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Speaker Introduction

Sabrina Miller received her doctorate in pharmacy from the University of Michigan College of Pharmacy. She then completed a PGY1 residency at the University of Utah Health and is now a PGY2 ambulatory care resident at the University of Utah Sugar House Health Center.

She is pursuing a career in ambulatory care, with an interest in providing care to underserved patients and an emphasis on public health.

Sabrina works with providers in the primary care setting providing medication assisted treatment for opioid use disorder, including buprenorphine products.

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UTAH SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Sabrina Miller, PharmD
PGY2 Ambulatory Care Resident
November 8, 2021

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The SCOOP on BUPrenorphine for Opioid Use Disorder

Sabrina Miller, PharmD
PGY2 Ambulatory Care Resident
University of Utah Health Sugar House Health Center
Sabrina.Miller@hsc.utah.edu

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Disclosure

- Relevant Financial Conflicts of Interest
  - **CE Presenter, Sabrina Miller, PharmD:**
    - None
  - **CE mentor, Keaton Crockett, PharmD, BCACP:**
    - None
- Off-Label Uses of Medications
  - None

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Learning Objectives

Pharmacist objectives:

- Describe the pharmacologic activity of buprenorphine products and how this is used to treat opioid use disorder (OUD)
- Create a dosing regimen for a patient starting a buprenorphine product
- Develop counselling points for buprenorphine products

Pharmacy technician objectives:

- Discuss the comorbidities that occur in opioid use disorders
- Describe the uses and formulations of buprenorphine products
- Analyze whether the legal requirements for a buprenorphine prescription have been met

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#thenntisright

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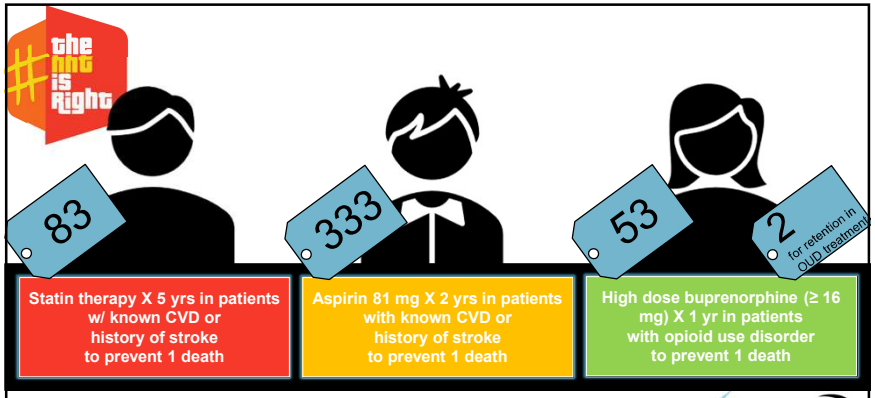

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Newman D (2013) Newman D (2011) Raleigh M (2017) Poorman E (2021)

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Buprenorphine Statistics

Larochelle M, et. Al (2018) Poorman E (2021) Schoenfeld E, et. Al (2020)

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Introduction to Opioid Use Disorder (OUD) and Treatment Options

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DSM-5 Definition of Opioid Use Disorder

A **problematic** pattern of opioid use leading to **problems or distress**, with at least two of the following occurring within a 12-month period:

- Taking larger amounts or taking drugs over a longer period than intended
- Persistent desire or unsuccessful efforts to cut down or control opioid use
- Spending a great deal of time obtaining or using the opioid or recovering from its effects
- Continued opioid use despite having recurring social or interpersonal problems
- Continued opioid use despite ongoing physical or psychological problem likely to have been caused or worsened by opioids
- Tolerance (i.e., need for increased amounts or diminished effect with continued use of the same amount)
- Experiencing withdrawal (opioid withdrawal syndrome) or taking opioids (or a closely related substance) to relieve or avoid withdrawal symptoms
- Giving up or reducing activities because of opioid use
- Using opioids in physically hazardous situations
- Craving, or a strong desire or urge to use opioids
- Problems fulfilling obligations at work, school or home

DSM-5 Clinical diagnostic criteria for opioid use disorder (2017)

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Opioid Epidemic

- Declared a public health emergency by the Department of Health and Human Services (HHS) in 2017
- HHS announced a 5-point strategy to combat the opioid crisis

5-Point Strategy to Combat the Opioid Crisis (2021) Image: HHS.gov

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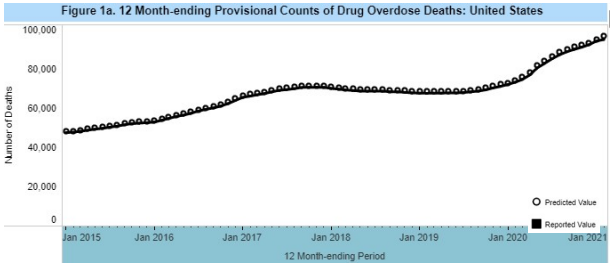
Overdose Deaths - Vital Statistics Rapid Release



- 1.6 Million people had OUD in 2019
- 95,133 overdose deaths from Feb 2020 to Feb 2021

Vital Statistics Rapid Release - Provisional Drug Overdose Data (2021) Image: CDC.gov

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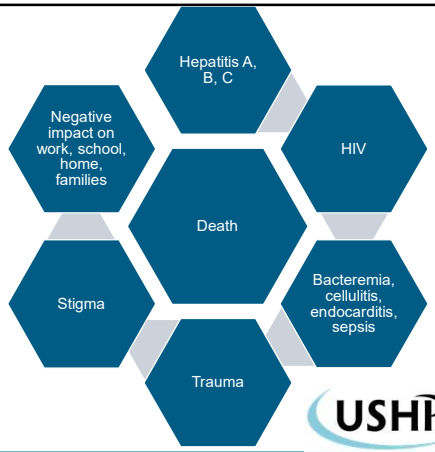
Opioid Use Disorder Complications and Comorbidities



StatPearls: Opioid Use Disorder (2021)

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American Society of Addiction Medicine (ASAM) Practice Guideline for the Treatment of OUD 2020

Opioid withdrawal treatment

- Using methadone or buprenorphine for management of withdrawal is recommended over abrupt cessation
- Opioid withdrawal on its own without ongoing treatment for OUD is not recommended

Opioid use disorder treatment

- All FDA approved medications for treatment of OUD should be available to all patients
- Clinicians should consider the patients preferences, past treatment history, current state of illness, and treatment setting when deciding between agents
- There is no recommended time limit for pharmacological treatment

ASAM Practice Guideline for the Treatment of OUD (2020)

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Treatment Options

Buprenorphine | Methadone | Naltrexone

ASAM Practice Guideline for the Treatment of OUD (2020)

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Utah State Targeted Response

- Enhancing existing evidence-based prevention activities
- Improving access to effective care
- Strengthening recovery support services
- Expanding naloxone distribution
- Increasing harm reduction activities
- Targeting unfunded, underserved youth (age 12-17) and adults at risk for, or with a diagnosed opioid use disorder (OUD)

Use of STR/SOR Utah to Address the Grant Funds to Address the Opioid Crisis (2019) Image: Wikimedia.org

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Missouri State Targeted Response Medication First Model

- Pharmacotherapy is discontinued only if it is worsening the person's condition
- Pharmacotherapy is delivered w/out arbitrary tapering or time limits
- Individualized psychosocial services are continually offered but not required as a condition of pharmacotherapy
- People w/ OUD receive pharmacotherapy treatment as quickly as possible, prior to lengthy assessments or treatment planning sessions

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10 Do's and Don'ts of the Medication First Model for OUD

1. Do not initiate a taper or discontinuation of buprenorphine or methadone in response to any client infraction (e.g., missing therapy sessions)
2. Do not mandate participation in individual or group counseling as a requirement for continued medical treatment (see #10)
3. Do not set a time limit for maintenance medical treatment
4. Do not encourage rapid buprenorphine taper protocols with the goal of transitioning to antagonist medications or no medications at all
5. Do not discharge a client based on positive drug test results for illicit substances

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10 Do's and Don'ts of the Medication First Model for OUD

6. Do not discharge a client from a residential setting without enough medication to supply them to their first outpatient physician visit
7. Do not withhold medical treatment if the treatment provider does not have staffing capacity to provide psychosocial services at the time the client presents
8. Do not switch a client from injectable to oral naltrexone solely for cost saving purposes
9. Do individualize dose decisions based on individual client factors
10. If and when adherence to treatment protocols becomes disrupted by client behavior, do increase client accountability measures (e.g., drug testing, frequency of medication/dosing visits) without discontinuing the needed medications

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Which of the following can be complications in patients with OUD? (select all that apply)

HIV	A
Hepatitis A, B, and C	B
Bacteremia	C
Cellulitis	D
Endocarditis	E

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Buprenorphine for OUD

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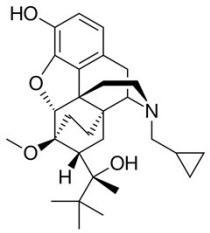
Mechanism of Action and Properties

- High-affinity binding to mu opiate receptors
- Lower intrinsic activity (partial agonist) compared to other full agonists such as heroin
- Slow dissociation and long half life (24-42 hours)
- Respiratory depression, sedation, and intoxication plateau at around 32mg, resulting in a lower risk of overdose, known as the ceiling effect



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Lexicomp: Buprenorphine (2021) DrugBank Online: Buprenorphine (2021) Gordon A (2021) Image: Wikimedia.org

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Buprenorphine-Naloxone Products

- Naloxone is an opioid antagonist
  - Kicks opioids off opioid receptors, then blocks the receptors
  - Reverses opioid overdoses
- Naloxone is used as an abuse deterrent
  - Will cause withdrawal if injected or insufflated
  - Buprenorphine-naloxone formulations are less likely to be diverted
- Minimal bioavailability if taken orally or sublingually

Gordon A (2021)

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Buprenorphine Initiation

Office Based

Home Based

Both are considered safe and effective

ASAM Practice Guideline for the Treatment of OUD (2020) Gordon A (2021)

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Preparing for Initiation

- Wait at least 12 hours since heroin or pain pills were taken
  - If patient is on methadone, taper the methadone dose to 30-40 mg/day and remain on that dose for ≥7 days. Wait 24 to 48 hours after the last dose of methadone and consider initiating buprenorphine at lower doses (2 mg)
- Patient should have at least 3 symptoms:
  - Shaking or tremors
  - Joint and bone aches
  - Chills or sweating
  - Anxiety or irritability
  - Goosebumps
  - Nausea or vomiting
  - Heaving yawning
  - Enlarged pupils
  - Diarrhea

ASAM Practice Guideline for the Treatment of OUD (2020) Gordon A (2021) Lexicomp: Buprenorphine (2021)

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Day 1 Initiation Dose

1. Take 4 mg of buprenorphine (half of an 8 mg film/tablet)

2. Wait an hour, if they still feel sick, they can take another 4 mg dose (half tablet/film)
3. Check every 3 to 6 hours, if they still feel sick take another 4 mg dose
4. Max dose on the first day: 12-16mg

Lexicomp: Buprenorphine (2021) ASAM Practice Guideline for the Treatment of OUD (2020)

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Day 2 and Onward

- Take the same total amount taken on day 1 (administered as 1 or 2 doses)

OR

- If they feel like they're in withdrawal, add another 4 mg to the previous days dose

OR

- If they feel sedated, reduce the previous days dose by 4 mg

OR

- Standardize the dose to 16 mg of buprenorphine daily until follow-up

Maximum maintenance dose: 24-32 mg

ASAM Practice Guideline for the Treatment of OUD (2020) Gordon A (2021) Lexicomp: Buprenorphine (2021)

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Buprenorphine Precipitated Withdrawal

- Can give another dose of buprenorphine, attempting to provide enough agonist effect from buprenorphine to suppress withdrawal

OR

- Stop initiation and provide symptomatic treatments

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Buprenorphine Titration Goals

- Alleviate (decreased or absent) withdrawal symptoms
- Decrease cravings
- Discontinue or markedly reduce use of other opioids
- Minimal to no side effects

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Buprenorphine Dosing Efficacy Treatment Retention

Buprenorphine Dose	N	Risk Ratio: Retained in Treatment Compared to Placebo (CI)
Low dose (2-6 mg)	1131	1.50 (1.19-1.88)
Medium dose (7-15 mg)	887	1.74 (1.06-2.87
High dose (≥ 16 mg)	1001	1.82 (1.15-2.90)

There is **high quality** of evidence that buprenorphine was **superior to placebo** medication in retention of participants in treatment **at all doses examined**

Mattick (2014)

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Buprenorphine Dosing Efficacy Suppressing Illicit Opioid Use

Buprenorphine Dose	N	Standardized mean difference (CI) of suppressing illicit opioid use measured by urinalysis compared to placebo
Low dose (2-6 mg)	487	0.10 (-0.80 to 1.01)
Medium dose (7-15 mg)	463	-0.08 (-0.78 to 0.62)
High dose (≥ 16 mg)	729	**-1.17** (-1.85 to -0.49)

There is **moderate quality** of evidence that only **high-dose buprenorphine** (≥ 16 mg) was **more effective** than placebo in **suppressing illicit opioid use** measured by urinalysis in the trials

Mattick (2014)

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Administration – Sublingual Tablet

- Very low bioavailability if swallowed, higher bioavailability when administered as a sublingual or buccal route
- If more than one sublingual tablet is needed, place all tablets in different places under the tongue at the same time
- To ensure consistent bioavailability, subsequent doses should always be taken the same way

Lexicomp: Buprenorphine (2021)

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Administration – Sublingual Film

- If more than one film is needed, the additional film should be placed under the tongue on the opposite side from the first film
- Minimize overlapping of films as much as possible
- Do not move film after placement
- If a 3rd film is necessary to achieve the prescribed dose, place it under the tongue on either side after the first 2 films have dissolved

Lexicomp: Buprenorphine (2021)

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Administration Tips

- Start with a moist mouth
- Avoid speaking
- If patient is cutting the films, they can cut the film while it is in the package to avoid getting moisture on the film
- After medication is completely dissolved, leave in mouth an additional 5 minutes, then spit remaining sputum to decrease stomach upset
- If using high doses and the patient is still having symptoms could consider avoiding acidic drinks (coffee or fruit juice) and nicotine products before administering the dose

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Adverse Drug Reactions

- Headache (7% to 37%)
- Nausea (5% to 15%)
- Constipation (>1% to 12%)
- Abdominal pain (11%)
- Dry mouth (a side effect for all opioids)

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Black Box Warnings

- Accidental exposure
- Risks of opioid addiction, abuse, and misuse
- Respiratory depression
- Neonatal opioid withdrawal syndrome
- Use with benzodiazepines or other CNS depressants, including alcohol
- Opioid analgesic risk evaluation and mitigation strategy (REMS)
- Risk associated with insertion and removal (subdermal implant)
- Risk of serious harm or death with intravenous administration (ER injection)

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Drug interactions – CNS depressants

- Black box warning:
  - Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death
  - Reserve concomitant prescribing of buprenorphine and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate
  - Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation
- FDA recommendation/ASAM guideline:
  - Should not be a reason to withhold or suspend treatment
  - The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction can outweigh these risks
  - Careful medication management by health care professionals can reduce these risks

Lexicomp: Buprenorphine (2021) ASAM Practice Guideline for the Treatment of OUD (2020)

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Drug Interactions – CYP3A4

- Buprenorphine is a CYP3A4/CYP3A5 metabolite
- Potent inhibitors/inducers may alter exposure to buprenorphine
- HIV medications: many anti-retrovirals affect buprenorphine levels and in some cases buprenorphine levels can affect anti-retroviral levels

Lexicomp: Buprenorphine (2021) ASAM Practice Guideline for the Treatment of OUD (2020)

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Monitoring Parameters

- Frequency of follow-up varies by patient; it could be every 3 days to a week or monthly
- Monitor efficacy with consideration of patient-centered goals
- Activity level
- Cravings/withdrawal
- Adverse effects

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Drug Testing

- Know the types of drug tests, their sensitivities, the drug metabolites, and whether the results of a drug test need to be verified
- Could test for norbuprenorphine (metabolite or buprenorphine) if there's a concern that a patient is diverting the medication
- Do not use in a punitive manner

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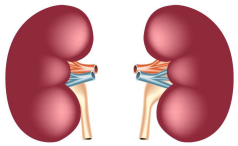
Special Populations: Renal Impairment

- No significant difference in kinetics, can be used in hemodialysis patients



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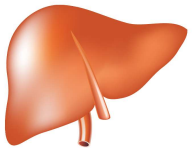
Special Populations: Hepatic Impairment

- Patients with hepatic impairment have reduced metabolism leading to increased buprenorphine blood levels
- Monitor closely
- No specific hepatotoxicity has been demonstrated



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Special Populations: Pain Patients

- For surgical operations
  - Pre-op: take last buprenorphine dose 24 hours prior to surgery
  - Post-op: different options
    - Start a full agonist – consider ER w/ IR for breakthrough pain
    - Re-start buprenorphine – might need more frequent dosing (analgesic effect shorter acting) and/or an increased total dose
- Acute pain
  - Split buprenorphine dose or increase dose
  - Stop buprenorphine and initiate full agonist therapy
- Chronic pain
  - Consider consulting a pain medicine specialist and a multidisciplinary team approach

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Special Populations: Pregnant Patients

- It is recommended to treat opioid use disorder with an opioid agonist medication during pregnancy
- Consider starting with or switching to equivalent dose of buprenorphine mono-product
  - First trimester: stabilize and find the lowest most effective dose
  - May need adjustments throughout pregnancy
  - Post-partum: transition to original pre-pregnancy dose and formulation
- Is safe to use during breastfeeding

ASAM Practice Guideline for the Treatment of OUD (2020)

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Buprenorphine Formulations for OUD

Sublingual Tablets:

- Suboxone® (buprenorphine 2-8 mg and naloxone 0.5-2 mg)[1]
- Subutex® (buprenorphine 2-8 mg)[1]
- Zubsolv® (buprenorphine 0.7-11.4 mg and naloxone 0.18-2.9 mg)[2]

Sublingual Films:

- Suboxone® (buprenorphine 2-12 mg and naloxone 0.5-3 mg)[1]

- **Buccal film:** Bunavail® (buprenorphine 2.1-6.3 mg and naloxone 0.3-1 mg)[2]
- **Subdermal implant:** Probuphine® (buprenorphine 74.2 mg)[3]
- **Subcutaneous extended-release injection:** Sublocade® (buprenorphine 100-300 mg)[3]

[1]Available as generic
[2]Use a dose conversion calculator, formulation dosing varies from Suboxone
[3]Risk Evaluation and Mitigation Strategy (REMS) program

Lexicomp: Buprenorphine (2021) Lexicomp: Buprenorphine-naloxone (2021)

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Buprenorphine Formulations for Pain

Transdermal Patches

- Butrans® (buprenorphine)[1] transdermal patches available as 5mcg/hr to 20 mcg/hr in weekly patches

Buccal Film

- Belbuca® (buprenorphine) available as 75 mcg to 900 mcg

Intravenous Injection or Intramuscular Injection

- Buprenex® (buprenorphine)[1] IM/IV injection available as 0.3 mg/mL

[1]Available as generic

Lexicomp: Buprenorphine (2021) Lexicomp: Buprenorphine-naloxone (2021)

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Audience Response Question

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Which of the following formulations of buprenorphine are FDA approved for pain? (select all that apply)

Sublingual tablets and films	A
Buccal films	B
IV injection	C
Transdermal patches	D

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True or False: Buprenorphine is a full opioid agonist

True	A
False	B

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Which of the following is an appropriate dosing regimen for buprenorphine initiation?

When a patient is in severe withdrawal, take 16 mg of buprenorphine as a single or divided dose	A
Determine the starting dose based on current opioid use and predicted needs	B
Let the patient self titrate every few hours with a max buprenorphine dose of 32 mg	C
With mild withdrawal symptoms, take 4 mg and titrate based on symptoms up to a max of 12-16 mg on day 1	D

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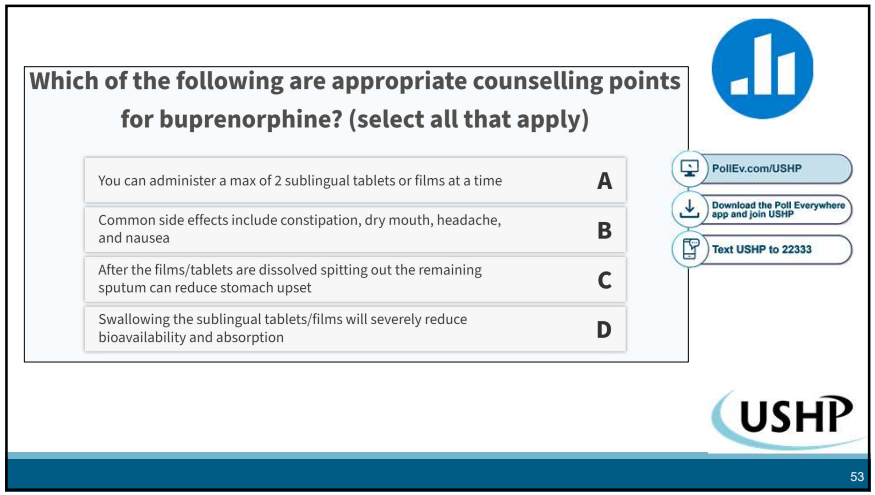

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DATA 2000 Waiver

- Customary notification of intent (NOI) requires eligible providers to undertake required training activities prior to their application to prescribe Buprenorphine
  - The Providers' Clinical Support System (PCSS) provides practitioner training
- Alternative type of NOI allows those providers who wish to treat up to 30 patients to forego the training requirement, as well as certification to counseling and other ancillary services (i.e., psychosocial services)
- Patient limits the1st year:
  - Most are limited to 30 patients at a single time
  - Certain conditions can be met to treat up to 100 patients at a single time

Become a Buprenorphine Waivered Practitioner (2021)

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CIII Prescription Requirements

- Dated and signed on the day when issued
- Contain the full name and address of the patient
- The drug name, strength, dosage form, quantity prescribed, and directions for use
  - Can take a verbal to change the product based on cost/insurance preferences
- The name, address, and registration number of the practitioner
- Expires after 6 months or 5 refills, whatever comes first

Become a Buprenorphine Waivered Practitioner (2021)

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Buprenorphine Prescription Requirements

- Prescriptions must have a XDEA number on it if the patient is using it for OUD
- XDEA not required if buprenorphine is being used for pain
- To look up waivered providers go to:
  - https://www.samhsa.gov/bupe/lookup-form

Code of Federal Regulations Title 21 (2020)

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Audience Response Question

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True or False: This prescription requires a XDEA identifier

Patient Name: John Doe
Patient Address: 1234 Willow Way SLC UT 84123
DOB: 1/1/1985

℞ Butrans (buprenorphine) 5 mcg/hr transdermal system

Apply 1 patch once weekly

#4

0 RF

Dr. Jane Doe 10/3/21

Dr. Jane Doe
1234 Wasatch Blvd SLC UT 84123
801-213-9999
DEA CD7344196

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True or False: This prescription requires a XDEA identifier

Patient Name: John Doe
Patient Address: 1234 Willow Way SLC UT 84123
DOB: 1/1/1985

℞ Buprenorphine-naloxone 8-2 SL tablets

Dissolve 2 tablets sublingually daily

#14

0 RF

Dr. Jane Doe 10/3/21

Dr. Jane Doe
1234 Wasatch Blvd SLC UT 84123
801-213-9999
DEA CD7344196

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Buprenorphine Statistics

38%
reduction in opioid overdose deaths 1 year following a non-fatal overdose

<1/3
of patients were provided any medication for OUD in the first year following a non-fatal overdose

<10%
of U.S. physicians have received waivers to prescribe buprenorphine (2007-2017 data)

Larochelle M, et. Al (2018) Poorman E (2021) Schoenfeld E, et. Al (2020)

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Pharmacist Roles

ENGAGING WITH PATIENTS AND PROVIDERS

ADVOCATING FOR PATIENTS AND PROGRAMING

REDUCING STIGMA

COUNSELLING AND HARM REDUCTION

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CE Code: (USHP will fill in)

Sabrina Miller, PharmD
PGY2 Ambulatory Care Resident
University of Utah Health Sugar House Health Center
Sabrina.Miller@hsc.utah.edu

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