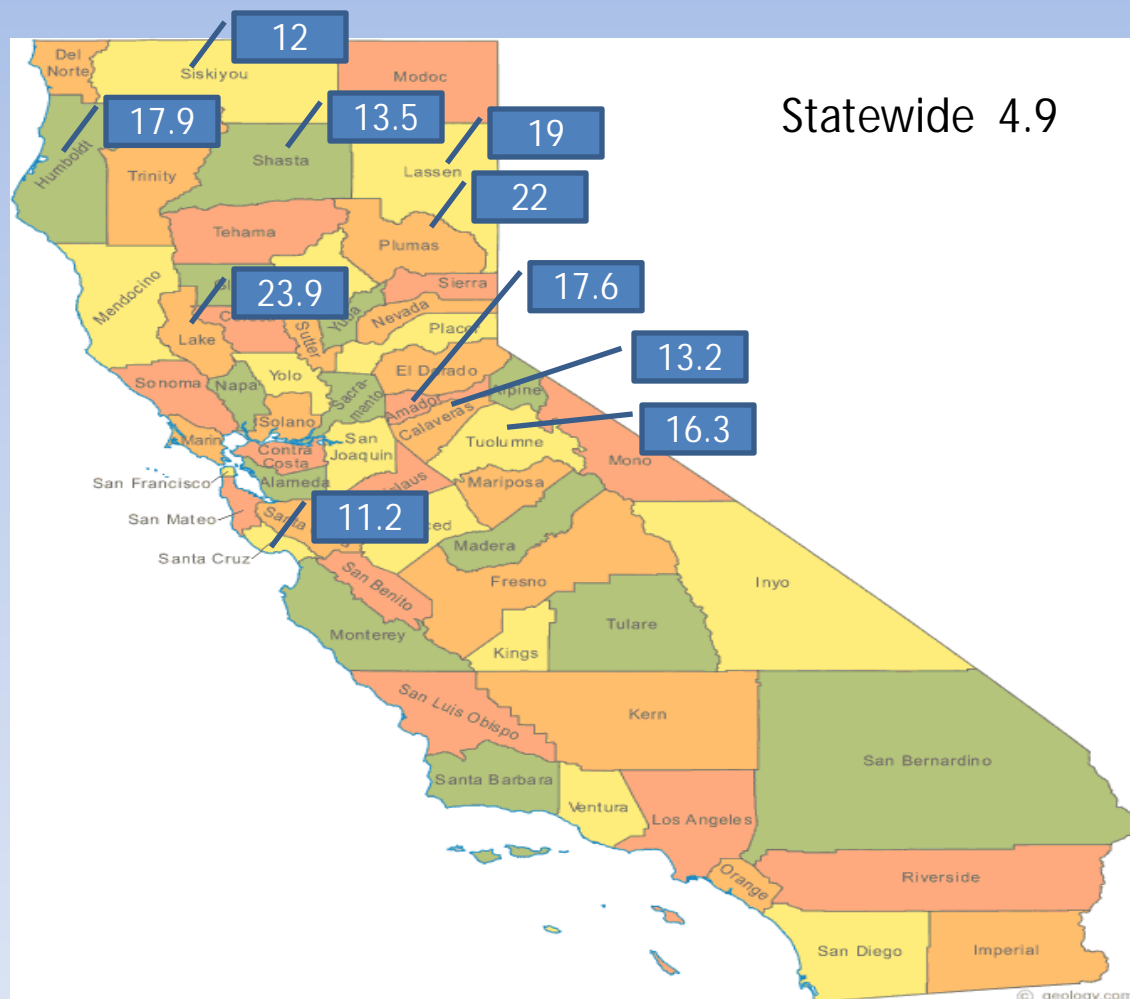


Buprenorphine Access in California

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Opioid Poisoning Deaths in California

5 year totals: 2008-2012 (All opioids, All intents) rate per 100,000

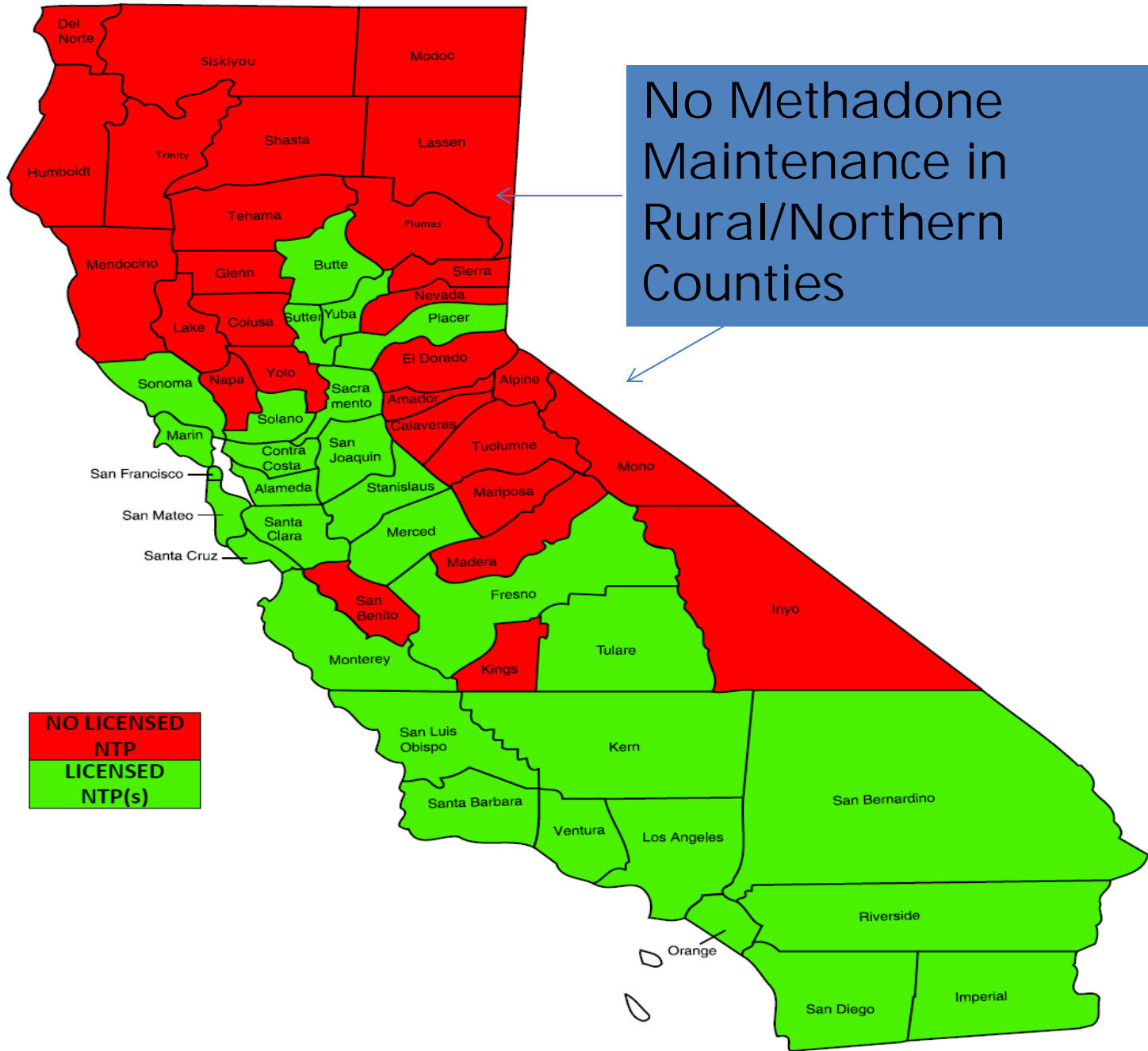


Source: CDPH Vital Statistics Death Statistical Master File

Prepared by CDPH, Safe and Active Communities Branch

Report generated from <http://epicenter.cdph.ca.gov> on Dec 19, 2014

No Methadone Maintenance in Rural/Northern Counties



**NO LICENSED
NTP**
**LICENSED
NTP(s)**

Treatment Saves Lives

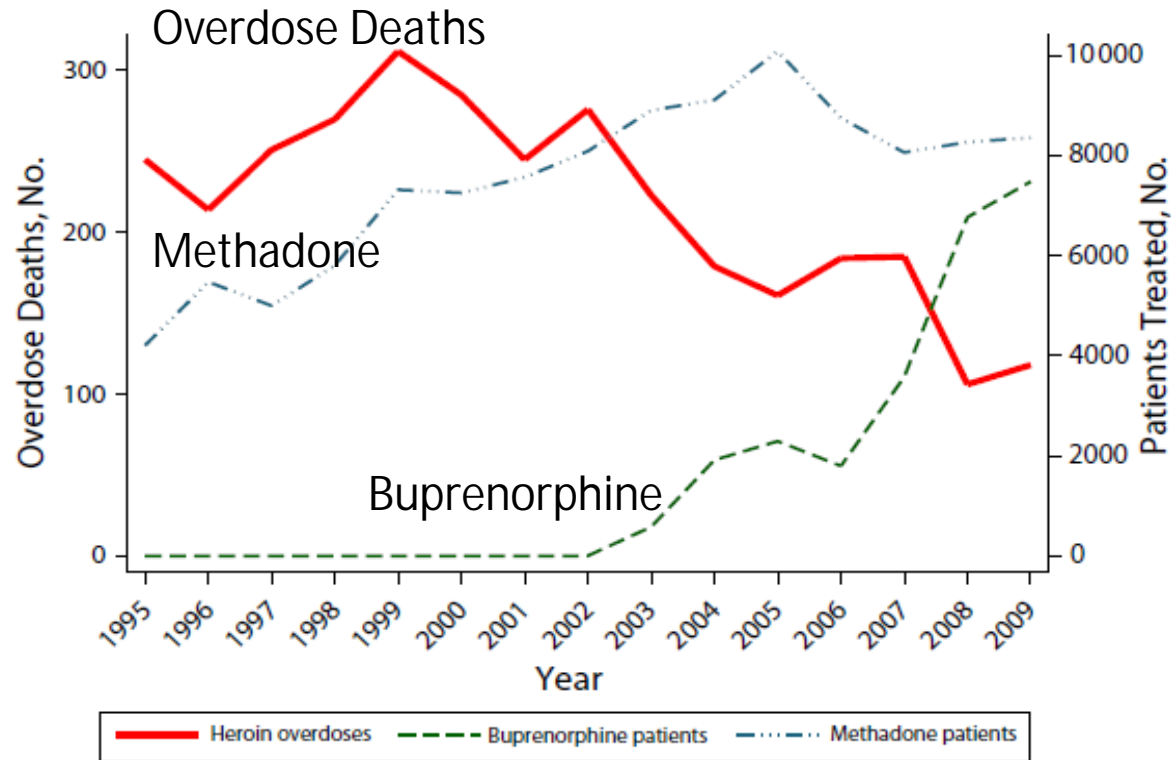


FIGURE 1—Heroin overdose deaths and opioid agonist treatment: Baltimore, MD, 1995–2009.

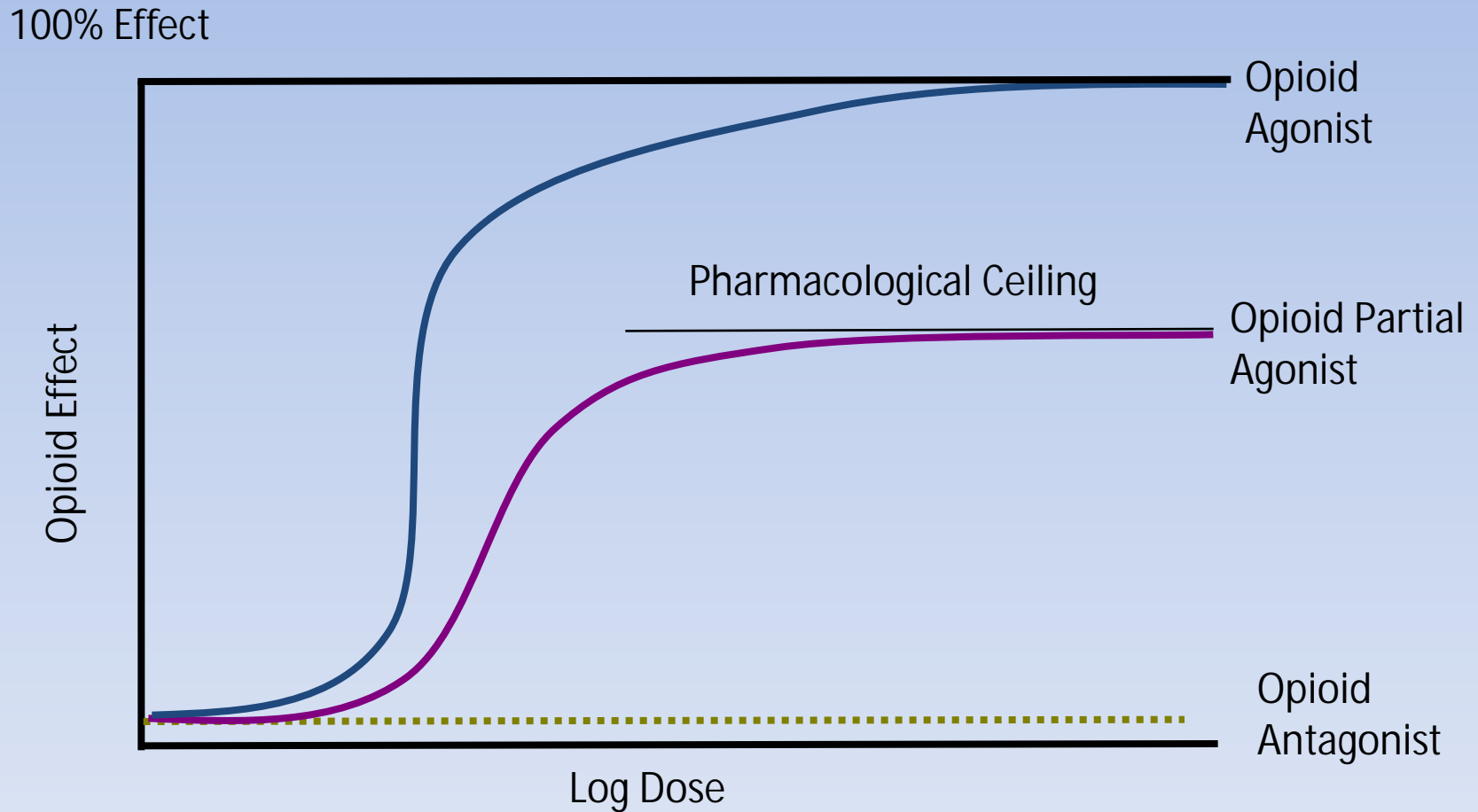
History of Buprenorphine

- Discovered in 1966
- Injectable form approved by FDA in 1985 for the treatment of pain (C-V)
- Sublingual form approved by FDA in 2002 for the treatment of opioid addiction (Rescheduled to C-III)
- Transdermal patch approved by FDA in 2010 and buccal film in 2015 for treatment of pain

How does it work

- Partial agonist on mu opioid receptor
 - Binds with high affinity and dissociates slowly
 - Pain relief, cravings, “high”
 - Slowed breathing, nausea, vomiting, constipation
- Antagonist on kappa opioid receptor
 - Interferes with the negative mood state of withdrawal

Spectrum of Opioid Activity



Dose Response Effects at 2mg, 4mg, and 8 mg sublingual dose

Physiological effects of increasing doses

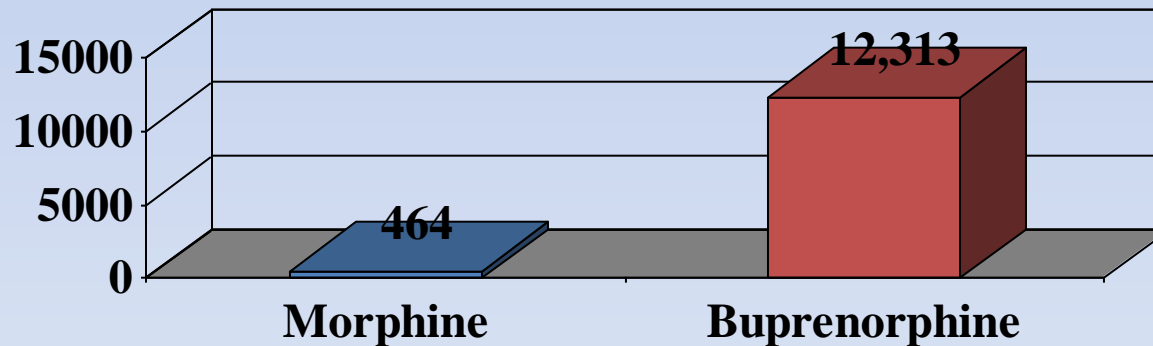
- No difference between doses in heart rate, blood pressure, respiration rate, or oxygen saturation

Subjective effect of increasing doses

- No difference in “drug liking” or intoxication

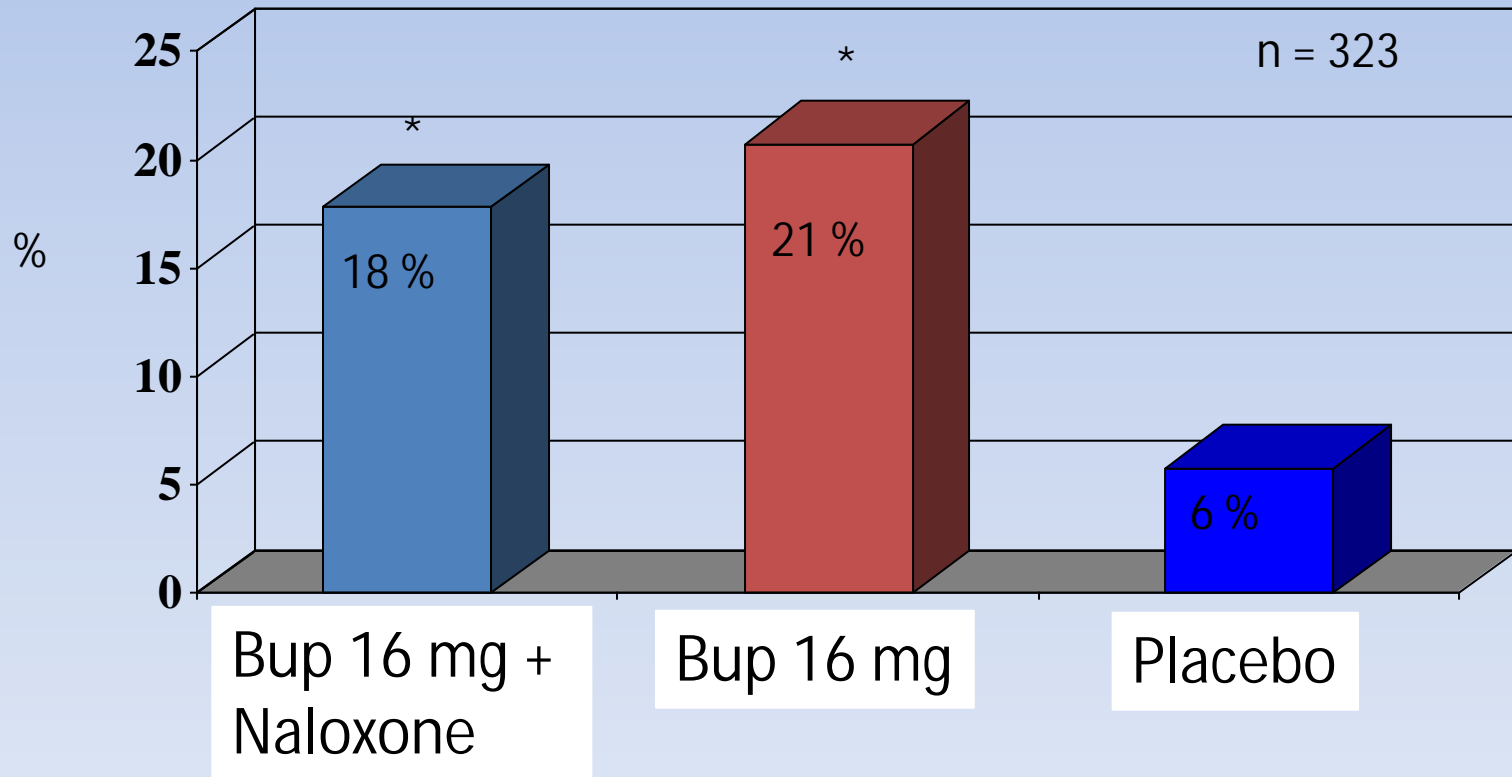
Wide Therapeutic Index

$$\text{Therapeutic Index} = \frac{\text{Median Lethal Dose}}{\text{Median Effective Dose}}$$

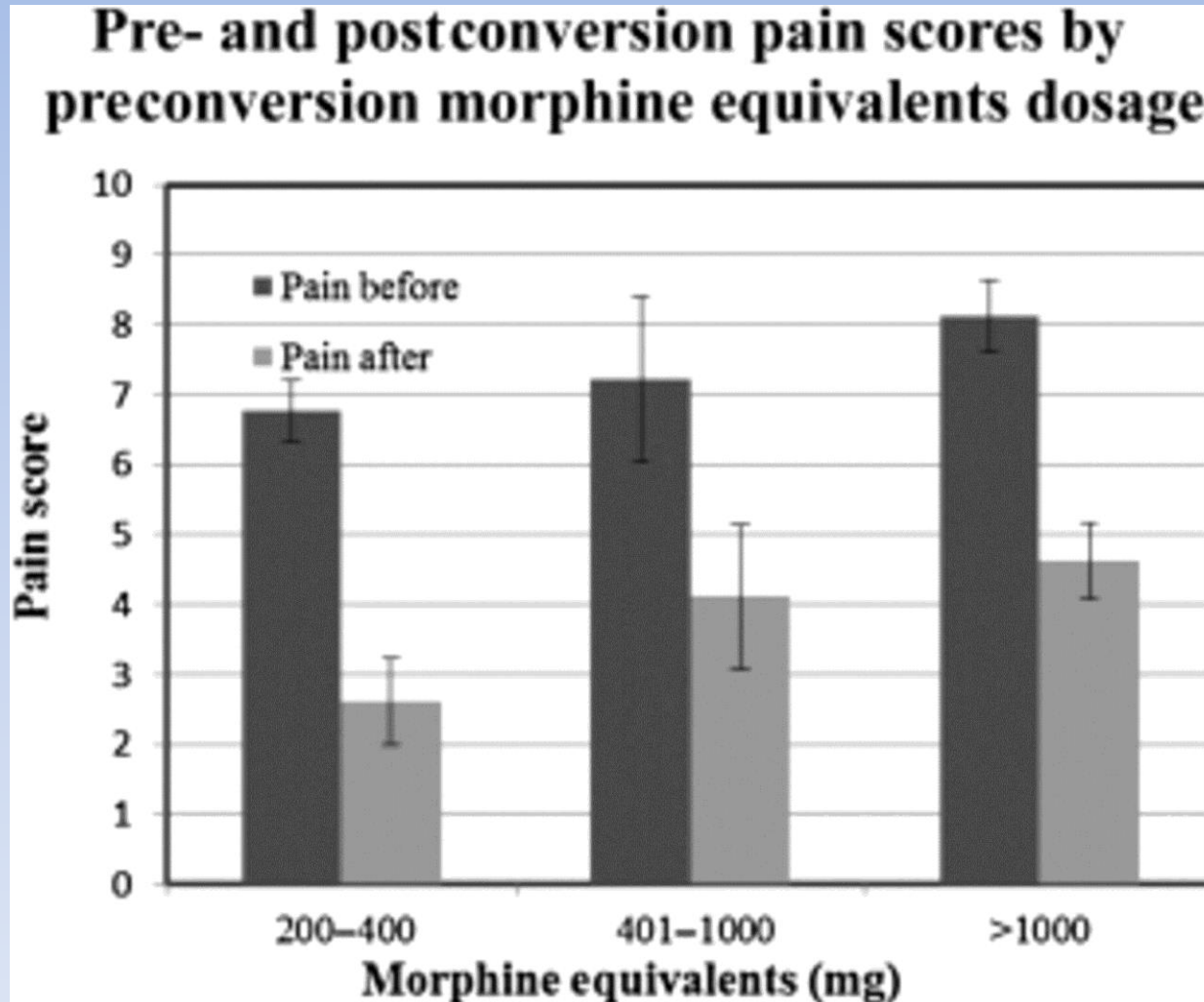


Buprenorphine for Addiction

Percentage of Opioid Negative Urine Samples



Switching to Buprenorphine for Pain



N = 35

Formulations

Dosage Form	Indication
Sublingual tabs/film	Addiction
Buccal film (high dose)	Addiction
Transdermal patch	Pain
Buccal Film (low dose)	Pain
Injectable	Pain

DATA 2000 Waiver: "X" number

- Allows qualified physicians to obtain a waiver from the requirement to obtain a separate DEA registration as a methadone clinic
- Can prescribe and administer schedule III - IV opioids FDA approved for the treatment of addiction
- Limited to 30 patients first year then may apply for a 100 patient limit (bill in Congress to increase to 250)

Prescribing Buprenorphine

Pain

- Any DEA-licensed prescriber (including mid-levels)
- Any formulation

Addiction

- DATA 2000 waived physicians
- Sublingual tablets/film
- buccal film (high dose)

Depends on the indication

Prescribing Buprenorphine

Pain + Addiction

What is the intended use?

Medi-Cal Coverage for Buprenorphine

- All formulations of buprenorphine are carved out from managed care regardless of the indication
- As of June of 2015 no TAR required for formulations FDA approved for addiction being used for addiction by a DATA 2000 waivered physician
- All other forms and indications require a TAR

Medi-Cal Coverage and Prescribing Requirements

Form	Indication	TAR	DATA 2000 waiver required
Sublingual Film/Tabs, Buccal film (high dose)	Addiction	No	Yes
	Pain	Yes	No
Transdermal patch	Pain	Yes	No
Buccal film (low dose)	Pain	Yes	No

Statewide Initiatives

- Removal of TAR requirement last June for addiction
- All plan letter to health plans (must cover physician services when prescribing buprenorphine as part of managed care)
- Drug Medi-Cal Organized Delivery System (to provide full spectrum of addiction treatment)
- CDC grant supporting academic detailing in high burden communities for providers and pharmacists
- HRSA funding for 36 clinics in CA to expand access to substance abuse services
- Opioid Safety Coalitions Network
- Plus everything CHCF is doing!