred for further assessment and/or evaluation at an OTP.
- There is also an emphasis on recruitment of physicians for buprenorphine waiver training and provision of continuing medical education in OUD

Inpatient Initiation of Medication-Assisted Treatment

- This system-based model involves the identification of OUD in the hospital, with initiation of MAT (methadone, buprenorphine/naloxone, or naltrexone) during the hospitalization by a multidisciplinary addiction consult service
- Patients are connected with primary care or specialty addictions care (patients initiated on methadone must be followed in an OTP), where treatment continues following hospital discharge.
- In some programs, when relevant, there is a buprenorphine "bridge" clinic for stabilization prior to transitioning to primary care.
- Ongoing psychosocial services are provided at primary care sites.

How can I get waivered?

- www.pcssmat.org
- American academy of addiction psychiatry
- American society of addiction medicine
- Quarterly VA/DoD trainings – Contact Ilene.Robeck@va.gov

Treating Pain in Patients with OUD

- New guidelines recommend non opioid therapies for pain that are all appropriate for patients with OUD
- Patients on Buprenorphine/Naloxone may benefit from a split dose. However the dose is titrated to address opioid dependence and not increased related to symptoms related to pain
- Cognitive therapies for functional restoration for pain and addiction go hand in hand. They can support and supplement each other

Adjuncts and Alternatives to Opioid Therapy are All Options for Patients

- Antidepressants
- Anticonvulsants
- Acetaminophen
- Medications for sleep – Non benzodiazepine
- Topical Agents

- Heat
- Prosthetic supports
- Physical therapy
- Exercise
- Cognitive-behavioral therapy
- Interventional Pain Management
- TENS Unit
- Complementary Integrated Health Approaches
- Self Care
- Coaching

Treating Pain Comorbidities is Important

- Depression
- PTSD
- Anxiety
- Obesity
- Nicotine Dependence
- Non nicotine SUD
- Sleep Apnea
- Sleep Disturbance
- Diabetes

Innovations to Help Integrate Care

- High Risk Pain Teams
- PACT based pain teams
- PACT Pain Champions
- VA Echo
- Expanded x waivered providers
- Pain Schools
- Expanded use of Complementary Integrated Options in PACT
- Coaching
- Whole Health Approaches
- PCMHI
- SUD services in PACT, Pain Clinics, Mental Health

2007 Launched the Buprenorphine in VA (BIV) Initiative

2008 Policy required access to medication for opioid use disorder

2009 Established National Office for Pain Management Practices

2011 Created standardized metrics for pain management therapies

2013 Launched the Opioid and Psychotropic Drug Safety Initiatives

2014 Began targeted interventions for opioid reduction and opioid overdose education and naloxone distribution

2016 Published VA-DoD Clinical Practice Guideline (CPG) on Management of Substance Use Disorders

Comprehensive Addiction and Recovery Act (CARA) response

2017 Published VA-DoD CPG on Opioid Therapy for Chronic Pain

Launched Academic Detailing OUD Campaign

Launched Psychotropic Drug Safety Initiative (PDSI) Phase 3

Gellad Good & Shulkin- JAMA

Supported by VA CESATE, SUD-QUERI, and VISN 4 MIRECC

Listserve Engagement
VHA National Buprenorphine
VHA National Opioids
VHA National Addictions
BIV

Guidances
Resource Guide, Protocol/SOP guides, guidance collections for common situations

In-Service Webinar Trainings
Conducted monthly
40-50 average attendance

Scholarship Reputation
Peer-reviewed published articles on buprenorphine usage, implementation, access, opioid-use disorder assessment

within VA

Answers to Common Inquires
Buprenorphine and Telehealth,
Model Informed Consent, policies and procedures

Sharepoint
These resources are broadcast to listserves and are available on the BIV Sharepoint site, hosted by OMHS

Monthly eNewsletter
"A Tool For Buprenorphine Care"
79 issues produced since 2007

Buprenorphine Consult Service
approximately 100 email contacts per month.

- S – Stepped Care Model for Opioid Use Disorder & Pain
- T – Treatment alternatives/Complementary care
- O – Ongoing monitoring of usage
- P – Practice Guidelines
- P – Prescription monitoring
- A – Academic Detailing
- I – Informed Consent for patients
- N – Naloxone distribution

Buprenorphine/Naloxone – Physician Management and CBT

- 24-week randomized clinical trial in 141 opioid-dependent patients in a primary care clinic. Patients were randomized to physician management or physician management plus cognitive behavioral therapy.
- Physician management was brief, manual guided, and medically focused; cognitive behavioral therapy was manual guided and provided for the first 12 weeks of treatment.
- The primary outcome measures were self-reported frequency of illicit opioid use and the maximum number of consecutive weeks of abstinence from illicit opioids, as documented by urine toxicology and self-report.
- Among patients receiving buprenorphine/naloxone in primary care for opioid dependence, the effectiveness of physician management did not differ significantly from that of physician management plus cognitive behavioral therapy.

Fiellin et al Am J Med. 2013 January ; 126(1): 74.e11–74.e17.

Standard Medical Management

- Initial SMM Visit Session (60 minutes)
- The essential elements of the initial SMM session are:
  - Establish rapport with the patient
  - Review medical, psychiatric, and substance abuse problems (30 minutes)
  - Review diagnosis with patient (5 minutes)
  - Develop the treatment plan, including explanation of buprenorphine (10 minutes)
  - Advise abstinence from all drugs
  - Refer to self-help group
  - Other referrals
  - Delineate and reinforce the program guidelines
  - Answer any questions the patient may have

Standard Medical Management

- Follow-up SMM Visit (15-20 minutes)
- Essential elements are outlined in structured visit note and include:
  - Review of medication adherence
  - Review of substance use since prior visit and beginning of treatment
  - Review response to medication (cravings, withdrawal, side-effects)
  - Review lifestyle changes (people, places, things) & level of self-help participation
  - Explore impact of addiction/recovery on function (social/family, employment, legal, financial)
  - Advise abstinence from all drugs
    - Offer support for patients' efforts to abstain from drug use
    - Provide brief education & advice on drug dependence & recovery
  - Address non-adherence (where necessary)
  - Make referrals (if necessary) and follow-up on earlier referrals
  - Dispense medication

Addiction treatment and a Biopsychosocial Approach to Pain Go Hand in Hand – Body

- Pain and addiction triggers
- The role of diet
- The role of exercise
- The role of pacing activities
- Safe medication Use
- Education

Addiction Treatment and Pain Treatment Go Hand in Hand - Spirit

Reduce sadness, helplessness

Information about pain and addiction

Meditation

Meaningful rituals

Spiritual healing

Support groups

Addiction Treatment and Pain Treatment Go Hand in Hand - Mind

Sleep hygiene

Relaxation, imagery

Distraction

Repattern thinking

Attitude adjustment

Reduce fear, anxiety, stress

Addiction Treatment and Pain Treatment Go Hand in Hand - Social Interactions

Functional restoration

Improved communication

Family Interaction

Problem Solving

Vocational Training

Volunteering

Support Groups

Topics for further research

- Is there a difference in relapse rate for patients with prescription oud alone, illicit oud alone, or oud related to both prescription and illicit opioids
- What is the true incidence of oud in all patients with chronic pain when all are screened
- Is there a validated screen for oud that can be used in pain clinic and primary care clinic settings
- Is there a difference is treatment outcomes (with and without MAT) for patients with prescription related oud diagnosed with mild, moderate or severe oud
- What is the difference in outcomes for patients on high dose opioids (90 mg ME or greater) who are tapered, switched to MAT for opioid dependence or maintained on full mu agonists for pain

Chronic Pain and OUD

- Common comorbidities that require simultaneous treatment
- Treating OUD allows for greater retention in treatment, improved ability to treat associated comorbidities and improved ability to use non opioid options for pain
- There are a number of non SUD models for OUD treatment with MAT that have demonstrated success.
- Cognitive approaches to pain and treating OUD go hand in hand allowing for medication management options in a number of different settings.