ACCEPT

Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

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Session Date: Friday, April 21, 2023

Didactic Topic and Presenter:
Low Dose Initiation of Buprenorphine for OUD: Approaches and Common Challenges

Randall Brown, MD, PhD, DFASAM
Professor - Department of Family Medicine and Community Health, University of Wisconsin School of Medicine and Public Health; Director - UW Hospital, Center for Addictive Disorders; Program Director - UW Addiction Medicine Fellowship Program

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- 12:15 PM: Attendance text-in – Introductions
- 12:25 PM: Case Presentation and Discussion
    - Presenter Alyssa Bruehlman, MD - *Addiction Medicine Fellow, University of Wisconsin*
- 1 PM: Didactic Presentation
    - Presenter: Randall Brown, MD, PhD, DFASAM
- 1:15 PM End of Session

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University of Wisconsin

ECHO ACCEPT
Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics
2022-2024
Low Dose Initiation of Buprenorphine for OUD: Approaches and Common Challenges
4/21/23
Didactic Presenter: Randall Brown, MD, PhD, DFASAM
Case Presenter: Alyssa Bruehlman, MD

Provided by the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP)

Intended Audience:

Nurses, Nurse Practitioners, Pharmacists, Physicians, Physician Assistants, Pharmacy Technicians, Psychologists, Social Workers, Patient/Caregivers, Students

Objectives:

As a result of this educational regularly scheduled series, learners as members of the healthcare team will be able to:

1) Identify challenges associated w/ buprenorphine initiation in setting of transition from methadone
2) Identify challenges associated w/ buprenorphine initiation due to illicit fentanyl
3) Describe low-dose buprenorphine approaches and rationale
4) Discuss feasibility and acceptability of high-dose buprenorphine initiation

implications

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Name	Role	Financial Relationship Disclosures	Discussion of Unlabeled/Unapproved uses of drugs/devices in presentation?	COI completion date
Randall Brown	RSS Chair	Usona Institute (Grant / Contract), multi-disciplinary association for psychedelic studies (Grant / Contract)	Yes	1/30/2023
Nada Rashid	RSS Coordinator	No relevant financial relationships to disclose	No	1/31/2023
Kathleen Maher	RSS Coordinator	No relevant financial relationships to disclose	No	1/30/2023
Ritu Bhatnagar	Planner	No relevant financial relationships to disclose	Yes	1/29/2023
Paul Hutson	Planner	No relevant financial relationships to disclose	Yes	1/28/2023
Susan Mindock	Planner	No relevant financial relationships to disclose	No	1/31/2023
Sheila Weix	Planner	No relevant financial relationships to disclose	No	2/3/2023
Kellene Eagen	Planner	No relevant financial relationships to disclose	No	1/27/2023
Joseph Galey	Planner	No relevant financial relationships to disclose	Yes	1/27/2023

David Leinweber	Planner	No relevant financial relationships to disclose	No	4/13/2023
Randall Brown	Presenter	Usona Institute (Grant / Contract), multi-disciplinary association for psychedelic studies (Grant / Contract)	Yes	3/28/2023
Alyssa Bruehlman	Presenter	No relevant financial relationships to disclose	No	4/12/2023
David Leinweber	Peer Reviewer	No relevant financial relationships to disclose	No	4/13/2023

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BUP-XR initiation in the setting of polypharmacy and transitions of care

Alyssa Bruehlman, MD
Addiction Medicine Fellow
UW Department of Family Medicine and Community Health

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Case Introduction

- 38 yo man with history of severe opioid use disorder, stimulant use disorder, psychiatric comorbidity, seizures, neuropathy, type 2 diabetes, hypertension who presents to re-establish care for OUD after incarceration and in setting of chapter 51 commitment

- Questions for discussion:
  - What are best practices following bup-XR injection?
  - How do we manage symptoms that don't align with our interpretation of physiology or pharmacology?
  - How do we improve patient care and communication between medical, psychiatric, addiction, and legal spaces?

Medical & Behavioral Health Diagnosis:	Current Medications:
• OUD, severe	• Buprenorphine 12mg SL daily
• Stimulant use disorder, ? Severity	
• Tobacco use	
• Psych:	• Asenapine 10mg SL daily
◦ Bipolar disorder	• Lorazepam 0.5mg TID prn
◦ Schizophrenia vs substance-induced psychotic disorder	
◦ PTSD	
• Seizures (postTBI, PNES?)	• Phenobarbital 65mg daily
• Polyneuropathy	• Pregabalin 300mg TID
• Type 2 Diabetes (A1c 5.0 in 8/2022)	• Metformin
• HTN	• Lisinopril-HCTZ
• GERD	• Pantoprazole
• History of HCV	

Care episodes over last 1 year

Feb - Apr 2022:
- Restart on buprenorphine after 19-month incarceration
- Struggles w/ BUP/NX and BUP at low doses, Declines other MOUD

June 2022:
- Unrelated PCP visit, reports attended OTP for MTD but interested in restart BUP/NX
- ED visit for MVA, paranoia. UDS + cocaine, amphetamine. Involuntary psych admission at OSH; restarted BUP/NX and tolerated
- ED visit x2 for seizure activity, EEG normal, neurology recommend d/c PHB for topiramate w/ outpt neuro f/up.
- Visit for Bup-XR. Med list unclear after discharge from psychiatry hosp – diazepam 5mg TID prn new Rx. UDS + methamphetamine, cocaine, benzos, bup. Appears sedated, XR injection deferred in favor of SL film.

August 2022
- Admitted after overdose. UDS + benzo, cocaine, opioids. Restart bup-nx. Seen again by neuro, recommend d/c PHB and diazepam, start oxcarbazepine. Transfer to inpt psych within our system
- New contact from Dane County re: chapter 51, staying at DC3

Sept 2022:
- Incarcerated
- ED visit for psych; admitted to inpatient psych at OSH. Restarted PHB and lorazepam. PHB now at 130mg BID

October 2022:
- PHB taper planning

November 2022
- Psych stay for SI. Dx with sedative hypnotic use disorder

Re-establish care

March 2023

- Discharged from incarceration and from OSH psych. Staying at CARE/crisis stabilization center. Med list: now with PHB daily and lorazepam 0.5mg TID prn. No outpatient psychiatrist

- ED visit x 1 for seizure activity. Neuro note states unclear dx, consider PNES. “can consider increase in PHB if patient desires.” Did not advise increase in benzo

- Seen at UC for anxiety, UC prescriber increased lorazepam to 1mg TID prn. Notes that he doesn’t have outpatient prescriber clarified.

- Re-established outpatient care for OUD with our office. Reports one-time heroin use since d/c from incarceration but maintained on BUP 12mg daily w/o lapse. **Describes “withdrawal” symptoms in nighttime, change to BUP/NX 8-2mg film BID x1 with plan for bup-XR injection**

Social History:	Family History:

• Social Factors/History:
  • Partner
  • Housing uncertain
  • Legal complications
  • Unemployed, no known SSI
	• Twin brother with SUD, schizophrenia

Patient strengths & protective factors:	Risk factors:
• Resilience • Gratitude	• Incarceration • Involuntary treatment with unclear trajectory • Multiple transitions of care • Polysubstance use, overdose • History suicide attempt, self-harm • Instability of home, work, relationships due to above

Labs

- Toxicology in our system rarely + for anything other than prescribed meds.
- UDS at OSH ED (often for psych symptoms) serially + for cocaine
- Most recent UDT+ for prescribed barbiturates, BUP/norBUP, lorazepam, pregabalin

Patient Goals & Motivations for Treatment

- Avoid what he feels are withdrawal symptoms
- Physical and mental comfort

Proposed Diagnoses

- Severe OUD
- Stimulant use disorder, at least mild
- ? sedative hypnotic use disorder
- Polypharmacy
- Psych comorbidity

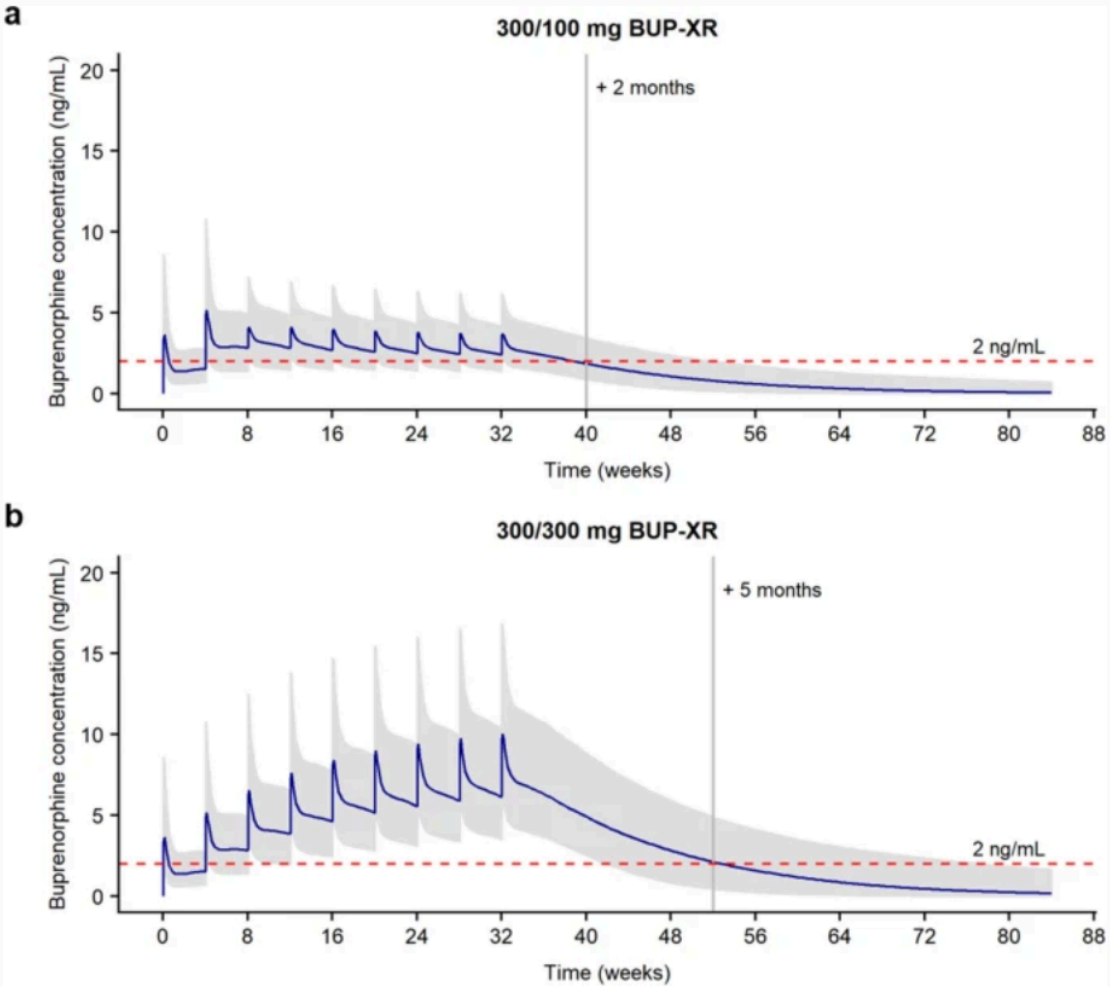
In the last 12 months:
Larger amounts or longer than than intended
Persistent desire or attempts to cut down or stop
Excessive time using, getting, recovering
Craving
Failure to fulfill a major role
Continued use despite social/interpersonal conflicts
Withdrawal from activities
Use in physically hazardous situations
Use despite knowing its doing harm
Tolerance (if applicable)
Withdrawal (if applicable)

Treatment Plan – OUD

- Received first BUP-XR 300mg dose
  - Rx for BUP/NX 4/1mg SL film BID prn withdrawal
- Sxs of nausea, vomiting, myalgias, diffuse joint pain, diaphoresis which improve s/p BUP/NX film and return 4-6 hours after dose
  - COWS < 10 w/ no objective signs
  - Time of last BUP/NX dose unknown
- Maintain BUP/NX 4/1mg BID prn until next bup-XR injection
  - Symptom and medication diary in the interim

BUP–XR

Fig. 6



Predicted decrease in buprenorphine plasma concentrations for BUP-XR dosing regimens following treatment interruption. **a** 300/100-mg dosing regimen 2; **b** 300/300-mg dosing regimen. Blue solid lines: median of the simulated data; gray shaded areas: 90% prediction intervals of simulated data. A total of nine subcutaneous injections were simulated in 5000 subjects. The horizontal red dashed line indicates the 2-ng/mL minimum concentration required for opioid blockade, as established from modeling and simulation and confirmed by clinical data (Nasser et al. [18])

Jones AK et al. Population Pharmacokinetics of a Monthly Buprenorphine Depot Injection for the Treatment of Opioid Use Disorder: A Combined Analysis of Phase II and Phase III Trials. *Clin Pharmacokinetics* 2021.

Treatment Plan – Psych and Seizures

- Communication with primary care and chapter 51 case manager
- Still working to establish with psychiatry
- Awaiting residential treatment bed but needs taper from PHB and benzos. Unknown who will direct taper plan for these meds.

Discussion questions:

- What are best practices following bup-XR injection?
- How do we manage symptoms that don't align with our interpretation of physiology or pharmacology?
- How do we improve patient care and communication between medical, psychiatric, addiction, and legal spaces?

DSM-5 Substance Use Disorder ("Addiction")

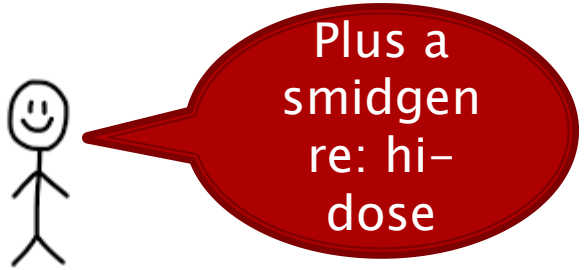
- Tolerance
- Withdrawal

} **Physical Dependence ≠ Use Disorder**

- Larger amts/longer periods than intended
- Persistent desire/failed attempts to quit/control use
- Much time obtaining/using/recovering
- Important activities sacrificed
- Continued use despite known adverse effects
- Failure to fulfill major obligations
- Recurrent hazardous use
- Craving
- Ongoing use despite interpersonal problems

2-3 = mild
4-5 = moderate
≥ 6 = severe

Low-dose initiation of buprenorphine: Approaches & common challenges



Randall Brown
UW ECHO ACCEPT
April 21, 2023

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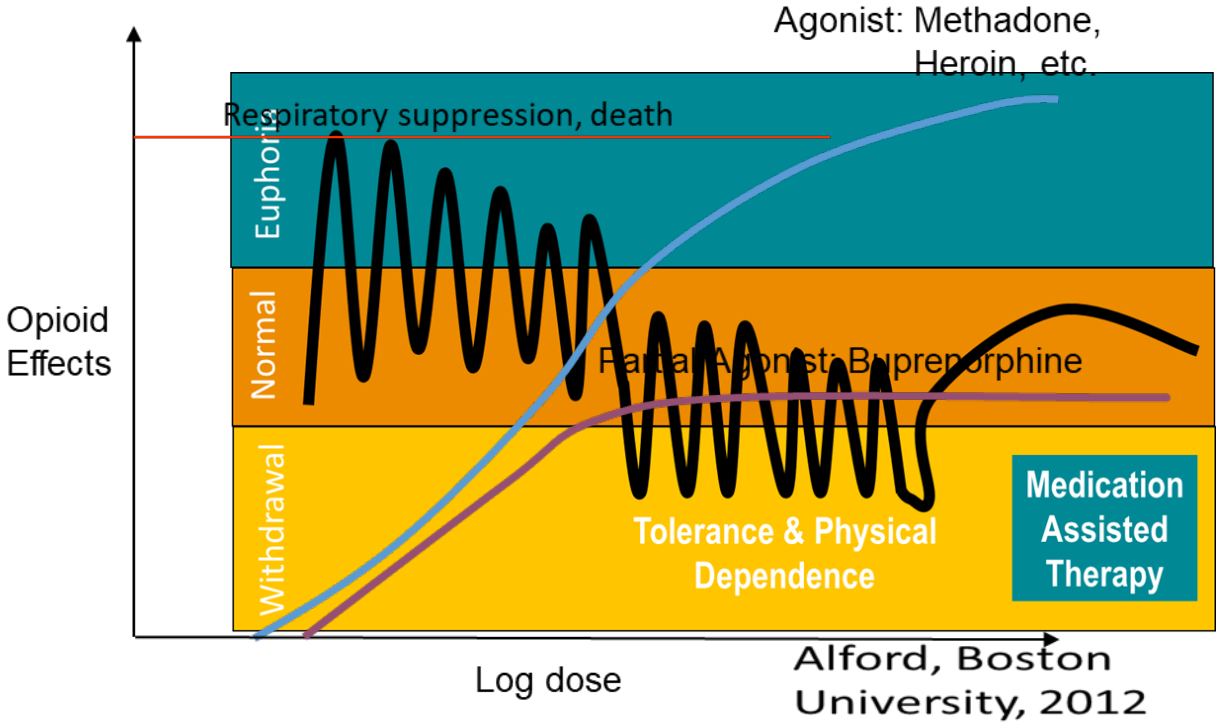
Buprenorphine for Opioid Use Disorder

- Partial opioid agonist w/ high μ-opioid receptor affinity & slow dissociation kinetics
- Long $t_{1/2}$ (26-37 hours)



Importance

- Partial agonist + high μ-opioid receptor affinity → buprenorphine may precipitate withdrawal in people physically dependent on full opioid
- May complicate transition from long-acting opioid
  - Methadone
  - Chronic fentanyl
- Complicated initiation/prolonged withdrawal symptoms ↓ likelihood of treatment engagement and retention

Conventional Transition from Methadone

- Taper to 30-40mg
- Stable on this dose x 7 days
- Buprenorphine initiation at 36-72 hours out from last dose
  - Can take weeks or months
  - Potential destabilization & OD risk as dose decreases & during abstinent window
  - Requires close monitoring and careful coordination at/with OTP

Fentanyl & Analogs

- ↑↑ presence in illicit supply
- Available literature re: pharmacodynamics pertains to commercially produced fentanyl
- High potency, highly lipophilic
  - → protracted excretion patterns
  - Urine testing may be positive days after last use
  - Extended μ-opioid receptor effects
  - ↑ risk for precipitated w/d w/ conventional initiation

Some Underpinnings of Low Dose Initiation

- Repetitive naloxone administration → max w/d Sx sooner; later decline despite ongoing admin
- 0.2mg IV buprenorphine did not → precipitated w/d
- So. . .
  - Repeated, adequately spaced (e.g. 12 hr) bupe may not ppt w/d
  - Slow bupe dissociation → gradual accumulation at μ receptors w/ repeated dosings
  - Over time, ↑ amt of full opioid replaced by bupe at μ receptors

Resnick et al, 1977. Clin Pharm Therapeutics
Mendelson et al, 1997. Biol Psychiatry

Case Series': Low Dose Initiation

- 3 hospitalized patients w/ OUD
- Daily methadone 40-100mg
  - 2 pt initiated on methadone during hospitalization
  - All were using illicit opioid prior to admission (use duration 2-10+ yr)
- All had co-morbid painful condition

Terasaki et al, 2019. PharmacoTx.

Table 1. Buprenorphine Microdosing Protocol Used by Our Team

Day	Buprenorphine dosage	Methadone dose
1	0.5 mg[a] SL once/day	Full dose
2	0.5 mg[a] SL twice/day	Full dose
3	1 mg SL twice/day	Full dose
4	2 mg SL twice/day	Full dose
5	4 mg SL twice/day	Full dose
6	8 mg SL once/day	Full dose
7	8 mg SL in A.M. and 4 mg SL in P.M.	Full dose
8	12 mg SL/day	Stop

SL = sublingually.
[a]For our buprenorphine formulation, one-quarter of a 2-mg sublingual strip was used.

Case Series': Low Dose Initiation

- 2 patients
  - 1 – prior initiation w/ withdrawal and "trauma reactivation" during conventional initiation
  - 2 – maintained on high doses of methadone + diacetylmorphine (heroin)

Case 1 →

Day	Buprenorphine (sl)	Street heroin (sniffed)
1	0.2 mg	2.5 g
2	0.2 mg	2 g
3	0.8+2 mg	0.5 g
4	2+2.5 mg	1.5 g
5	2.5+2.5 mg	0.5 g
6	2.5+4 mg	0
7	4+4 mg	0
8	4+4 mg	0
9	8+4 mg	0

Hammig et al, 2016. Subst Abuse Rehabil.

IMPACT at OHSU: Inpatient case series

- Initiation w/ 20mcg bup patch day 1 w/ similar gradual dose escalation through day 7 to 8mg BID. Then patch DC'd.
- Special considerations
  - H/O precipitated w/d may → post-traumatic stress response
  - Transition from methadone
    - Consider reduction to 80mg prior to initiation
    - Consider cross taper of methadone
    - Counsel re: possibility of some w/d Sx and provide adjuncts PRN
  - Maximize pain control in pts w/ co-occurring pain w/ high affinity full mu agonists

Button et al 2022. J Addxn Med.

IMPACT at OHSU: Inpatient case series #2

- Rapid low-dose initiation

Day 1	Bup 20mcg/h	0.48mg	Continue
Day 2	1mg SL TID	3mg	Continue
Day 3	1mg SL Q 3 (8a–11p)	6mg	Continue
Day 4	1mg SL @ 6am; 8mg SL at 9am	9mg + additional PRN	Continue PRN

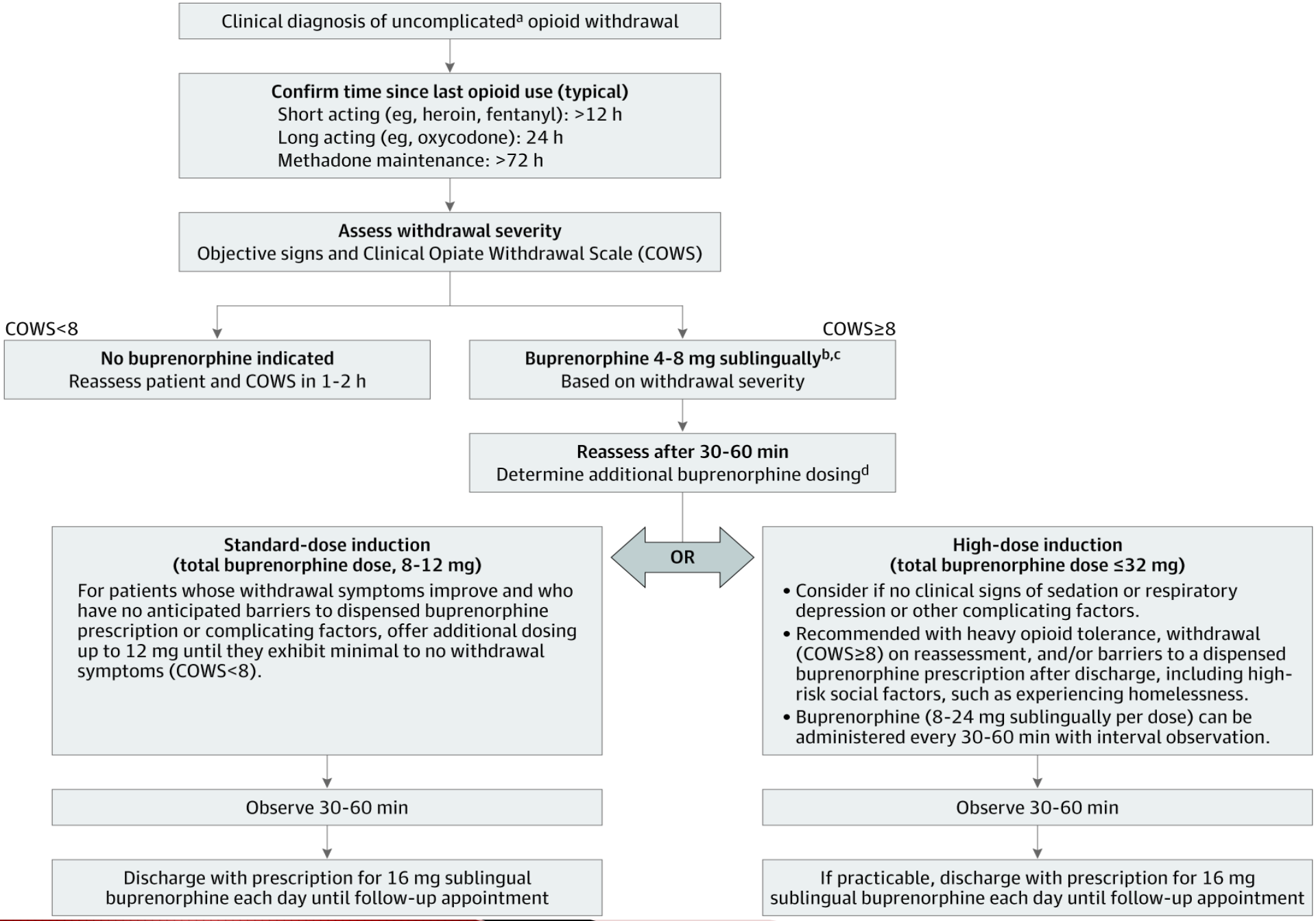
- 24 pts all received full opioid agonist ($\bar{x}$ = 171 MME); > 50% reporting fentanyl use
- 19 completed initiation within 72 hr w/ no precip w/d
- Fewer reporting fent use at < 48 hr completed (3/5)

Sokolski et al 2023. J Addxn Med.

High-dose initiation

- Case series 579 ED visits (391 unique pts) with OUD b/t 1/2018 and 12/2018
- 366 high-dose initiations (> 12 mg bup monoproduct) by 54 unique clinicians
- No resp depression
- 5 cases precipitated w/d
  - 4 occurred after 8mg, so were unrelated to hi-dose protocol
  - 5th case occurred after pt tolerated initial 8mg, then received additional 24mg

Herring et al 2021. JAMA Netw Open.


Clinical diagnosis of uncomplicated[a] opioid withdrawal
Confirm time since last opioid use (typical)
Short acting (eg, heroin, fentanyl): >12 h
Long acting (eg, oxycodone): 24 h
Methadone maintenance: >72 h
Assess withdrawal severity
Objective signs and Clinical Opiate Withdrawal Scale (COWS)
COWS<8
COWS≥8
No buprenorphine indicated
Reassess patient and COWS in 1-2 h
Buprenorphine 4-8 mg sublingually[b,c]
Based on withdrawal severity
Reassess after 30-60 min
Determine additional buprenorphine dosing[d]
Standard-dose induction
(total buprenorphine dose, 8-12 mg)
For patients whose withdrawal symptoms improve and who have no anticipated barriers to dispensed buprenorphine prescription or complicating factors, offer additional dosing up to 12 mg until they exhibit minimal to no withdrawal symptoms (COWS<8).
OR
High-dose induction
(total buprenorphine dose ≤32 mg)
• Consider if no clinical signs of sedation or respiratory depression or other complicating factors.
• Recommended with heavy opioid tolerance, withdrawal (COWS≥8) on reassessment, and/or barriers to a dispensed buprenorphine prescription after discharge, including high-risk social factors, such as experiencing homelessness.
• Buprenorphine (8-24 mg sublingually per dose) can be administered every 30-60 min with interval observation.
Observe 30-60 min
Observe 30-60 min
Discharge with prescription for 16 mg sublingual buprenorphine each day until follow-up appointment
If practicable, discharge with prescription for 16 mg sublingual buprenorphine each day until follow-up appointment

Also see. . .

- De Aquino et al, 2020. J Addiction Med.
- Martin L et al, 2019. Canadian J Addiction.
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