We encourage you to use these slides when teaching. If you do, please cite this source and note any changes made.

- The Immersion Training in Addiction Medicine Program

Optimizing Safety in People with Addictions

Alex Walley

CRIT/FIT/JFIT/AFIT – May 2017

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Morning Report Case

- You are called to admit a 29 yo woman with polydrug overdose, complicated by aspiration, and a left arm cellulitis. She was found unresponsive in the bathroom of a restaurant with a syringe, cooker and filters.
  - Works as a waiter
  - Injecting heroin daily since age 23.
  - Uses cocaine on the weekends and drinks alcohol after work
  - Trades sex for drugs, when money is short
  - Prescribed clonazepam, clonidine and gabapentin for panic disorder and mood stabilization
  - Treated with methadone and buprenorphine in the past when pregnant
  - Intends to use again on discharge

  Despite your best brief intervention and motivational interviewing…
  - ***She is not interested in treatment at this time.***

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Learning objectives

At the end of this session, you should be able to:

1. Define harm reduction and apply it to public health
2. Explain the rationale and evidence for:
   a. needle syringe access
   b. supervised injection facilities and
   c. naloxone rescue kits for overdose prevention

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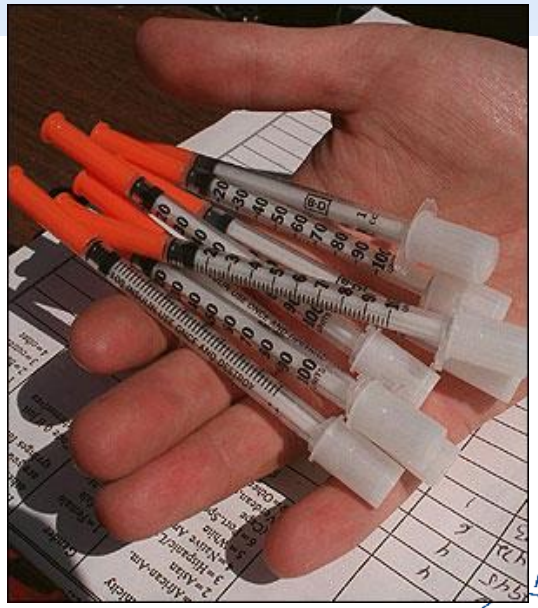
What is Harm Reduction?

- Practical strategies and ideas to reduce substance use consequences
  - A movement for social justice built on a belief in, and respect for, the rights of people who use substances
    - Harmreduction.org
- Interventions guided by risk-benefit analysis
  - Abstinence is not a prerequisite to care



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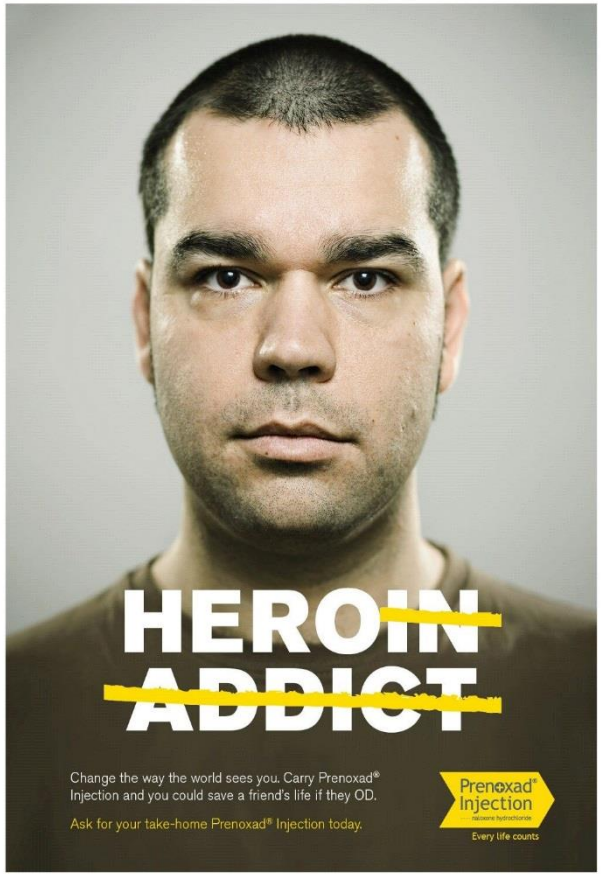
Harm Reduction Interventions

- Opioid agonist treatment to reduce HIV and mortality
  - Treatment continuity post-incarceration
- Needle and syringe programs to reduce HIV and injection risk
  - Pharmacy access needles and syringes
- Drug consumption rooms for injection risk and overdose mortality
- Naloxone rescue kits for opioid overdose mortality
- Pre and Post exposure prophylaxis
- Housing first programs
- Shelter-based alcohol administration
- Bad date sheets



http://www.emcdda.europa.eu/best-practice/harm-reduction

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Needle Syringe Access

Slide from Sarah Wakeman

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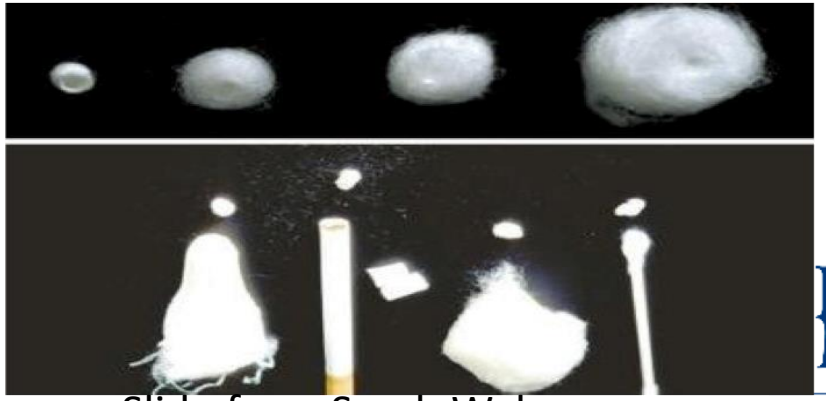
Filters

- Used to trap particulate matter
- Cotton balls, Q tip, tampon, cigarette filter
- Require manipulation with fingers
- Contamination with skin flora
- Ideal filter small, preformed (dental pellet)



Slide from Sarah Wakeman

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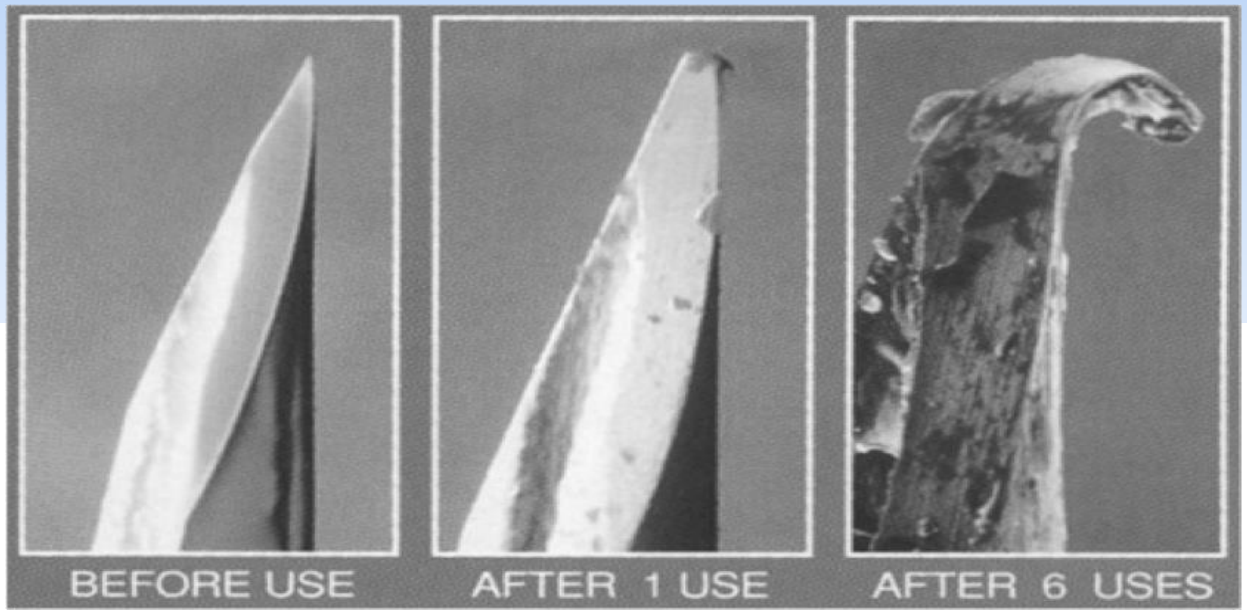
Syringes and needles



- New needle and syringe each injection
- Needle dulls with each use
- Bleach is option
- Don’t use syringe to divide dose or mix heroin

Slide from Sarah Wakeman

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Change in HIV seroprevalence with and without needle-syringe programs

	Cities with NSPs	Cities without NSPs
All cities	-5.8% per year	+5.9% per year
Cities with seroprevalence <10%	-1.1% per year	+16.2% per year

Hurley et al. Lancet 1997:349; 1797-1800.
www.unodc.org/documents/hiv-aids/EFA%20effectiveness%20sterile%20needle.pdf

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Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxymorphone — Indiana, 2015

Caitlin Conrad[1], Heather M. Bradley[2], Dita Broz[2], Swamy Buddha[1], Erika L. Chapman[1], Romeo R. Galang[2,3], Daniel Hillman[1], John Hon[1], Karen W. Hoover[2], Monita R. Patel[2,3], Andrea Perez[1], Philip J. Peters[2], Pam Pontones[1], Jeremy C. Roseberry[1], Michelle Sandoval[2,3], Jessica Shields[4], Jennifer Walthall[1], Dorothy Waterhouse[4], Paul J. Weidle[2], Hsiu Wu[2,3], Joan M. Duwve[1,5] (Author affiliations at end of text)

MMWR / May 1, 2015 / Vol. 64 / No. 16

-> March 26, 2015 – Gov. Pence issued emergency order permitting needle-syringe distribution

-> May 2015 – Indiana law passed allowing needle-syringe distribution in communities with an HIV epidemic

-> Jan 2016 federal funding ban ended

- Injection partners range from 1 to 6

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Overdose prevention

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The Addiction Crisis

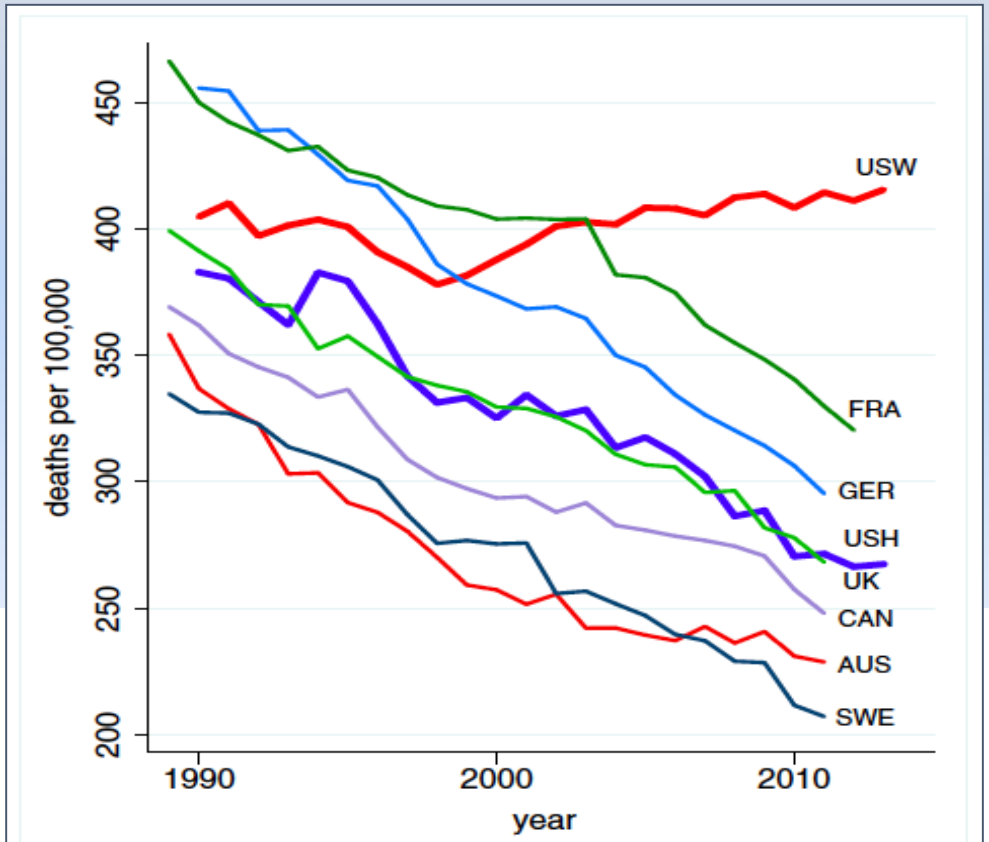

Fig. 1. All-cause mortality, ages 45–54 for US White non-Hispanics (USW), US Hispanics (USH), and six comparison countries: France (FRA), Germany (GER), the United Kingdom (UK), Canada (CAN), Australia (AUS), and Sweden (SWE).

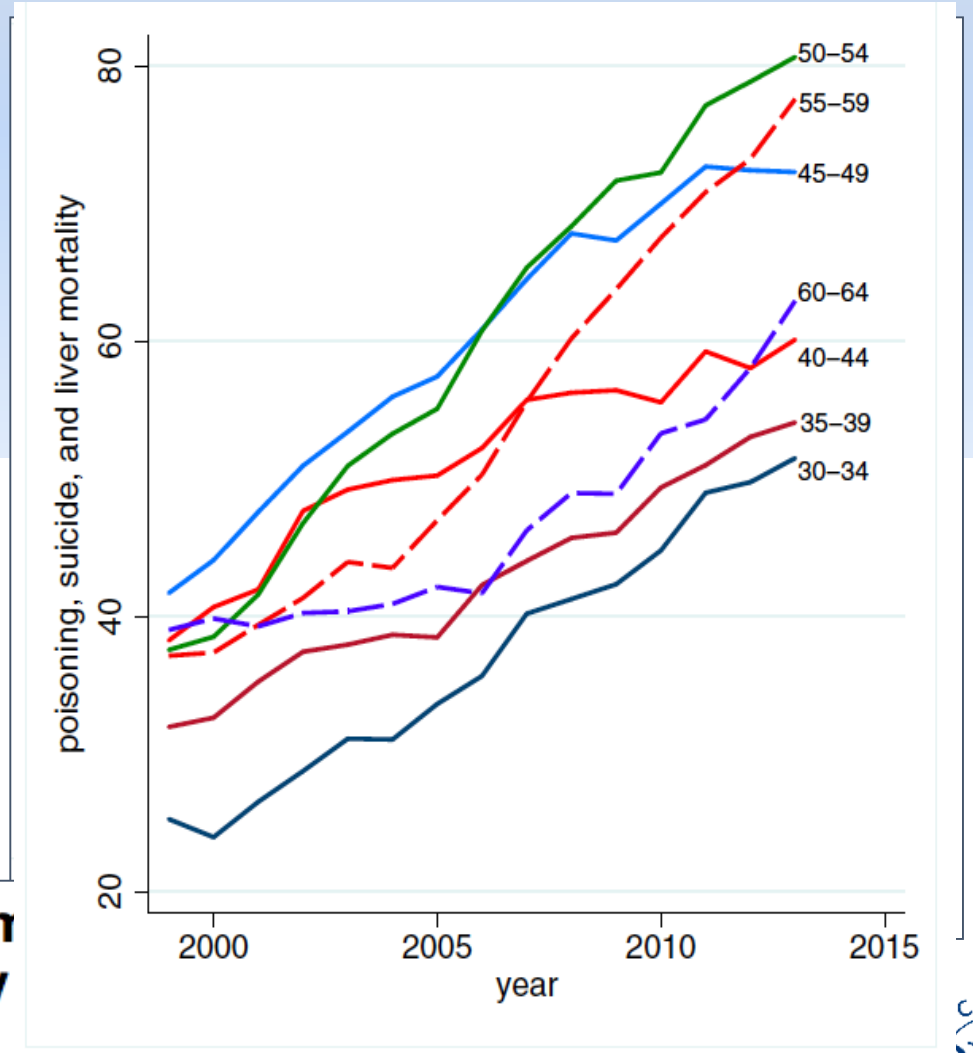

Fig. 4. Mortality by poisoning, suicide, chronic liver disease, and cirrhosis, white non-Hispanics by 5-y age group.

PNAS

Rising morbidity and mortality in midlife an non-Hispanic Americans in the 21st century

Anne Case[1] and Angus Deaton[1]

Woodrow Wilson School of Public and International Affairs and Department of Economics, Princeton University, Princeton,

Contributed by Angus Deaton, September 17, 2015 (sent for review August 22, 2015; reviewed by David Cutler, Jon Skinner

This paper documents a marked increase in the all-cause mortality of middle-aged white non-Hispanic men and women in the United States between 1999 and 2013. This change reversed decades of progress in

the United Kingdom (UK), Canada (C
Sweden (SWE). The comparison is similar for other Organisation
for Economic Co-operation and Development countries.

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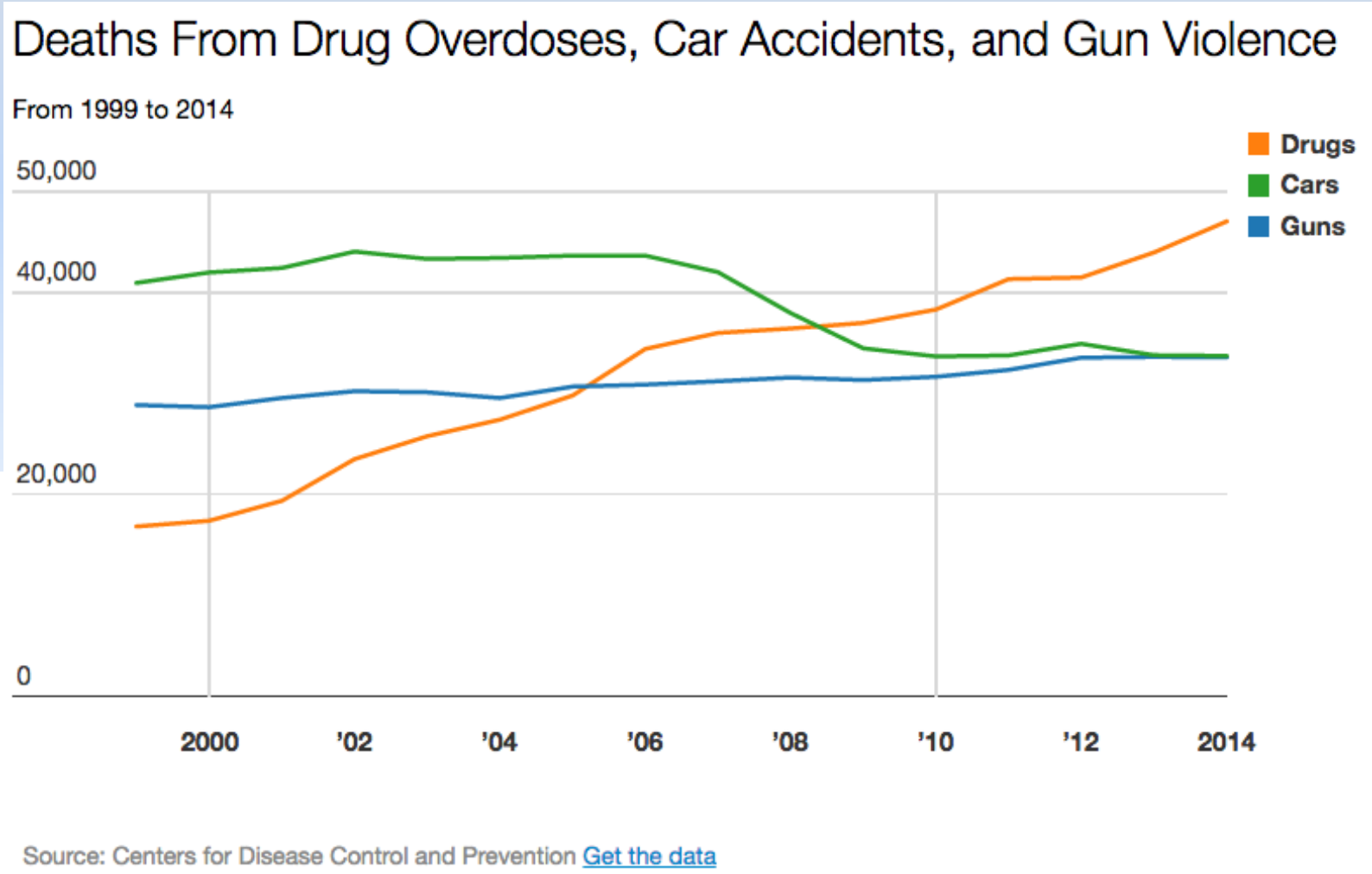

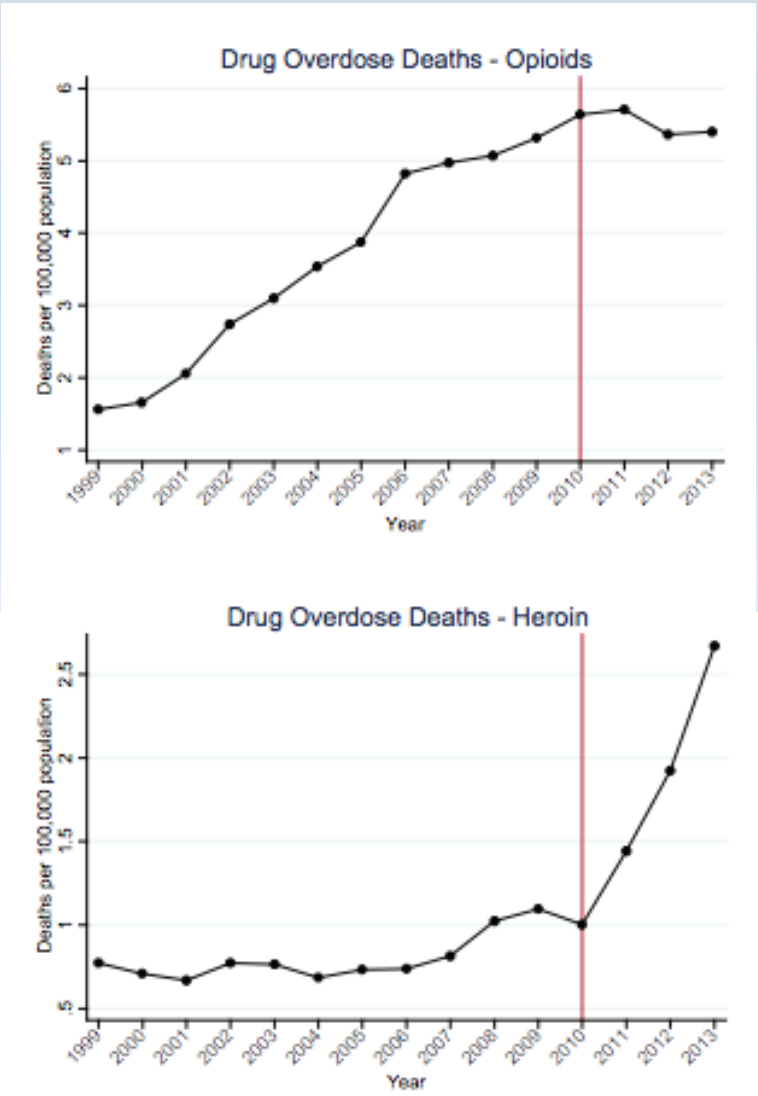

Alpert A, Powell D, Pacula RL. Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids. National Bureau of Economic Research; 2017 Jan 5.

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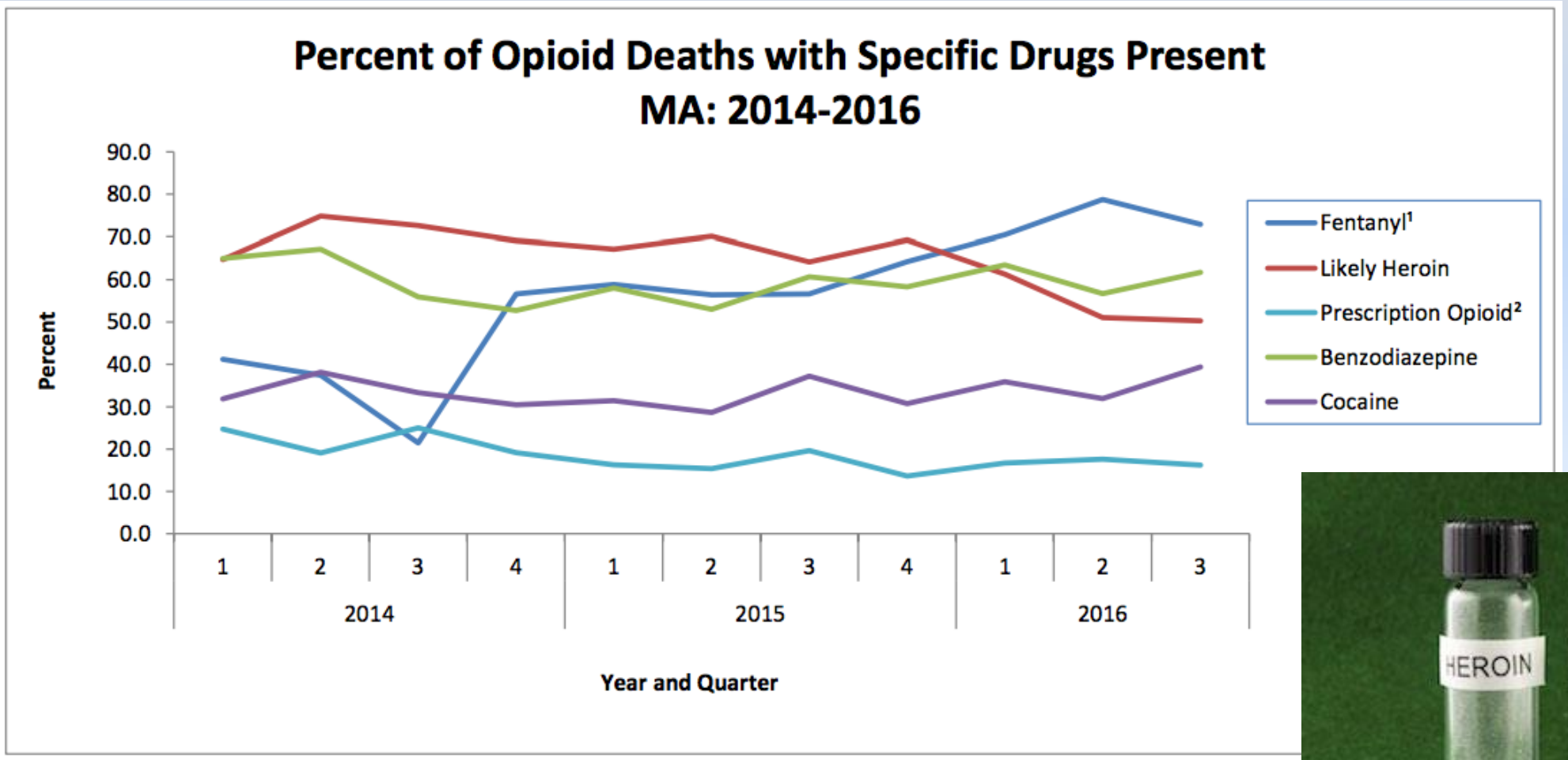

1. This is most likely illicitly produced and sold, **not** prescription fentanyl
2. Prescription opioids include: hydrocodone, hydromorphone, oxycodone, oxymorphone, and tramadol

New Hamsphire State Police Forensic Lab

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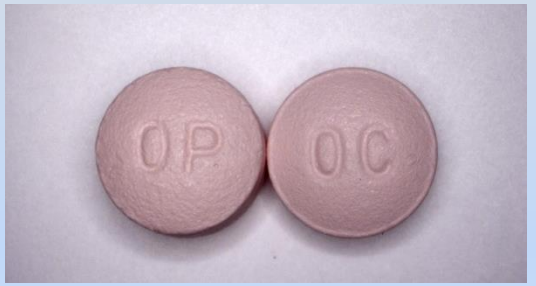
Why a surge in overdoses?



DEA Official Blames Fentanyl-Heroin Mixture from Mexico for Recent Fatal Overdoses

The fentanyl-laced dope plaguing the northeastern United States is being made south of the border, according to officials.

- Prescription opioids for pain
- Transitioning to heroin and illicitly-made fentanyl
- Erratic and more deadly heroin and fentanyl supply
  - *Overdose response window has shrunk from minutes to hours to seconds to minutes*
- Polysubstance use (including polypharmacy)

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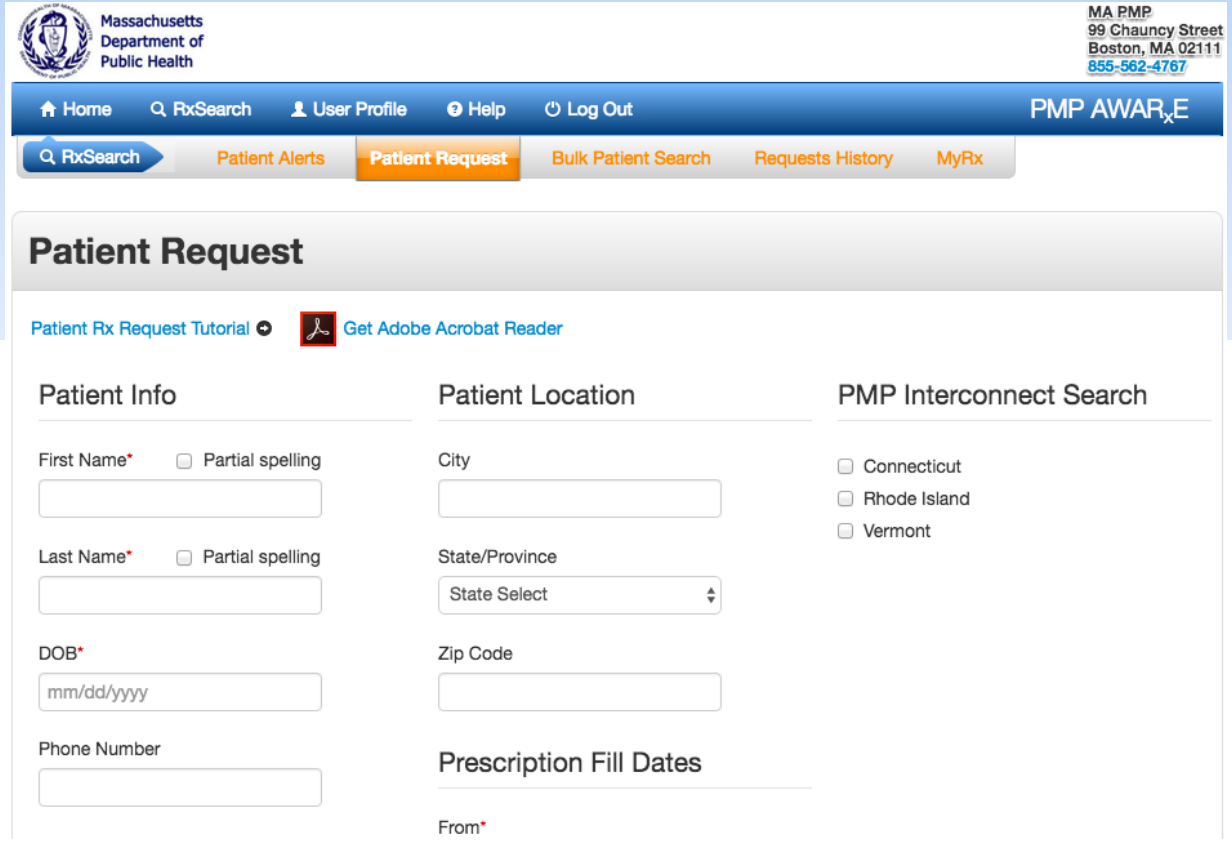
Strategies to address opioid use and overdose

- **Prescription monitoring programs**
  - Paulozzi et al. Pain Medicine 2011
- Prescription drug take back events
  - Gray et al. Arch Intern Med 2012; 172: 1186-87
- Safe opioid prescribing education
  - Albert et al. Pain Medicine 2011; 12: S77-S85
- Opioid agonist treatment
  - Clausen et al. Addiction 2009:104;1356-62
- Supervised injection facilities
  - Marshall et al. Lancet 2011:377;1429-37
- Overdose Education and Naloxone Distribution



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www.scopeofpain.com

www.opioidprescribing.com

www.pcss-o.org

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MEDICAL NEWS
& PERSPECTIVES

Methadone Treatment Marks 40 Years

Bridget M. Kuehn

FORTY YEARS AND COUNTLESS POlitical firestorms after it was first introduced, methadone maintenance for the treatment of opioid addiction remains a standard therapy in the field of addiction treatment.

The publication on August 23, 1965, of positive results from a small clinical trial of methadone as a treatment for heroin addiction in *JAMA* marked a sea change in the treatment of addiction (Dole and Nyswander. *JAMA*. 1965; 193:646-650). The study, conducted at Rockefeller University in New York City by Vincent P. Dole, MD, and the late Marie E. Nyswander, MD, suggested that a medication could be used to control the cravings and withdrawal that often lead to relapse in individuals with opioid addiction who attempt to quit.

The work, along with subsequent research by Dole, an endocrinologist, Nyswander, a psychiatrist, and colleagues established the concept of opioid addiction as a chronic disease, similar to diabetes, that as such required

now head of the Laboratory of the Biology of Addictive Diseases at Rockefeller University, explained that work conducted by the group in 1964 and published in 1966 established that methadone blocked the effects of heroin and stabilized patients, who prior to treatment oscillated between feeling

Ingbert Grüttner/The Rockefeller University

done treatment, the ap
always struggled for accep
the forces of public opini
tics. "There is a stigma ag
tions, addicts, and—sadly
providers," said Kreek, a
supporter of the methado

"THE FARM"

Methadone maintenance
resented a reversal of the t
approach to treating dru
said David F. Musto, MD
turer at Yale and expert
policy. A 1919 Supreme
sion had established tha
alone did not justify phys
ing addicts with opioids. B
cision, some physicians ha
acting opioids to treat indi
opioid addiction.

The Drug Enforcement
tion, in fact, considered D
illegal and had threatened
him prior to the 1965 pub
defy the US government wa
litical courage," said Jeron
who became the first natio

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Boston Globe – December 27, 2015


EDITORIAL I CRISIS PROPORTIONS

Massachusetts needs safe injection sites

AFP/GETTY IMAGES

A client of the Insite supervised injection Center in Vancouver, Canada, collected her kit in 2011.

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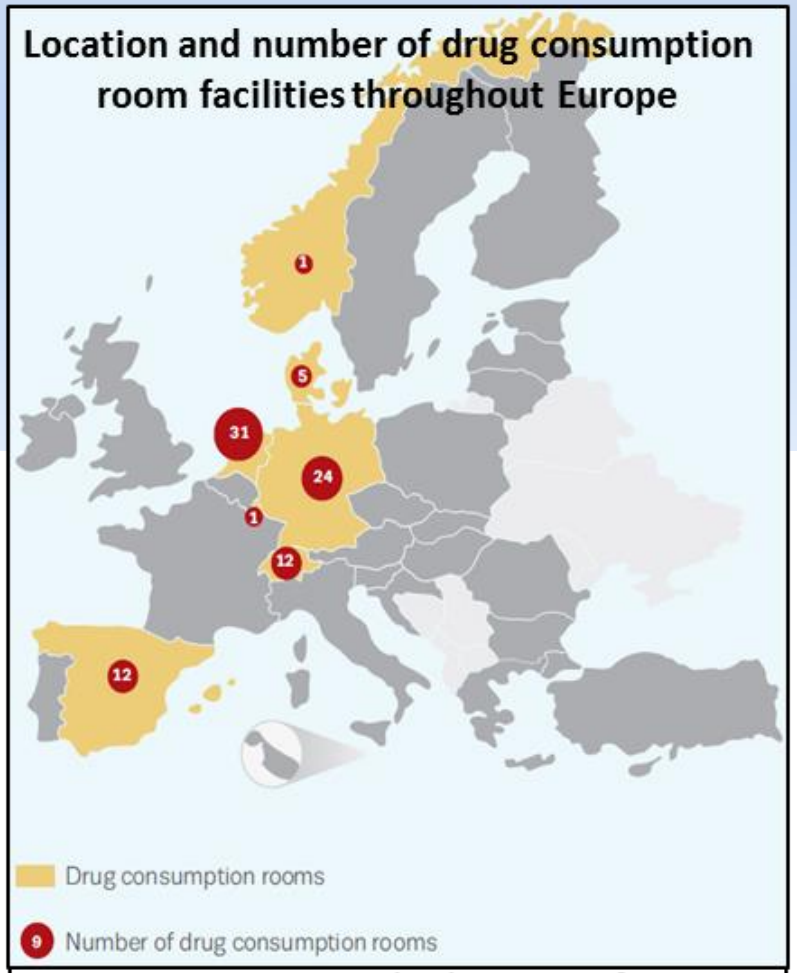
Supervised Injection Facilities

- Legal facilities where people can inject pre-obtained drugs under supervision
- Objectives: Public Health + Public Safety
  - Reduce overdose
  - Reduce injection-related infections
  - Improve access to substance use disorder treatment
  - Reduce public drug use
  - Improve neighborhood security
- Existing Facilities
  - 86 facilities throughout Europe
  - Vancouver, Canada
  - Sydney, Australia



Source: European Monitoring Centre for Drugs and Drug Addiction, Updated June 2015

BOSTON HEALTH CARE *for the* HOMELESS PROGRAM

Slide(s) courtesy of Jessie Gaeta

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SIFs Reduce Overdose Mortality

Methods: Population-based overdose mortality rates were examined in the 500m surrounding the SIF before and after its opening and compared with before and after rates in the rest of the city of Vancouver.

Results: In the area around the SIF overdose mortality **decreased 35%**, compared with a 9.3% reduction in the rest of the city.

	ODs occurring in blocks within 500 m of the SIF*		ODs occurring in blocks farther than 500 m of the SIF*	
	Pre-SIF	Post-SIF	Pre-SIF	Post-SIF
Number of overdoses	56	33	113	88
Person-years at risk	22 066	19 991	1 479 792	1 271 246
Overdose rate (95% CI)*	253·8 (187·3–320·3)	165·1 (108·8–221·4)	7·6 (6·2–9·0)	6·9 (5·5–8·4)
Rate difference (95% CI)*	88·7 (1·6–175·8); p=0·048	..	0·7 (-1·3–2·7); p=0·490	..
Percentage reduction (95% CI)	35·0% (0·0%–57·7%)	..	9·3% (–19·8% to 31·4%)	..

SIF=supervised injection facility. Pre-SIF period=Jan 1, 2001, to Sept 20, 2003. Post-SIF period=Sept 21, 2003, to Dec 31, 2005. *Expressed in units of per 100 000 person-years.

Table 2: **Overdose mortality rate in Vancouver between Jan 1, 2001, and Dec 31, 2005 (n=290), stratified by proximity to the SIF**

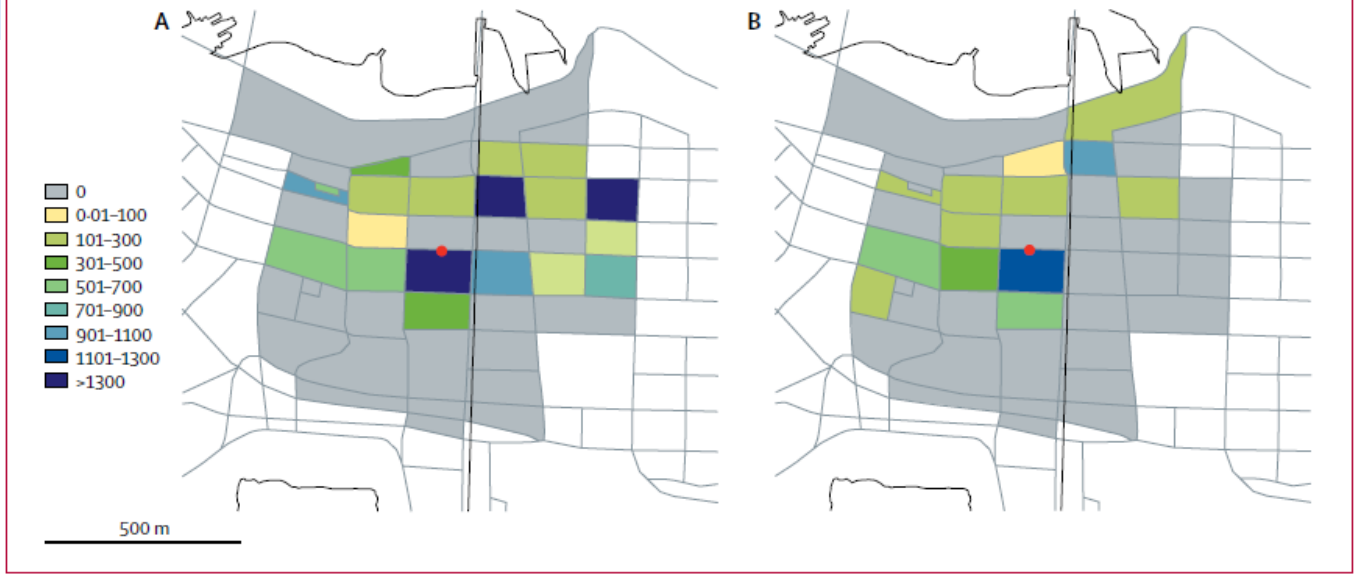

Figure 2: **Fatal overdose rates before (A) and after (B) the opening of Vancouver's SIF (shown in red) in city blocks located within 500 m of the facility**
Rates are given in units of 100 000 person-years and were calculated by aggregating the locations of death to the dissemination block level as shown.

BOSTON HEALTH CARE *for the* HOMELESS PROGRAM

Slide courtesy of Jessie Gaeta

Marshall, B. et al. (2011). Reduction in overdose mortality after the opening of North America's first medically supervised safer injecting facility: a retrospective population-based study. *Lancet*, *377*(9775):1429-37.

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Legal and Logistical Barriers to SIF

1. **Federal** crack house statutes make it a crime to maintain a facility for the purpose of using substances
2. **State** laws would have to shield programs from local and state law enforcement
3. **Local** law enforcement, neighborhoods, and business community would need to support it
4. Adequate **funding** is needed to ensure the program is implemented correctly
5. An **empowered group of people who use drugs** is needed to ensure this works

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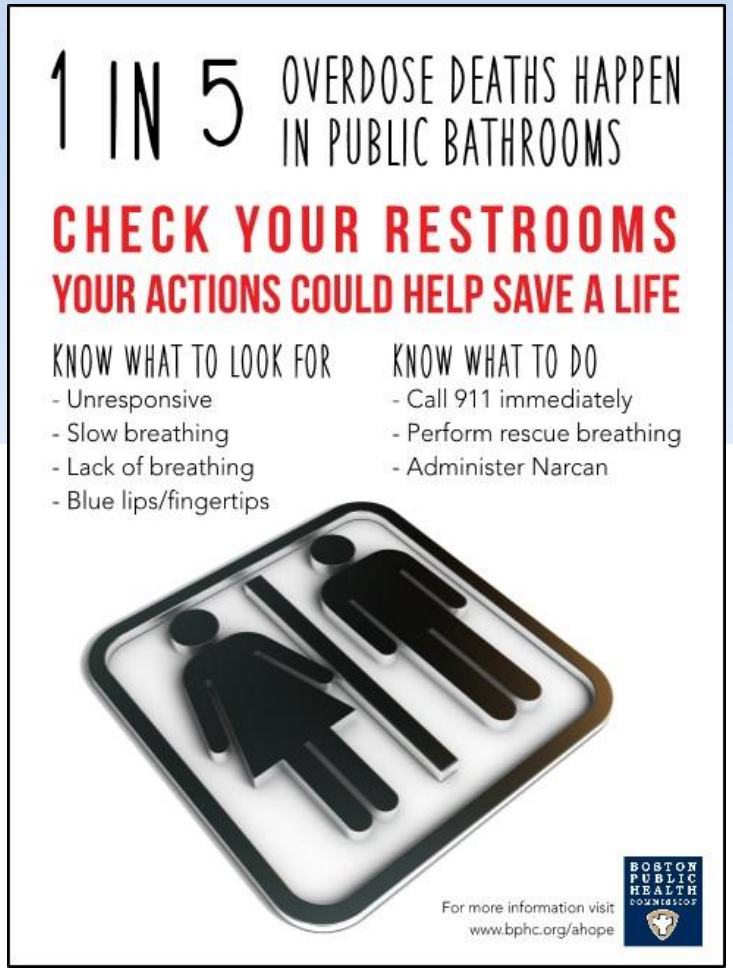
Bathrooms are injection facilities: How to make them safer?

Outfit bathrooms with:

- Secure biohazard boxes
- Good lighting
- Mirrors
- Doors that open out
- Call button
- Intercomm system
- Timer with monitor
  - 10min? 5min? 2min?
- Safer injection equipment
- Naloxone rescue kit



Wolfson-Stofko B, Bennett AS, Elliott L, Curtis R. Drug use in business bathrooms: An exploratory study of manager encounters in New York City. International Journal of Drug Policy. 2017 Jan 31;39:69-77.

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- **Overdose Education and Naloxone Distribution**

	Injectable (and intranasal- IN) generic[1]	Intranasal branded[2]	Injectable generic[3]	Injectable generic	Auto-injector branded
Brand name		Narcan Nasal Spray			Evzio Auto-Injector
Product comparison					
					
FDA approved Labeling includes instructions for layperson use	X (for IV, IM, SC)	X X	X	X	X X
Layperson experience	X		X		X
Assembly required	X		X	X	
Fragile	X				
Can titrate dose	X		X	X	
Strength	1 mg/mL	4 mg/0.1 mL	0.4 mg/mL OR 4 mg/10 mL	0.4 mg/mL	0.4 mg/0.4mL
Total volume of kit/package	4 mg/4 mL	8 mg/ 0.2 mL	0.8 mg/2 mL OR 4 mg/10 mL	0.8 mg/2 mL	0.8 mg/0.8 mL
Storage requirements (All protect from light)	Store at 59-86 °F Fragile: Glass.	Store at 59-77 °F Excursions from 39-104 °F	Store at 68-77 °F Breakable: Glass.	Store at 68-77 °F Breakable: Glass.	Store at 59-77 °F Excursions from 39-104 °F
Cost/kit[4]	$$	$$	$	$	$$$[5]

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Rationale for overdose education and naloxone distribution

- Most opioid users do not use alone
- Known risk factors:
  - Mixing substances, abstinence, using alone, unknown source
- Opportunity window:
  - Opioid overdoses take minutes to hours and is reversible with naloxone; seconds to minutes with fentanyl
- Bystanders are trainable to recognize and respond to overdoses
- Fear of public safety

PRESCRIBE TO PREVENT

[Patient education videos and materials at prescribetoprevent.org]

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How to Respond in an Overdose

Steps to teach patients, family, friends, caregivers

Recognize overdose

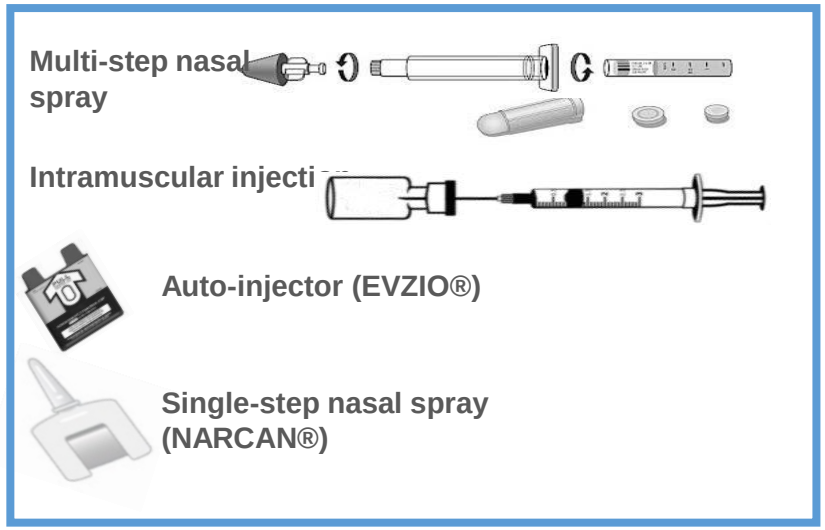
1

Call 911 for help

2

Administer naloxone
as soon as it is available

3 4



Rescue breathe/ chest compressions
per rescuer's level of training

5

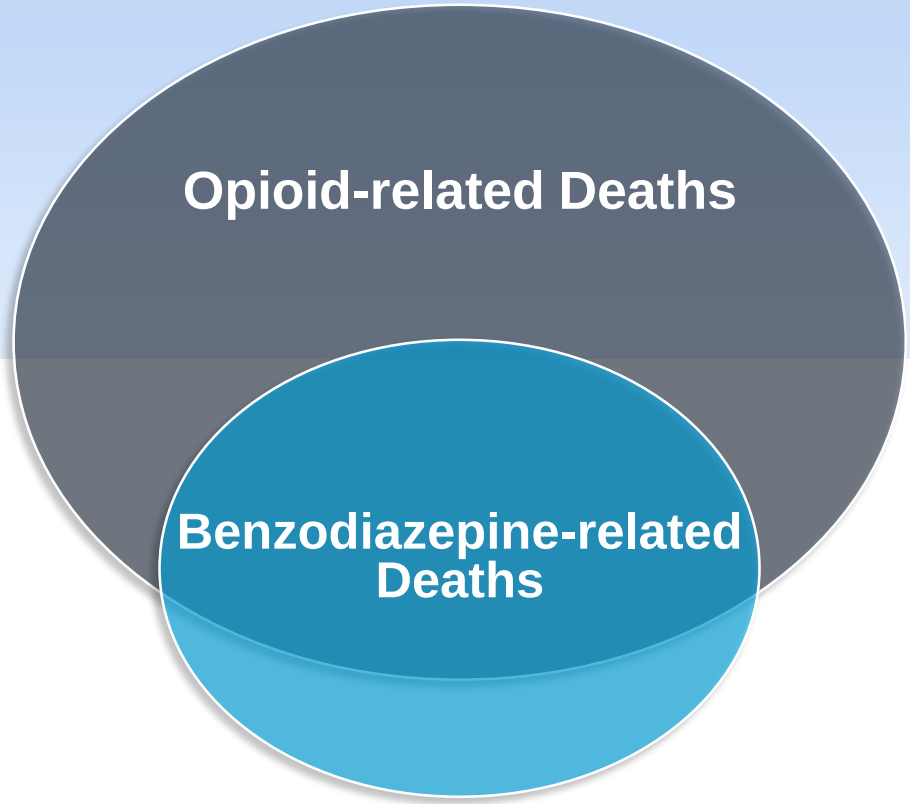
Stay until help arrives
Place in recovery position if breathing

PRESCRIBE TO PREVENT

Benzodiazepines and Opioids

Jointly contribute to overdose deaths

- Benzodiazepines are present in 31% of opioid-related overdose deaths
- Opioids are present in 75% of benzodiazepine-related overdose deaths[1]
- Among people prescribed opioids, the risk of overdose deaths is 3.8 times higher for people prescribed benzos also[2]
- 8/31/16– FDA announced black box warning for opioid pain and cough meds and benzodiazepines regarding risk of the combined use of opioids and benzos



1. Jones CM and McAninch JK. Am J Prev Med. 2015 Oct;49(4):493-501.
2. Park TW, et al. BMJ. 2015 Jun 10;350:h2698.
3. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

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“Street pills”

- Benzodiazepines
  - Clonazepam (Klonopin)
  - Alprazolam (Xanax)
  - Diazepam (Valium)
  - Also Z drugs –ambien and lunesta

- Clonidine (Catapress)
- Promethazine (Phenergan)
- Quetiapine (Seroquel)
- Gabapentin (Neurontin)
  - Pregabalin (Lyrica)
- Buproprion (Wellbutrin)

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Evaluations of Overdose Education and Naloxone Distribution Programs

Feasibility

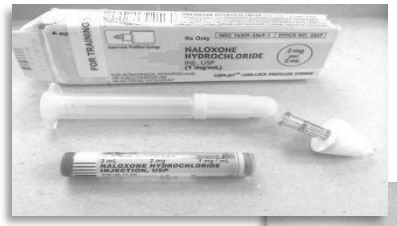
- Piper et al. Subst Use Misuse 2008: 43; 858-70.
- Doe-Simkins et al. Am J Public Health 2009: 99: 788-791.
- Enteen et al. J Urban Health 2010:87: 931-41.
- Bennett et al. J Urban Health. 2011: 88; 1020-30.
- Walley et al. JSAT 2013; 44:241-7. (Methadone and detox programs)

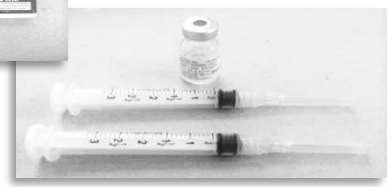
Increased knowledge and skills

- Green et al. Addiction 2008: 103;979-89.
- Tobin et al. Int J Drug Policy 2009: 20; 131-6.
- Wagner et al. Int J Drug Policy 2010: 21: 186-93.

No increase in use, increase in drug treatment

- Seal et al. J Urban Health 2005:82:303-11.
- Doe-Simkins et al. BMC Public Health 2014 14:297.
- Jones et al. Addictive Behaviors 2017:71:104-6





Reduction in overdose in communities

- Maxwell et al. J Addict Dis 2006:25; 89-96.
- Evans et al. Am J Epidemiol 2012; 174: 302-8.
- Walley et al. BMJ 2013; 346: f174.
- Coffin et al. *Ann Intern Med* 2016; 1-8.

Cost-effective

$438 (best)
$14,000 (worst) per quality-adjusted life year gained

Coffin and Sullivan. Ann Intern Med. 2013 Jan 1;158(1):1-9.

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Risk Compensation and Moral Hazard
->> Narcan Party Urban Legend = Fake News

'Drug dealers are throwing Narcan parties'

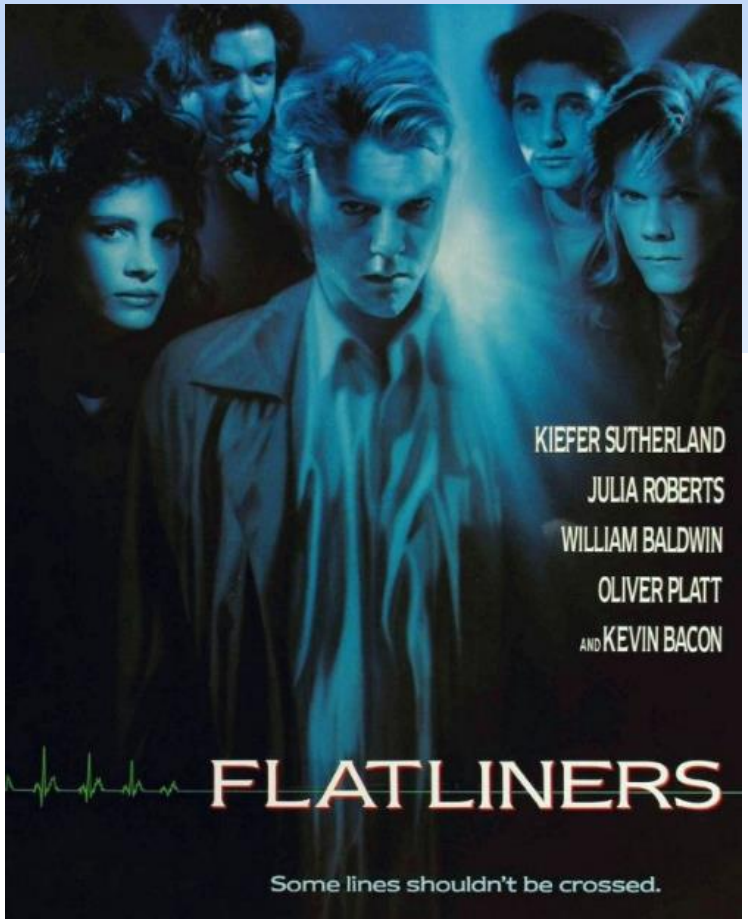
- Aug. 2016 previous assertions by two legislators in PA:
  - http://www.upgruv.com/lawmakers-hesitant-to-expand-narcan-access-1957206979.html
- The TV story March 2017 in PA:
  - http://www.wgal.com/article/police-raising-concerns-about-narcan-parties-offering-drugs-and-antidote-to-users/9165193

Naloxone distribution does *not* increase drug use

- Maxwell et al.,Journal of Addictive Diseases, 2006;
- Seal et al., Journal of Urban Health, 2005;
- Wagner et al., 2010 International Journal of Drug Policy;
- Doe-Simkins et al, BMC Public Health, 2014
- Jones et al. Addictive Behaviors 2017:71:104-6

Similar examples:

- Seat belts do not cause more motor vehicle deaths, but reduce them
- Syringe distribution does not increase HIV transmission, but reduces
- Vaccinations & condoms do not increase sexually transmitted infections
- Fire extinguishers do not cause fires, but reduce their consequences



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AMA
AMERICAN MEDICAL ASSOCIATION

"The **AMA** has been a longtime supporter of increasing the availability of Naloxone for patients, first responders and bystanders who can help save lives and has provided resources to bolster legislative efforts to increase access to this medication in several s

www.ama-assn.org/ama/pub/news/ne
07-naxolene-product-approval.page

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

"**APhA** supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose"

www.pharmacist.com/policy/controlled-substances-and-other-medications-potential-abuse-and-use-opioid-reversal-agents-2

NATIONAL DRUG CONTROL STRATEGY

2013

Community management of opioid overdose

World Health Organization

ASAM
American Society of Addiction Medicine

Public Policy Statement on the Use of Naloxone for the Prevention of Drug Overdose Deaths

ASAM Board of Directors
April 2010

"Naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal side effects... Naloxone can be administered quickly and effectively by trained professional and lay individuals who observe the initial signs of an opioid overdose reaction."

www.asam.org/docs/publicy-policy-statements/1naloxone-1-10.pdf

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Morning Report Case

- You are called to admit a 29 yo woman with polydrug overdose, complicated by aspiration, and a left arm cellulitis. She was found unresponsive in the bathroom of a restaurant with a syringe, cooker and filters.
  - Works as a waiter
  - Injecting heroin daily since age 23.
  - Uses cocaine on the weekends and drinks alcohol after work
  - Trades sex for drugs, when money is short
  - Prescribed clonazepam, clonidine and gabapentin for panic disorder and mood stabilization
  - Treated with methadone and buprenorphine in the past when pregnant
  - Intends to use again on discharge

  Despite your best brief intervention and motivational interviewing…
  - ***She is not interested in treatment at this time.***

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Case

1. Discuss her addiction treatment options – conduct a brief intervention
    - Residential treatment, intensive outpatient, pharmacotherapy, 12-step groups
2. Review her injection and other drug use routine for knowledge and readiness
    - Educate/ re-enforce safer use strategies
        - NSP, keeping substances safe from others, not using alone, tester shots, PrEP
3. Ask her about her overdose experience
    - Make a plan with her to reduce her own overdose risk and how to respond to others
    - Prescribe naloxone rescue kit if available
4. Work to reduce sexual risk
    - Condoms
    - PEP and PrEP
5. Screen her for interpersonal violence.
    - Offer IPV and sex worker services info
5. Express concern about her polypharmacy and polysubstance use and discuss strategies to reduce
    - Speak to the prescriber of her clonazepam, clonidine, and gabapentin so the prescriber is aware of the overdose
    - Encourage closer monitoring and a risk-benefit analysis for safety

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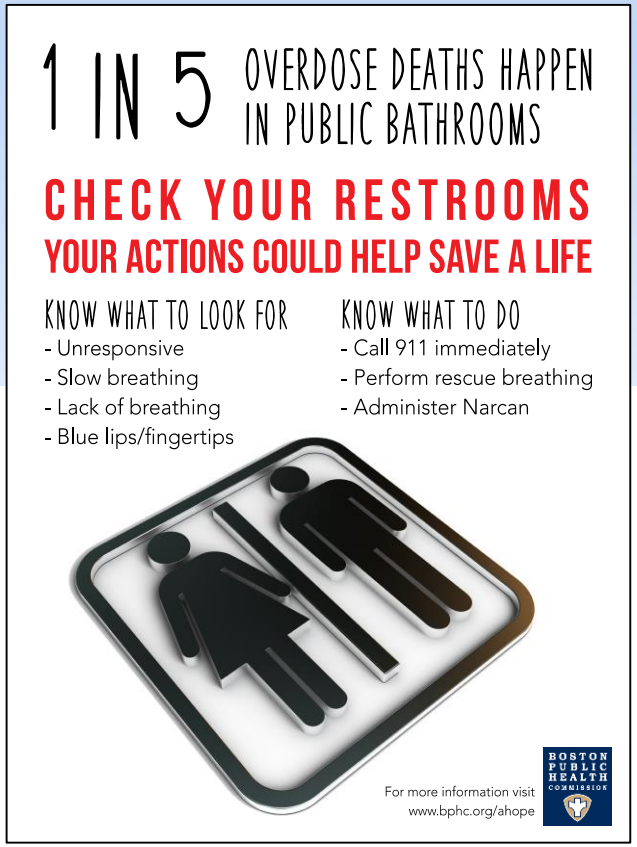
Learning objectives

At the end of this session, you should be able to:

1. Define harm reduction and apply it to public health
2. Explain the rationale and evidence for:
   a. needle syringe access
   b. supervised injection facilities and
   c. naloxone rescue kits for overdose prevention



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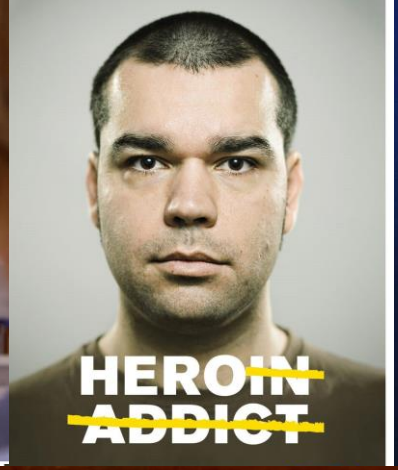

Thank you awalley@bu.edu

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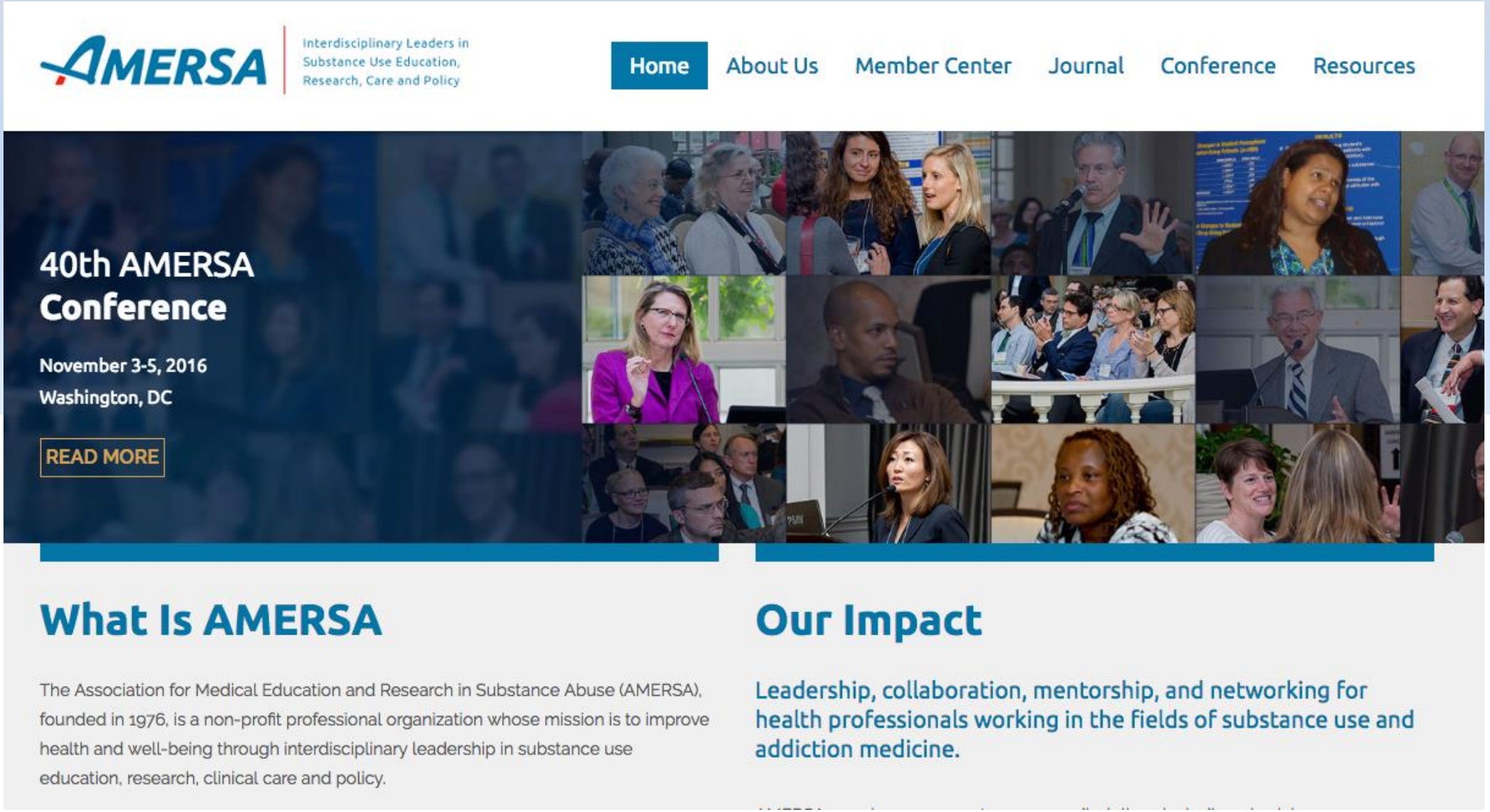

Go to AMERSA.ORG

Travel award deadline: May 13, 2016 Workshop, poster, and oral deadline: May 20, 2016

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PRESCRIBE TO PREVENT

Prescribe Naloxone, Save a Life

PRESCRIBERS PHARMACISTS PATIENT EDUCATION RESEARCH & LEGAL ADVOCACY FAQ

Welcome to PrescribeToPrevent.org

New strategies to address overdose

- Pharmacy interventions
- Safe spaces for oversedation
- Bathroom safety
- Supervised injection facilities
  - Marshall et al. Lancet 2011:377;1429-37
- Heroin maintenance
- On-call recovery coaches
- Knock and Talk outreach
- Public health-public safety surveillance and rapid response

Boston Globe – December 27, 2015

EDITORIAL I CRISIS PROPORTIONS

Massachusetts needs safe injection sites

AFP/GETTY IMAGES

A client of the Insite supervised injection Center in Vancouver, Canada, collected her kit in 2011.

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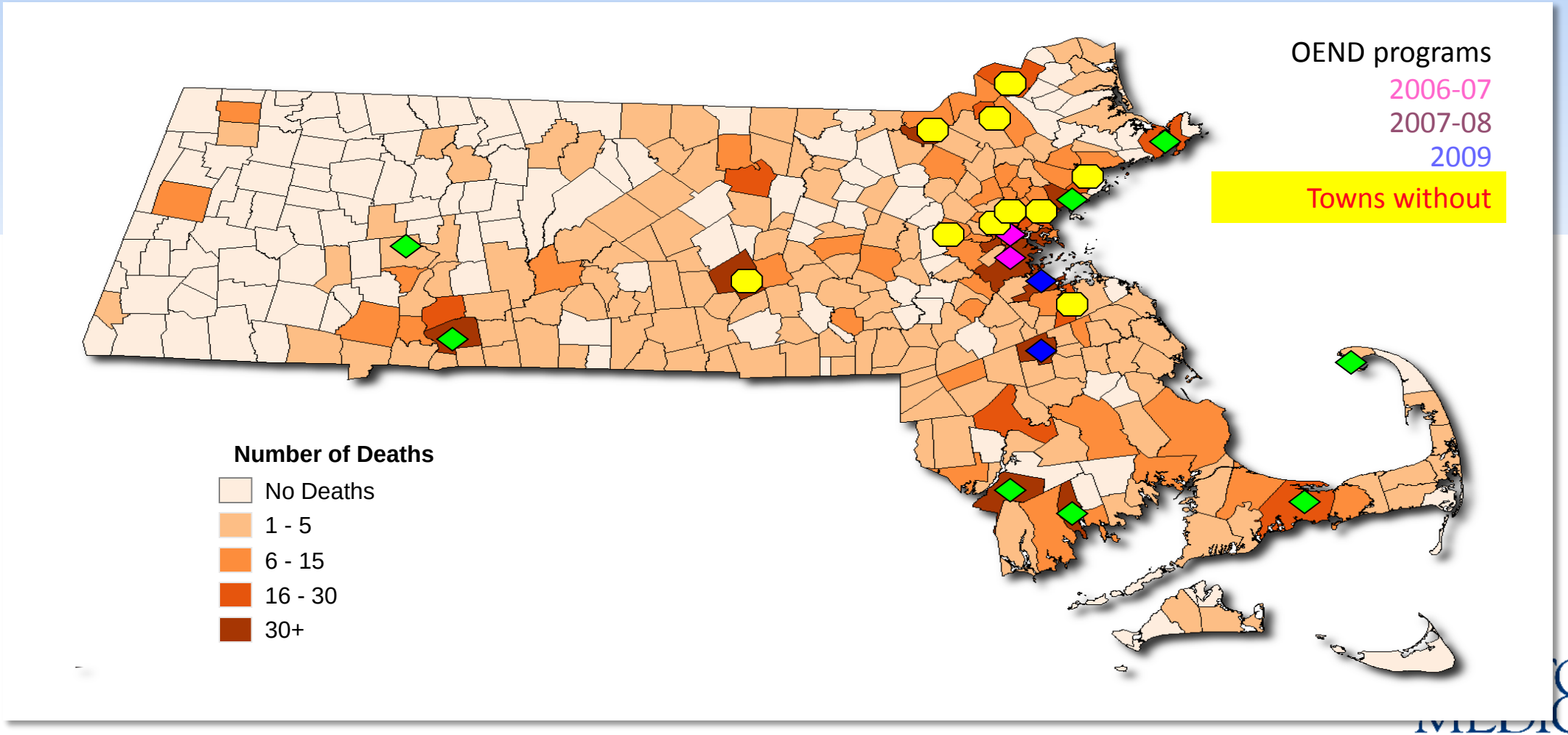
Opioid Overdose Related Deaths: Massachusetts 2004 - 2006



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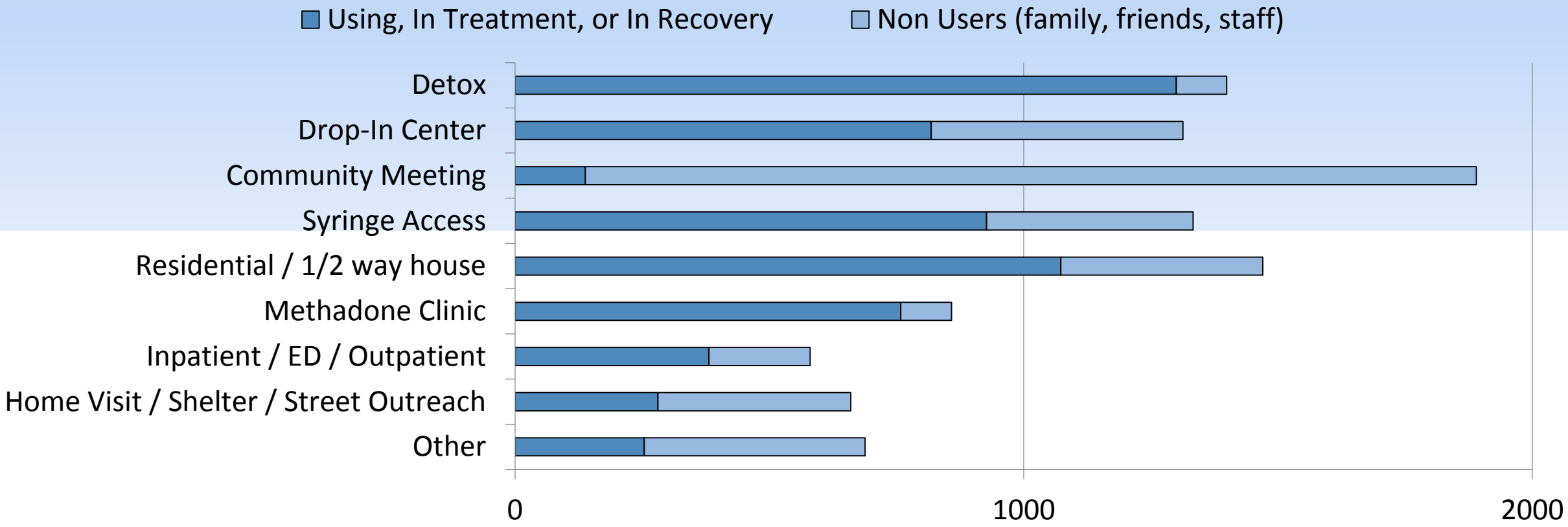
Enrollment locations: 2015 data only



Program data from people with location reported: Users: 6,094 Non-Users: 4,485

Since 2007 > 52,000 enrollees

> 8,700 overdose rescues documented

In first half of 2016: 6999 enrollees

1527 overdose rescues

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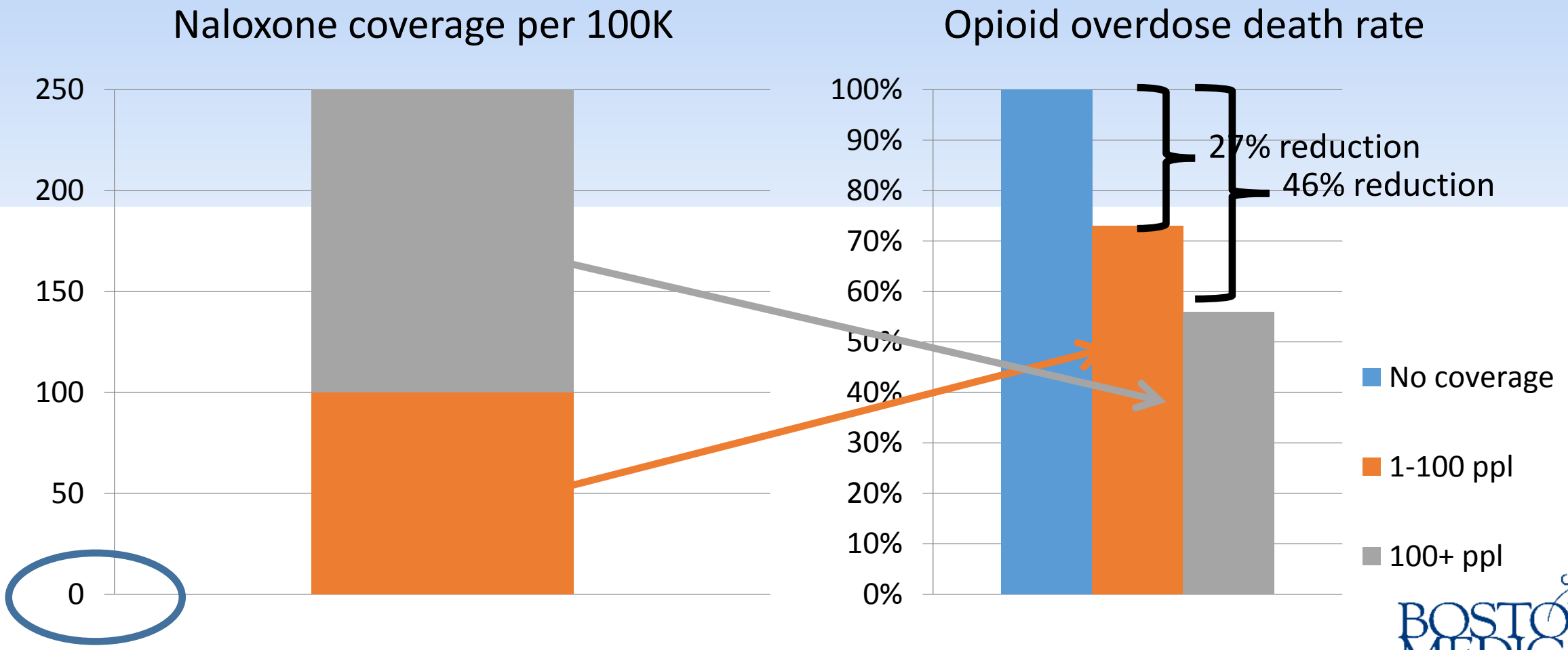
Fatal opioid OD rates by OEND implementation



Walley et al. *BMJ* 2013; 346: f174.

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Successful strategies for HIV/AIDS and parallel opportunities for overdose reduction

Treatment <---------> Prevention

Successful strategies for HIV/AIDS	Parallel opportunities for overdose reduction
• HIV testing and risk reduction counseling	• Overdose risk assessment and reduction counseling
• Needle-syringe distribution	• Naloxone rescue kit distribution
• Targeted outreach /peer-driven interventions	• Targeted outreach /peer-driven interventions
• Supervised injection facilities	• Supervised injection facilities
• Anti-retroviral therapy and opioid agonist treatment	• Medication for opioid use disorders
• Comprehensive, collaborative, longitudinal care for individuals with HIV infection	• Comprehensive, collaborative, longitudinal care for individuals with addictions
• Coordinated prevention and treatment strategy across public health and the healthcare system	• Coordinated prevention and treatment strategy across criminal justice, law enforcement, public health and healthcare systems
• Major funding across public health and the healthcare system of evidence-based interventions	• Major funding across criminal justice, law enforcement, public health and healthcare systems of evidence-based interventions

Walley AY. Preventive Medicine 2015.

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Walley AY. Preventive Medicine 2015.

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Get involved:
Enter Annual Public Awareness Poster Contest

- MOON Study website taking submissions through March 31st, 2016
- Contest open to anyone, up to 2 submissions permitted
- 2-$1000 first prizes, 2-$500 second prizes
- Posters to be made accessible online to communities, pharmacies for public awareness of naloxone access
- Will focus group test the winning posters in subsequent year

- **www.bmc.org/moon-study**

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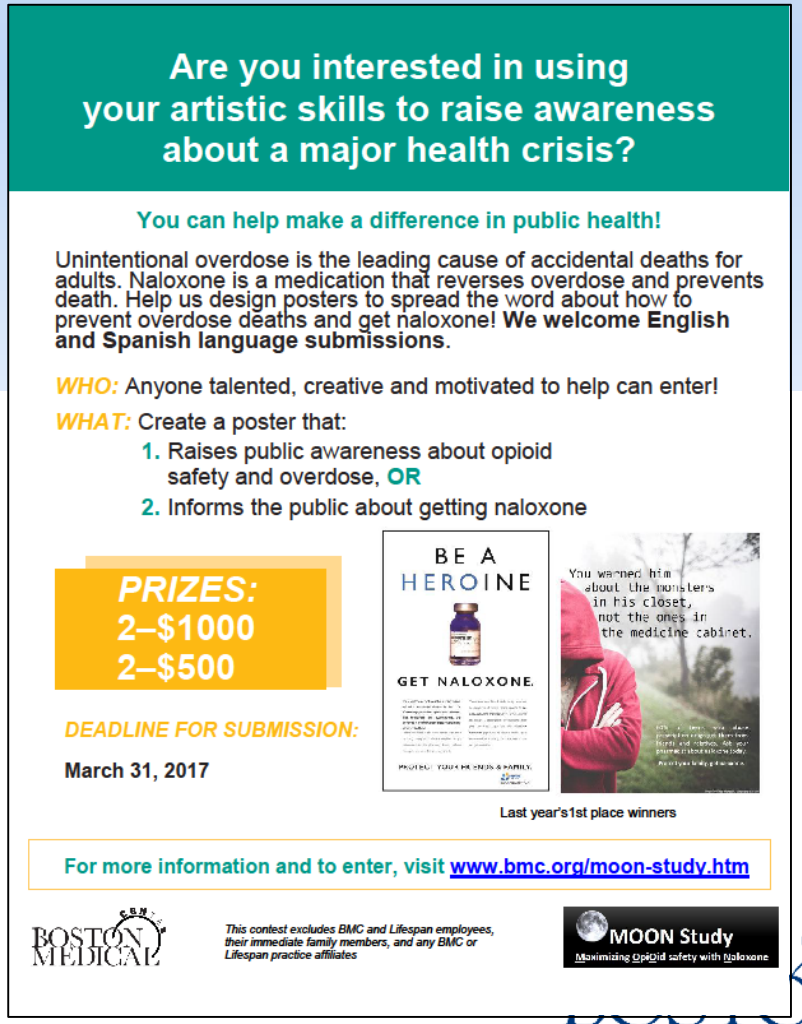
MOON Study Poster Contest

The Maximizing OpiOiD safety with Naloxone Study is accepting submissions for its annual Poster Contest!

- **English and Spanish submissions welcomed.**
- Deadline to submit: March 31, 2017
- $3,000 in cash prizes
- Posters may be used by community groups, pharmacies, and health departments to raise awareness about opioid safety, overdose, and the availability of naloxone.

www.bmc.org/moon-study.htm



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Annals of Internal Medicine

ORIGINAL RESEARCH

Nonrandomized Intervention Study of Naloxone Coprescription for Primary Care Patients Receiving Long-Term Opioid Therapy for Pain

Phillip O. Coffin, MD, MIA; Emily Behar, MA; Christopher Rowe, MPH; Glenn-Milo Santos, PhD, MPH; Diana Coffa, MD; Matthew Bald, MD; and Eric Vittinghoff, PhD

- **Objective:** To evaluate the feasibility and effect of implementing naloxone prescription to patients prescribed opioids for chronic pain at 6 safety-net primary care clinics
- **Results**
  - 38% of 1985 patients receiving long term opioids co-prescribed naloxone rescue kits
    - Patients with higher opioid doses and previous opioid-related ED visits were more likely to be prescribed naloxone kits
  - Opioid-related ED visits were reduced by 47% at 6 months and 63% at 12 months among those who were co-prescribed naloxone, compared with those who were not
  - No change was detected in the net prescribed opioid doses for patients who were co-prescribed naloxone

Coffin PO, et al. Nonrandomized intervention study of naloxone coprescription for primary care patient receiving long-term opioid therapy for pain. *Ann Intern Med* 2016; 1-8.

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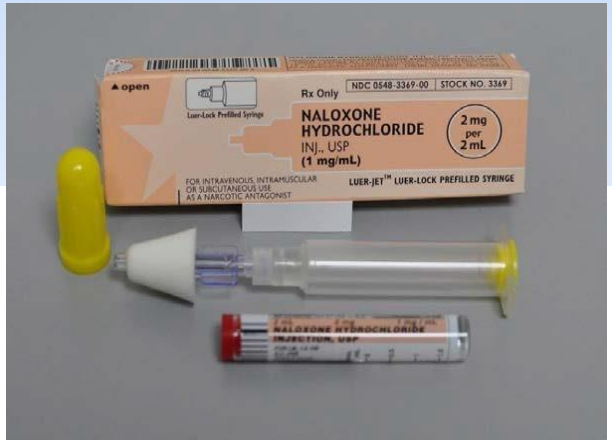
Naloxone formulations



Nasal with atomizer
"Multi-step"*
1 dose = **2mg/2ml**
IN
$$

NEW: Nasal Spray
"Single-Step"
1 dose = **4mg/0.1ml** IN
$$

Auto-injector*

1 dose = **0.4mg/1ml** IM
$$$$

Intramuscular Injection
1 dose = **0.4mg/1ml** IM
$

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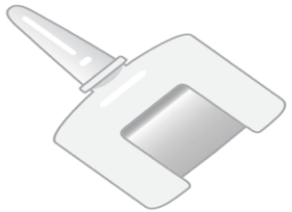
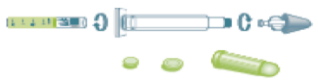
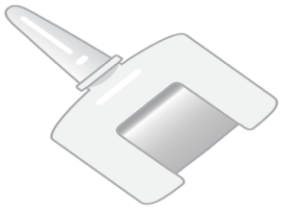
	Injectable (and intranasal- IN) generic[1]	Intranasal branded[2]	Injectable generic[3]	Injectable generic	Auto-injector branded
Brand name		Narcan Nasal Spray			Evzio Auto-Injector
Product comparison					
					
FDA approved Labeling includes instructions for layperson use	X (for IV, IM, SC)	X X	X	X	X X
Layperson experience	X		X		X
Assembly required	X		X	X	
Fragile	X				
Can titrate dose	X		X	X	
Strength	1 mg/mL	4 mg/0.1 mL	0.4 mg/mL OR 4 mg/10 mL	0.4 mg/mL	0.4 mg/0.4mL
Total volume of kit/package	4 mg/4 mL	8 mg/ 0.2 mL	0.8 mg/2 mL OR 4 mg/10 mL	0.8 mg/2 mL	0.8 mg/0.8 mL
Storage requirements (All protect from light)	Store at 59-86 °F Fragile: Glass.	Store at 59-77 °F Excursions from 39-104 °F	Store at 68-77 °F Breakable: Glass.	Store at 68-77 °F Breakable: Glass.	Store at 59-77 °F Excursions from 39-104 °F
Cost/kit[4]	$$	$$	$	$	$$$[5]

	Injectable (and intranasal- IN) generic[1]	Intranasal branded[2]	Injectable generic[3]	Injectable generic	Auto-injector branded
Brand name		Narcan Nasal Spray			Evzio Auto-Injector
Product comparison					
					
Prescription variation					
Refills	Two	Two	Two	Two	Two
Rx and quantity	#2 2 mL Luer-Jet™ Luer-Lock needleless syringe plus #2 mucosal atomizer devices (MAD-300)	#1 two-pack of two 4 mg/0.1 mL intranasal devices	#2 single-use 1 mL vials OR #1 10mL multidose vial PLUS #2 3 mL syringe w/ 23-25 gauge 1-1.5 inch IM needles	#2 single-use 1 ml vials PLUS #2 3 mL syringe w/ 23-25 gauge 1-1.5 inch IM needles	#1 two-pack of two 0.4 mg/0.4 mL prefilled auto-injector devices
Sig. (for suspected opioid overdose)	Spray 1 ml (1/2 of syringe) into each nostril. Repeat after 2-3 minutes if no or minimal response.	Spray 0.1 mL into one nostril. Repeat with second device into other nostril after 2-3 minutes if no or minimal response.	Inject 1 mL in shoulder or thigh. Repeat after 2-3 minutes if no or minimal response.	Inject 1 mL in shoulder or thigh. Repeat after 2-3 minutes if no or minimal response.	Inject into outer thigh as directed by English voice-prompt system. Place black side firmly on outer thigh and depress and hold for 5 seconds. Repeat with second device in 2-3 minutes if no or minimal response.
Ordering information					
How supplied	Box of 10 Luer-Jet™ prefilled glass syringes	Two-pack of single use intranasal devices	Box of 10 single-dose fliptop vials (1 ml) OR Case of 25 multi-dose fliptop vials (10 ml)	Box of 10 single-dose fliptop vials	Two pack of single use auto-injectors + 1 trainer
Web address	Amphastar.com / Teleflex.com	Narcannasalspray.com	Hospira.com	Mylan.com	Evzio.com

Active overdose prevention advocacy efforts

- Pharmacy access to naloxone rescue kit
- Insurance coverage for naloxone rescue kits regardless of opioid using status
- Integrating naloxone training into Basic Life Support education
- Integration of addiction treatment and harm reduction education into the curriculum
- Safe spaces, drug consumption rooms, supervised infection facilities, heroin maintenance

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Law that limits liability and promotes help-seeking, third party prescribing
Massachusetts - August 2012:

Good Samaritan provision:

•Protects people who overdose or seek help for someone overdosing from being charged or prosecuted for drug possession

- Protection does not extend to trafficking or distribution charges

Patient protection:

•A person acting in good faith may *receive a naloxone prescription, possess naloxone and administer naloxone* to an individual appearing to experience an opiate-related overdose.

Prescriber protection:

•Naloxone or other opioid antagonist *may lawfully be prescribed and dispensed to a person at risk of experiencing an opiate-related overdose or a family member, friend or other person* in a position to assist a person at risk of experiencing an opiate-related overdose. For purposes of this chapter and chapter 112, any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

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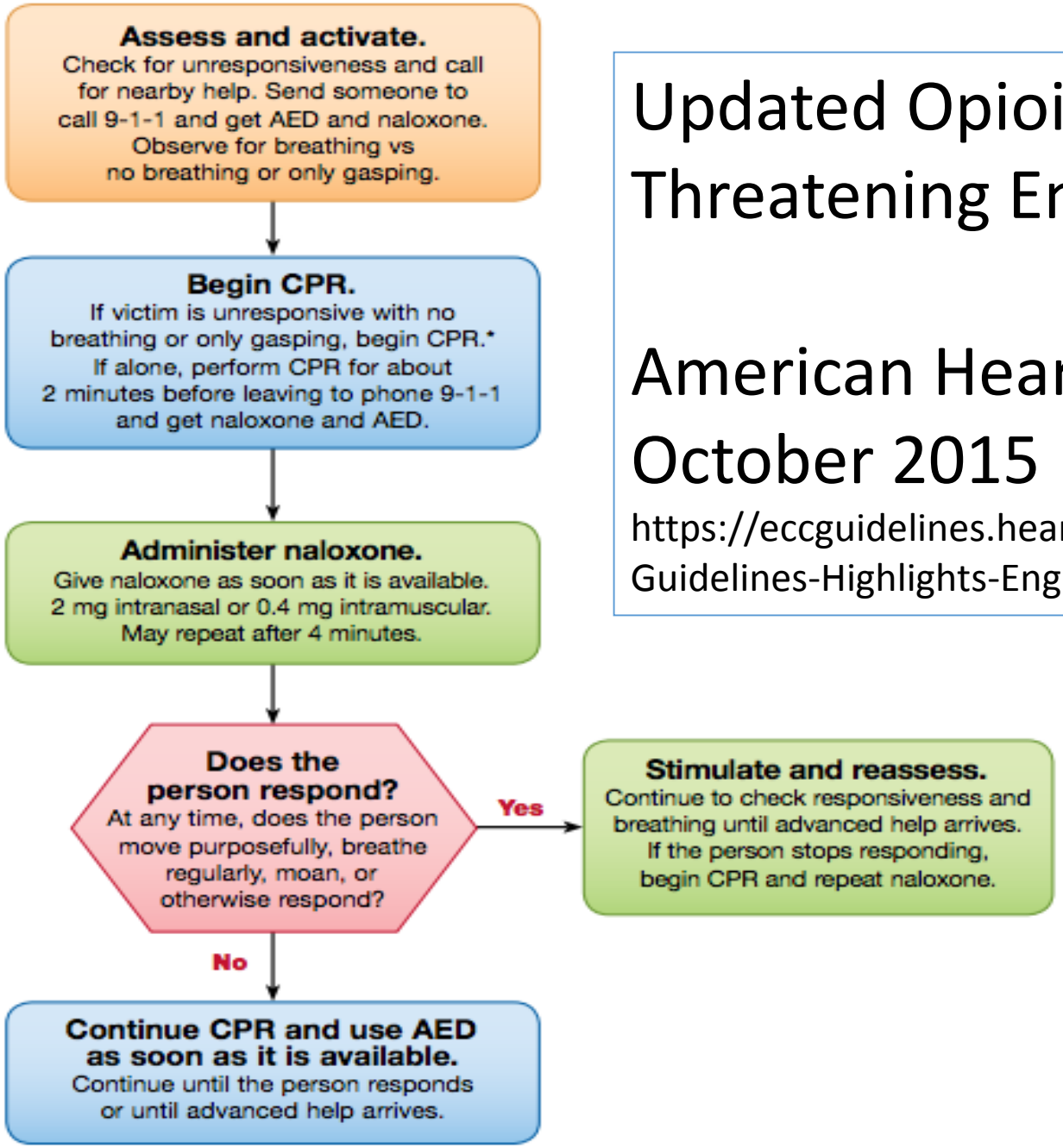

Updated Opioid-Associated Life Threatening Emergency (ADULT) Algorithm

American Heart Association Guidelines October 2015

https://eccguidelines.heart.org/wp-content/uploads/2015/10/2015-AHA-Guidelines-Highlights-English.pdf

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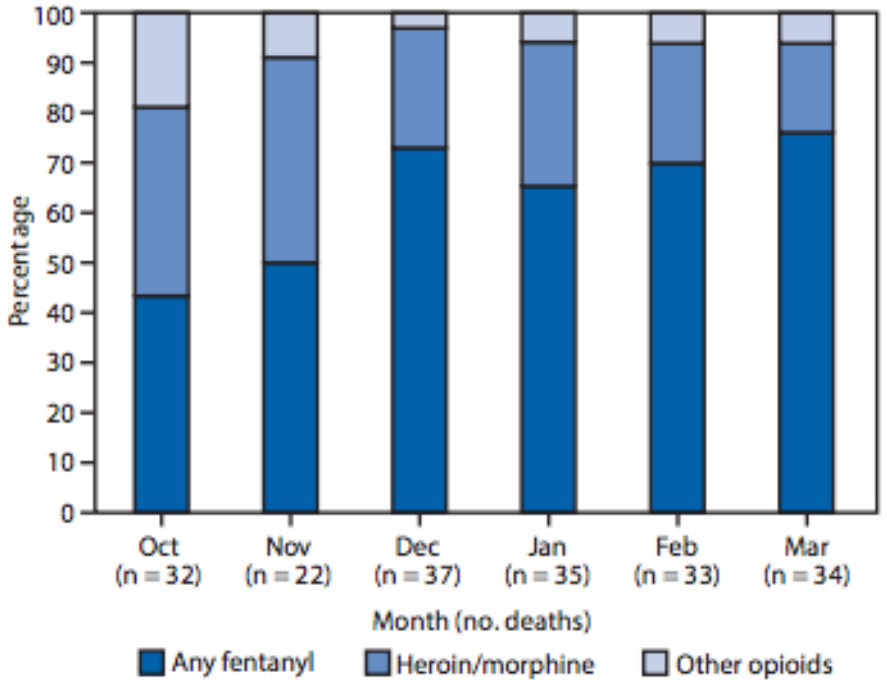
Morbidity and Mortality Weekly Report

Characteristics of Fentanyl Overdose — Massachusetts, 2014–2016

Nicholas J. Somerville, MD[1,2]; Julie O'Donnell, PhD[1,3]; R. Matthew Gladden, PhD[4]; Jon E. Zibbell, PhD[4]; Traci C. Green, PhD[5]; Morgan Younkin, MD[6]; Sarah Ruiz, MSW[2]; Hermik Babakhanlou-Chase, MPH[2]; Miranda Chan, MPH[2]; Barry P. Callis, MSW[2]; Janet Kuramoto-Crawford, PhD[1]; Henry M. Nields, MD, PhD[7]; Alexander Y. Walley, MD[2,5]

CDC-Mass DPH mixed methods investigation that included death record reviews and qualitative interviews with people who use opioids and had either witnessed or survived an overdose

FIGURE. Percentage of opioid overdose deaths involving fentanyl, heroin/morphine (without fentanyl), and other opioids (without fentanyl, heroin/morphine) — Barnstable, Bristol, and Plymouth counties, Massachusetts, October 2014–March 2015



Illicitly manufactured fentanyl (IMF) responsible for opioid overdose deaths

"So, now what they [people selling illicit drugs] are doing is they're cutting the heroin with the fentanyl to make it stronger. And the dope [heroin] is so strong with the fentanyl in it, that you get the whole dose of the fentanyl at once rather than being time-released [like the patch]. And that's why people are dying—plain and simple. You know, they [people using illicit drugs] are doing the whole bag [of heroin mixed with fentanyl] and they don't realize that they can't handle it; their body can't handle it."

Overdoses involving IMF are acute and rapid

"A person overdosing on regular dope [heroin] leans back and drops and then suddenly stops talking in a middle of a conversation and you look over and realize that they're overdosing. Not like with fentanyl. I would say you notice it [a fentanyl overdose] as soon as they are done [injecting the fentanyl]. They don't even have time to pull the needle out [of their body] and they're on the ground."

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Naloxone reverses overdoses involving IMF; multiple doses often required

"So he put half [one dose] up one nose [nostril] and half [one dose] up the other nose, like they trained us to do, and she didn't come to. So he put water on her face and kind of slapped her, which doesn't really make you come to [regain consciousness]. It doesn't. So he pulled out another thing of Narcan [brand of naloxone] and he put half of it [another dose] up one nose and then she came to…She just didn't remember anything. She said, 'What happened? I remember washing my hands and, like, what happened?' We said, 'You just overdosed in this room!' So yeah, it was wicked scary."

Self-protective measures often employed

"Like I will do a very, very, very little bit of fentanyl…and if I don't feel it, I will do that little bit plus half. I'm just not going to throw the whole thing in the cooker and then do it, no way. I just know better."

Co-use of opioids and benzodiazepines

"My daughter's mother had benzos. And when she did one bag of heroin she already had done four or five Klonopin [brand of clonazepam] and she just died. That was it. She went into a coma for the night and she was dead in the morning."

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Morbidity and Mortality Weekly Report

Characteristics of Fentanyl Overdose — Massachusetts, 2014–2016

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A comprehensive public health response to address overdoses related to IMF

1. Fentanyl should be included on standard toxicology screens
2. Adapt existing harm reduction strategies, such as direct observation of anyone using illicit opioids, ensuring bystanders are equipped with naloxone
3. Enhanced access and linkage to medication for opioid use disorders

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Overdose Education and Naloxone Rescue

What people need to know:

1.Prevention - the risks:

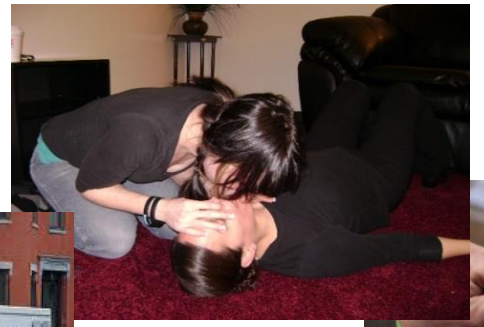
- Mixing substances
- Abstinence- low tolerance
- Using alone
- Unknown source
- Chronic medical disease
- Long acting opioids last longer

2.Recognition

- Unresponsive to sternal rub with slowed breathing
- Blue lips, pinpoint pupils

3.Response - What to do

- Call for help
- Rescue breathe
- Administer naloxone, continue breathing
- Recovery position
- Stay until help arrives



PRESCRIBE TO PREVENT

[Patient education videos and materials at prescribetoprevent.org](prescribetoprevent.org)

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David Satcher, Surgeon General 2000

After reviewing all of the research to date, the senior scientists of the Department and I have unanimously agreed that there is conclusive scientific evidence that **syringe exchange programs**, as part of a comprehensive HIV prevention strategy, **are an effective public health intervention that reduces the transmission of HIV and does not encourage the use of illegal drugs.** In many cases, a **decrease in injection frequency** has been observed among those attending these programs. In addition, when properly structured, syringe exchange programs provide a unique opportunity for communities to reach out to the active drug injecting population and **provide for the referral and retention of individuals in local substance abuse treatment and counseling programs** and other important health services.

- www.csam-asam.org/evidence-based-findings-efficacy-syringe-exchange-programs-analysis-scientific-research-completed-ap

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