Using Sublocade in Your MAT Program

Agenda

- Panelist Introductions
- Overview: pharmacology, giving the injection, patient selection
- Sublocade in practice: lessons from Chapa-De Indian Health
- Discussion
- Questions + Answers
- Closing

Today's Speakers

David Kan, MD, DFASAM
Chief Medical Officer, Bright Heart Health
Volunteer Clinical Faculty, University of California, San Francisco

Annie Mascorro, RN, PHN, CARN
Nurse Case Manager
Substance Use Disorders
Chapa-De Indian Health

Long Acting Injectible Buprenorphine (LAI-BUP)

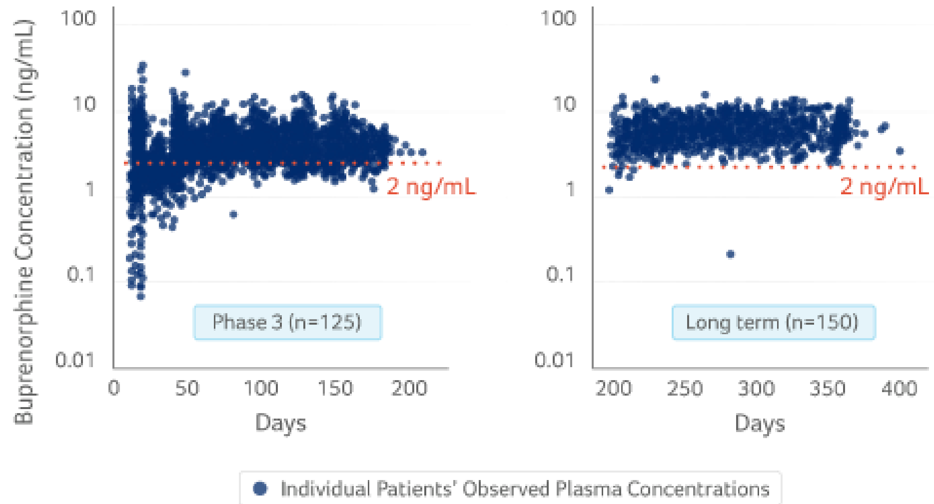
An Introduction

David Kan, MD, DFASAM
Chief Medical Officer, Bright Heart Health

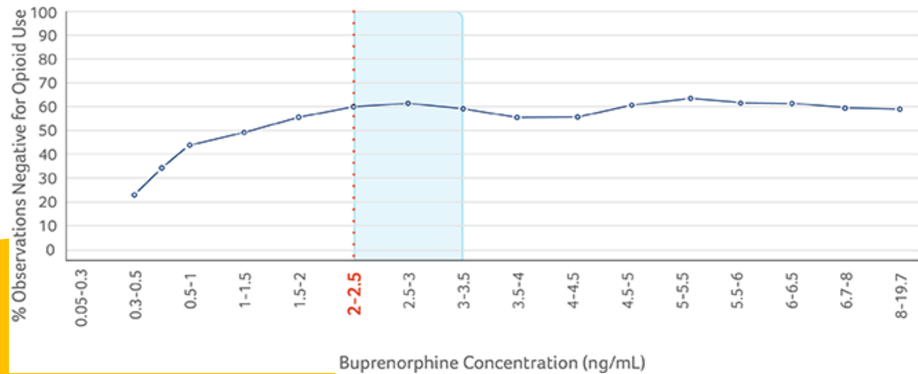
What is LAI-BUP?

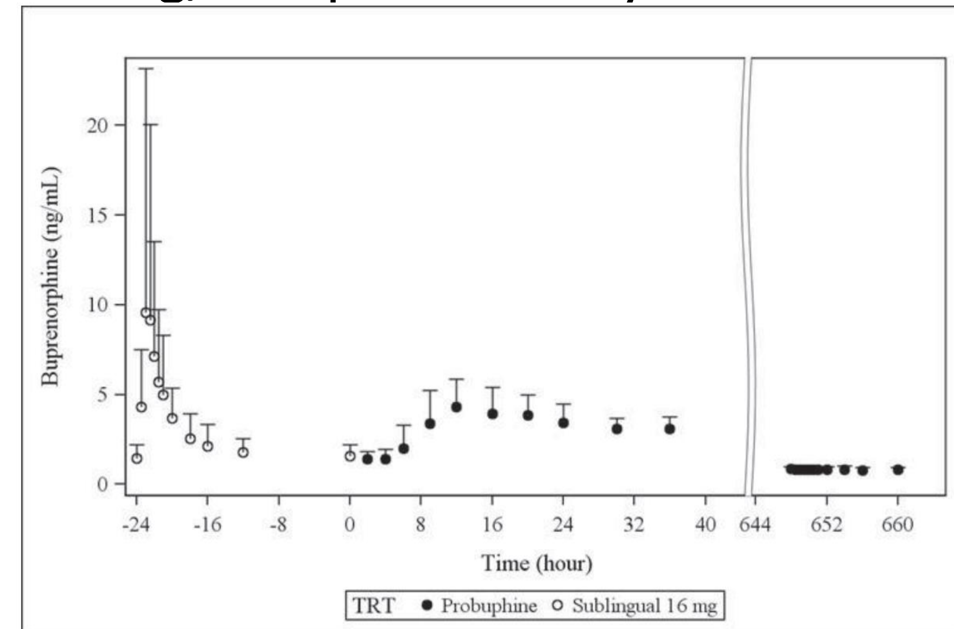
Serum Levels – LAI-BUP v. Probuphine

- LAI-BUP
  - >2 ng/ml during injection
  - Detectable >2ng/ml up to 1 year+
- Probuphine Implant – 6 months
  - ~1ng/ml up to 180 days



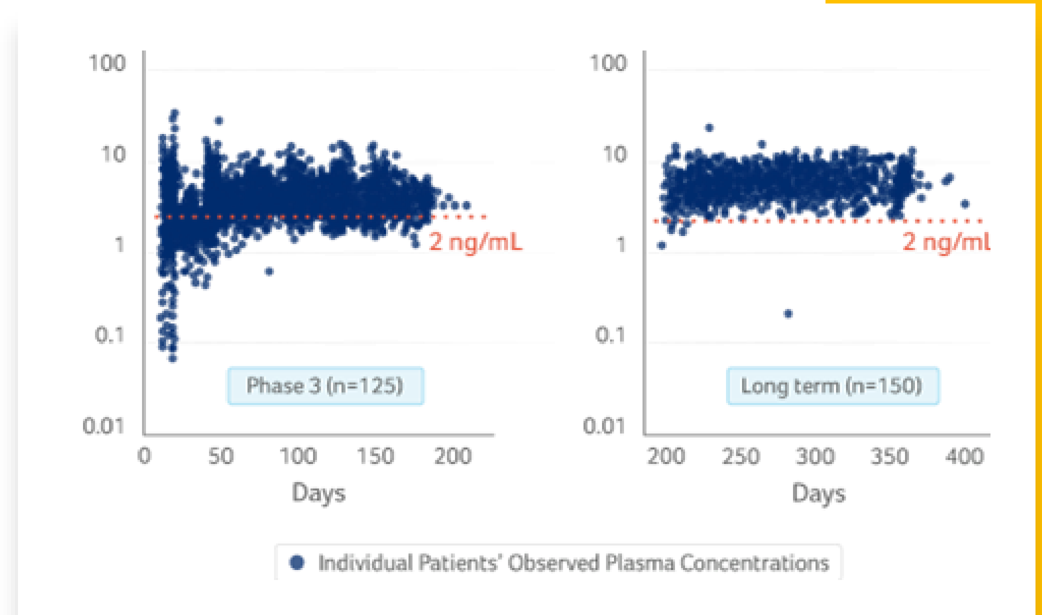
Mean	300 mg* (first injection)	100 mg† (ss)	300 mg† (ss)
$C_{avg,ss}$ (ng/mL)	2.19	3.21	6.54
$C_{max,ss}$ (ng/mL)	5.37	4.88	10.12
$C_{min,ss}$ (ng/mL)	1.25	2.48	5.01

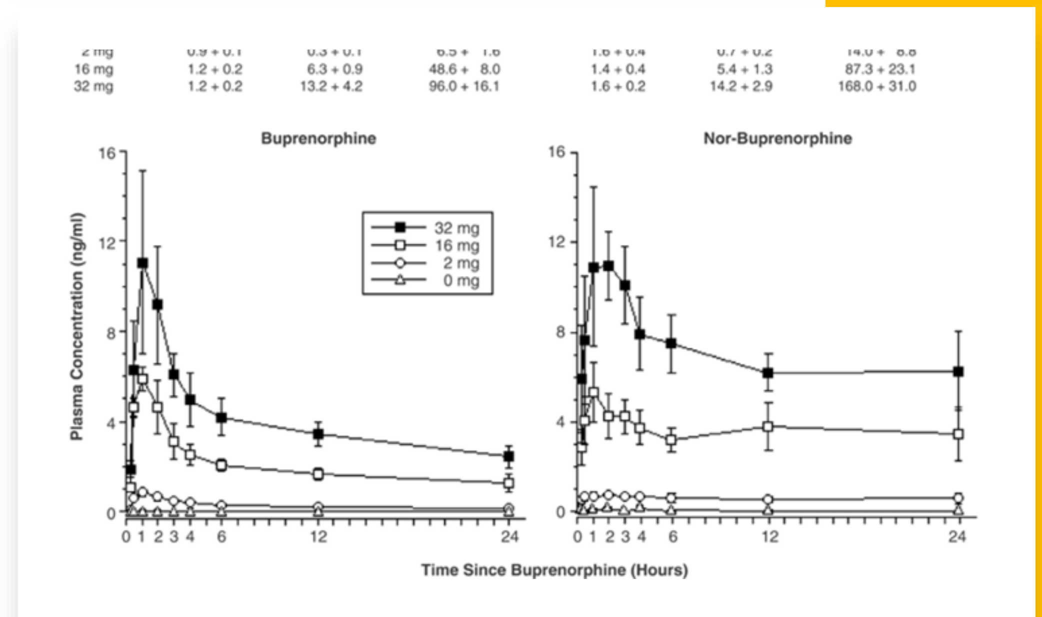




LAI-BUP v. SL BUP/BUP-NLX

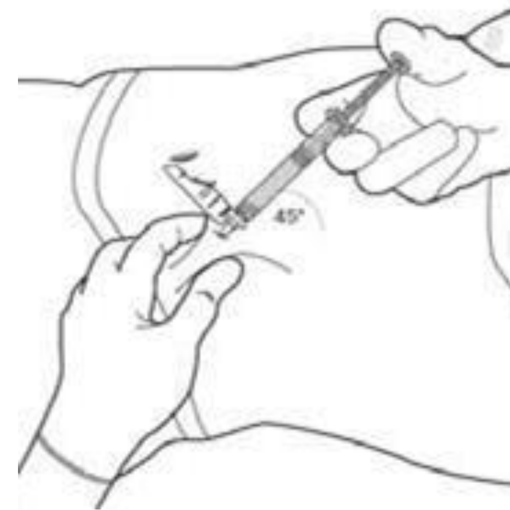
- LAI-BUP
  - >2 ng/ml during injection
  - Detectable >2ng/ml up to 1 year+ after six injections
- SL BUP/BUP-NLX
  - Dose Dependent
  - Greater level initially
  - Level drops over 24 hours

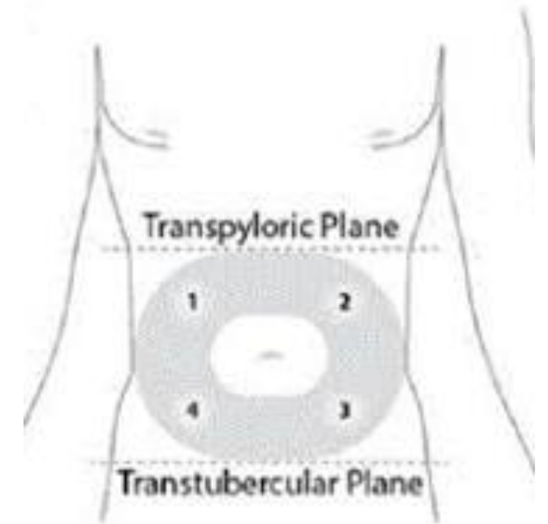


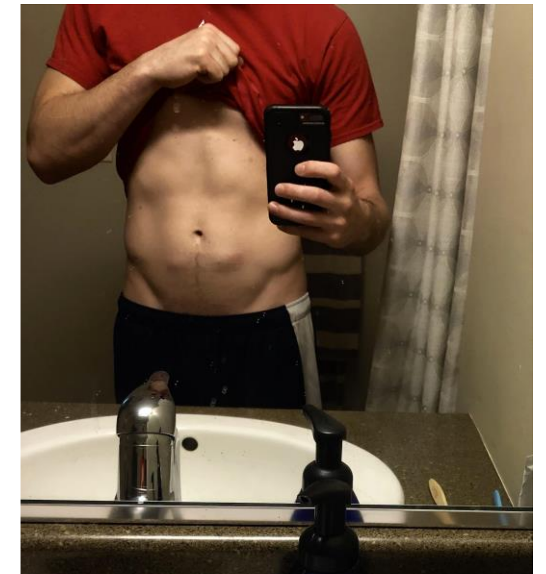


Induction Basics

- Stable on at least Buprenorphine 8-24 mg SL daily x 7 days minimum
- Can use if patient is positive for other drugs including opioids
- Dosing:
  - 300mg SQ q 28 days x 2 THEN
  - 100mg SQ q 28 days thereafter







Injection Strategies

- Ask patients about comfort with needles (cue-induced cravings)
  - Consider recommending support activity post injection
    - Mutual Support / Distraction / Calling sponsor / Going to a group / Etc.
- Counsel that first two injections will have most pain
  - 1.5 ml vs. 0.5ml
- Pain Management
  - Local Lidocaine infiltration – 10 minutes prior to injection
  - Topical Lidocaine (Synera) – 30 minutes prior to injection
  - Ethyl Chloride spray – freezing agent
- Allow patients time prior to sitting up

Adverse Effects

- Opioid Type
  - Respiratory Suppression, sleep apnea, hypotension, androgen side effects
- Common
  - Injection site reaction (erythema, pruritis)
  - Constipation
  - Headache
  - Nausea
  - Sedation
  - LFT increase (recommend LFTs if staying on 300mg dose)
- Uncommon
  - Infection

Alternatives to LAI-BUP

- Psychosocial only
  - Least effective, high rates of return to use
- Methadone
  - OTP only
- SL Buprenorphine or BUP-NLX
  - Adherence issues
- LAI Naltrexone
  - Harder to induce – 72% LAI NTX vs. 94% SL BUP[1]
- Probuphine
  - 6-month implant for 8mg SL BUP only (trough dosing)

1. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32812-X/fulltext

Effectiveness of LAI-BUP

- 12 months of injections[1]
  - Quality of life stable or improved
    - Start to 49 weeks
  - Treatment Effective Assessment scores improved
  - Employment rates increased by 7%
  - Patient satisfaction with medication 88%
- Limitations
  - Open label
  - 50% dropout
    - Loss to follow-up
    - Withdrawal of consent
  - 80% stayed on 300mg dose

1. https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(19)30168-0/fulltext

LAI-BUP Challenges

- Staff time
  - Estimate 15-25 minutes per prescription for specialty pharmacy route
  - Electronic Prescribing Ideal
  - Ordering medications
  - Accepting Delivery (Tue-Fri)
- NEVER GIVE TO PATIENT DIRECTLY
  - Risk of death with intravenous use
- Medication Storage
  - Need to log medications
  - Patient / Lot number

Experiential Notes

- Maintenance
  - 300/300/100
    - Missed doses are usually fine
  - 300 continuously
    - Co-morbid stimulant use
    - Continued opioid positive UDS
    - LFT monitoring
- Tapering
  - To be determined
  - Have had range of experiences
  - One shot and done
  - Tapered within doses
- Patient reports
  - 300mg/1.5ml hurts
  - Pain lasts 1-3 minutes then stops quickly
  - More SQ fat is better tolerated
  - Tattoos is a mixed predictor
  - Helps with pain management
  - Taste of SL buprenorphine terrible

Experiential Notes Continued

- Acute Pain Management
  - Consider full gamut of options
    - Local anesthesia
    - Regional blocks
    - NSAIDS/IV acetaminophen
  - Full Agonists
    - Work for surgical pain
    - Hydromorphine / Fentanyl – pKa can compete with buprenorphine
    - No ”high” but effective
    - Dose clinically
    - Doses may be high
    - Important to stay ”ahead” of pain

Questions and
Comments

Sublocade in a Primary Care MAT Program

Annie Mascorro, RN, CARN

Chapa-De Indian Health

Auburn/Grass Valley, CA

Chapa-De operates **two private, non-profit community health centers** and is governed by an American Indian Board of Directors. The Board of Directors includes members of the United Auburn Indian Community, which is Chapa-De's supporting Tribe. Under UAIC's authority, Chapa-De contracts with Indian Health Services (IHS) to provide **no-cost or low-cost services and medications to verified American Indians and Alaska Natives** from federally recognized tribes. We also welcome **low-income individuals and families.**

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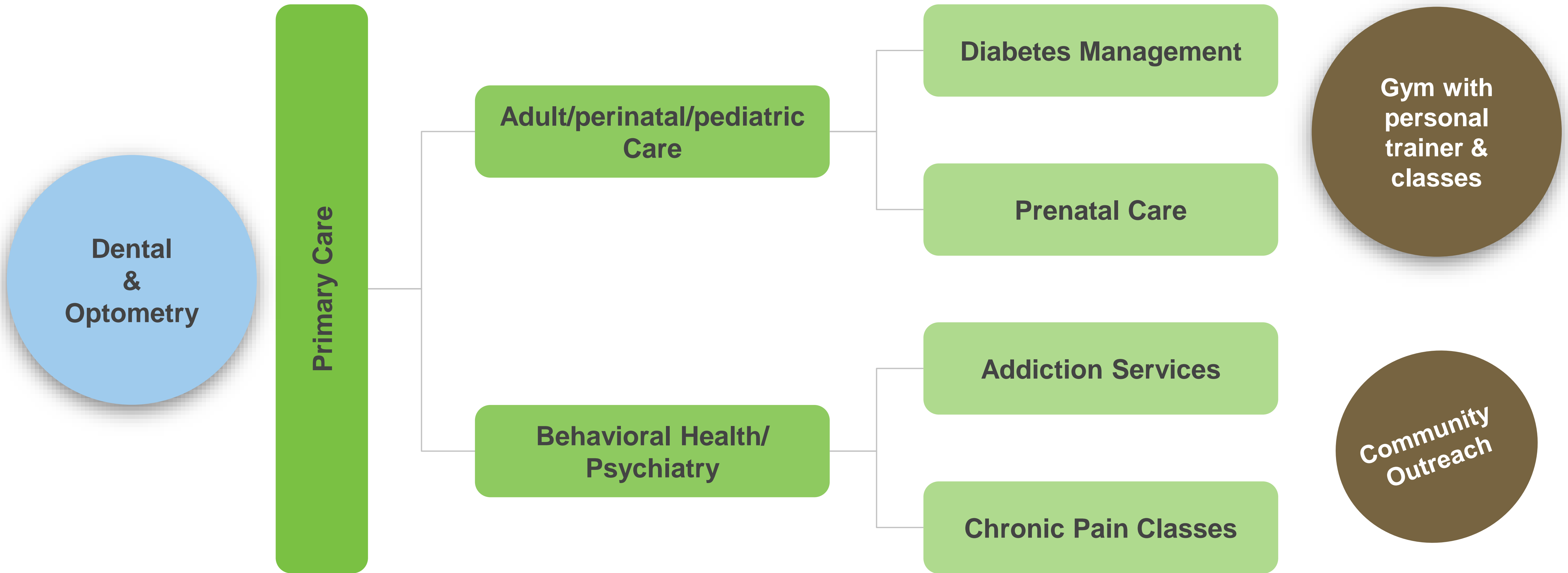
INDIAN HEALTH
11660-11670-11690

Chapa-De is part of a Nisenan phrase that means "where the valley meets the foothills"

Services Offered at Chapa-De



Chapa-De Indian Health

SUD Team - Auburn

Julie Garchow, MD

Alinea Stevens, MD

Natalia Orozco, FNP

Annie Mascorro, RN

Monique Vorous, PsyD

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SUD Team - Grass Valley

Michael Quion, MD

Sara Bland, DNP, FNP

Kylie Timmerman, RN

Donita King, LMFT

Janet Blawn, LMFT

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Medication Assisted Treatment Program at Chapa-De

- RN Case Manager Run
- Team includes RN Case manager, Providers (MDs and FNPs), Therapists and a Psychologist
- Program includes weekly refill groups run by RNs, therapists and providers
- Patients begin with weekly group visits and progress to bi-weekly and then monthly with individual appointments as needed
- Centering model is used for groups
- Patients receive a behavioral health intake and ongoing care if desired

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Sublocade Timeline

- **Nov 2017:** FDA Approved
- **Nov 2018:** Medi-Cal coverage became available
- **Nov 2018 - May 2020:** Worked with Acaria specialty pharmacy to order Sublocade for individual patients- involved an application process, wait times, and monthly phone calls for refills
- **Dec 2019:** Our head Pharmacist and Clinical Pharmacist pursued REMS certification and Buy and Bill in order to stock Sublocade in our pharmacy
- **May 2020:** We now stock 300mg and 100mg Sublocade in our pharmacy not tied to specific prescriptions

Number of patients who have been on Sublocade since Nov 2018:

- **Auburn 10**
- **Grass Valley 10**

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Workflow for In-house and Specialty Pharmacy

- Provider and RN Case Manager provide education on Sublocade to patient and discuss options
- Patient agrees to adhere to all program requirements even if that involves more appointments than the monthly injection. Clear boundaries are communicated about expectations and grounds for termination of Sublocade and a return to SL Buprenorphine.
- Once patient decides to pursue treatment with Sublocade the provider sends a prescription to the pharmacy for the loading dose, 300mg. If using a specialty pharmacy, the RNCM fills out the application form, prints out a current CURES report, insurance info, and medical summary and faxes to the specialty pharmacy. A paper rx is included or an electronic order is sent.

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Workflow for In-house and Specialty Pharmacy

- If in-stock and patient is appropriate for the medication it can be administered right away. If not in-stock, the pharmacist will order it and patient can be scheduled in a few days for an initial loading dose. If using a specialty pharmacy, staff from the pharmacy will call with an update and confirmation of the rx. They will call once it has been approved by Medi-Cal and a shipping date will be set up. This can take 2-3 weeks
- Patient presents to clinic, provides a UDS, is assessed by a provider, and is given the SQ injection by a provider, nurse, or medical assistant. Staff giving the injection needs to be familiar with the Sublocade injection training video.
- Patient is scheduled for next month's injection.

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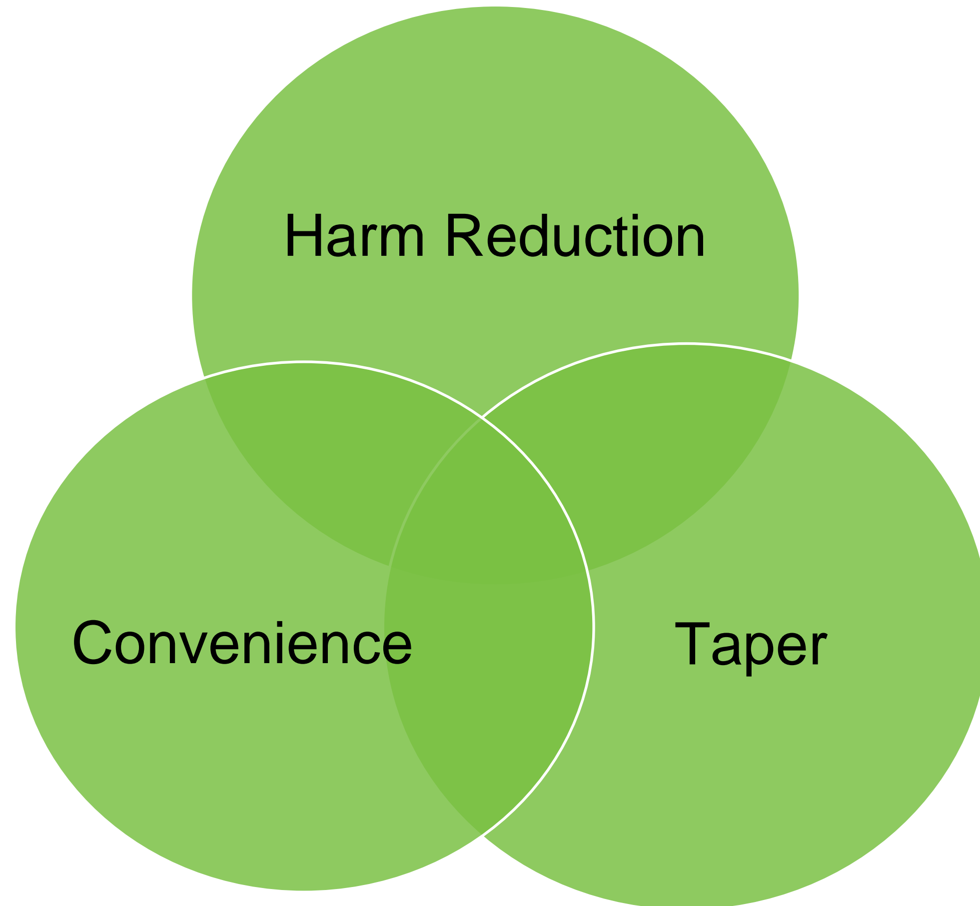
Sublocade as a Clinical Tool



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Advantages

- Effective harm reduction for unstable patients at high risk of overdose who do not show up for their appointments.
- Provides convenience for stable patients who are busy and don't want to have to keep track of medications and take them daily. Injection appointments are made around their schedule.
- Allows patients who cannot get to the clinic (transportation issues, distance, travel, jail, residential treatment, etc.) to continue MAT.
- May help patients who have an unhealthy relationship with pills break the cycle of taking something when they feel bad or stressed.

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Advantages Continued

- Can help stabilize patients who forget to take their medication or who take more than prescribed and then run out before their next prescription is due.
- Will likely prevent diversion which could help address polysubstance use.
- Reassures patients who are anxious about missing a prescription or getting their refill late.
- Creates an opportunity for a very slow taper off the medication for patients who wish to stop taking Buprenorphine.

Disadvantages

- Takes away an incentive for frequent visits.
- May lead to less care if patient comes in only once per month.
- Does not address polysubstance use.
- Some report it is a painful injection.
- Possibility of injection site soreness or infections.
- Some patients do no like the small lumps left in their abdomen with each injection.
- Requires staff to administer the medication.
- May not be available in the pharmacy at all times.
- Patient may miss the ritual/comfort of taking medication each day.

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Considerations for COVID-19

- Where will the medication be administered?
- Is it safe to have healthy patients come into the clinic for the injection?
- Should patients be switched to SL Suboxone during the pandemic?

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Questions?

Feel free to contact me:

Annie Mascorro, RN, CARN

amascorro@chapa-de.org

(530) 887-2804

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Discussion

Discussion

- What factors influence a health center’s decision to work with a specialty pharmacy or choose buy and bill?
- What factors influence patient selection?
- Describe some of the the tradeoffs you’ve encountered with Sublocade.

- Join the conversation!
- Use the chat box or unmute yourself to weigh in (*6)

Specialty Pharmacy

- Send Order to Specialty Pharmacy
- Prior authorization common
  - Not with MediCal
- Need patient consent to ship
- Receive Medication
- Log Medication
- Give Medication

Buy and Bill

- Purchase Directly from Specialty Pharmacy
  - State Medical License
  - DEA – license (indiv + facility)
  - Tax exemption forms
  - Billing and shipping information
  - Corporate entity information
- Prior authorization common
  - Not with MediCal
- Log supply
- Give Medication
- Bill Insurance for medication

Perspectives on Patient Selection

Annie

- Miss appointments and refills regularly
- Have an unhealthy relationship with their medication
- Are not taking their SL Buprenorphine as prescribed
- Are homeless and have no safe place to store medication
- Have a history of diversion or suspected diversion
- Have concurrent Stimulant Use Disorder
- Have a planned jail sentence in a jail that does not offer MAT
- Are going to residential treatment where no MAT is offered
- Are moving and looking for a new MAT provider
- Are stable and don’t want to take medication every day
- Would like a slow taper with minimal withdrawal symptoms

David

- Considerations
  - Patient preference
  - Adherence
  - Taste
  - Clinical Efficacy
  - NTX → BUP → Methadone
    - Easy
  - Methadone → BUP → NTX
    - More challenging
- Missed shot?
  - Most patients are fine
- Severe liver disease
  - No guidance on dose change
  - Medication release is mechanical
  - Medication metabolism

Questions?

Next Steps

The breakout room will close at 1:50 pm and you'll be automatically sent back to the main Zoom room (your line will be muted)

Please fill out the poll/survey – it will help CCI in planning the final webinar in this series (on July 23).

Thank you!

Appendix

Paying for LAI-BUP

- 3rd part payor
  - $1600/injection
- Copay assistance programs
  - ~$5 copay
- MediCal
  - Free

Medicare Billing v Other Payers

		OPIOID TREATMENT PROGRAM	PHYSICIAN OFFICE	HOSPITAL OUTPATIENT
	Claim Form	CMS-1500	CMS-1500	CMS-1450
MEDICARE[6]	Professional Services	G2069	G2086 and G2087	96372
	SUBLOCADE		Q9991 or Q9992	Q9991 or Q9992
ALL OTHER PAYERS	Professional Services	96372	96372	96372
	SUBLOCADE	Q9991 or Q9992	Q9991 or Q9992	Q9991 or Q9992

Billing Codes

- Opioid Use Disorder
  - F11.2XX
- National Drug Code

NDC	MILLIGRAMS	NDC FORMAT FOR CLAIMS	NDC LOCATION ON CLAIM FORMS
12496-0100-01	100 mg	N412496010001	• CMS-1500: Box 24A • CMS-1450: Field 42
12496-0300-01	300 mg	N412496030001	• CMS-1500: Box 24A • CMS-1450: Field 42

- CPT Code

CPT CODE	DESCRIPTION
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

https://www.insupport.com/pdf/billing-coding-guide.pdf

- Product Specific HCPCS Codes

HCPCS CODE	DESCRIPTION	NUMBER OF UNITS
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	1
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	1

- G Code

G CODE	DESCRIPTION
	Weekly Codes in OTP Setting
G2069	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)
G2074	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program)
	Monthly Codes in Physician Office Setting
G2086	Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month
G2087	Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month