PainWeek®

Bupe'd or Duped?
Is Buprenorphine for Everyone?

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Titles & Affiliations

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Disclosures

Affiliation	Role/Activities
Axial Healthcare Inc	Consultant – Design, review, and implement opioid metrics and peer review utilizing claims data
ASHP	Opioid REMS virtual CE design, presentation
Auburn University/AL Dept of MH	Speaker – Opioid Crisis CE Programs
Rockpointe, Inc	REMS opioid presentation/lecture, OUD Program (a continuing education company)
Purdue Pharma LP	Epidemiology Advisory Board – Category 4 Post-Marketing Studies for OxyContin

Titles and Affiliations

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Disclosures

Affiliation	Role/Activities
Abbott Laboratories	Speaking, non-speakers bureau
AcelRx Pharmaceuticals	Acute perioperative pain (speakers bureau, consulting, advisory boards)
BioDelivery Sciences International	Collaborative publications, consulting, advisory boards
Firstox Laboratories	Micro serum testing for substances of abuse (consulting)
GlaxoSmithKline (GSK)	Collaborative non-paid poster presentations)
Medscape/WebMD	Presentations / webinars on medication assisted treatment (MAT) for opioid-use disorder
Pharmacy Times	Webinars, writing/publishing
Practical Pain Management	Co-Editor-At-Large, writing, and editing
Rockpointe, Inc	REMS opioid presentation/lecture (a continuing education company)
Scilex Pharmaceuticals	Collaborative non-paid publications
Salix Pharmaceuticals	Speakers bureau, consultant, advisory boards
Trinity Health, Inc.	Direct patient care, virtual consultations for pain management akin to a virtual private medical practice

Learning Objectives

- Differentiate buprenorphine products and indications for pain vs OUD
- Describe emerging strategies and national trends in buprenorphine prescribing
- Highlight opposing views on widespread adoption of buprenorphine/naloxone use outside of addiction settings
- Analyze the impact of long-term harm reduction vs rehabilitation toward outcomes in recovery and pain management.

Pretest Question #1

Which of the following are true regarding buprenorphine?

A. Prescribing clinicians are required to complete an eight-hour training course to qualify for a waiver to prescribe buprenorphine for pain

B. All buprenorphine products can be legally prescribed for analgesia by non-certified clinicians with proper DEA license

C. No buprenorphine products are specifically FDA approved for chronic pain management

D. Pharmacologically, buprenorphine is equally dangerous to most other opioids

Pretest Question #2

Which of the following are true regarding buprenorphine formulations approved by FDA for OUD?

A. Only physicians with a DEA x-waiver may prescribe for OUD
B. Opioid Treatment Programs (OTP) can prescribe buprenorphine/naloxone for OUD
C. Office-based Opioid Treatment (OBOT) programs can prescribe methadone for OUD
D. CARA legislation allows x-waivered providers to expand treatment above previous limit of 100 patients

Pretest Question #3

Which of the following are true regarding buprenorphine?

A. Street value is low
B. Prescriptions are increasing while all other opioids are decreasing
C. Ceiling effect on respiratory function is outside the therapeutic range
D. Utility in OUD attributable to partial agonist activity at mu opioid receptors

Opioid Pharmacology 101

- Opioid pharmacology
  - Agonist, partial agonist, agonist/antagonist, antagonist
- There are three opioid receptors (μ, δ, and κ) that are distributed throughout the body and CNS, and elicit different responses when activated
- CO2 accumulation and diminished chemoreceptor response may lead to the lethal effect of respiratory depression

Opioid Receptor	Desired Activity	Disadvantages when activated
μ	Peripheral Analgesia, euphoria?	Sedation, euphoria, respiratory depression, bradycardia, N/V, and decreased GI motility
δ	Spinal and supraspinal analgesia	Decreased GI motility
κ	Spinal analgesia	Diuresis and dysphoria
ORL1	Spinal Analgesia	Sedation

Günther T, Dasgupta P, Mann A, Miess E, Kliewer A, Fritzwanker S, Steinborn R, Schulz S. Targeting multiple opioid receptors–improved analgesics with reduced side effects?. British journal of pharmacology. 2018 Jul;175(14):2857-68.
Gudin J, Fudin J. A narrative pharmacological review of buprenorphine: a unique opioid for the treatment of chronic pain. Pain and Therapy. 2020 Jan 28:1-4.

Pharmacology & PK of Buprenorphine

- Highest affinity for the μ-receptor compared to all other opioid agonists and antagonists
  - Higher than _____?
- Slow dissociation rate from the μ-receptor
- Competitive binding of buprenorphine at low doses
  - Not displaced by full agonists at moderate to high doses
  - Considerations for surgery?
- Undergoes extensive N-dealkylation via CYP3A4 into norbuprenorphine, and glucuronidation into buprenorphine-3-glucuronide and norbuprenorphine-3-glucuronide (all inactive metabolites)
- Half-life ≈ 26 hours

McNicholas L. US Department of Health and Human Services. 2004. Pages 11-24.

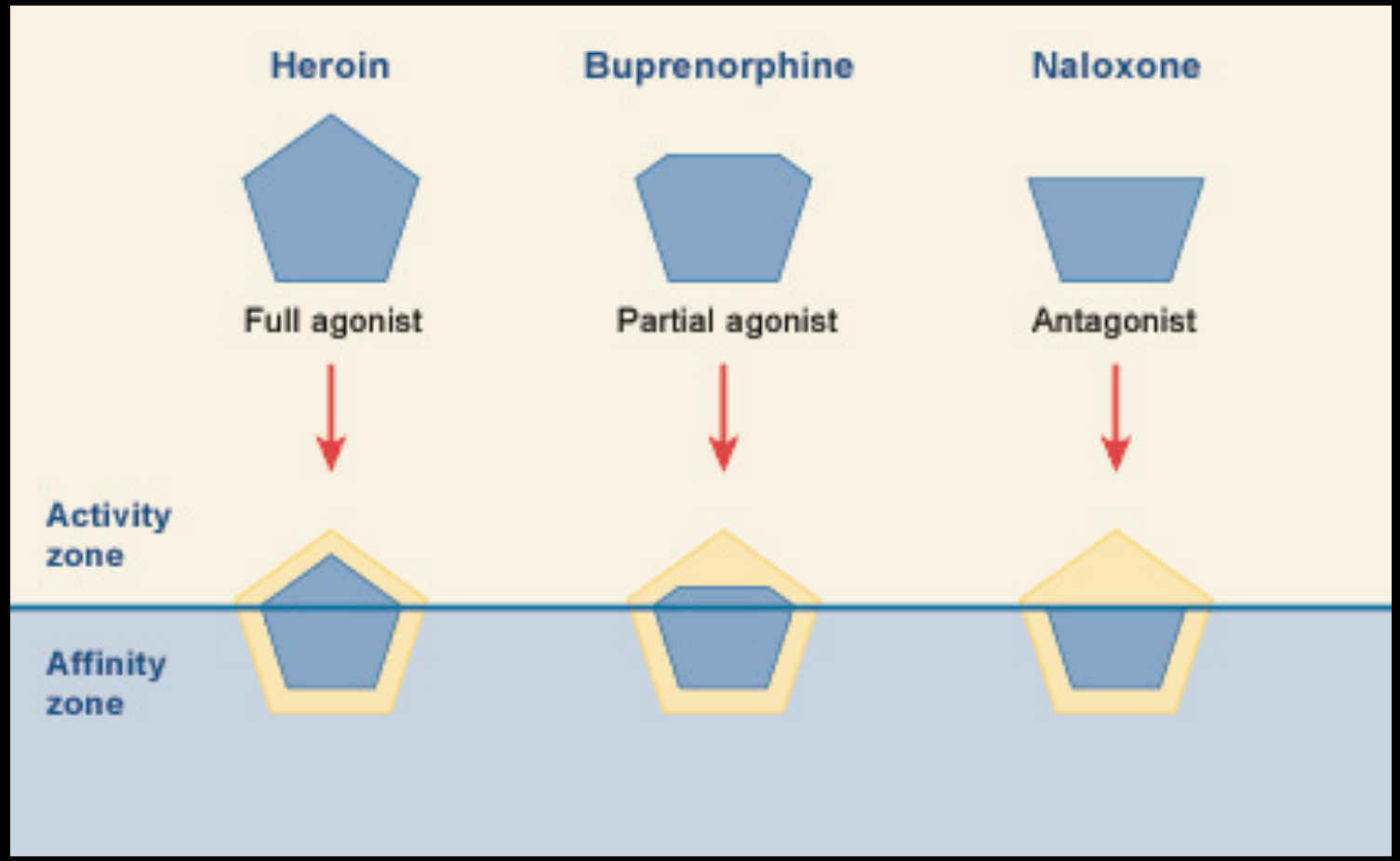
Mu Receptor Binding Affinity of Buprenorphine

Opioids	Range of Ki Value
Buprenorphine	0.21- 1.5
Naltrexone	0.4-0.6 (antagonist effects)*
Fentanyl	0.7-1.9
Methadone	0.72-5.6
Naloxone	1.0-3.0 (antagonist effects)*
Morphine	1.02-4
Pentazocine	3.9-6.9
Codeine	65-135

**Wang D, Sun X, Sadee W. Different effects of opioid antagonists on μ-, δ-, and κ-opioid receptors with and without agonist pretreatment. Journal of Pharmacology and Experimental Therapeutics. 2007 May 1;321(2):544-52.

Volpe DA, Tobin GA, Mellon RD, Katki AG, Parker RJ, Colatsky T, Kropp TJ, Verbois SL. Uniform assessment and ranking of opioid mu receptor binding constants for selected opioid drugs. Regulatory Toxicology and Pharmacology. 2011 Apr 1;59(3):385-90.

Opioid Pharmacology Schematic



Important Qualities

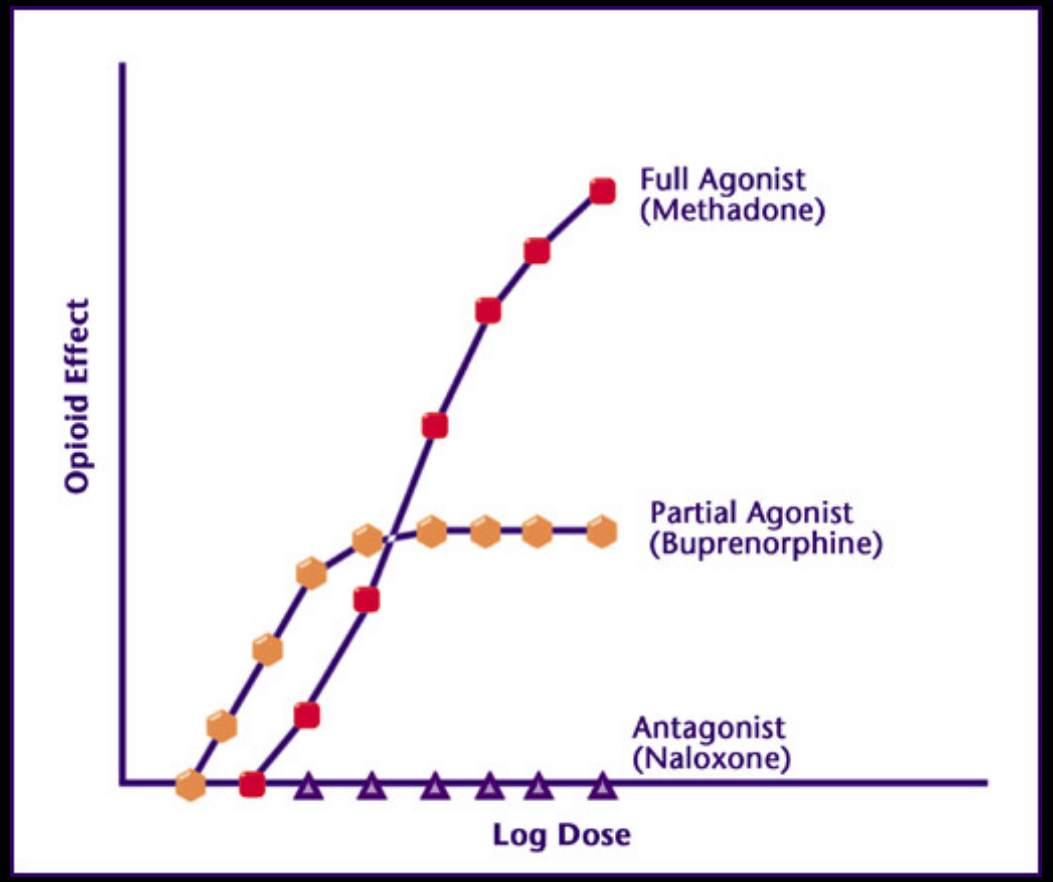
1. Affinity (pull towards receptor)
2. Binding Affinity (ki,)
3. Receptor Dissociation
   - Consider methadone
4. Potency (chemical configuration)

Keep an Open Mind / Be "Impartial"

- Partial agonist at the μ-receptor and a potent antagonist at the κ-receptor
  - Lower intrinsic activity at μ-receptors in comparison to full μ-agonists
- Flattened dose-response curve (ceiling effect):
  - At lower dosages there are dose-related increases in efficacy
  - Eventually escalating doses result in plateaued efficacy
- Ceiling on euphoria and CO2 accumulation decreases
  - Abuse liability
  - Risk of OIRD and overdose

Gudin J, Fudin J. A narrative pharmacological review of buprenorphine: a unique opioid for the treatment of chronic pain. Pain and Therapy. 2020 Jan 28:1-4.

Conceptual Dose-Response Curves of Three Opioids



McNicholas L. US Department of Health and Human Services. 2004. Pages 11-24.

Clarifying the Terms

- Affinity is the thermodynamically driven chemical attraction between a drug and a receptor.
- Intrinsic activity is the biological stimulus imparted by a drug to a receptor.
  - Buprenorphine has high affinity for mu-opioid receptors
  - Buprenorphine has low in vitro intrinsic activity as measured by binding in several receptor binding assays.
- Efficacy relates to the level of drug-induced effect in a given application.
  - Although buprenorphine is labeled as a partial agonist (<100% effect produced by a 'full' agonist), that 100% depends on certain conditions.
    - For example, in the same in vitro assays in which buprenorphine produces <100% effect, morphine likewise produces <100% effect (Raffa: "..a fact perhaps not widely known).

Raffa RB, Haidery M, Huang HM, Kalladeen K, Lockstein DE, Ono H, Shope MJ, Sowunmi OA, Tran JK, Pergolizzi Jr JV. The clinical analgesic efficacy of buprenorphine. Journal of clinical pharmacy and therapeutics. 2014 Dec;39(6):577-83.

Drilling Down

- Buprenorphine is considered is a partial agonist with very high binding affinity for the mu-opioid receptor
- Antagonist with high binding affinity for the delta and kappa opioid receptors
- Agonist with low binding affinity for the opioid receptor-like 1 receptor
- Partial agonist at the ORL1 opioid receptor
  - –BUT…
    - It does not provide partial analgesia
    - In fact, provides analgesia equivalent to that of full mu-opioid receptor agonists.

Gudin J, Fudin J. A narrative pharmacological review of buprenorphine: a unique opioid for the treatment of chronic pain. Pain and Therapy. 2020 Jan 28:1-4.

Beta Arrestin

- Phosphorylation at specific amino acid residues on receptor cytoplasmic domain may lead to b-arrestin recruitment
  - An adaptor protein that regulates receptor function and signal transduction activity
- BA recruitment causes receptor internalization and downregulation of mu-opioid receptor signaling
  - BA signaling is associated with OIRD and abuse
- Buprenorphine is a unique opioid…
  - Bupe stimulates sufficient G-protein signaling while limiting BA recruitment
  - The balance between G-protein and BA signaling may determine the extent of analgesia versus the adverse effects

Gudin J, Fudin J. A narrative pharmacological review of buprenorphine: a unique opioid for the treatment of chronic pain. Pain and Therapy. 2020 Jan 28:1-4.

Buprenorphine Formulations *per Indication*

Medication Assisted Treatments (MAT)

- Suboxone (buprenorphine/naloxone) SL film
  - Generic available as of June 14, 2018
- Subutex (buprenorphine) SL tablet
- Zubsolv (buprenorphine/naloxone) SL tablet
- Bunavail (buprenorphine/naloxone) buccal films
- Generic buprenorphine/naloxone SL tablet
- Sublocade (buprenorphine) subcutaneous injection once monthly
- Probuphine (buprenorphine) intradermal Implant

Analgesics

- Butrans
- Belbucca
- Buprenex
- Subutex (off-label use)

Available Doses of Buprenorphine/Naloxone Combination Products

Suboxone SL Tablet	Suboxone SL Film	Zubzolv SL Tablet	Bunavail Buccal Film
2 / 0.5 mg	2 / 0.5 mg	1.4 / 0.36 mg	----------
4 / 1 mg	4 / 1 mg	----------	2.1 / 0.3 mg
8 / 2 mg	8 / 2 mg	5.7/ 1.4 mg	4.2 / 0.7 mg
12 / 3 mg	8 / 2 mg + TWO 2 / 0.5mg films	----------	6.3 / 1 mg

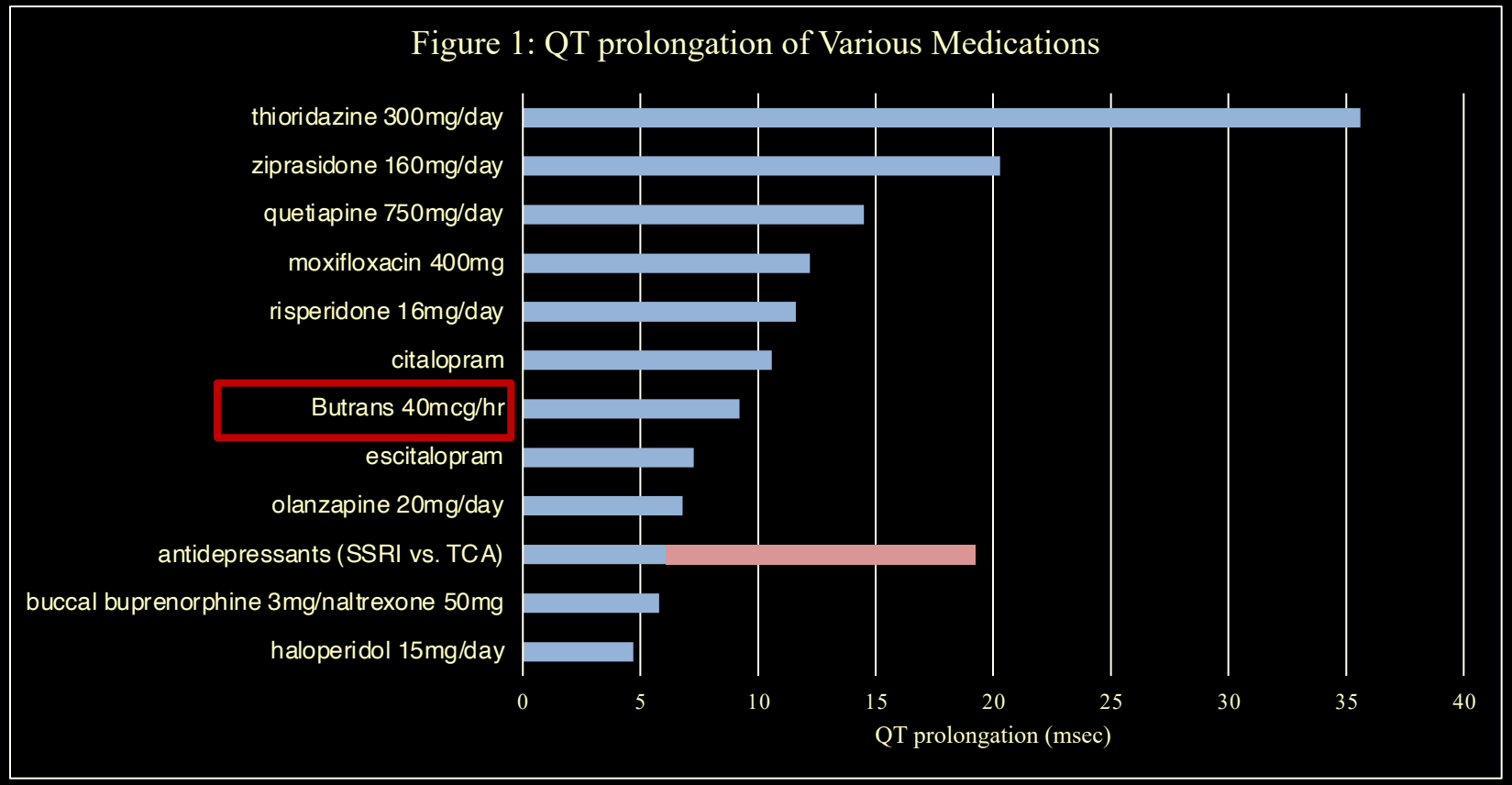
Fudin J, Cleary J, Gottwald J. A Brief Review of Buprenorphine Products. Pharmacy Times. March 22, 2016. Available at http://www.pharmacytimes.com/contributor/jeffrey-fudin/2016/03/a-brief-review-of-buprenorphine-products

Buprenorphine Product Bioavailability

PRODUCT	Available Strengths	PERCENT BIOAVAILABILITY
Belbuca (buccal film)	75, 150, 300, 450, 600, 750, 900mcg	45-65 %
Butrans (TD patch)	5, 7.5, 10, 15, 20 mcg/hr	15 %
Subutex (SL) Suboxone/Bunavail/ Zubsolv	See previous slide	29 +/- 10 %
Buprenex (injectable)	0.3mcg/mL	100%

Revised from:
Bettinger JJ, Fudin J, Argoff C. Buprenorphine and Surgery: What's the Protocol? In Kean N, 2nd ed., Opioid Prescribing and Monitoring—How to Combat Opioid Abuse and Misuse Responsibly. Chap. 6. Pg. 73-78. Pub. Vertical Health, LLC. September 2017.

QTC PROLONGATION COMPARISON



Jeffrey Fudin, Jacqueline Pratt Cleary, Joseph Gottwald. A Review of Buprenorphine Products. Published online 3/22/2016. http://www.pharmacytimes.com/contributor/jeffrey-fudin/2016/03/a-brief-review-of-buprenorphine-products.

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Buprenorphine for OUD

Epidemiology

Retrospective Cohort Study:

- Half of the events occurred within the first year of opioid prescriptions
- 33% of events occurred between 1-2 years after opioid initiation
- 13% of events occurred between 2-3 years after opioid initiation
- Overall incidence of drug overdose women > men (0.76% vs 0.56%)

Liang Y, Turner B. National Cohort Study of Opioid Analgesic Dose and Risk of Future Hospitalization. *J Hosp Med.* 2015; 10(7):425-431.

Epidemiology

Retrospective Cohort Study:

- 90 day exposure windows
- Unadjusted overdose risk per annum in >100mg MEDD was 1.8%
- There were seven non-fatal overdose events for every fatal overdose event
- Majority of overdose events occurred in those receiving low to moderate doses of opioids
- 50-100mg HR 3.73 (all overdoses) and HR 3.11 (serious overdoses)
- >100mg HR 8.87 (all overdoses) and HR 11.18 (serious overdoses)

Dunn K, Saunders K, Rutter C et al. Overdose and prescribed opioids: Associations among chronic non-cancer pain patients. *Ann Intern Med.* 2010; 152(2):85-92.

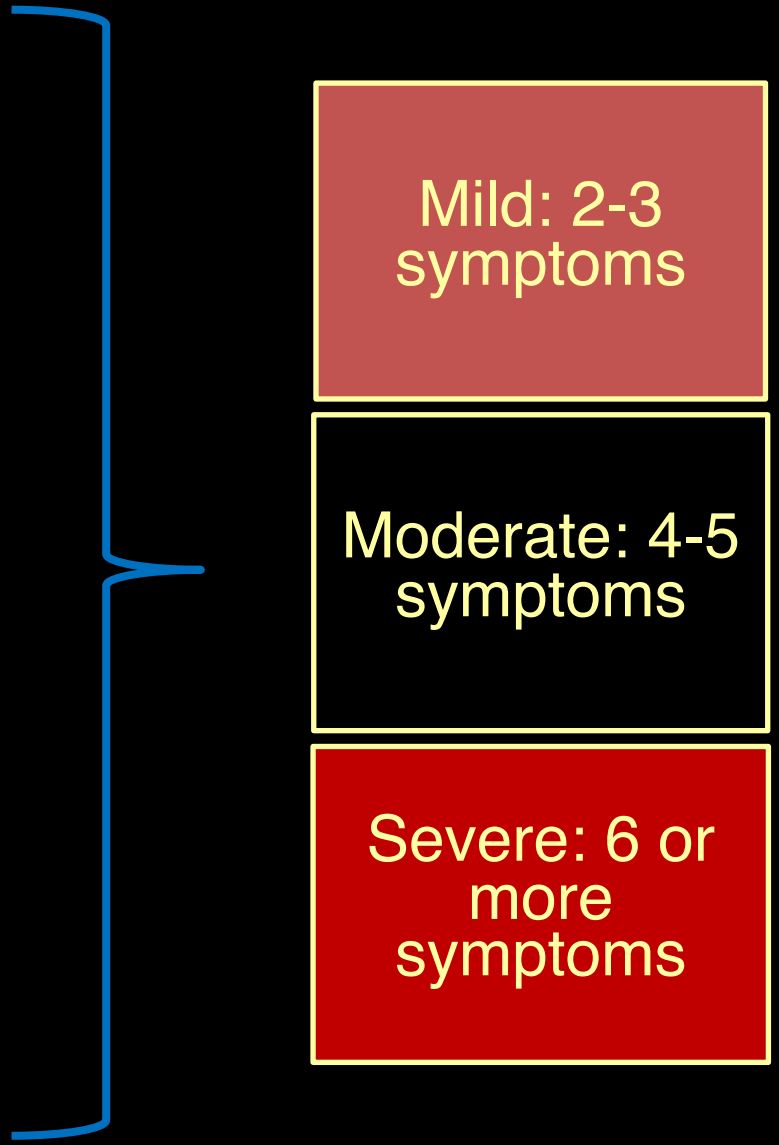
Pain & Substance Use Disorders

- 50% or more of patients in SUD settings report pain
- 30% of patients in specialty pain care have current SUD
- Pain is associated with increased risk of SUDs
  - Majority are alcohol use disorders
- VHA Study of SUD patients (N=5,195,551) reporting pain:
  - 44.5% arthritis
  - 32% back pain
  - 5.6% neuropathic pain
  - 2.1% migraines
- Chronic pain associated with poorer outcomes following SUD treatment
  - More likely to drop out of treatment or be abstinent at 1 year

Potter JS et al. *J Subst Abuse Treat*. 2010;38(Suppl 1):S80-6.
Morasco BJ et al. *J Pain*. 2011;12(3):352-9.

OUD: Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5)

DSM-5 Criteria
Taking larger amounts or longer period than intended
Persistent desire or unsuccessful efforts to cut down or control opioid use
Great deal of time spent in obtaining, using, or recovering from opioid use
Craving, or strong desire or urge to use opioids
Recurrent use resulting in failure to fulfill major obligations at work, school, or home
Continued use despite persistent or recurrent social/interpersonal problems caused by use
Important activities given up due to use
Use in situations where it is physically hazardous
Continues use despite physical/psychological problems due to use
+/- Tolerance and Withdrawal

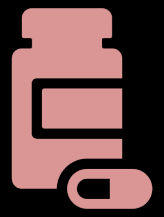


Clinical Conundrum

You have a patient with a long history of opioid therapy and recently the decision was made to taper to lower MEDD as recommended by national guidelines. The patient has struggled with opioid taper and despite slowing the taper, you have begun to see aberrant behaviors including routinely running out early. Where do you go from here?

1. Increase back to previously stable dose
2. Rapid taper and detox
3. Discuss concerns for overuse and evaluate for OUD
4. Start suboxone off-label for pain

Fast Facts About OUD Treatment



30-fold increase in death risk in the 2 weeks after treatment interruption

California based study:

Immediate access to medication treatment = lifetime savings up to $3.8 billion

Integration of buprenorphine Treatment in primary care:

Better retention rates

Fewer Hospital Stays

Lower Total Cost

Treatment Settings in OUD

Certified Outpatient Treatment Program (OTP)

- Federally regulated
- Medication Options
  - **Methadone**
  - Buprenorphine
  - Naltrexone

Office Based Outpatient Treatment (OBOT)

- General or specialty care
- Data 2000
- Comprehensive Addiction Recovery Act (CARA)
- Medication options
  - Buprenorphine
  - Naltrexone

Establishing Care in Opioid Use Disorder
US Office-Based Opioid Treatment (OBOT)

Provider Action	ASAM	SAMHSA	VA/DoD	FSMB
Past Medical History and Physical Assessment	Comprehensive medical history: physical exam, evaluate for infectious diseases, pregnancy, lab tests	Comprehensive assessment: Physical exam; complete history; conditions related to drug abuse, lab tests	History and physical exam, lab tests	Physical exam; thorough medical history; communicable diseases, UDT, PDMP
Mental Health Assessment	Psychiatric stability Psychiatric disorders	Mental status examination Formal psychiatric assessment (if indicated)	Mental Status examination Psychiatric stability Psychiatric disorders	Psychiatric history Psychiatric disorders Readiness to participate in Tx
Substance Use History	Confirm OUD Diagnosis Substance abuse history	Confirm OUD diagnosis; screen for drug or alcohol-related disorders	Confirm OUD Diagnosis; Treatment should be offered for each SUD	Confirm OUD Diagnosis; Use of other substances Past treatment experience
Social History	Identify barriers to recovery: living situation, financial concerns, social support	Social support, family history, readiness to change	Assess psychosocial functioning and environment	Access to social supports, family, friends, housing, employment, finances and legal problems
Psychosocial Assessment	Assessment of psychosocial needs Medications but one aspect of treatment	Needs assessment; incorporate plan for engaging in psychosocial interventions into treatment plan	Needs Assessment Supportive counseling Referral to community services	Baseline Assessment; Level of psychological and social functioning or impairment
Patient Selection	OBOT vs OTP consider: • Psychosocial situation • Co-occurring disorders • Treatment retention vs risk of diversion Active use of other drugs, associated with poorer prognosis. Not a reason to deny Tx	OBOT: • Reasonable compliance • Motivation & desire Tx • History of stable treatment • Psychosocial supports • Psychiatric stability • Adequate treatment resources • Comorbid substance abuse	OBOT vs OTP: • Patient preference • Stable patients • Provide needed resources • None/few failed attempts at Tx Difficulty accessing OTP	OBOT: • Ability to offer/refer for psychosocial services • Readiness to change • May be candidates even with previous failures
Agreement	Informed consent	Informed consent; treatment plan; provider and patient sign	Not specified	Treatment agreement and informed consent should be signed by patient

ASAM = American Society of Addiction Medicine; SAMHSA = Substance Abuse and Mental Health Services Administration; VA/DoD = Veteran's Affairs/Department of Defense; FSMB = Federation of State Medical Boards; WHO = World Health Organization; MAT = Medication Assisted Treatment; Tx = Treatment; OUD = Opioid Use Disorder

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Atkinson TJ, et al. *Am J Managed Care*. 2019; 25(3):e88-e97.

U.S. Unique Approach to MAT

Two Treatment Settings Available:

1. **Outpatient Treatment Program (OTP) [Example: methadone clinic]**
   - Most common approach used worldwide
   - Intensive treatment program
   - Recommended for high risk patients
   - Required evaluations with psychiatrist
     - Counseling
   - Patients present daily for observed medication administration
   - OTP's can offer both methadone & buprenorphine
   - Traditionally mostly cash ($12-16/day); recently began taking some insurance
   - May earn right to "carry" or take home medication for a few days

U.S. Unique Approach to MAT

Two Treatment Settings Available:

2. Office-Based Outpatient Treatment (OBOT) [Example: suboxone clinic]

- **DATA 2000 allows physicians to prescribe buprenorphine for OUD in office practice**
  - 24 hours of training, submit waiver notification form, DEA assigns X license #
  - 1st year 30 patients
  - NOI- Request increase to 100 patients
- **Comprehensive Addiction Recovery Act (CARA) Effective 7/22/2016**
  - Section 303- authorizes NPs & Pas to obtain waiver for DEA X license
- **42 CFR Part A (RIN 0930-AA22)-HHS Rule Effective 8/6/2016**
  - Increase to 275 patients

Patient Follow-up and Monitoring in OUD
US Office-Based Opioid Treatment (OBOT)

Provider Action	ASAM	SAMHSA	VA/DoD	FSMB
Visit Frequency	Frequently during initiation (at least weekly); stable patients (at least monthly)	Frequently during induction, stabilization. Weekly, biweekly, or monthly depending on stability.	Twice weekly, then weekly, then biweekly up to 12 weeks	Frequently until stable; follow-up frequency based on compliance and high risk behaviors
Duration	No time limit. Taper/discontinuation is a slow process and requires careful consideration of factors including: • Treatment engagement • Patient stability • Patient preference • Improved social support	Maintenance can be short-term (1 year) up to lifetime. Duration depends on patient: • Stability • Preference	No time limit Longer durations (>90 days) associated with improved outcomes	Recommend at least a year; Longer duration associated with better outcomes Relapse risk is highest in first 6-12 months of abstinence
Prescription Frequency	Weekly or monthly	Weekly or monthly	Not specified	As needed until next visit, Coincides with follow-up based on compliance and high risk behaviors
Usual Dosing	8-16 mg daily FDA limits at 24 mg daily No evidence at higher doses but increased diversion risk Divide dose for comorbid pain diagnosis	Nearly all patients will stabilize on daily doses of 16-24 mg; some, however, may require up to 32 mg daily.	• 12-16 mg • Moderate evidence higher dosing is more effective • Divide daily dose for concurrent chronic pain	8-24 mg; some may require up to 32 mg daily.
UDT	Baseline; Frequently; Random preferred	Baseline; At least monthly	Baseline; Frequent; at provider discretion	Baseline; Routinely; Recommended and included in treatment agreement
Pill Counts	Unscheduled recall visits	Not specified	Not specified	Recommended and included in treatment agreement
PDMP	Verify abstinence	Not specified	Not specified	Baseline; Routinely; Recommended to verify abstinence and included in treatment agreement

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Buprenorphine

Receptor activation:

- μ-opioid agonist – partial
- κ-opioid antagonist
- δ-opioid antagonist

Receptor Kinetics:

- Highest affinity of all opioids
- Slow receptor association (30min)
- Very slow receptor dissociation (166min)

Receptor saturation:

- 2mg SL tablet – 36-50% saturation
- 16mg SL tablet – 79-95% saturation

Pharmacology:

- Semi-synthetic derivative of thebaine
- 20-40 times more potent than morphine

Reversal:

- 2-3 times more potent at displacing fentanyl
- 40 times dose of naloxone required to reverse buprenorphine compared to fentanyl

Elimination half-life:

- Single administration – 25hrs
- Multiple administrations – 32-36hrs

Greenwald et al. *Neuropsychopharm.* 2003; 28:2000-2009
Boas et al. *Br J Anaesth.* 1985; 57: 192-196.

Buprenorphine Prescribing on the Rise

Traditional opioid prescribing is declining

- DEA announced mandatory 25% reduction in production from pharmaceutical companies
- Result of decreased prescribing

Buprenorphine Prescribing is Increasing

Opioid Use Disorder (OUD)

- Brixadi® SQ Inj (2020 tentative approval)
- Sublocade® SQ Inj (11/30/17)
- Probuphine® (5/26/16)
- Bunavail® (6/6/2014)

OUD (Cont'd)

- Zubsolv® (7/3/2013)
- Suboxone®
  - Sublingual tablet (10/8/2002)
  - Buccal Film (8/30/2010)

Chronic Pain

- Belbuca® (10/13/2015)
- Butrans® (6/30/2010)

Polling the Audience

- What issues do you see with increased emphasis on buprenorphine prescribing?
- Please use the chat box to direct the conversation toward a buprenorphine topic of interest
- We look forward to discussing both sides of the issue
- X-waiver issues when prescribing high dose bupe products for pain vs. FDA buccal films/transdermal formulation

The Debate

Faculty will respond to audience questions and banter/debate them. The list below will be used if no questions are available.

- Complex Persistent Opioid Dependence (CPOD)
- The NEW Pill Mills?
- Off-label use for pain
- Disparity between formulations available in USA vs Europe
- Stigma of buprenorphine
- MEDD concerns with formulations used for OUD

Post-Test Question #1

Which of the following are true regarding buprenorphine?

A. Prescribing clinicians are required to complete an eight-hour training course to qualify for a waiver to prescribe buprenorphine for pain

B. All buprenorphine products can be legally prescribed for analgesia by non-certified clinicians with proper DEA license

C. No buprenorphine products are specifically FDA approved for chronic pain management

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Post-Test Question #3

Which of the following are true regarding buprenorphine?

A. Street value is low

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D. Utility in OUD attributable to partial agonist activity at mu opioid receptors

Questions?