

Opioid Safety with Naloxone:

A Life-saving Tool for California Physicians

Presented March 27, 2014



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Disclosures

- No financial disclosures
- Discussion of naloxone by intranasal administration, a route not yet FDA approved
- No support from the pharmaceutical industry was used for this educational activity.

California Law

- AB635 in effect since 1 January 2014
- Designed to encourage CA healthcare providers and community programs to widely distribute naloxone
- Expands previous naloxone legislation in CA:
 - Allows for prescription and distribution throughout the state.
 - Protects licensed health care professionals from civil & criminal liability when they prescribe, dispense, or oversee distribution via a standing order of naloxone via an overdose prevention program or standard medical practice.
 - Permits individuals to possess and administer naloxone in an emergency and protects these individuals from civil or criminal prosecution for practicing medicine without a license.
 - Clarifies that licensed prescribers are encouraged to prescribe naloxone to individual patients on chronic opioid pain medications to address prescription drug overdose.

Naloxone Safety Profile

- Short-acting (30-60 minutes), highly specific, high affinity mu opioid receptor antagonist
- The only element of the coma cocktail that can be safely administered alone
- Only contraindication is a known allergy to naloxone
- Opioid withdrawal symptoms generally mild at lay-distributed doses
- Opioid effect will return, a significant concern mostly for long-acting opioids, so call 911
- Essentially no effects if opioids not present

Concept of Lay Naloxone

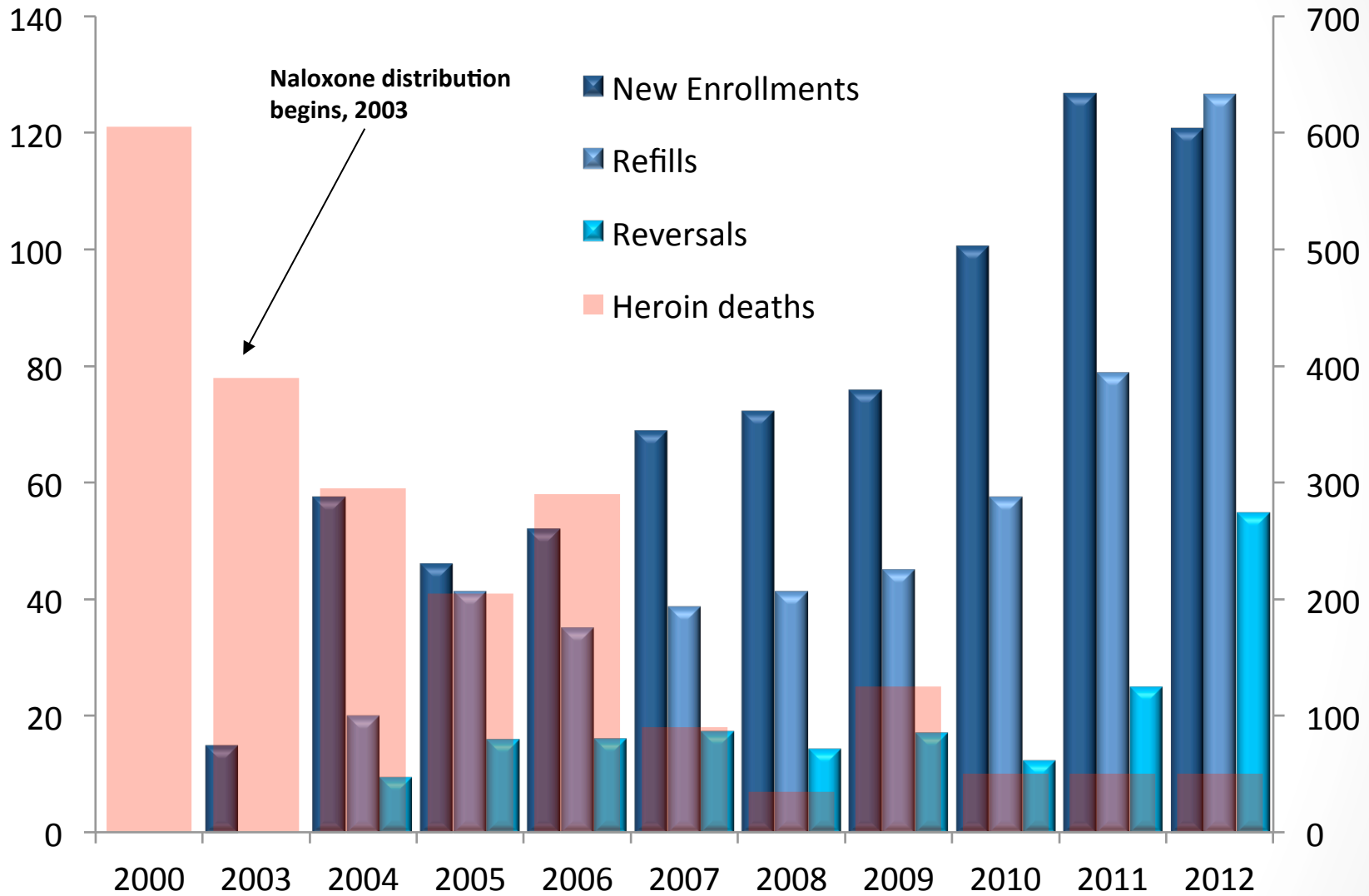
- Overdose usually witnessed (McGregor, Addiction 1998)
- Death takes a while (Sporer, Ann Intern Med 1999)
- EMS not routinely accessed (Coffin, Ann Emerg Med, 2009)
- Naloxone very safe and very effective (
<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM300866.pdf>)
- More rapid reversal with naloxone improves outcomes (Gonzva, Am J Emerg Med 2013)
- Possible behavior change (Lankenau, J Comm Hlth 2013, Kral J Urb Hlth, 2005)

Fatal Opioid Overdose Rates by Naloxone Implementation in MA

Cumulative enrollments per 100,000 population	ARR*	95% CI
No enrollment	Ref	-
1-100	0.73	0.57-0.91
>100	0.54	0.39-0.76

* Adjusted Rate Ratios (ARR) adjusted for city/town population rates of age<18, male, race/ ethnicity (Hispanic, white, black, other), below poverty level, medically supervised inpatient withdrawal treatment, methadone treatment, BSAS-funded buprenorphine treatment, prescriptions to doctor shoppers, year

Heroin-related Deaths, San Francisco, 1999-2012



*Heroin death data (left axis) compiled from San Francisco Medical Examiner Reports, www.sfgsa.org, fitted to tailing fiscal year, no data for 2001-2002; Naloxone data (right axis) from DOPE Project enrollments and refills

US Programs:

- CDC MMWR, 2012: Over 50,000 drug users (and their friends/family) trained between 1996-2010. Over 10,000 reversals reported. <http://www.cdc.gov/mmwr/pdf/wk/mm6106.pdf>
- **60 programs distributing or prescribing naloxone, with approximately 240 individual sites, in 18 US states.***
- In 2012, 55% of naloxone distributed was injectable (either 10ml or 1ml) and 45% was intranasal.

**unpublished results of 2013 US naloxone programs survey, completed by the Harm Reduction Coalition*

Models for prescribing naloxone

- Provider writes prescription, patient fills at pharmacy
 - Setting: clinic with insured patients, pharmacies alerted to prescribing plans, may need to have atomizers on-site for intranasal formulation, consider providing informational brochure
- Provider writes prescription and directly dispenses pre-assembled naloxone kit
 - Setting: medical care with resources to have and maintain kits on-site
- Prescriber writes non-patient specific *standing order* for community-based program or treatment program, program staff provide the education and distribute pre-assembled kits
 - Setting: “Overdose prevention programs”, commonly found at programs like syringe exchanges, drug treatment programs, drop-in centers, etc. Law requires overdose prevention/management education if distributing under standing order

Non-patient specific standing order

- Used in San Francisco, Massachusetts, North Carolina, Illinois, and other sites to facilitate wider distribution of naloxone to drug users and other potential bystanders.
- Issued by individual prescribers or medical professionals in health departments.
- Generally includes:
 - Authority to issue standing order (e.g. CA AB635)
 - What is ordered (e.g. order/stock supplies, dispense, administer)
 - Protocol (who can dispense, who can receive, education, record keeping)
 - Order to dispense
 - Prescriber signature, date, expiration date
 - There are no predetermined guidelines in the legislation
- Sample of SFDPH standing order:

<http://harmreduction.org/wp-content/uploads/2012/02/Standing-Order-IM.pdf>

How to prescribe naloxone

- Two formulations
 - Injectable
 - Naloxone 0.4mg/1ml single dose vial, inject 1 ml IM if overdose. Call 911. Repeat if necessary. #2.
 - IM syringes (3ml 25 g 1" syringes are recommended) #2
 - Intranasal (off-label)
 - Naloxone 2mg/2mL prefilled syringe, spray ½ into each nostril if overdose. Call 911. Repeat if necessary. #2
 - MAD (Mucosal Atomization Device) nasal adapter. #2
(access for pharmacies may be complicated)
- Recipient need not be the person to whom naloxone is administered
- SBIRT codes cover education in 15 minute intervals
 - Medicare – G0396
 - MediCal – H0050
 - Commercial – CPT 99408

Pharmacy access

- Consider contacting pharmacies your patients access prior to prescribing naloxone is new for most pharmacists.
- Ordering:
 - Injectable, NDC#00409-1215-01
 - Intranasal, NDC#76329-3369-01
 - MAD nasal devices produced by Teleflex
- Counseling:
 - Instruct patients to administer if non-responsive from opioid use and how to assemble for administration.
 - Include family/caregivers in patient counseling or instruct patients to train others.
- Billing:
 - Naloxone covered by MediCal (as “carve-out” so submit directly to FFS MediCal – do NOT send a PA to the HMO plan), and many other plans
 - MAD device requires pro forma TAR with 24 hours turnaround

Talking about “opioid safety”

- Prescription opioid users, including former heroin users, may not perceive their own “overdose” risk
- Consider focusing on “**opioid safety**” with language such as:
 - “Opioids can sometimes slow or even stop your breathing”
 - “Naloxone is the antidote to opioids – to be [sprayed in the nose / injected] if there is a bad reaction where you can’t wake up”
 - “Naloxone is for opioid medications like an Epi-Pen is for someone with an allergy”

Do you take strong
pain medications?

For example:

Percocet, Vicodin, methadone, oxycodone,
morphine, MSContin, Dilaudid, fentanyl,
or any other “opiate” medication?



Ask your provider for naloxone!!

Naloxone is an antidote sprayed into the nose if you are too sleepy or can't be woken up due to these pain medications.

Talk to your provider for more information.

Patient education




- Minimum care would involve ensuring patients know:
 - When to administer naloxone
 - How to administer naloxone
 - To alert others about the medication and how to use it
- Broader education, usually for dispensing under standing orders, is undefined but generally includes:
 - Opioid overdose risk factors
 - Recognizing and responding to an “overdose”
 - stimulation (sternal rub)
 - calling 911
 - administering naloxone
 - performing rescue breathing or chest compressions
 - stay with person



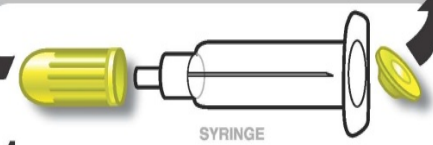
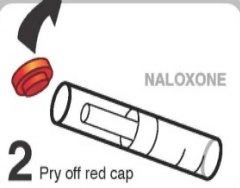
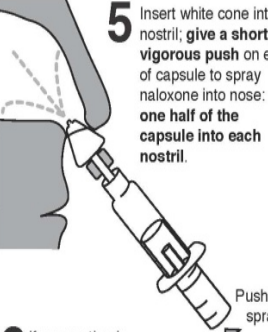
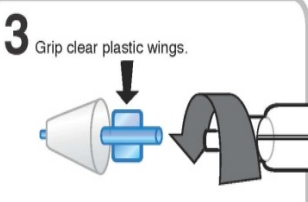
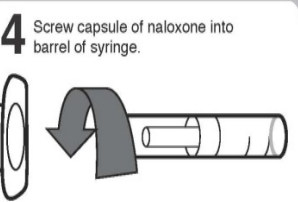
Administering naloxone IM & IN



HOW TO GIVE INTRAMUSCULAR NALOXONE


 <p>1. Remove cap from naloxone vial and uncover the needle</p>	 <p>2. Insert needle through rubber plug with vial upside down Pull back on plunger and take up 1 mL</p>	 <p>3. Inject 1 mL of naloxone at a 90 degree angle into a large muscle (upper arm/thigh, outer buttocks)</p>
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 <p>1 Pull or pry off yellow caps SYRINGE</p>	 <p>2 Pry off red cap NALOXONE</p>	 <p>5 Insert white cone into nostril; give a short, vigorous push on end of capsule to spray naloxone into nose: one half of the capsule into each nostril. Push to spray.</p>
 <p>3 Grip clear plastic wings.</p>	 <p>4 Screw capsule of naloxone into barrel of syringe.</p>	

6 If no reaction in 2-5 minutes, give the second dose.

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Funding

- County general fund (to purchase materials for pre-assembled kits and other costs)
- SAMHSA SAPT HIV-set aside funds
 - The purpose of the HIV-Set Aside is to provide HIV early intervention services to clients in substance abuse treatment programs (and out-of-treatment injection drug users).
- Billable to select insurances, including MediCal, many part D programs, and others
- Current *retail* costs for an injectable kit of naloxone (2 doses, 2 syringes) is ~\$70 and intranasal (2 doses, 2 atomizers) is ~\$50
- Cost-effectiveness (*Coffin & Sullivan, Annals of Int Med, 2013*)

Resources for providers

- Naloxone Program Implementation Manual and online resources:
www.harmreduction.org/issues/overdose-prevention/tools-best-practices
- AHRQ description of Massachusetts naloxone program:
<http://www.innovations.ahrq.gov/content.aspx?id=3912>
- Clinic-based prescribing information and guidelines:
www.prescribetoprevent.org
- Pharmacy resources: www.stopoverdose.org
- Advocacy film and materials: Reach for Me: Fighting to End the American Drug Overdose Epidemic www.reach4me.org
- Research updates and other overdose-related news:
www.overdosepreventionalliance.org

Resources for recipients

- Videos about naloxone, opioid safety/overdose, and how to respond in emergencies:
 - <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/overdose-videos/>
 - www.prescribetoprevent.org/video
- How to find a community-based naloxone distribution program (for parents and drug users who do not have access through the health care system):
<http://www.overdosepreventionalliance.org/p/od-prevention-program-locator.html>

Resources for families:

- Learn to Cope: online discussion forum for parents of drug users: <http://www.learn2cope.org/>
- Grief Recovery from a Substance Passing (GRASP), for people who have lost a loved one to overdose: <http://grasphelp.org/>
- Broken No More, a support group and advocacy organization for parents interested in advocating for drug policy reform: <http://broken-no-more.org/>
- Al-anon and Nar-anon, 12 step recovery groups for families and friends affected by another person's drinking or drug use.

Resources on CSAM Website

- All of these links are available on a Naloxone Resource Page on the CSAM website
<http://www.csam-asam.org/naloxone-resources>
- Also on the Naloxone Resource Page
 - This webinar
 - 3 short videos:
 - “Talking to Patients about Naloxone in a Primary Care / Pain Clinic Setting”
 - “Talking to Patients about Naloxone in Drug Treatment Setting”
 - “Inside the Naloxone Kit”
 - Patient handouts

Summary

- California State law permits and encourages:
 - prescribers to prescribe naloxone to anyone at risk of experiencing *or* witnessing an opioid overdose
 - prescribers to issue a standing order to an overdose program under which program staff may distribute naloxone
 - naloxone recipients to administer naloxone to others in the case of suspected opioid overdose
- Education can be brief or more detailed; SBIRT codes are available for billing
- Naloxone is covered by MediCal (bill to FFS); pharmacies may need guidance on dispensing and may not yet be able to access the atomizer
- Naloxone access for laypersons is an evidence-based intervention that reduces mortality from overdose