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Opioid Safety with Naloxone

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Opioid Safety with Naloxone



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Disclosures

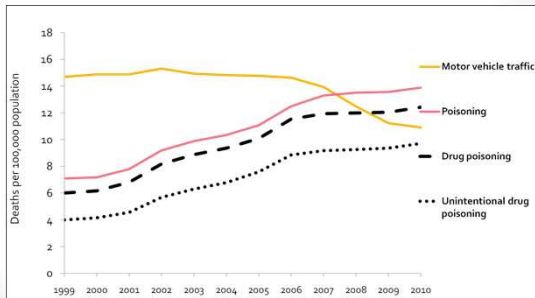
- No financial disclosures
- Discussion of naloxone by intranasal administration, a route not yet FDA approved
- No support from the pharmaceutical industry was used for this educational activity.
- Slides prepared with Eliza Wheeler, MPH, director of the Drug Overdose Prevention and Education Project

Outline

- Background of opioid overdose
- Concept of lay naloxone
- Data for lay naloxone
- Legal framework
- Models of naloxone prescription
- Logistics of naloxone prescription

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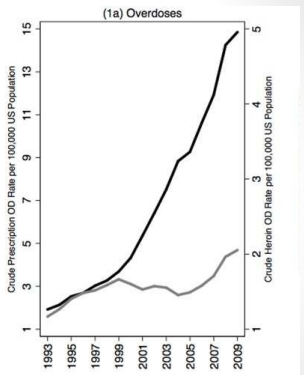
Poisoning: Leading cause of injury death



SOURCE: CDC/NCHS, National Vital Statistics System; and Warner M, Chen LH, Makuc DM, Anderson RN, Minino AM. Drug poisoning deaths in the United States, 1980-2008. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics; 2011. Slide courtesy of Traci Green

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Opioid analgesic overdose mortality rates

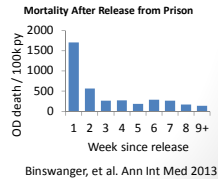


Unick, Plos One 2013

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Major opioid overdose risk factors

- Prior overdose
 - Overdose in any 1 year predicts a 6-fold increased likelihood of overdose in the subsequent year
 - Any history of overdose predicts a 4-fold increased risk of mortality (Australian Treatment Outcome Study)
- Concomitant use of other substances
 - Sedatives
 - Alcohol
 - Cocaine
- Reduced tolerance



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 effective (Termon G, 2012 FDA Hearing on Naloxone)
- More rapid reversal with naloxone may reduce need for advanced respiratory support (Gonzalo, Am J Emerg Med 2013)
- Possible behavior change (Lankou, J Comm Hlth 2013, Kral J Urb Hlth, 2005)

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

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/mm5106.pdf>
- **60 programs distributing or prescribing naloxone, with approximately 240 individual sites, in 18 US states.***

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

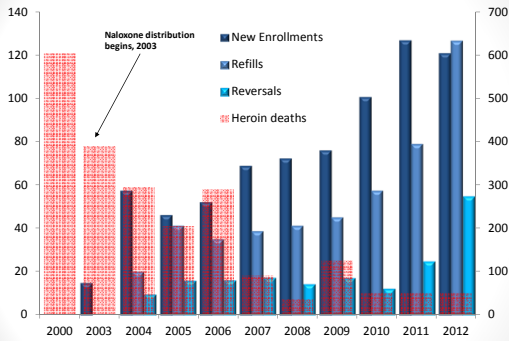
Fatal Opioid Overdose Rates by Naloxone Implementation in MA

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

Walley, BMJ 2013

Heroin-related Deaths, San Francisco, 1999-2012



*Heroin death data (left axis) compiled from San Francisco Medical Examiner Reports, www.sfcds.org, fitted to trailing fiscal year, no data for 2000-2002; Naloxone data (right axis) from DOPH Project enrollments and refills

Cost-effectiveness

	No Naloxone	Naloxone
Incremental cost per QALY gained, \$	-	421
Kits needed to prevent 1 death, <i>n</i>	-	164

Population outcomes (per 200 000 heroin users)

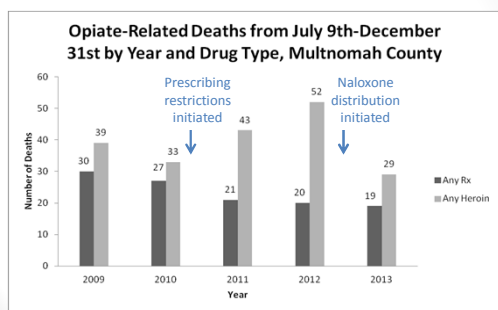
Baseline scenario		
Lifetime overdoses, <i>n</i>	918 509	930 759
Lifetime overdose deaths, <i>n</i>	27 406	25 613
Naloxone kits delivered, <i>n</i>	-	294 484

Naloxone distribution reduces overdose risk†

Lifetime overdoses, <i>n</i>	918 509	698 868
Lifetime overdose deaths, <i>n</i>	27 406	18 835
Naloxone kits delivered, <i>n</i>	-	307 712

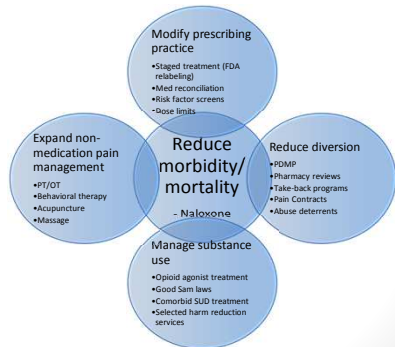
Coffin & Sullivan, Ann Int Med 2013

Opioid stewardship and naloxone



Trends in opiate-related deaths in Multnomah County, 2014
web.multco.us/news/report-trends-opiate-related-deaths

Naloxone and the Opioid Safety Agenda



Naloxone and the Law

- Naloxone is **not** a controlled substance; prescribing naloxone to a patient is no different than prescribing other routine medications
- States in **orange** have added legal protections, such as authorizing:
 - Prescribing/dispensing to potential bystanders
 - Administration of naloxone by lay bystanders
 - Prescribing/dispensing by standing order or directly from pharmacies
 - [Example of standing order](#)



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.

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*By health departments or in states with legislative authorization (CA, IL, KY, NC, NJ, VT)

Target Groups for Naloxone

- Heroin users
- Correctional populations
- Substance use treatment patients
- Family / friends
- First responders

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How to prescribe naloxone

- **Injectable**
 - **Vial:**
 - Naloxone 0.4mg/1mL IM if overdose. Call 911. Repeat if necessary. #2.
 - IM syringes (3ml 25 g 1" syringes are recommended) #2
 - Autoinjector: Evzio, 0.4mg naloxone (*available July 2014*)
- **Intranasal (off-label)**
 - Naloxone 2mg/2mL needleless 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 rapidly improving*)
- **SBIRT codes cover education in 15 minute intervals**
 - Medicare – G0396
 - Medicaid – H0050
 - Commercial – CPT 99408

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Administering naloxone IM & IN

HOW TO GIVE INTRAMUSCULAR NALOXONE

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Patient education

- Minimum care involves 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, 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



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Pharmacy access

- Consider contacting pharmacies your patients access prior to prescribing naloxone; this is new for most pharmacists.
- Ordering:
 - Injectable vial, NDC#00409-1215-01
 - Intranasal, NDC#76329-3369-01
 - MAD nasal (Teleflex; carried by McKesson, other distributors pending)
 - Evzio, expected to be available July 2014
- 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:
 - Varies by state (e.g. Medicaid Fee for Service rather than contracted)
- [Additional information for pharmacists](#)

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Experience with Clinic-Based Naloxone

- Project Lazarus in North Carolina (Albert, et al., Pain Med 2011)
- Naloxone For Opioid Safety Evaluation (NOSE)
 - Primary care clinics in San Francisco safety net system
 - Naloxone prescribed to all patients receiving chronic opioids
 - Initiated spring of 2013, final clinic enrolled April 2014
 - Funded by the National Institute on Drug Abuse
 - 555 patients prescribed naloxone since initiation

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Emerging Themes Among Patients Prescribed Naloxone

- Naloxone alerts patients to risks of opioids
 - *"It made me think that I was playing with my life"*
 - *"I've probably been a little more cautious. Just being careful to take the right amount, count the hours, you know, think more cautiously about dosing"*
- Naloxone increases patient comfort
 - *"It just reassures me that if I do have a breathing problem, that drug is there to solve the problem"*
 - *"It's a great idea ... There have been at least 1 or 2 times where I've been the one to go 'oh wait, I just took a pill 20 minutes ago and I just took another - oops!' it does happen, even to young people who aren't fuzzy ..."*

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Preliminary data from "Naloxone for Opioid Safety Evaluation", 2014

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"



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Funding for Programs

- 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 some Medicaid plans, many part D programs, and others
- Current costs for an injectable vial or intranasal kit of naloxone is ~\$50; price for autoinjector not yet known

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Resources for providers

- Naloxone Program Implementation Manual: 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
- www.csam-asam.org/naloxone-resources
- 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

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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>

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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.

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Summary


- Naloxone access for laypersons is an evidence-based intervention that reduces mortality from overdose
- Any prescribers can provide naloxone to patients at risk of an opioid overdose; in states with additional legislation:
 - prescribers can:
 - provide naloxone to anyone at risk of witnessing an overdose
 - issue a standing order authorizing others to distribute naloxone
 - naloxone recipients may 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 many MediAid programs; pharmacies may need guidance and atomizer access is limited
- Patients are receptive to naloxone prescription and there may be ancillary behavioral benefits

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Questions

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