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- A series focused on providing substantive knowledge on important issues in public health law
  - May qualify for CLE credits, details will be sent after the webinar
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  - Including public health lawyers, officials, practitioners, policy-makers, advocates and more
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U.S. Community-based naloxone programs

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Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
U.S. Community-based naloxone programs

Overview

- History and current state of community-based naloxone programs
- Existing program models
- Program snapshots: San Francisco and Massachusetts
- New developments, issues and considerations, and next steps
U.S. Community-based naloxone programs

- Originated in needle exchange and harm reduction programs as an extension of services for injection drug users
- Earliest take-home naloxone efforts in Chicago, 1996.
- Principles and beliefs of the first OD/naloxone programs:
  - Overdose deaths are preventable, there is often a window of opportunity to reverse the overdose
  - Drug users are logical first responders, and are willing and capable of responding to ODs
  - There are very real social and legal barriers to accessing EMS
  - Putting naloxone into the hands of drug users is both empowering and life-saving
U.S. Community-based naloxone programs

Overdose prevention programs: US

- CDC MMWR based on survey of programs known to the Harm Reduction Coalition, October 2010
- As of 2010, there were 48 known programs, representing 188 community-based sites in 15 states and DC.

From 1996 to June 2010:
- 53,032 individuals have been trained in naloxone administration and overdose response
- 10,171 overdose reversals reported
- Majority of take-home naloxone programs are located at needle exchanges in the US
- Majority of individuals trained are drug users

CDC MMWR February 17, 2012  http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6106a1.htm
FIGURE 2. Number (N = 188) and location* of local drug overdose prevention programs providing naloxone in 2010 and age-adjusted rates† of drug overdose deaths§ in 2008 — United States

* Not shown in states with fewer than three local programs.
† Per 100,000 population.
U.S. Community-based naloxone programs

MMWR:

- 38,860 doses of naloxone were distributed by programs in the year prior to the survey
- 87.5% of programs distribute parenteral naloxone (delivered by intramuscular injection)
- 8.3% of programs provide only intranasal naloxone
- 4.2% of programs provide both intranasal and parenteral naloxone
U.S. Community-based naloxone programs

Program Models

- State or City Public Health Department fund and have a role in administering the naloxone program
  - i.e. Massachusetts, New York, Washington, New Mexico, Ohio, San Francisco, Baltimore

- Non-profit CBO provides overdose prevention services and access to naloxone w/out state or city involvement using non-governmental grants
  - i.e. Pennsylvania, Connecticut, Michigan, Wisconsin, Colorado

- Naloxone is prescribed during a visit with a care provider and filled at a pharmacy or dispensed during the visit:
  - i.e. Project Lazarus, Duquesne University pilot
U.S. Community-based naloxone programs

Program Models

- Medical personnel are involved directly
  - Programs that have an advanced practice nurse or physician present when naloxone is distributed to “sign-off” on prescriptions, trainings done by non-medical staff
- Standing order
  - Written by medical director of the program to allow distribution by trained non-medical staff
- Prescription is issued to participant and filled at a pharmacy (clinic-based naloxone prescription)
U.S. Community-based naloxone programs

Program Snapshot: DOPE Project, San Francisco

- Funded by the San Francisco Department of Public Health since 2000, currently at $73K per year.
- In 2000, started teaching rescue breathing and calling 911, in addition to overdose prevention strategies (no naloxone).
- Began distributing naloxone in 2003 under the supervision of nurse practitioners who worked under Medical Director Dr. Joshua Bamberger. NPs were present while naloxone trainings happened, signed off on prescriptions while DOPE staff did the trainings.
- In May 2010, DOPE began distributing intranasal naloxone under standing orders.
- Provide access to naloxone at all SF needle exchange programs and sites, methadone maintenance programs and other community-based programs.

Over 3,400 trained, over 5,540 kits distributed
As of June 2012, 782 reported reversals
Heroin-related deaths, San Francisco 1993-2010

Naloxone distribution begins, 2003

*Data compiled from San Francisco Medical Examiner's Reports, www.sfgsa.org

**No data available for FY 2000-2001
Program Snapshot: Massachusetts OEND

- Model state-wide naloxone distribution program
- Standing order, works from State DPH regulation
- All programs receive their naloxone from MDPH for distribution
- Integrated into treatment, corrections, parents groups, SBIRT, HIV prevention, etc.
- Excellent data collection system
- Collaboration between BSAS and OHA
- SAMHSA’s CSAP grant to BSAS for MASSCALL2 programs in 15 communities with high overdose burden to implement opioid overdose prevention strategies
- Training and equipping BLS, Fire and law enforcement with naloxone
Enrollments and Rescues: 2006-2012

- **Enrollments**
  - 12,367 individuals
  - 300 per month

- **Rescues**
  - 1301 reported
  - 30 per month

- AIDS Project Worcester
- AIDS Support Group of Cape Cod
- Brockton Area Multi-Services Inc. (BAMSI)
- Bay State Community Services
- Boston Public Health Commission
- Northeast Behavioral Health
- Cambridge Cares About AIDS
- Greater Lawrence Family Health Center
- Holyoke Health Center
- Learn to Cope
- Lowell Community Health Center
- Seven Hills Behavioral Health
- Tapestry Health
- SPHERE
Enrollment locations: 2008-present

- Detox
- Syringe Access
- Drop-In Center
- Community Meeting
- Other SA Treatment
- Methadone Clinic
- Inpatient/ ED/ Outpatient
- Home Visit/ Shelter/ Street Outreach

Number enrolled:
- Using, In Treatment, or In Recovery
- Non Users (family, friends, staff)

Program data

Data from people with location reported: Users: 7,220  Non-Users: 3,522
U.S. Community-based naloxone programs

New Developments:

- Increased media attention
- Buy-in from federal and (select) state, county and local agencies
- Increase in opioid analgesic (prescription drug) deaths
- Naloxone distribution in urban areas targeting solely injectors is not meeting national need
- Ft Bragg Army base, Operation OPIOIDSafe
- UN Commission on Narcotic Drugs passed Overdose Resolution
- Primary care, pain management and pharmacy-based naloxone prescription programs are evolving
- New programs in Denver, Seattle, Ohio, Redding and Humboldt, CA
Kits Using Naloxone Revive Addicts After Opiate Overdose

BY JACQUE HOFFMAN

Next to car crashes, opiate overdoses are the leading cause of accidental death in the United States. In Europe, a lethal overdose occurs every four hours.

In poorer countries the problem is harder to measure, but in some places it is most likely even worse.

When a person overdoses on opiate, his breathing becomes shallow and may eventually stop. Friends may be afraid to call an ambulance for fear of arrest. In remote areas, an ambulance may come too late, after oxygen deprivation has caused brain damage or death.

Yet naloxone, a medicine that blocks opiate receptors, can revive even the most comatose drug user. Used for decades by surgeons and paramedics, the drug has been shown to work when administered by bystanders in American cities.

Recently groups in Eastern Europe and Central Asia have been distributing "overdose rescue kits," which usually contain two doses of naloxone and two syringes. These groups operate in a legal gray area by training addicts and their families to administer the drug themselves in the event of an overdose.

Aside from saving lives, the kits give addicts a reason to return to treatment centers, where they may receive HIV testing or counseling.

In China, hot line operators dispatch rescue kits via motorcycle to desperate callers. In Afghanistan, an overdose rescue program relies on the same "dialled injectors" whom addicts pay to shoot them up with heroin.

New Pilot Nasal Mist Program To Stop Drug Overdoses In Ohio

PORTSMOUTH, Oh. (SWAZI) -- In 2010, four Ohioans died of an unintentional drug overdose every single day.

In Portsmouth, Ohio the health department is spearheading a statewide pilot program to help prevent accidental opiate deaths.

The key is in a nasal spray.

"87% of the time, in Scioto County, the people who died of fatal overdose had someone with them who witnessed it," Lisa Roberts with the Portsmouth City Health Department said. "In rural counties, it takes a very long time for the ambulance to get there, about 20 minutes, so in that time, it's too late."

The pilot program is called PROJECT DAWN. It's named overdose two years ago.

DAWN stands for D-aths A-voided W-ith N-aloxone

The drug, being administered in the nasal spray, is Naloxone health department.

Naloxone is a liquid prescription medication that works to it works by removing the drug from the receptors in the brain opiate drug, including life threatening symptoms such as rc abuse and no other usage except for opiate receptor bloc

A Lifesaving Overdose Antidote Should Be Made More Widely Available

A new CDC report finds that naloxone, a drug that reverses overdose, could save thousands of lives if public health agencies distributed it more broadly

By MAIA SZALAVITZ | @maiasz | February 17, 2012 | 5
U.S. Community-based naloxone programs

Federal Agency Involvement

- SAMHSA creating Overdose Prevention Tool Kit for OTPs
- MMWR on OD/naloxone programs
- FDA workshop, April 2012 and follow-up calls about drug shortages with naloxone advocates
- “Dear Colleague” letter from Rep. Mary Bono Mack (R-CA) to HHS demanding national OD prevention campaign, including naloxone, July 2012
- NIDA just recently funded the first R01 to include naloxone prospectively (WA).
- ONDCP Meetings and 2012 Drug Strategy, ONDCP Director Gil Kerlikowske visited Project Lazarus
- American Medical Association (AMA) resolution supporting naloxone distribution
U.S. Community-based naloxone programs

Issues and Considerations

- Prescription status of naloxone is still a barrier (esp regarding 3rd party administration)
- Lack of designated funding streams to support existing naloxone distribution programs
- Drug shortage and price increases
- Difficulty in implementing naloxone prescription due to multiple players that must coordinate, billing, etc.
U.S. Community-based naloxone programs

Next Steps

- Implement naloxone co-prescription pilots
- Integrate OD Prevention into drug treatment programs
- Improve overdose surveillance
- Gather more information about prescription drug users to help design meaningful interventions
- Evaluate efficacy of naloxone co-prescription (naloxone distribution programs have already been shown to be efficacious)
U.S. Community-based naloxone programs

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Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
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Objectives

- Provide an overview of legal and regulatory barriers to naloxone access
- Describe legal/regulatory interventions to reduce opioid overdose death via
  - Increased access to naloxone (“naloxone access laws”)
  - Increased access to emergency responders (“Good Samaritan laws”)
- Highlight promising legal and regulatory strategies
Naloxone Access: Legal and Regulatory Considerations

Overview

- Fatal opioid overdose is at epidemic levels

- Opioid overdose death is largely preventable
  - Long period in which reversal is possible
  - Reversal easily accomplished w/ naloxone

- Law and regulation are a barrier to naloxone access

- Amending law and regulation to improve naloxone access is likely an extraordinarily effective and cost-effective intervention
Naloxone Access: Legal and Regulatory Considerations

Law as barrier to naloxone access

- **Barrier 1: Civil/Regulatory**
  - Naloxone is a prescription drug
    - Not a controlled substance
  - Need someone with prescribing power
    - Prescribers are in short supply
  - Need to comply with state practice laws
    - In general, prescriber and patient must be in same place at same time
    - In general, cannot prescribe to 3rd party
Law as barrier to naloxone access

- Barrier 1: Civil/Regulatory
  - Prescriber concerns re: civil liability
    - Particularly where ordinary standard of care not followed
  - Samaritan concerns re: civil liability
    - Many existing state Good Samaritan laws provide some protection
- Price and availability concerns
Law as barrier to naloxone access

- Barrier 2: Criminal
  - Bystanders w/ naloxone may fear criminal sanctions for its use
    - Unauthorized practice of medicine
    - Possession of prescription drug (naloxone) w/o prescription
  - Bystanders w/o naloxone may fear calling 911
    - Fear arrest for drug possession, outstanding warrants or other reasons
      - Lots of evidence that this fear is both real and justified
    - General fear of police and police practice
Removal of law as barrier

- All of these legal/regulatory barriers are unintended consequences of attempts to address other problems

- Unfortunately, they have an extraordinarily severe side effect: thousands of preventable deaths per year

- Luckily, they can be easily modified to remove that side effect while maintaining original intent
Naloxone Access: Legal and Regulatory Considerations

Possible solutions: Regulatory

- Make naloxone available OTC
  - Movement afoot
    - In general, time-consuming and expensive

- Ease rules regarding importation of naloxone
  - Has happened from time to time but not long-term solution

- Ensure that take-home naloxone is covered by insurance plans
  - Some movement here
Possible solutions: Access

- Remove the possibility of civil and professional penalties for prescribers and administrators acting in good faith

- Remove the possibility of criminal penalties for prescribers and administrators acting in good faith

- Explicitly endorse 3rd party prescription

- As of Oct. 15, 2012, 8 states (NM, NY, IL, WA, CA, RI, CT and MA) have explicitly amended law to increase access in these ways
Possible solutions: Good Sam

- Existing Good Samaritan laws provide protection from \textit{civil} liability
  - But overdose bystanders are mainly worried about \textit{criminal} penalties

- Enter the overdose Good Samaritan law
  - Modeled after alcohol Good Sam policies now enacted on many college campuses, as well as ‘Baby Moses’ laws

- As of Oct. 15, 2012, ten states (NM, WA, NY, CT, IL, CO, RI, FL, MA and CA) have passed overdose Good Sam laws
States w/ drug overdose Good Sam laws

Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
Discussion

- Good Sam laws in particular seem to have a lot of traction
  - First law passed by New Mexico in 2007
  - 1 in 2010 (WA), 2 in 2011 (NY, CT), 6 so far in 2012 (IL, CO, RI, FL, MA, CA)
  - Legislation pending in several other states

- Initial evidence suggests legal change -> behavior change
  - Turns out that most officers don’t actually like arresting people who call 911
  - However, serious problems with funding, lack of knowledge/education

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Naloxone Access: Legal and Regulatory Considerations

Discussion

- Other legal & regulatory changes may be worth considering
  - Standing orders for lay dispensing
  - Physician training re: pain management
  - Co-prescription as standard of care

- Also need for non-legal interventions
  - Basic research into opioid alternatives

- Need for strong evaluation, but very little downside to moving forward
Conclusion

- Common sense and emerging evidence suggest that laws that make it easier for lay people to access naloxone, administer naloxone, and summon emergency assistance in the event of overdose can save lives and resources.

- Since such laws have possibility to save thousands of lives annually and no readily apparent downside, they should be enacted widely and with haste.

- As with all policy interventions, results should be independently and rigorously evaluated.
Naloxone Access: Legal and Regulatory Considerations

Questions?

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Opioid Overdose Prevention -
Expanding access to new populations and settings

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Opioid Overdose Prevention-Expanding access to new populations and settings

Outline

- Continue community based OD education & naloxone distribution models
- Expand OD education & naloxone distribution
  - Why?
  - How?
- Increase awareness and support OD & THN
  - Working with law enforcement
  - How to frame

Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
Opioid Overdose Prevention-Expanding access to new populations and settings

OD Education & Take-Home-Naloxone Maintaining and Increasing access

Maintain, support, and expand community based education and delivery models

• Critical population, essential providers

harmreduction.org

peoplesharmreductionalliance.org

Wheeler et al. MMWR 61(06)101-105

Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
Opioid Overdose Prevention—Expanding access to new populations and settings

OD & Take-home-naloxone knowledge: Why expand?

- High Death Rate
  - Opioid overdose continues as a major cause of fatal poisonings
- Rx users infrequently addressed
  - Rx-involved deaths surpass heroin-involved deaths, yet many fewer programs address Rx
OD & Take-home-naloxone knowledge: Why expand?

- Use common outside of urban cores
  - Prior programs have focused on urban areas, but Rx is more geographically dispersed
  - Heroin use appears to be expanding geographically as well
OD & Take-home-naloxone knowledge: Why expand?

- Many who die-
  - received Rx from medical provider and/or
  - received care from a medical provider recently
    - both heroin and Rx users
- Therefore involving the medical system and providers seems appropriate
OD & Take-home-naloxone knowledge: How to increase

General awareness needed that opiate overdoses can be *prevented* and if they occur they can be *reversed* with naloxone

- National problem, need broad awareness
- Local problem, need concrete solutions
- Supply and demand need to be built

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Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
Opioid Overdose Prevention-Expanding access to new populations and settings

OD & Take-home-naloxone knowledge: How to increase

Professional and Governmental guidance/support needed
Antidote/Naloxone - Increasing access

- Medical providers can prescribe to potential overdose victims
  - and if possible to potential witnesses
    - Local laws and regulations may need changing
- Settings- Primary care, Emergency Dept, Pharmacy, Drug treatment, Jail/Prisons
  - Not all providers are aware of issue or receptive to the idea that they should be involved
Opioid Overdose Prevention—Expanding access to new populations and settings

Antidote/Naloxone - Increasing access

- Pharmacists could directly prescribe & dispense
  - Lowers $ and increases access tremendously in terms of time burden and geography
  - Collaborative practice agreement or other models

http://hopeandrecovery.org/searchbox.html
Opioid Overdose Prevention-Expanding access to new populations and settings

Antidote/Naloxone - Increasing access

- Insurance (public and private) could cover Rx costs
  - Several state’s Medicaid cover take-home-naloxone
- Overdose education and prescribing time could be reimbursed
  - SBIRT codes should allow reimbursement for prescribers’ time educating about overdose
  - Pharmacists’ time educating could be reimbursed
Antidote/Naloxone - Increasing access

- Naloxone cost issues need to be examined. Inconsistent availability and cost.
- Regulatory barriers (prescription status)
- Nasal formulation could be improve and approved.

Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
Fear of law enforcement - How to minimize

- Good Samaritan laws at State level can change practice OR perception
- Prosecutorial/Police policy at municipal level can be changed or made explicit
- Police could be trained and allowed to administer naloxone e.g. Quincy Mass
Fear of law enforcement - How to minimize

- Public health-Law enforcement need to discuss overdose as public safety issue to change practice -> perceptions -> behaviors
- Training police and public essential
  - Transparency can help build trust
  - Law enforcement is a critical partner & messenger
Framing

- Overdoses are first and foremost a medical emergency
  - Goal is to medicalize overdose and take-home naloxone by framing as injury prevention
  - This normalizes by bringing it into the mainstream
- Overdose education is critical
  - evidence that those trained often decrease overdose risk behaviors by decreasing use and seeking treatment
  - Should be framed as OD Education + Take-home naloxone
    - Potentially get better health outcomes and acceptability
Opioid Overdose Prevention—Expanding access to new populations and settings

More information

- [www.prescribetoprevent.org](http://www.prescribetoprevent.org)
- [www.stopoverdose.org](http://www.stopoverdose.org)
  Initial OD Good Sam Law evaluation supported by the *RWJF Public Health Law Research* program
- [www.harmreduction.org](http://www.harmreduction.org)
- [www.overdosepreventionalliance.org/](http://www.overdosepreventionalliance.org/)
  OD Education and THN in E.D. NIDA Study
  [http://tinyurl.com/9k8tokn](http://tinyurl.com/9k8tokn)

Take-Home Naloxone for Opioid Overdose: Exploring the Legal, Policy and Practice Landscapes
Opioid Overdose Prevention-Expanding access to new populations and settings

Question & Answer

Type your question in the Q and A panel