

ACCEPT

Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics

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For attendance, purposes please text the following code: FURQES to 608-260-7097

Session Date: Friday, October 20, 2023

Didactic Topic and Presenter:

Buprenorphine - LAI Clinical Pearls: Real World Lessons

Alison Miller, DO - Clinical Associate Professor, DFMCH

- 12:15 PM: Attendance text-in Introductions
- 12:25 PM: Didactic Presentation and Discussion
 - o Presenter: Alison Miller, DO Clinical Associate Professor, DFMCH
- 1:15 PM End of Session

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2023 Universal Activity Number (UAN): JA0000358-0000-23-025-L01-P; JA0000358-0000-23-025-L01-T

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This session is designed to meet the requirements outlined in the Medication Access and Training Expansion (MATE) Act. (Click here for more information.) Number of hours: 1



ECHO ACCEPT

Addiction & Co-morbid Conditions: Enhancing Prevention & Therapeutics 2022-2024

Buprenorphine – LAI Clinical Pearls: Real World Lessons 10/20/23

Didactic Presenter: Alison Miller, DO

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:

- List the unique pharmacologic properties of extended-release buprenorphine
- Assess common patient concerns such as getting "too much" or "too little" medication, and injection site complications
- Apply "tricks of the trade", discuss sublingual buprenorphine supplementation, and novel dosing protocols
- Explain common social/logistical challenges that arise with using extended-release buprenorphine

Policy on Disclosure

It is the policy of the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP) to identify, mitigate and disclose all relevant financial relationships with ineligible companies* held by the speakers/presenters, authors, planners, and other persons who may influence content of this accredited continuing education (CE). In addition, speakers, presenters and authors must disclose any planned discussion of unlabeled/unapproved uses of drugs or devices during their presentation. For this accredited continuing education activity, all relevant financial relationships have been mitigated and detailed disclosures are listed below.

* Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. The ACCME does not

consider providers of clinical service directly to patients to be ineligible companies.

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
Alison Miller	Presenter	No relevant financial relationships to disclose	No	10/8/2023

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Buprenorphine – LAI
Clinical Pearls
Real World Lessons
October 20, 2023
ECHO ACCEPT



By the end of the presentation, attendees will be able to:

- List the unique pharmacologic properties of extended-release buprenorphine
- Assess common patient concerns such as getting "too much" or "too little" medication, and injection site complications
- Apply "tricks of the trade", discuss sublingual buprenorphine supplementation, and novel dosing protocols
- Explain common social/logistical challenges that arise with using extendedrelease buprenorphine



Background

- UW Health Family Medicine Yahara
 - Outpatient Primary Care Clinic, Monona, WI
 - Behavioral Health RNCC
 - Peer Support on site

Over 100 patients

591 injections (slicer dicer)

Currently using one monthly injectable Buprenorphine – LAI (long acting injectable) SUBLOCADE – 300mg & 100 mg

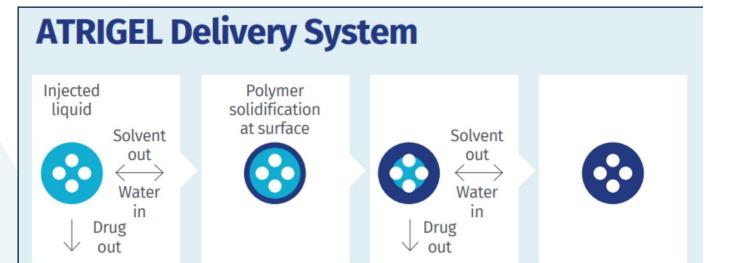
FDA May 2023 Brixadi weekly and monthly (lots of different doses)

All pictures are de-identified and have permission from patient

No disclosures



Phenomenal Pharmacology – HOW IT WORKS



SUBLOCADE™ sustained-release formulation of buprenorphine. SUBLOCADE™ uses the ATRIGEL delivery system, a solution consisting of a biodegradable poly-(DL-lactide-co-glycolide) co-polymer dissolved in N-methyl pyrrolidone (NMP), a water-miscible biocompatible solvent. After subcutaneous injection, NMP interacts with body fluids that replace the NMP in the matrix, triggering polymerization. Buprenorphine trapped inside the polymer formed in situ is gradually released over a one-month period as the polymer biodegrades



Average Plasma Concentration of Buprenorphine

SL 12 mg	Steady state	1.71 ng/mL
SL 16 mg	Steady state	2.31 ng/mL
SL 24 mg	Steady state	2.91 ng/mL
300 mg	1st injection	2.19 ng/mL
100 mg	Steady state*	3.12 ng/mL
300 mg	Steady state**	6.54 ng/mL

Monthly dose (mg) regimen: *300-300-100-100-100-100 ** 300-300-300-300-300

After 6 months of LAI

Indivior, Sublocade Prescribing Information

PEARLS – Prior to Initial Injection

Insurance

- Prior Auth on every patient, WI Medicaid fully covers it. Medicare ONLY denied x 1 (Care Wisconsin)
- Issues: cover for 1 yr ONLY or will not cover both SL and SQ LETTERS
- Considered a medical bill not a pharmacy bill deductibles
- Pharmacy
- Specialty mail order pharmacies/ REMS
- Storage
- Keep refrigerated ** use within 7 days after defrosted **
- Initiation
- Buprenorphine SL 7 days dose prior to initial injection (package insert)





Case 1: Initial Injection & Induction

- MG 25 yr Male chronic pain football player in HS and college
- Was given opioids to help with pain and realized it helped his anxiety as well.
- Tried SL Bup but would not take consistently
- Works as a bartender and bouncer
- Has an opportunity to move to NJ with his partners family
- Agrees to LA Buprenorphine Injection
- Instructions to macro-dose and daily strip use and return in one week
- One week later did not use a strips until this morning (16 mg)
- COWS score 16, does not feel good
- What would you do? Return in one week? In clinic Induction?
- What are the risks of giving too early? What doses would you give?

Day #2 Post -injection

- 300 mg SQ given in clinic monitored in clinic for 1 hr NO PWD
- Patient described last night as "rough" did not feel well, but NO PWD
- Feels much better this morning
- Leaving for NJ tomorrow
- Peer Support helped him find support in NJ
- BH-RNCC able to continue connection with move
- New job did not have insurance
- Still under care of Mom since 25

MyChart Message - MG

portal! I would love to share my story. Just give me details and I can write out my story or whatever you guys wanna do georgia and I wanna help other people. As of today Ive still stone cold sober not touched anything in over a year plus. But with that I have had to deal with my real mental issues that pushed me to go through what ive been through. I have chronic ptsd and stuff and I still have some days that are harder than others my i dont have insurance out here for coverage only back at home for a bit longer. I work my ass off everyday but someday i just wake up and my body just feels everything and i can admit some days i get a vit of a craving not for opiates but just anything to make whatever im going thru go away and then all my anxiety comes im These very physical forms. Its almost like i smell the air of the rooms i was in when i uses to be abused. My body goes into fight or flight and my blood is rushing thru my veins like theres a gun to my head. I dont speak about my medical history at all at work because honestly ive found people are very hurtful towards my community and i dont wanna be judged or held down because of it but i gotta admit there

Pre-Anesthesia Injection PEARLS

PEARL: off label administration of numbing agent

Our protocol: 1-2 ml of SQ lidocaine given prior to injection

Warmer the injection

15-20 min room temp

Warm in hand

Pinch skin and let go when medicine in

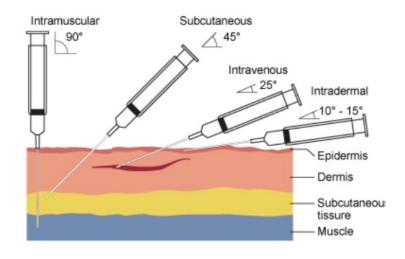
Give injection quick burning starts at 10 sec

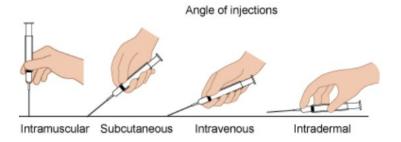
ICE PACK





SQ – Administration LAI Buprenorphine





STEP 6: PINCH THE INJECTION SITE

Pinch the skin around the injection area. Be sure to pinch enough skin to accommodate the size of the needle. Lift the adipose tissue from the underlying muscle to prevent accidental intramuscular injection.

Figure 6



STEP 7: INJECT THE MEDICATION

SUBLOCADE is for subcutaneous injection only. Do not inject intravenously, intramuscularly, or intradermally [see Warnings and Precautions (5.1, 5.6)].

Insert needle fully into the abdominal subcutaneous tissue. Actual angle of injection will depend on the amount of subcutaneous tissue.

Use a slow, steady push to inject the medication. Continue pushing until all of the medication is given.

Figure 7



STEP 8: WITHDRAW THE NEEDLE

Indivior, Sublocade Prescribing Information

Case #2

- TK Long standing Hz of Opioid and Stimulant use
- Longest Abstinent Methadone for 3 yrs
- Has been on SL strips for 6 months but moving into a sober living where he is not allowed to use strips
- Has been abstinent from opioids still use stimulants a few times a month
- Started IM Buprenorphine 300 mg Nov 2021
- 1 week after 4th injection MyChart message received
- Redness and pain at site of injection reassurance
- Next day Photo attached

MyChart – Media Photo WHAT DO YOU THINK HAPPENED?



Follow Up

- Given intradermal NOT subcutaneously
- Skin area became red and painful and necrotic
- Made sure he had enough strips
- He did feel like he had more cravings increased Bup SL to 12 mg a day
- Unsure of absorption during this month
- Area did get worse the eschar was debrided/removed
- Antibiotics given Augmentin

Case # 2 Continued

- TK's lesion healed
- Continued with 300 mg LA Buprenorphine
- Still using strips down to 8 mg a day (4 mg twice a day)
- Completed 6 months of 300 mg LA Buprenorphine
- Still using strips but down to 4 mg a day (2mg twice a day)
- No use opioids in 9 months and no stimulants in 3 months

What would you do? Continue on 300 mg? Lower to 100 mg like the package insert? Wean strips?

Peer Support – Education (SL strip use)

- Ex: Conversation have with patients
- What is going on before you take the strip?
- Emotional "booby" trap what is going on?
- Physical vs emotional
- If I don't take it I will not be able to work Or I cannot care for my family
- Change is a process
- Listening skills
- Trust



PEARLS - Dosing Considerations

- "Usual" 300 x 2 then 100 mg if still using opioids stay on 300 mg for 6 months or longer?
- Interval is supposed to every 28 days
- First SHOT wears off after 3 weeks increased cravings
- Strongly recommend strips to be used the 3rd to 4th week
- Recommend second injection 3 weeks after initial one
- Using strips first few months, difficult to STOP using strips
- Support to stop strips peer support

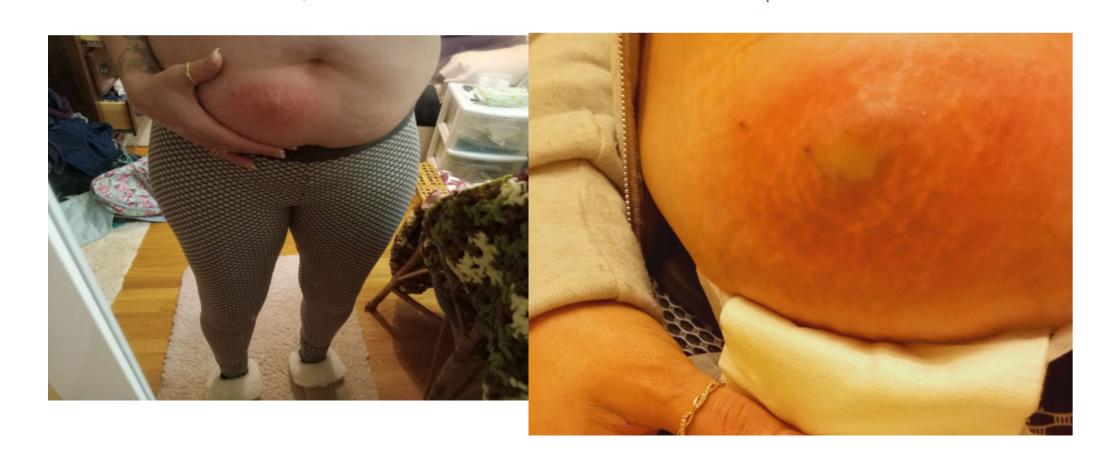




Case #3 - SD

- 35 yr old female on 12-16 mg SL Bup for OUD
- Waiting for sentencing in a Northern WI County
- Encouraged to switch to 300 mg BUP LAI given X1 prior to sentencing (not able to use strips in jail)
- Did return to clinic 3 weeks later sentencing got postponed for 6 months
- Hesitant to continue with LA Bup (does not want something in her body and wants to continue w/strips)
- After shared decision making agree to 2nd injection and strips
- MyChart message received one week later

MyChart Photo – What is Going On? 1 week post injection



Outcome:

- Initial
- warm compresses and oral antibiotics (Bactrim)
- Return if symptoms worse
- Next day Symptoms worse
- -I&D performed
- -IM Ceftriaxone x 3 days
- -Every other day wound exploration and packing
- -8 inches of packing placed



- Avoid the belt line
- Avoid rubbing the area
- Expect the "nodule" to be there for 3-4 months
- OK to do sitting down in thin patients
- Anesthesia pain is 10 seconds after the injection ICE



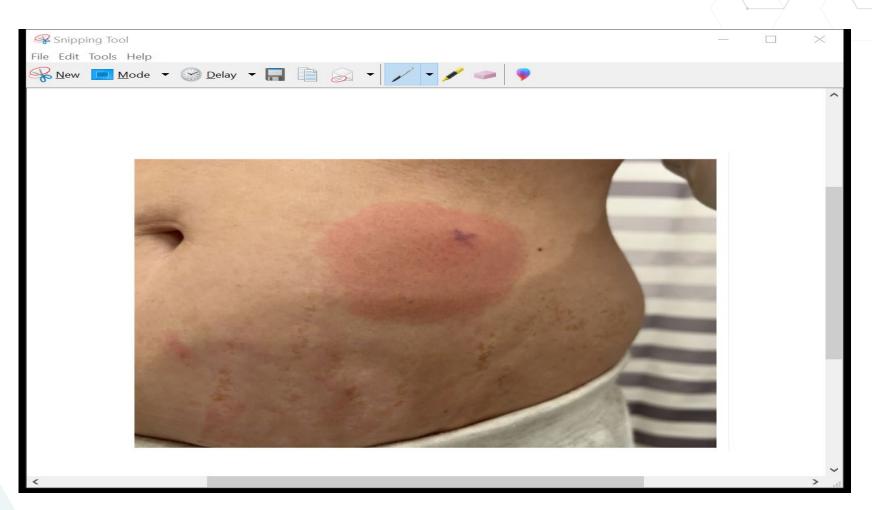


Another MyChart Message





Another picture





Last One





Case #4 WM 36 yr old male

- Prior to incarceration at county jail received one dose of 300 mg IM Bup to prevent w/d
- 8 months later is getting released and jail re-entry coordinator wants to give him IM Naltrexone
- Urine is positive for Bup
- Jail is concerned about diversion (jail does do subutex)
- They will not give IM Naltrexone
- We are seeing him the day of release to discuss options
- What do you recommend?



Naltrexone Challenge

- Obtain Baseline COWS if <4 OK to proceed with challenge
- Give oral Naltrexone 25 mg po and observe for 60 90 min
- If no change in COWS OK to give XR-Naltrexone
- If COWS is worse support with w/d medications
- How did WM do? Next Step?



Case 5 — Using LA- Bup to WEAN OFF BL bup?

- 45 yr on Bup for >10 yrs
- Dose 4 mg twice a day, admits to some days not taking the 2nd dose
- Wants to get his pilot license back so wants to wean off, has tried but anxiety gets too high
- LAI Buprenorphine discussed
- What dose would you start?
- What would recommend about strip dosing?
- By the start of 4th injection no longer using strips
- How many months would you continue?
- How many weeks apart would you recommend?

One and Done

- Curbsiders Fall 2023 Dr. Ken Lee
- Canada
- "One and done" on 8 mg or less give 100 mg of sublocade some may require a 2nd injection but if require a 3rd they are not ready
- Works 50% of the time
- Limited studies ONLY Case Reports use LAI bup
- Journal of Addiction Medicine, 2021
- 3 case reports of success all received 1 injection of Buprenorphine 100 mg 2 of the cases for Opioid dependence on full Opioid Agonist and 1 on strips



Case #6: Follow up @ 7 weeks ??

- Patient returns for injection #2
- Denies any use
- Would you give another 300 mg?
- UDS? NO POC, would not show fentanyl
- Test Dose with a SL strip to see if PWD?
- Shared decision making