Overdose education and naloxone rescue kits in Massachusetts

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Disclosures –
Alexander Y. Walley, MD, MSc

• The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:
  – Consultant for Social Sciences Innovation Corp. which is developing a training module for first responders

• My presentation will include discussion of “off-label” use of the following:
  – Naloxone is FDA approved as an opioid antagonist
  – Naloxone delivered as an intranasal spray with a mucosal atomizer device has not been FDA approved and is off label use

• Funding: CDC National Center for Injury Prevention and Control 1R21CE001602-01
Learning objectives

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

1. Describe the epidemiology of overdose
2. Know the rationale for naloxone rescue kits and how they have been implemented
3. Integrate overdose prevention and naloxone rescue kits into medical settings
More Opioid Overdose Deaths than MVA Deaths in Massachusetts


The source of the data is: Registry of Vital Records and Statistics, MA Department of Public Health
More Opioid Overdose Deaths than MVA Deaths in Massachusetts


Rate of opioid-related fatal overdoses in MA in 2006 was 9.9 per 100K

The source of the data is: Registry of Vital Records and Statistics, MA Department of Public Health.
CHAPTER 4: BREAK THE CYCLE OF DRUG USE, CRIME, DELINQUENCY, AND INCARCERATION

Advocate for Action: Lieutenant Detective Patrick Glynn

With the implementation of the Overdose Education and Naloxone Distribution program by the Massachusetts Department of Public Health Bureau of Substance Abuse Services, the Commonwealth has become a nationwide leader in overdose education, prevention, and intervention. Lt. Det. Patrick Glynn directs the naloxone program in Quincy, Massachusetts, which is credited with reversing more than 100 potentially fatal drug overdoses—giving individuals a second chance to change their lives for the better. Lt. Det. Glynn is a staunch advocate for wider adoption of the program after all Quincy law enforcement officers were trained in 2010 to use naloxone to reverse opioid overdoses. As many communities see increased rates of heroin abuse, younger ages of initiation, and continuing challenges related to opioid pain reliever abuse, it is increasingly important to spread awareness that overdoses can be prevented and that simple-to-use medicines are available to reverse overdoses. Overdose education and naloxone availability are important parts of our efforts to decrease abuse of opiates (pharmaceutical or heroin) and save lives. As Lt. Det. Glynn has stated:

I believe we have spread the word that no one should fear calling the police for assistance and that the act of life is just a 911 call away. We have also reinforced with the community that the monster is not in the cruise but indeed the officer represents a chance at life.

Det. Glynn exemplifies how the law enforcement and public health communities can partner to reduce drug use and save lives.

D. Equip Health Care Providers and First Responders To Recognize and Manage Overdoses

In 2012, the FDA, NIDA, SAMHSA, and the Centers for Disease Control and Prevention (CDC) worked together to develop approaches to reduce opioid overdose fatalities and identify issues related to more widespread availability of and access to naloxone. A detailed discussion of the Administration’s overdose prevention and intervention efforts is included under “Policy Focus: Preventing Prescription Drug Abuse.”
Consider prescribing naloxone along with the patient’s initial opioid prescription.

store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742

...you may wish to encourage the prescription of naloxone, a non-abusable, short-term antidote to opioid overdose, to high risk individuals...

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

Adopted by ASAM Board of Directors April 2010

• “ASAM supports the increased use of naloxone in cases of unintentional opioid overdose, in light of the fact that 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
About Naloxone

- Naloxone reverses opioid-related sedation and respiratory depression = pure opioid antagonist
  - Not psychoactive, no abuse potential
  - May cause withdrawal symptoms
- May be administered IM, IV, SC, IN
- Acts within 2 to 8 minutes
- Lasts 30 to 90 minutes, overdose may return
- May be repeated
- Narcan® = naloxone
Rationale for overdose education and naloxone rescue kits

PREVENT:
• Known risk factors:
  – Mixing substances, abstinence, using alone, unknown source, co-morbidity

RECOGNIZE:
• Most opioid users do not use alone
• Bystanders are trainable to recognize and respond to overdoses

RESPOND:
• Opportunity window:
  – Opioid overdoses take minutes to hours and are reversible with naloxone
  – Rescue breathing
• Fear of public safety
Evaluations of overdose education and naloxone distribution programs

- **Feasibility**
  - Piper et al. Subst Use Misuse 2008; 43; 858-70
  - Enteen et al. J Urban Health 2010: 87; 931-41
  - Walley et al. JSAT 2013; 44:241-7 (Methadone and detox programs)

- **Increased knowledge and skills**
  - Green et al. Addiction 2008: 103; 979-89

- **No increase in use, increase in drug treatment**
  - Doe-Simkins et al. BMC Public Health 2014 14:297

- **Reduction in overdose in communities**
  - Maxwell et al. J Addict Dis 2006:25; 89-96
  - Walley et al. BMJ 2013; 346: f174

  - $438-$14,000 (best-worst case scenario) for every quality-adjusted life year gained
Massachusetts Department of Public Health program
MA Timeline: Key events & players

• 2000-2004: underground user networks
• 2005: 2 underground community based organizations
  – Boston EMTs equipped with IN via special project waiver
• 2006: underground suspended >> incorporated, 2 city governments
• 2007: city, state government, CBOs
• 2009: expansion to more CBOs and outreach
• 2010: first responders – police and fire and Basic EMTs
• 2011: parents organizations
• 2012: legislature passed good sam and limited liability protection
• 2014: Governor declares public health crisis – further removes barriers to first responders and facilitates pharmacy standing orders
Implementing the Massachusetts public health pilot: December 2007

- Pilot program conducted under DPH/Drug Control Program regulations (M.G.L. c.94C & 105 CMR 700.000)
- Medical Director issues standing order for distribution
- Naloxone may be distributed by public health workers
Massachusetts DPH standing order

- Authorizes Registered Programs to maintain supplies of nasal naloxone kits
- Authorizes Approved Opioid Overdose Trainers to possess and distribute nasal naloxone to approved responders
- Authorizes Approved Opioid Overdose Responders who are trained by Approved Opioid Overdose Trainers to possess and administer naloxone to a person experiencing an overdose
Program Components

- Approved staff enroll people in the program and distribute naloxone
- Curriculum delivers education on OD prevention, recognition, and response
- Referral to treatment available
- Reports on overdose reversals are collected as enrollees return for refills
- Enrollment and refill forms submitted to MDPH
- Kits include instructions and 2 doses
Staff Training and Support

Staff complete:

- 2 hour didactic training
- At least 4 supervised bystander training sessions

Sites participate in:

- Quarterly all-site meetings
- Monthly adverse event phone conferences
Mass DPH Community Program Enrollments and Rescues: 2006-2013

• **Enrollments**
  – >22,000 individuals
  – 17 per day

• **Rescues**
  o >2,600 reported
  o 2.4 per day

- AIDS Action Committee
- AIDS Project Worcester
- AIDS Support Group of Cape Cod
- Brockton Area Multi-Services Inc. (BAMSI)
- Boston Public Health Commission
- Greater Lawrence Family Health Center
- Health Innovations
- Holyoke Health Center
- Learn to Cope
- Lowell House/ Lowell Community Health Center
- Manet Community Health Center
- North Suffolk Mental Health
- Seven Hills Behavioral Health
- Tapestry Health
- SPHERE
## Enrollee characteristics: 2006-2013

<table>
<thead>
<tr>
<th>Category</th>
<th>User n=15,064</th>
<th>Non-User n=7,199</th>
</tr>
</thead>
<tbody>
<tr>
<td>Witnessed overdose ever</td>
<td>74%</td>
<td>41%</td>
</tr>
<tr>
<td>Lifetime history of overdose</td>
<td>48%</td>
<td></td>
</tr>
<tr>
<td>Received naloxone ever</td>
<td>39%</td>
<td></td>
</tr>
<tr>
<td>Inpatient detox, past year</td>
<td>64%</td>
<td></td>
</tr>
<tr>
<td>Incarcerated, past year</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>Reported at least one overdose rescue</td>
<td>8.2%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

Program data
# OEND program rescues: 2006-2013

<table>
<thead>
<tr>
<th></th>
<th>Active use, in treatment, in recovery N=2,052</th>
<th>Non-User (family, friend, staff) N=195</th>
</tr>
</thead>
<tbody>
<tr>
<td>911 called or public safety present</td>
<td>33%</td>
<td>60%</td>
</tr>
<tr>
<td>Rescue breathing performed</td>
<td>33%</td>
<td>29%</td>
</tr>
<tr>
<td>Stayed until alert or help arrived</td>
<td>90%</td>
<td>93%</td>
</tr>
</tbody>
</table>

Program data
## Adverse Events:
### Aug 2006 - Dec 2013

<table>
<thead>
<tr>
<th>Event</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>16/2580</td>
<td>0.6%</td>
</tr>
<tr>
<td>Overdose requiring 3 or more doses</td>
<td>115/2414</td>
<td>5%</td>
</tr>
<tr>
<td>Recurrent overdose</td>
<td>9/2655</td>
<td>0.3%</td>
</tr>
<tr>
<td>Withdrawal symptoms after naloxone</td>
<td>340/687</td>
<td>49%</td>
</tr>
<tr>
<td>Difficulty with device</td>
<td>17/2655</td>
<td>0.6%</td>
</tr>
<tr>
<td>Negative interactions with public safety</td>
<td>171/762</td>
<td>22%</td>
</tr>
<tr>
<td>Confiscations</td>
<td>276/7357</td>
<td>4%</td>
</tr>
</tbody>
</table>

Program data
Withdrawal symptoms after naloxone

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>N=687</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>51%</td>
</tr>
<tr>
<td>Irritable or angry</td>
<td>22%</td>
</tr>
<tr>
<td>Dope sick</td>
<td>24%</td>
</tr>
<tr>
<td>Physically combative</td>
<td>3%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>11%</td>
</tr>
<tr>
<td>confused, disoriented, headache, aches and chills, cold, crying, diarrhea, happy, miserable</td>
<td></td>
</tr>
</tbody>
</table>
Objective: Determine the impact of opioid overdose education with intranasal naloxone distribution (OEND) programs on fatal and non-fatal opioid overdose rates in Massachusetts

Opioid Overdose Related Deaths: Massachusetts 2004 - 2006
Opioid Overdose Related Deaths: Massachusetts 2004 - 2006

Number of Deaths
- No Deaths
- 1 - 5
- 6 - 15
- 16 - 30
- 30+

OEND programs
- 2006-07
- 2007-08
Opioid Overdose Related Deaths: Massachusetts 2004 - 2006

Number of Deaths
- No Deaths
- 1 - 5
- 6 - 15
- 16 - 30
- 30+

OEND programs
- 2006-07
- 2007-08
- 2009
Opioid Overdose Related Deaths: Massachusetts 2004 - 2006

Number of Deaths
- No Deaths
- 1 - 5
- 6 - 15
- 16 - 30
- 30+

OEND programs
- 2006-07
- 2007-08
- 2009
- Towns without
### Fatal opioid OD rates by OEND implementation

<table>
<thead>
<tr>
<th>Cumulative enrollments per 100k</th>
<th>RR</th>
<th>ARR*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute model:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No enrollment</td>
<td>Ref</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>Low implementation: 1-100</td>
<td>0.93</td>
<td>0.73</td>
<td>0.57-0.91</td>
</tr>
<tr>
<td>High implementation: &gt; 100</td>
<td>0.82</td>
<td>0.54</td>
<td>0.39-0.76</td>
</tr>
</tbody>
</table>

* Adjusted Rate Ratios (ARR) All rate ratios adjusted for the city/town population rates of age under 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, and year

Fatal opioid OD rates by OEND implementation

Naloxone coverage per 100K

Opioid overdose death rate

# Opioid-related ED visits and hospitalization rates by OEND implementation

<table>
<thead>
<tr>
<th>Cumulative enrollments per 100k</th>
<th>RR</th>
<th>ARR*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute model:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No enrollment</td>
<td>Ref</td>
<td>Ref</td>
<td>Ref</td>
</tr>
<tr>
<td>Low implementation: 1-100</td>
<td>1.00</td>
<td>0.93</td>
<td>0.80-1.08</td>
</tr>
<tr>
<td>High implementation: &gt; 100</td>
<td>1.06</td>
<td>0.92</td>
<td>0.75-1.13</td>
</tr>
</tbody>
</table>

* Adjusted Rate Ratios (ARR) All rate ratios adjusted for the city/town population rates of age under 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, and year

INPEDE OD Study

Summary

1. Fatal OD rates were decreased in MA cities-towns where OEND was implemented and the more enrollment the lower the reduction

2. No clear impact on acute care utilization
Venues and Models
Enrollment locations: 2008-2013

Data from people with location reported: Users: 13,775  Non-Users: 6,618
Massachusetts - Passed in August 2012:
An Act Relative to Sentencing and Improving Law Enforcement Tools

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.
States with naloxone laws - 2014

Network for Public Health Law
www.networkforphl.org
March 27, 2014

- The Governor’s Public Health Emergency declaration provided emergency powers to DPH Commissioner Cheryl Bartlett, RN. At the Governor’s direction, the Public Health Council passed a regulation that:

  - Universally permit first responders to carry and administer Naloxone (Narcan), a safe and effective opioid antagonist that, when timely administered, can reverse an overdose and save a life.

  - Naloxone will also be made widely available through standing order prescription in pharmacies in order to provide greater access to family and friends who fear a loved one might overdose.
# Police and Fire naloxone rescues in Massachusetts 2010-2013

<table>
<thead>
<tr>
<th>Town</th>
<th>Rescues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quincy Police start 2010</td>
<td>203</td>
</tr>
<tr>
<td>Revere Fire start 2010</td>
<td>114</td>
</tr>
<tr>
<td>Gloucester Police + Fire start 2011</td>
<td>4</td>
</tr>
<tr>
<td>Weymouth Fire start 2013</td>
<td>50</td>
</tr>
<tr>
<td>Saugus Fire start 2013</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>381</strong></td>
</tr>
</tbody>
</table>

Why does Gloucester have so few rescues?

- Their EMS is fire department-based and has short response times.
- EMS usually arrives first.
Other venues and models

- Emergency Department SBIRT
- Post-incarceration
- Prescription naloxone
  - Prescribetoprevent.org

Binswanger et al. NEJM 2007
How do you incorporate overdose education and naloxone rescue kits into medical practice?

1. Prescribe naloxone rescue kits
   • PrescribeToPrevent.org

2. Work with your OEND program
Implementing OEND in MMT and detox

<table>
<thead>
<tr>
<th>Model</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Staff provide OEND on-site</td>
<td>• Good access to OEND</td>
<td>• Patients may not disclose risk</td>
</tr>
<tr>
<td></td>
<td>• OD prevention integrated</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Outside staff provide OEND on-site</td>
<td>• OD prevention integrated</td>
<td>• Community OEND program needed</td>
</tr>
<tr>
<td></td>
<td>• Interagency cooperation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low burden on staff</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. OE provided onsite, naloxone received off-site</td>
<td>• OD prevention integrated</td>
<td>• Increased patient burden to get naloxone</td>
</tr>
<tr>
<td></td>
<td>• Interagency cooperation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Outside staff recruit near MMT or detox</td>
<td>• Confidential access to OD prevention</td>
<td>• OD prevention not re-enforced in treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Not all patients reached</td>
</tr>
</tbody>
</table>

**Don’t forget the staff:** Among 29 MMT and 93 detox staff who received OEND, 38% and 45% respectively reported witnessing and overdose in their lifetime.

Practical Barriers to Prescribing Naloxone

1. Prescriber knowledge and comfort
2. How to write the prescription?
3. Does the pharmacy stock rescue kits?
   - Rescue IN kit with MAD?
     - Walgreens, CVS coming soon
   - Rescue IM kit with needle?
4. Who pays for it?
   - Insurance in Massachusetts covers intranasal kits
   - The MAD costs $3 each>> $6-7 per kit
   - Work with your pharmacy to see if they will cover it for your patient
Legal Barriers to Prescription Model

“Prescribing naloxone in the USA is fully consistent with state and federal laws regulating drug prescribing. The risks of malpractice liability are consistent with those generally associated with providing healthcare, and can be further minimized by following simple guidelines presented.”

1. Only prescribe to a person who is at risk for overdose
2. Ensure that the patient is properly instructed in the administration and risks of naloxone