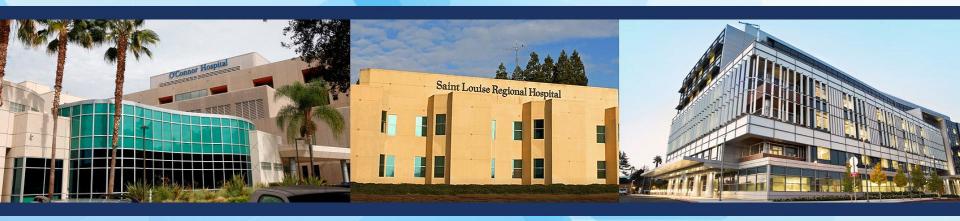
# Impact of Clinical Pharmacists on Homeless Outcomes and Medication Adherence



Lawrence Chang, Pharm.D., BCACP, Sophie Nguyen, Pharm.D., and Michael Wong, Pharm.D.









#### Disclosures

- Potential conflicts of interest: None
- Sponsorship: None
- Proprietary information or results of ongoing research may be subject to different interpretations





#### County of Santa Clara Health System

Vision: Better Health for All

Mission: Provide high-quality, compassionate, accessible healthcare regardless of patient's ability to pay



#### **Health System Includes:**

- Behavioral Health Services Department
- Public Health Department
- Emergency Medical Services Agency
- Custody Health Services Department
- Valley Health Plan



#### Santa Clara Valley Medical Center

- 731-bed safety-net teaching hospital
- Level 1 Trauma & Regional Burn Center



#### O'Connor Hospital

- 358-bed acute care community hospital
- Level III Community NICU
- Accredited Cancer Care Program



#### St. Louise Regional Hospital

- 93-bed community hospital
- Designated Primary Stroke Center



#### **Health Centers**

- 15 outpatient pharmacy locations
- Valley Specialty Center
- Homeless Healthcare Program

Dedicated to the health & well-being of all communities in Santa Clara County

# **County of Santa Clara**







## Santa Clara County









## Santa Clara County











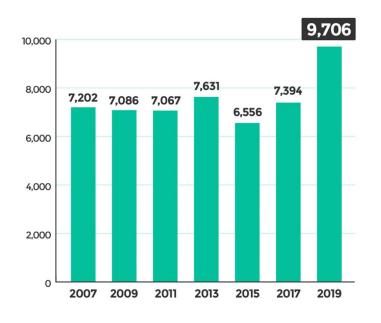






## Homelessness in Santa Clara County

#### **Homeless Population by Year**



•In 2019, there were 9,706 people experiencing homelessness in Santa Clara County - the 4th highest total of any community in the country.

•Increase of 31% from 2017





#### Rent in Santa Clara County

#### Earned income growth for full-time wage and salary workers Santa Clara County, CA: 2000-2019 20% 16% 14% 10% 4% 0% -7% -10% -8% -20% 10th 20th 50th 90th 80th percentile percentile percentile percentile percentile

#### RENTERS NEED TO EARN 2.8 TIMES MINIMUM WAGE TO AFFORD MEDIAN ASKING RENTS



Source: CoStar Group average asking rent for two bedroom as of January 2021. Bureau of Labor Statistics Average Annual Wage Data for California Occupations, 2020.



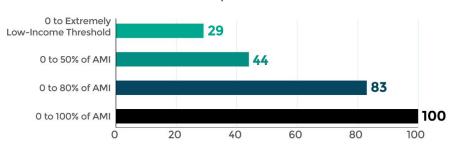




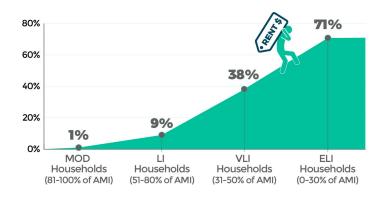
## Rent in Santa Clara County

Rent Burden: 71% of extremely low-income (ELI) households spend more than 50% of their income on rent and utilities

Affordable & Available Rental Homes "Per 100 Renter Households"
San Jose Metropolitan Area: 2019



#### **Percent of Households Severely Rent Burdened**





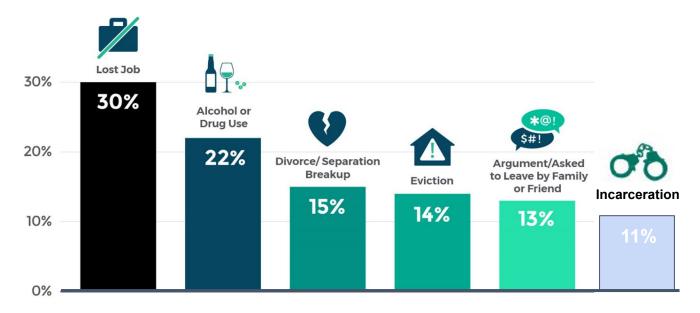




## Homelessness in Santa Clara County

#### PRIMARY EVENT OR CONDITION THAT LED TO HOMELESSNESS:

Top Responses from the 2019 Homeless Census & Survey

















Mission of Valley Homeless Healthcare Program

We wish to promote human dignity, relieve suffering and provide hope so that people can achieve their full potential and improve their quality of life.





#### **Core Values**

- Innovation and Creativity
- Providing compassionate care that centers around our patients' needs
- Provide services by many team members from different areas of expertise, working together to treat the whole person





We are a patient centered, integrated healthcare team consisting of:

Medical Providers (MD/NP)

Nurses

Medical Social Workers

**Psychiatrists** 

**Outreach Workers** 

Occupational Therapy

**Pharmacists** 

**Medical Assistants** 

**Psychologists** 

Health Service Representatives

**Outreach Drivers** 

Dietician







#### We serve the homeless population through:

- Four fixed clinic sites
  - Alexian Clinic/ Gender Clinic
  - Homefirst Shelter Clinic
  - Bill Wilson
  - Hope Clinic
- Mobile Medical Van
  - Reentry Clinic
  - Mobile Medical Unit
  - Teen Van
- Backpack Medicine Team
- Medical Respite Program
- Patient Outreach

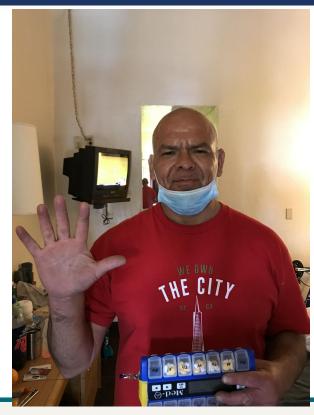








#### **Case Presentation**









#### **Case Presentation**

JC is a 52 year old male with a past medical history of resistant hypertension, CKD, T2DM, HFpEF, Afib, stroke in 2005, and TBI.

He presents to clinic for refill of medications. Medical records were checked and it appears he received medications the day prior from pharmacy. Patient states he can't remember what happened to the medications.

Pertinent Baseline Labs/ Vitals (3/2020):

BP: 210/141

HbA1c: 11.6%







## Roles of a Pharmacist







#### Medication Adherence

#### World Health Organization (2003)

- •"Increasing the effectiveness of <u>adherence interventions</u> may have greater impact on the health of the population than any improvement in specific medical treatments."
- •"Long-term adherence to chronic medications has been estimated to be <u>as low as 50%</u>."









#### Cost of Medication Non-Adherence

#### Financial Burden

•"Of all medication-related hospital admissions in the United States, 33 to 69 percent are due to poor medication adherence, with a resultant cost of approximately \$100-289 billion a year."











#### Major Predictors of Poor Adherence

#### *NEJM* (2005)

T	able 2. Maj	or Predictors	of Poor Ad	herence to	Medication,	According	to Studies o	f Predictors.
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Predictor Study

Presence of psychological problems, particularly van Servellen et al., 51 Ammassari et al., 52 Stilley et al. 53 depression

Presence of cognitive impairment Stilley et al.,53 Okuno et al.54

Treatment of asymptomatic disease Sewitch et al.,55

Inadequate follow-up or discharge planning Sewitch et al., 55 Lacro et al. 56

Side effects of medication van Servellen et al. 51

Patient's lack of belief in benefit of treatment Okuno et al.,54 Lacro et al.56

Patient's lack of insight into the illness

Poor provider–patient relationship Okuno et al.,54 Lacro et al.56

Presence of barriers to care or medications van Servellen et al., 51 Perkins 57

Missed appointments van Servellen et al., 51 Farley et al. 58

Complexity of treatment Ammassari et al. 52

Cost of medication, copayment, or both Balkrishnan, 59 Ellis et al. 60



Lacro et al.,56 Perkins57





## Motivational Interviewing (MI)

#### Tips:

- Medication adherence is <u>HARD</u>
  - Roll with the resistance, and use harm reduction
- Stay curious
  - Until they feel like you truly "get" it, it'll be hard for you to convince them to change.
- Change can happen IF and ONLY IF a person wholeheartedly internalizes the discrepancy between their goal and behavior







## Motivational Interviewing (MI)

#### So what's an example?

"You need to take your medications."

•"You told me a lot about <u>your goals to lower your sugars so you can prevent amputations</u>. It seems clear to me that being independent and working is so important to you. At the same time, we're both noticing how <u>drinking 4-6 sodas/day</u> worsens your sugars. What do you think about that? How do you want your habits to <u>change for the better</u>?"







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Side effects of medication

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Missed appointments

Complexity of treatment

Cost of medication, copayment, or both

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#### Major Predictors of Poor Adherence

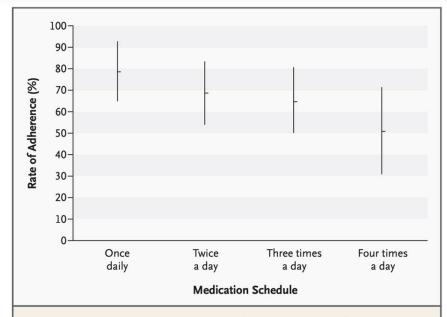


Figure 1. Adherence to Medication According to Frequency of Doses.

Vertical lines represent 1 SD on either side of the mean rate of adherence (horizontal bars). Data are from Claxton et al. $^7$ 

Frequency of dosing is inversely related to adherence.







## Simplifying Regimens

#### **Decreasing Frequency**

- Atorvastatin 40 mg or Lantus 20 units at bedtime
  - Once daily
- Metoprolol tartrate 25 mg twice daily
  - Metoprolol <u>succinate</u> 50 mg once daily
- Glipizide 5 mg twice daily with food
  - Glipizide <u>XL</u> 10 mg once daily (regardless of food?)
- Isosorbide dinitrate 20 mg TID and hydralazine 25 mg TID
  - Isosorbide <u>mononitrate</u> 60 mg once daily and hydralazine 25 mg <u>twice daily</u>
  - Bonus: BiDil (isosorbide dinitrate-hydralazine) 20-37.5 mg twice daily







## Simplifying Regimens

#### Reducing Pill Burden

#### Medications to re-evaluate:

- Vitamins/Minerals (Folic Acid, Thiamine, Iron, etc.)
- Aspirin 81 mg?
- Temporary long-term treatments
  - DAPT? Anticoagulation? Bisphosphonates?
- Acid Reducers (PPIs?)
- As-needed medications (laxatives, stool softeners, etc)



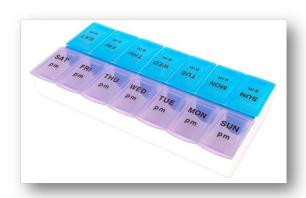




## Strategies to Improve Adherence

#### Non-Clinical:

- Pill box
- Blisterpacking medications













## Outreaches Visits by Pharmacists

- Patients staying in homeless shelters, temporary housing and streets
- Disabled who are unable to walk to a primary care clinic or make appointments
- Cognitively impaired patients who cannot manage their medicines independently







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#### Patient Case









## Patient Case





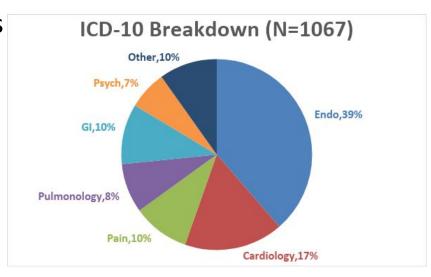




#### Pharmacists' Clinical Interventions

Report of **ICD-10 codes** of all disease states intervened by VHHP pharmacists

- N = 1067 ICD-10 codes
- Average 1.9 problems/visit
- Diabetes most commonly addressed
- Area to improve: psychiatry support
  - Psychiatric collaborative practice agreement (first for depression)









### Diabetes Management Strategies

- Collaborative practice protocol
- Outreaches visits
- Freestyle Libre System
- Non-insulin agents: SGLT2 inhibitors,
   GLP1 receptor agonist













## Frestyle Libre System









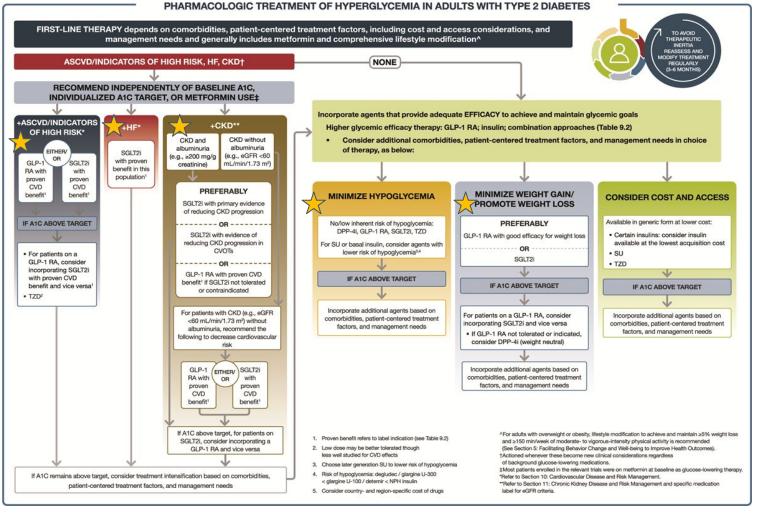
# Pharmacologic Approaches to Glycemic Treatment

2022 ADA Guidelines









## SGLT2 Inhibitors

Blocks reabsorption of glucose and facilitates its excretion in the urine

#### FDA-approved:

- Empagliflozin (Jardiance)\*
- Dapagliflozin (Farxiga)\*
- Canagliflozin (Invokana)
- Ertugliflozin (Steglatro)

\*HFrEF Benefit with/without DM CKD Benefit (all agents)

#### Side effects:

- Risk for UTI (females: 18%; males: 4%)
- Genitourinary fungal infection (~4-6%)
- Increased urine output (~3-5%)
  - Hypotension
  - Dehydration

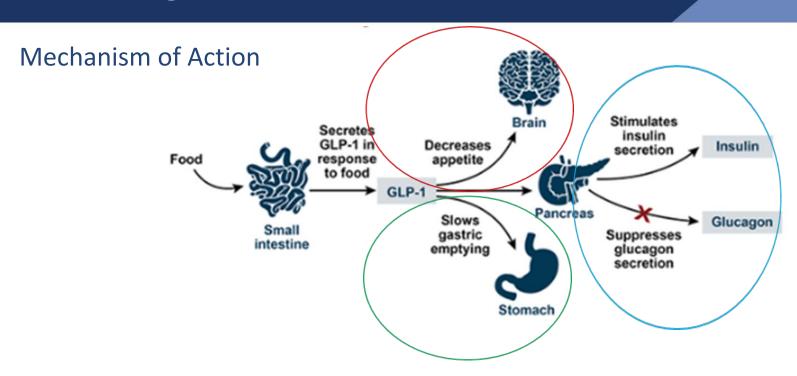








## **GLP-1** Agonists



Meier JJ. Nat Rev Endocrinol. 2012;8:728-742.







# Injectable GLP-1 Agonists

- Injectable
- Strong efficacy (A1c >↓1-2%)
- Available once daily/weekly!
- CV Benefit
- Weight Loss
- GI side effects





#### Once weekly



★ Dulaglutide (Trulicity)

Exenatide (Bydureon BCise)

Once daily:

Liraglutide (Victoza)

Lixisenatide (Adlyxin)







# *Oral* GLP-1 Agonist

## Rybelsus® (semaglutide)

- Can be difficult for patients
- Administer on:
  - Empty stomach,
  - at least 30 minutes before first food, beverage, or other oral medications of the day
  - with ≤4 oz of plain water only.
  - Manufacturer recommends eating 30 to 60 minutes after the dose.









# Dulaglutide (Trulicity)

## **Trulicity Steps:**

- 1) Remove gray cap
- 2) Turn pen from "locked" position to "unlocked"
- 3) Press green button to inject SQ



Recently approved 3 mg and 4.5 mg strengths! (in addition to 0.75 mg and 1.5 mg)







# Semaglutide (Ozempic)

### Ozempic steps:

- 1) Attach pen needle (included in the box)
- 2) Dial the dose
- 3) Inject into abdomen like an insulin pen



Recently approved 2 mg strength! (in addition to 0.25 mg, 0.5 mg and 1 mg)







# Once Daily Medications

Metformin ER (500 mg & 750 mg; 1000 mg ER covered by Medi-Cal)

### **Glipizide XL**





#### **SGLT2**-metformin ER

- Xigduo XR (dapagliflozin-metformin ER)
- Synjardy XR (empagliflozin-metformin ER)
- Invokamet XR (canagliflozin-metformin ER)









# **Diabetes Agents**

	Drug Class	A1c Benefit	Clinical Benefits	Risk of hypoglycemia	Weight Change	Side Effects
	Metformin	High (>1–2%)	CV benefit	None	Neutral	<ul><li>Diarrhea/GI upset</li><li>ER formulation: less ADRs</li><li>Vitamin B12 deficiency</li></ul>
	SGLT2 Inhibitors	Intermediate (>0.5–1%)	CV benefit CKD benefit CHF benefit	None	Loss	Risk for UTI/fungal infection (♀>♂) Caution hypotension/dehydration FDA warning: amputations?
<b>★</b>	GLP-1 Agonists	High (>1–2%)	CV benefit CKD benefit	None	Loss	Nausea (16-20%), diarrhea, abdominal pain, constipation <b>BBW</b> : Risk of Thyroid C-cell tumors (only seen in rats/mice)
	DPP-4 Inhibitors	Intermediate (>0.5–1%)	None	None	Neutral	Nasopharyngitis (5%) Alogliptin/Saxagliptin: CHF warning
	Sulfonylureas	High (>1–2%)	None	Yes	Gain	Hypoglycemia
	Thiazolodinediones	High (>1–2%)	None	None	Gain	Edema BBW: Congestive Heart Failure





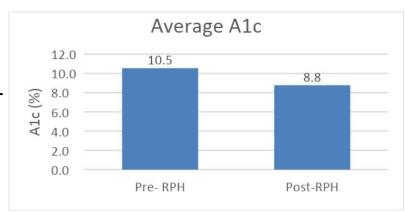


# Diabetes Management Outcomes

**Sample size**: N = 110 patients

**Time window**: Jan 2021 through March 2021

**Average A1c reduction**: -1.7%



<u>Clinical significance</u>: an A1c reduction of just -0.8% was shown to be associated with a 45% lower risk of cardiovascular death according to an observational study published by the American Diabetes Association (ADA)







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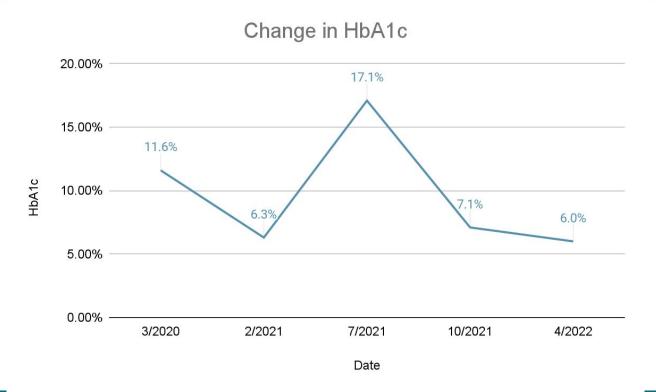
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## Patient Case









# Patient Case











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Pertinent Baseline Labs/ Vitals (3/2020):

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HbA1c: 11.6%







# Blood Pressure Management Strategies

- Blood pressure cuff
- Pill boxing
- Combination pills
- Home visits













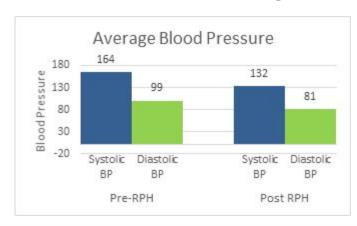


# **Blood Pressure Management**

**Sample size**: N = over 120 patients

Average BP reduction: 32 points in SBP and 18 points in diastolic BP.

Mean BP after pharmacist intervention was 132/81, which met PRIME target and almost met stricter BP goal of AHA/ACA







# Patient Case



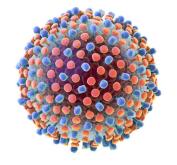








## Hepatitis C Burden in the US



Hepatitis C virus infection (HCV) has impacted approximately 4.6-4.9 million people in the United States, of whom <u>41 percent</u> are homeless, incarcerated, or institutionalized

An estimated 55% to 85% of the infected population develop chronic hepatitis, 30% will later progress to <u>cirrhosis</u>, and 2% will develop <u>hepatocellular</u> <u>carcinoma (HCC)</u>

Injection drug use accounts for nearly **two-thirds** of acute HCV infections







## Fact or Fiction?

#### Myths about Hepatitis C

- Treatment is complicated and should be reserved for GI/ID specialists
- Hepatitis C medications cause many side effects
- Patients who actively use drugs or alcohol are poor candidates for treatment
- Patients need to be highly adherent to successfully achieve SVR12
- Homeless patients need more support than other patients





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## Features of our HCV Program

#### Treatments led by Pharmacy team

- Increased multidisciplinary supports for patients: transportation, mental health
- Aggressive outreach (med delivery, search for people who are lost to follow up)
- Integrating treatment with primary care (suboxone for patient with opioid use disorder)

Increase chance of patient completing treatment

\*Treatment initiated only in non-cirrhotic and compensated cirrhotic patients







# Simplified Regimens for Treatment Naive Patients

#### Non-Cirrhotic and Compensated Cirrhotic patients

1. Mavyret x 8 weeks taken with food

2. <u>Epclusa</u> x 12 weeks











# Hepatitis C management Outcomes

N = 61 patients

Time window: Jan 2020 through Aug 2021

Most are complicated by social barriers and psychiatric conditions, as well as substance use disorder:

Opioid use disorder: 23%

Active Methamphetamine use: 21%

Alcohol use disorder: 18%



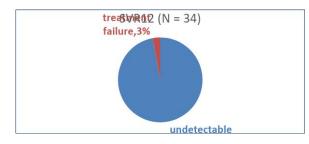




## Results

61 patients completed treatment, 28/61 (46%) had compensated cirrhosis

- 34 patients obtained SVR12
- 33/34 (97%) patients had undetectable SVR12
- 1 patient failed treatment



#### Excluded:

- 14 patients who completed treatment but did not get SVR12 drawn.
- 13 patients not due for SVR12 at the time of analysis







# **Opioid Use Disorder**







# Opioid Use Disorder (OUD)

#### Buprenorphine

• First agent available in the U.S. (FDA-approved in 2002) for office-based treatment of **Opioid Use Disorder** under the Drug Abuse Treatment Act of 2000 (DATA 2000)

- Partial μ-receptor agonist
  - Blocks μ-receptor while providing some therapeutic effect
- Typically, sublingual formulation prescribed (target dose: 24 mg/day)







## **OUD Treatment Considerations**

- Targets based on Trough Plasma Concentrations
  - ≥1 ng/mL: Withdrawal Suppression
  - ≥2-3 ng/mL: Blockade of Opioid Reinforcement/Effect

- Potential Issues with SL formulation:
  - Fluctuations in concentration
  - Medication non-adherence
  - Risk of diversion and/or misuse

Pharmacokinetic parameters	SUBUTEX daily stabilization			
Mean	12 mg (steady-state)	24 mg (steady-state)		
C <sub>avg,ss</sub> (ng/mL)	1.71	2.91		
C <sub>max,ss</sub> (ng/mL)	5.35	8.27		
C <sub>min,ss</sub> (ng/mL)	0.81	1.54		







# Long-Acting Injectable (LAI) Buprenorphine

- 1-month SQ Injection (Approved by FDA in 2017)
  - Loading Dose = 300 mg monthly x2
  - Maintenance Dose = 100 mg monthly (300 mg maintenance dose is off-label)
- Opioid blockade from 1<sup>st</sup> dose
- Consistent blockade (≥2 ng/mL) during maintenance therapy

Table 6. Comparison of Buprenorphine Mean Pharmacokinetic Parameters Between SUBUTEX and SUBLOCADE

OUDLOCADL						
Pharmacokinetic parameters	SUBUTEX daily stabilization		SUBLOCADE			
Mean	12 mg (steady-state)	24 mg (steady-state)	300 mg# (1st injection)	100 mg* (steady-state)	300 mg* (steady-state)	
C <sub>avg,ss</sub> (ng/mL)	1.71	2.91	2.19	3.21	6.54	
C <sub>max,ss</sub> (ng/mL)	5.35	8.27	5.37	4.88	10.12	
C <sub>min,ss</sub> (ng/mL)	0.81	1.54	1.25	2.48	5.01	

#Exposure after 1 injection of 300 mg SUBLOCADE following 24 mg SUBUTEX stabilization

<sup>\*</sup>Steady-state exposure after 4 injections of 100 mg or 300 mg SUBLOCADE, following 2 injections of 300 mg SUBLOCADE



# Risk Evaluation and Mitigation Strategy (REMS)

## **Black Box Warning**

"Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously."

#### **Roadblocks**:

- SUBLOCADE REMS Program
- Schedule III Drug
- Specialty Drug









## Role of a Pharmacist in OUD

#### LAI-Buprenorphine Case Management

- Resolve insurance issues, ensure PA is submitted/approved (if needed)
- Coordinate delivery (same-day or ahead of time)
- Manage inventory
- Monitor sobriety and cravings/withdrawal symptoms
- Patient outreach prior to next dose







## Role of a Pharmacist in OUD

#### **Clinical Outcomes**

#### Between 5/2021 and 5/2022:

- 101 total successful administrations of Sublocade
- Out of the 28 unique patients, 14 of them (50%) received at least 3 consecutive injections and reached steady state.





# A Special Message!















# **Questions?**

Thanks for attending our session!

Lawrence Chang: <u>Lawrence.Chang@hhs.sccgov.org</u>

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Michael Wong: MichaelA.Wong@hhs.sccgov.org





