

Naloxone Supply in California

Presented by
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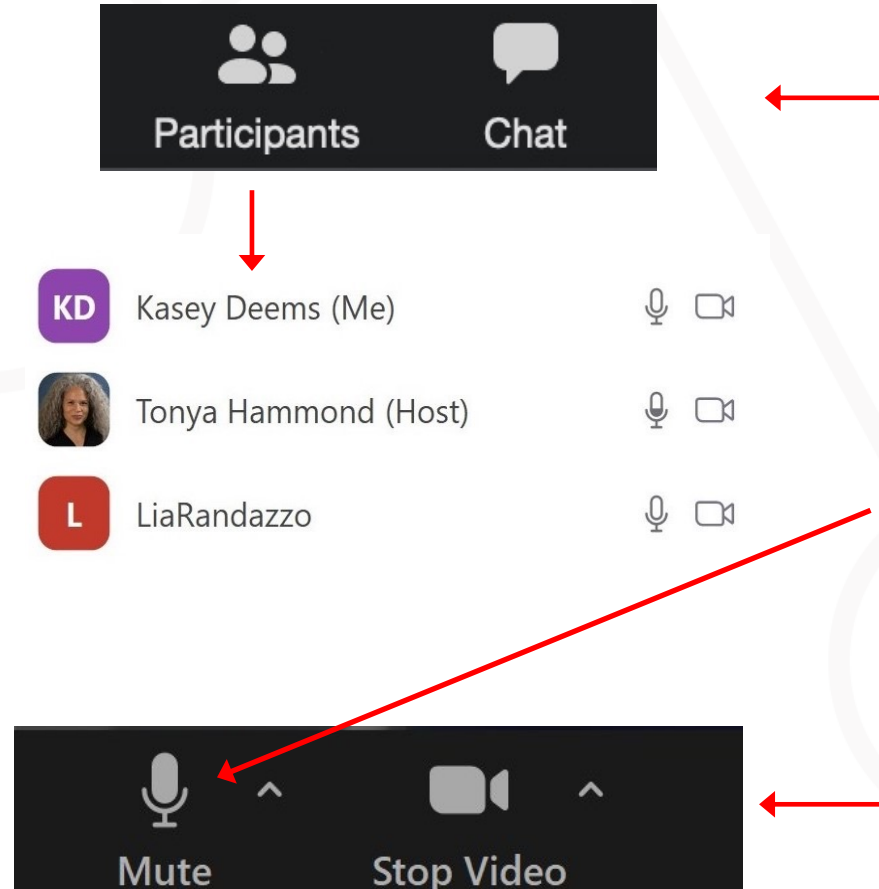
OVERDOSE
PREVENTION
NETWORK CALIFORNIA



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California Overdose Prevention
Network (COPN) Impact Coach



**Mary Maddux-Gonzalez,
MD, MPH**



Learning Objectives

- Participants will understand why there have been supply shortages of naloxone in CA.
- Participants will learn how the state is working to address the shortage.
- Participants will learn about injectable naloxone options and availability.



Poll Question #1

Do you distribute naloxone in your current role?

a) Yes

b) No





Poll Question #2

In the past 6 months have you had a time when you could not keep naloxone in stock, were worried about stock, or could not afford it?

- a) Yes
- b) No



Harm Reduction Specialist at
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Matt Curtis, MPH



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Understanding Community Naloxone Access in California

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A brief history of community naloxone access

- Naloxone hydrochloride, the antidote to an opioid overdose, has been **distributed by harm reduction programs since 1996** in the US.
- Until 2015, most naloxone distributed to people who use drugs was generic 0.4mg/ml naloxone for intramuscular injection (IM). In a few higher-resourced early adoption states such as NY, NM and MA, an off-label nasal naloxone system was distributed in addition to injectable.
- **In 2015, nasal Narcan was approved** by the FDA and Adapt Pharma/Emergent Biosolutions achieved market dominance and high product visibility.
- **Many harm reduction programs across the country distribute IM naloxone due to its low-cost, their high-volume needs, and participant preference.**
- In 2020, harm reduction programs in the US distributed over 1.3 million doses of generic IM naloxone to people who use drugs and others likely to witness an overdose.
- Many programs distribute both forms of naloxone so they can meet the demand for high-volume distribution and offer participants a choice in product based on preference and comfort level.

Timeline of Affordable Naloxone

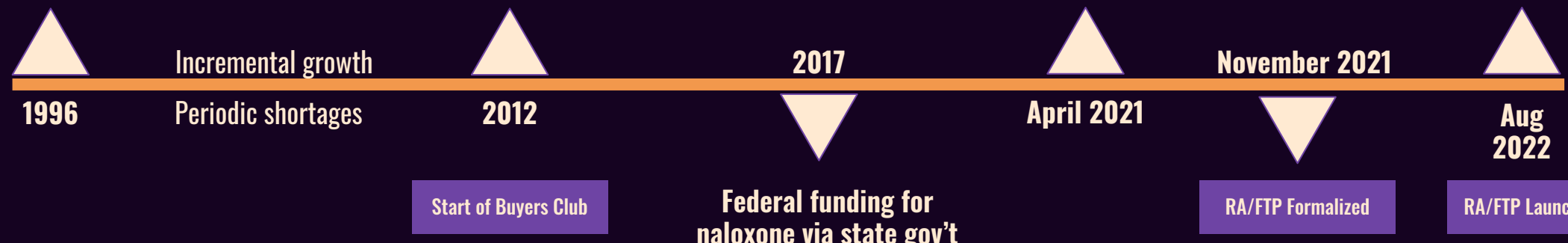


First community based distribution program (Chicago Recovery Alliance)

Negotiated first low-cost contract

Pfizer manufacturing shortage

+ Shortage resolved (anticipated)
+ 2nd manufacturer
+ Online store



Leading Principles

Widespread naloxone access is a necessary, if insufficient, intervention in reversing the overdose mortality crisis.

State governments have substantial power to eliminate policy barriers to access and should act aggressively to do so.

Overdose Education and Naloxone Education (OEND) providers shouldn't wait for the government to act.

Naloxone Distribution In Practice

Programs have capacity to scale up but are hampered by cost and access restrictions.

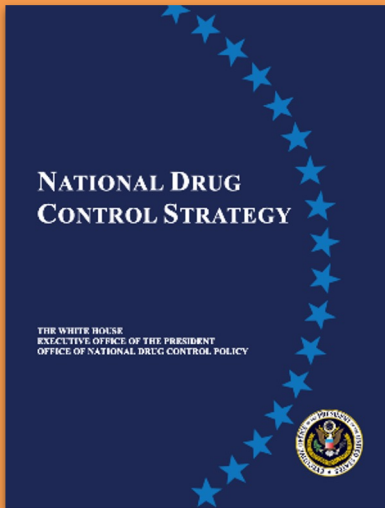
More federal funding for outreach workers would be immensely helpful for a rapid response.

Community-based naloxone distribution: Evidence-based model



Strong & Explicit Federal Support

But significant barriers remain.



April 2022
<https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf>

“Objective 1: The number of drug overdose deaths is reduced by 13% by 2025”

The ideal solution would be to make naloxone available without a prescription (OTC).

Harm Reduction

Harm reduction is an approach that emphasizes working directly with people who use drugs to prevent overdose and infectious disease transmission, improve the physical, mental, and social wellbeing of those served, and offer flexible options for accessing substance use disorder treatment and other health care services. In other words, harm reduction is people-centered. It means helping people who use drugs access services they need to stay alive. It means building trust with them so that when they wish to seek help, they know where to turn.

Focus Area: Expanding access to naloxone, an opioid overdose reversal medication, which could save tens of thousands of lives in a short period of time.

Specifically, the Biden-Harris Administration’s focus on harm reduction includes naloxone, drug test strips, and syringe services programs. Syringe services programs are community-based programs that can provide a range of services, including links to substance use disorder treatment; access to and disposal of sterile syringes and injection equipment; and vaccination, testing, and links to care and treatment for infectious diseases. Syringe services programs can be a critical intervention to reduce overdose deaths and communicable disease. Access to these

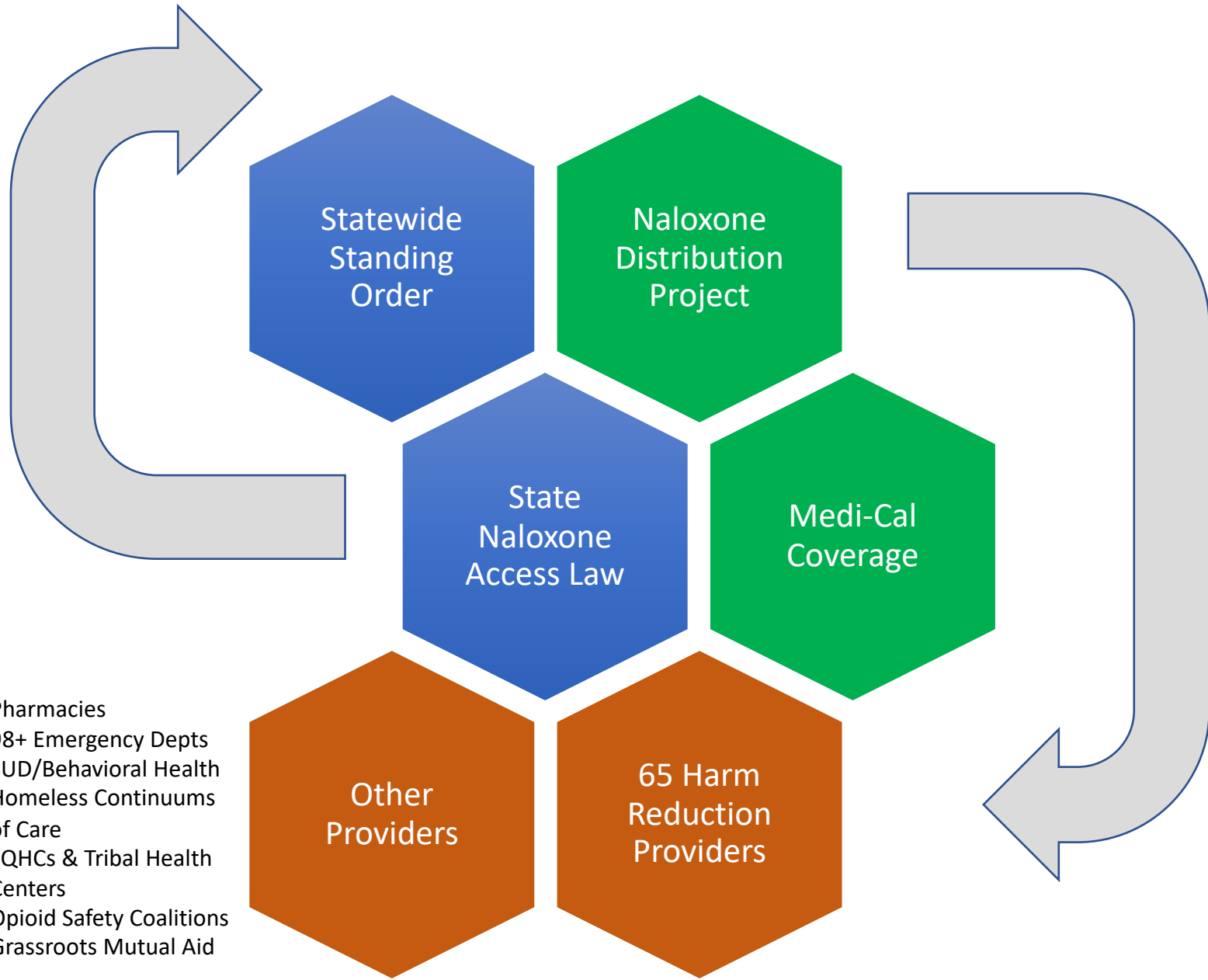
“There is no moral, medical, or safety-related reason for these life-saving overdose reversal agents to remain locked under prescription regulations.”

- Dr. Jame Madara
American Medical Association

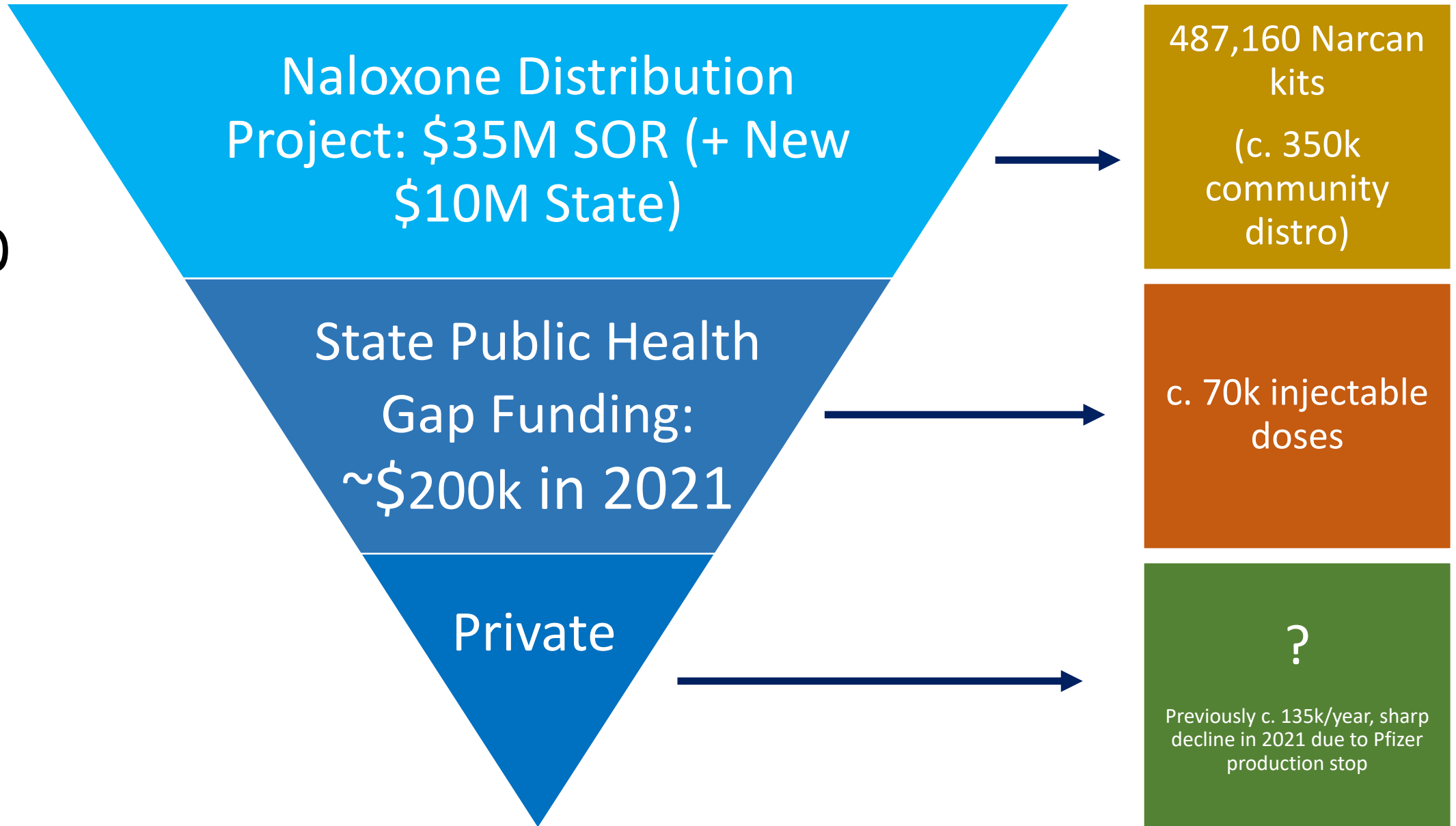
What are we trying to do in California?

- **Make naloxone available at no cost** to organizations doing overdose education and naloxone distribution (OEND) with most people likely to witness an overdose.
- **'Saturation' approach**, e.g. with county-level benchmarks of 1 kit per 100 population and 50 kits per opioid overdose death.
- **Prioritize organizations reaching people at highest risk of overdose**, and integrate OEND in multiple settings: harm reduction, SUD treatment, emergency departments, homeless & housing services, FQHCs, tribal health centers, mutual aid.
- **Ensure long-term budget sustainability** incl via use of affordable naloxone products.

Policy & Program



Funding



Fiscal Year 21-22

Naloxone Distribution Project: \$35M SOR (+ New \$10M State)

State Public Health Gap Funding: ~\$200k in 2021

Private

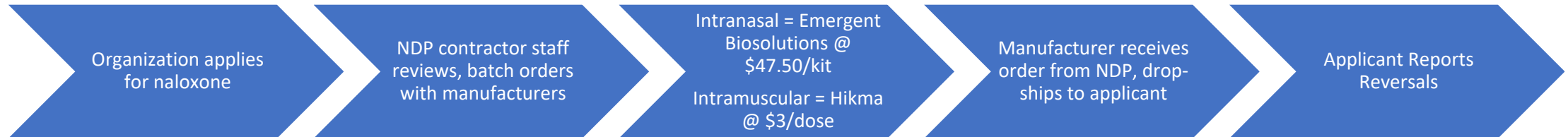
487,160 Narcan kits
(c. 350k community distro)

c. 70k injectable doses

?

Previously c. 135k/year, sharp decline in 2021 due to Pfizer production stop

NDP Statewide, Centralized Supply Process



Application Requirements:

- ❖ Eligibility = valid and active business license, FEIN number, or tax exempt letter
- ❖ Copy of standing order and prescriber license (may use CDPH statewide standing order)
- ❖ Explanation of distribution plan
- ❖ Agree to reporting requirements

How do we know how we're doing?

Going back to at least Alex Walley & company's 2013 ecological study of Massachusetts naloxone access it's been clear that **the gold standard metric is the quantity of naloxone available to people who use opioids.**



RESEARCH

Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis

OPEN ACCESS

Alexander Y Walley *assistant professor of medicine, medical director of Massachusetts opioid overdose prevention pilot*^{1,3}, Ziming Xuan *research assistant professor*², H Holly Hackman *epidemiologist*³, Emily Quinn *statistical manager*⁴, Maya Doe-Simkins *public health researcher*¹, Amy Sorensen-Alawad *program manager*¹, Sarah Ruiz *assistant director of planning and development*⁵, Al Ozonoff *director, design and analysis core*^{3,6}

¹Clinical Addiction Research Education Unit, Section of General Internal Medicine, Boston University School of Medicine, Boston, MA, USA; ²Department of Community Health Sciences, Boston University School of Public Health, USA; ³Massachusetts Department of Public Health, USA; ⁴Data Coordinating Center, Boston University School of Public Health, USA; ⁵Design and Analysis Core, Clinical Research Center, Children's Hospital Boston, USA; ⁶Department of Biostatistics, Boston University School of Public Health, USA

Abstract

Objective To evaluate the impact of state supported overdose education and nasal naloxone distribution (OEND) programs on rates of opioid related death from overdose and acute care utilization in Massachusetts.

Design Interrupted time series analysis of opioid related overdose death and acute care utilization rates from 2002 to 2009 comparing community-year strata with high and low rates of OEND implementation to those with no implementation.

Setting 19 Massachusetts communities (geographically distinct cities and towns) with at least five fatal opioid overdoses in each of the years 2004 to 2006.

Participants OEND was implemented among opioid users at risk for overdose, social service agency staff, family, and friends of opioid users.

Intervention OEND programs equipped people at risk for overdose and bystanders with nasal naloxone rescue kits and trained them how to prevent, recognize, and respond to an overdose by engaging emergency medical services, providing rescue breathing, and delivering naloxone.

Main outcome measures Adjusted rate ratios for annual deaths related to opioid overdose and utilization of acute care hospitals.

Results Among these communities, OEND programs trained 2912 potential bystanders who reported 327 rescues. Both community-year

strata with 1-100 enrollments per 100 000 population (adjusted rate ratio 0.73, 95% confidence interval 0.57 to 0.91) and community-year strata with greater than 100 enrollments per 100 000 population (0.54, 0.39 to 0.76) had significantly reduced adjusted rate ratios compared with communities with no implementation. Differences in rates of acute care hospital utilization were not significant.

Conclusions Opioid overdose death rates were reduced in communities where OEND was implemented. This study provides observational evidence that by training potential bystanders to prevent, recognize, and respond to opioid overdoses, OEND is an effective intervention.

Introduction

Poisoning, nine out of 10 of which are related to drug overdoses,¹ has surpassed motor vehicle crashes to be the leading cause of death by injury in the United States.² Overdose is also a major cause of death in Canada,³ Europe,⁴ Asia,^{5,6} and Australia.⁷ In the United States, increases in fatal overdose since the mid-1990s have been driven by the growth in prescriptions for opioid analgesics⁸ and their non-medical use.^{9,10} Opioid related emergency department visits and admissions to hospital have increased over the same period.¹¹ In Massachusetts, since

How do we know how we're doing?

More recently, Michael Irvine, Traci Green & colleagues sought to model the **amount of naloxone needed to ensure availability in 80% of witnessed opioid overdoses**, based on different types of predominate opioids in a local market.

Estimating naloxone need in the USA across fentanyl, heroin, and prescription opioid epidemics: a modelling study



Michael A Irvine, Declan Oller, Jesse Boggis, Brian Bishop, Daniel Coombs, Eliza Wheeler, Maya Doe-Simkins, Alexander YWalley, Brandon D L Marshall, Jeffrey Bratberg, Traci C Green



Summary

Background The US overdose crisis is driven by fentanyl, heroin, and prescription opioids. One evidence-based policy response has been to broaden naloxone distribution, but how much naloxone a community would need to reduce the incidence of fatal overdose is unclear. We aimed to estimate state-level US naloxone need in 2017 across three main naloxone access points (community-based programmes, provider prescription, and pharmacy-initiated distribution) and by dominant opioid epidemic type (fentanyl, heroin, and prescription opioid).

Methods In this modelling study, we developed, parameterised, and applied a mechanistic model of risk of opioid overdose and used it to estimate the expected reduction in opioid overdose mortality after deployment of a given number of two-dose naloxone kits. We performed a literature review and used a modified-Delphi panel to inform parameter definitions. We refined an established model of the population at risk of overdose by incorporating changes in the toxicity of the illicit drug supply and in the naloxone access point, then calibrated the model to 2017 using data obtained from proprietary data sources, state health departments, and national surveys for 12 US states that were representative of each epidemic type. We used counterfactual modelling to project the effect of increased naloxone distribution on the estimated number of opioid overdose deaths averted with naloxone and the number of naloxone kits needed to be available for at least 80% of witnessed opioid overdoses, by US state and access point.

Findings Need for naloxone differed by epidemic type, with fentanyl epidemics having the consistently highest probability of naloxone use during witnessed overdose events (range 58–76% across the three modelled states in this category) and prescription opioid-dominated epidemics having the lowest (range 0–20%). Overall, in 2017, community-based and pharmacy-initiated naloxone access points had higher probability of naloxone use in witnessed overdose and higher numbers of deaths averted per 100 000 people in state-specific results with these two access points than with provider-prescribed access only. To achieve a target of naloxone use in 80% of witnessed overdoses, need varied from no additional kits (estimated as sufficient) to 1270 kits needed per 100 000 population across the 12 modelled states annually. In 2017, only Arizona had sufficient kits to meet this target.

Interpretation Opioid epidemic type and how naloxone is accessed have large effects on the number of naloxone kits that need to be distributed, the probability of naloxone use, and the number of deaths due to overdose averted. The extent of naloxone distribution, especially through community-based programmes and pharmacy-initiated access points, warrants substantial expansion in nearly every US state.

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Roughly we could adopt a simple comparative measure

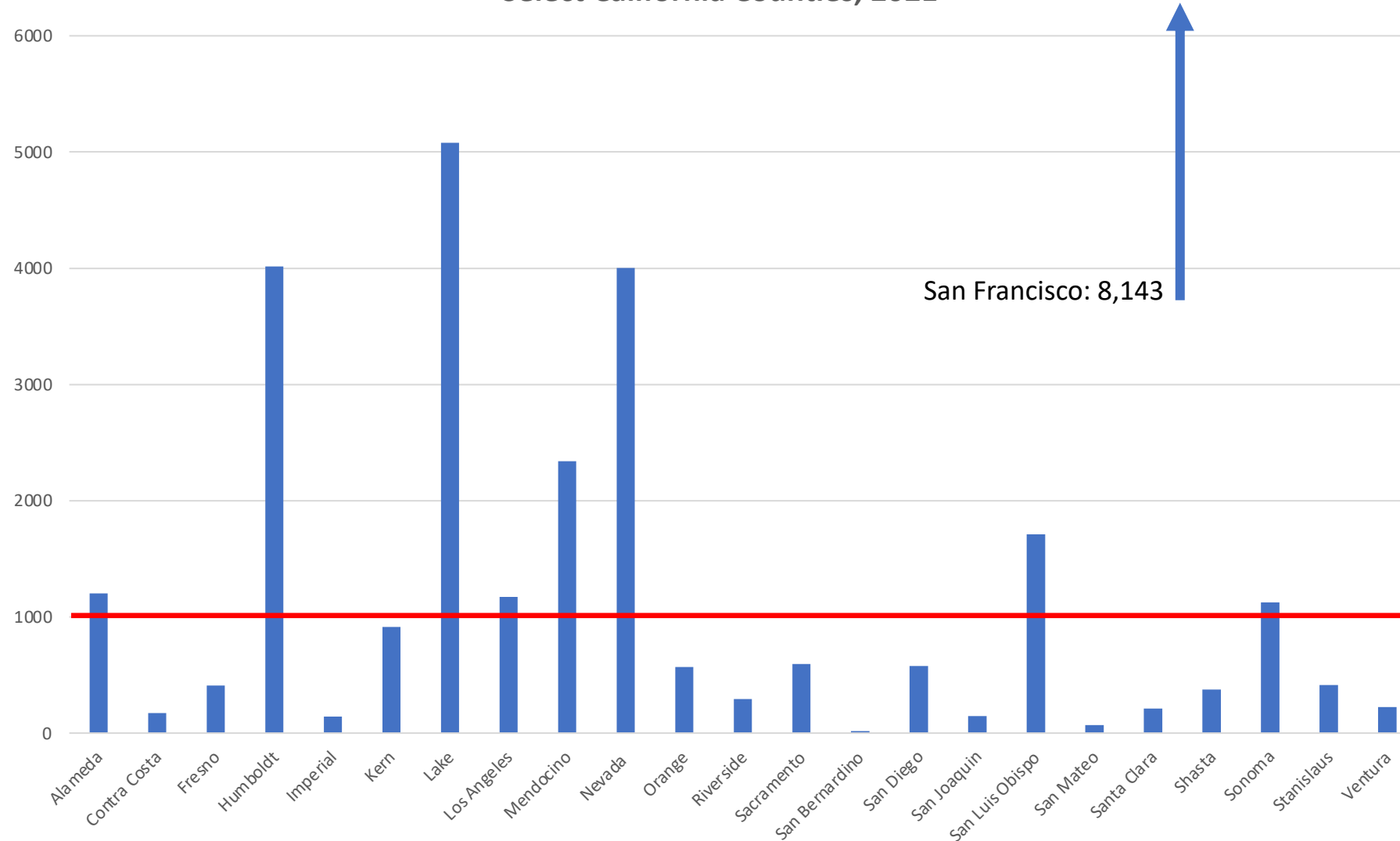
One naloxone kit distributed to community members per 100 local population (“1% coverage”)

Responsive to overall population in an area. In California there is *some* regional variation in estimated opioid use disorder and overdose deaths, but the range is fairly narrow (e.g. 1-2% OUD prevalence)

50 kits distributed to community members per opioid overdose death.

Responsive to local differences in factors affecting overdose risk.

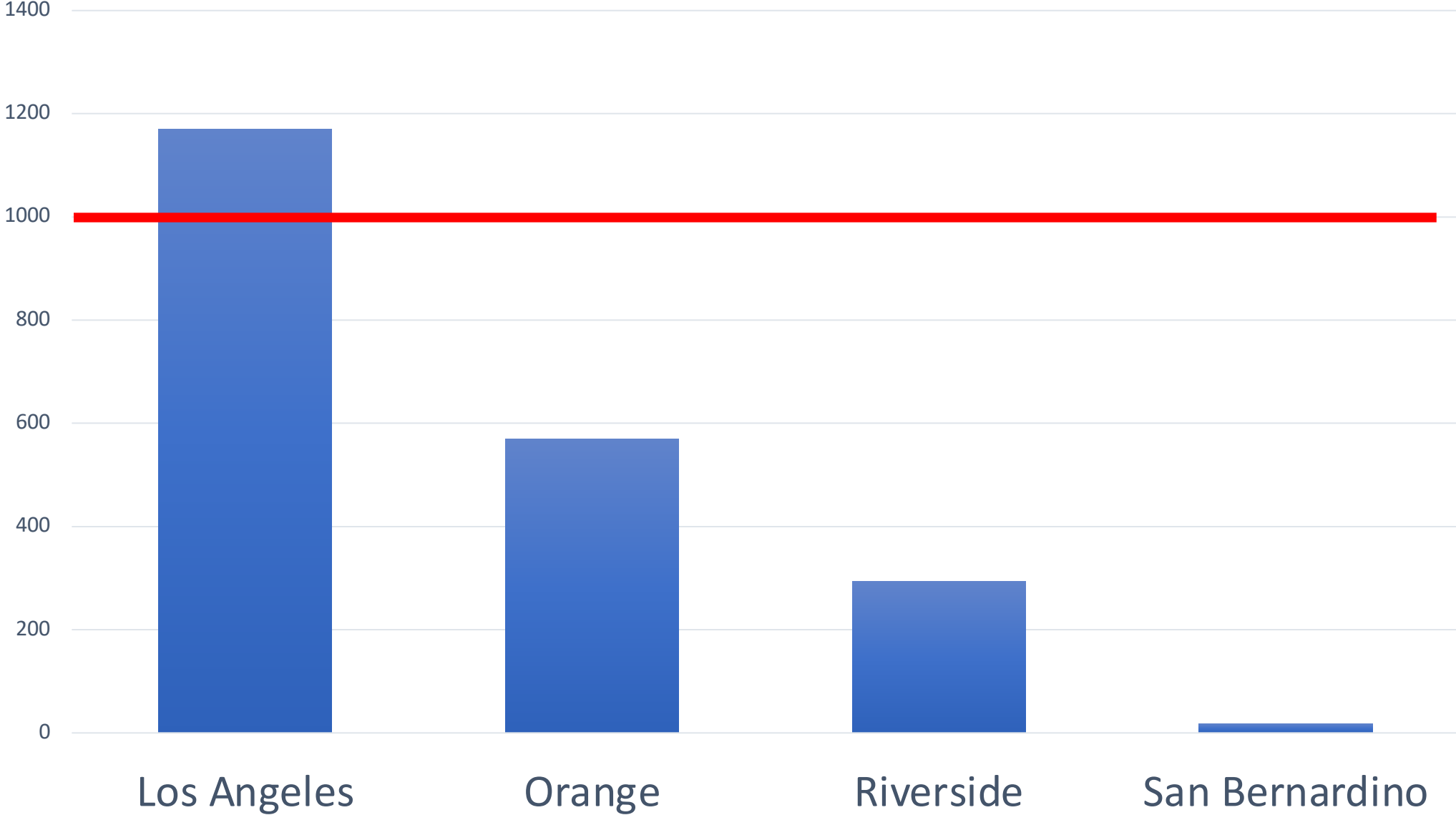
NDP Community Distribution Naloxone Kits per 100k Population Select California Counties, 2021



Only includes DHCS Naloxone Distribution Project data, 2021

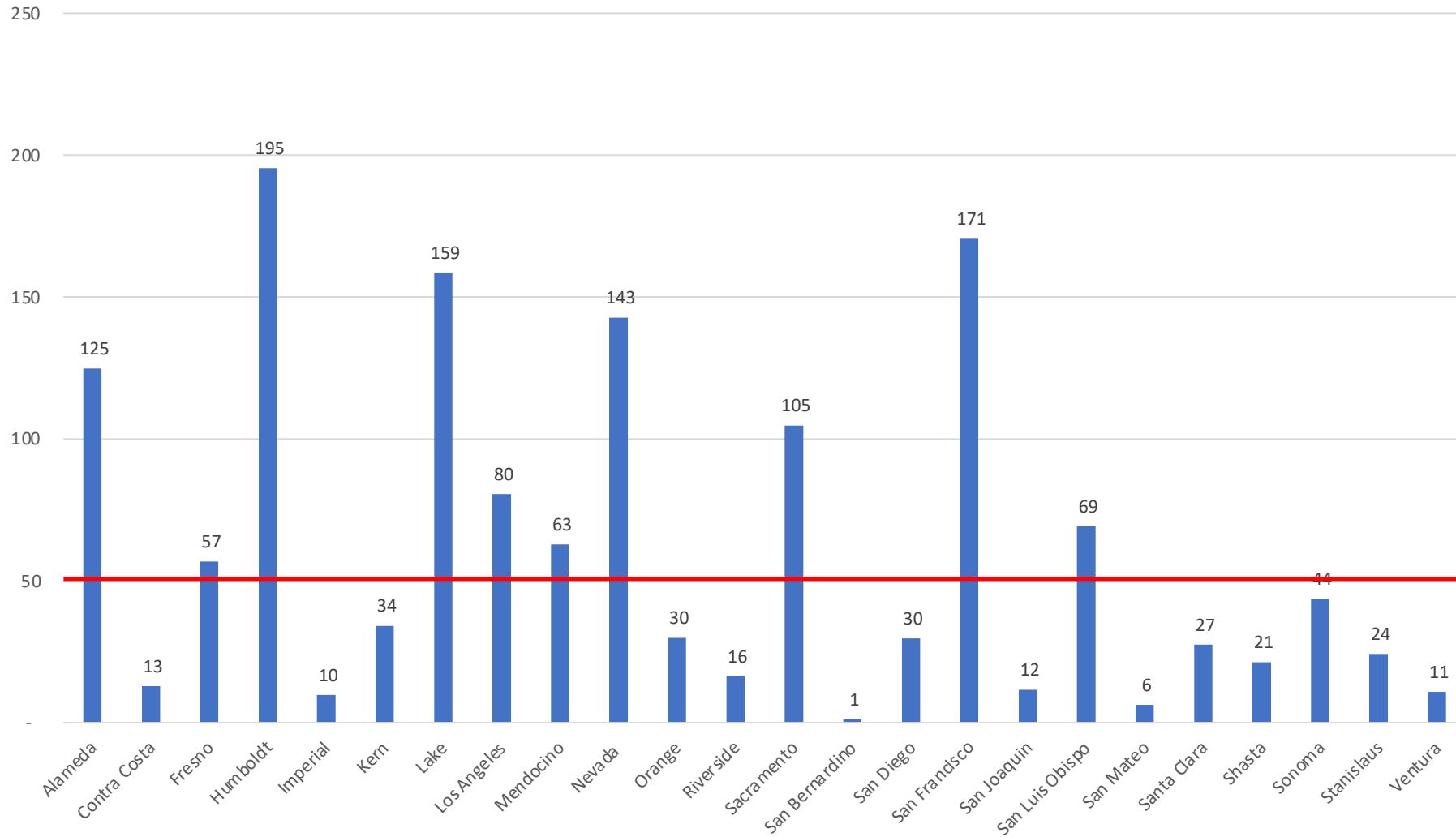
Naloxone Kits per 100k Population, 2021

Target: 1,000/100k (1%)



Only includes DHCS Naloxone Distribution Project data, 2021

Community Distribution Naloxone Kits per Opioid Overdose Death Select California Counties, 2021



Only includes DHCS Naloxone Distribution Project data, 2021

Next Steps

Roll out injectable to double amount of available naloxone.

Fix geographic gaps.

Build out OEND infrastructure, prioritizing 11 counties without SSPs and 100k+ population.

New interdepartmental group focused on mortality reduction in key counties: naloxone access, low-barrier medication for opioid use disorder, safe drug consumption services, social determinants approaches.

A few links

- [CDPH statewide naloxone standing order](#)
- [DHCS Naloxone Distribution Project](#)
- [CDPH Harm Reduction Programs](#)

Discussion





Discussion

Why don't we just have free, widespread, over-the-counter naloxone already?
What are things that COPN members can do to reduce barriers to access?

What are some strategies that local groups should adopt to reach people most likely to benefit from naloxone access?

How do we better measure the impact of our naloxone distribution programs?



Reflection Questions



In the Q & A box...

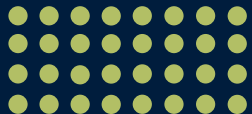
What's one (or three) thing(s) you could do in the next few months to improve your overdose education and naloxone distribution (OEND) work based on the discussion today?





In the Q & A box...

How can we shape the local and state policy environment to reach people most likely to benefit from naloxone access?



Q & A



Contacts



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Thank you!
**Let us know how we can
support your overdose
prevention efforts.**

Contact us at
copn@healthleadership.org

For more resources and to sign up
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OVERDOSE
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UPCOMING NOPN WEBINAR

988 is Here: How to Align Efforts and Leverage America's New Hotline to Prevent Overdose

Thursday, August 18, 2022
11:30 AM – 12:30 PM PT

