PARTNERING WITH PHARMACISTS: NALOXONE PRESCRIBING AND DISPENSING TO PREVENT OVERDOSE DEATHS (AOAAM)

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The overarching goal of PCSS-O is to make available the most effective substance abuse treatments to serve patients in a variety of settings, including osteopathic physicians, family practice physicians, pharmacists, and clinicians who practice in rural communities.
OBJECTIVES

- Identify the role naloxone has in opioid overdose prevention and treatment
- List three ways to best educate patients and caregivers on overdose management
- Describe the implementation of a collaborative practice agreement for naloxone (CPAN) in community pharmacies
EXISTING PARTNERSHIPS PHARMACISTS

- Prescription Monitoring Program (PMP)
- Opioid substitution therapies
  - Methadone
  - Buprenorphine
- Harm Reduction
  - New needles
  - Condoms
  - Drug testing
  - Referrals
- Dispense and counsel on prescription opioids
Fairhaven man arrested in string of pharmacy robberies

December 16, 2013 2:50 PM

FAIRHAVEN — Police seized more than 1,600 pills and $8,000 in cash from a Laurel Street residence Friday while investigating a series of 10 drug store robberies.

The robberies occurred in numerous pharmacies in several municipalities between the months of September and November, according to police. Each pharmacy received a call from an anonymous male demanding oxycodone and other opiate-based pain killers. In some cases the caller threatened to detonate a bomb in the store unless a pharmacist placed their entire inventory of painkillers in the drive-thru drawer. In other cases, the caller threatened to shoot the pharmacist.

Seattle, Washington (CNN) -- Less than two hours after picking out a man in a police lineup who held up his drugstore, pharmacist Mike Donohue was being robbed.

Again.

The new robber's face was hidden under the hood of a bulky black sweatshirt. He rocked back and forth anxiously, with his right hand planted in his pocket.
NEW YORK — A wave of pharmacy robberies is sweeping the United States as desperate addicts and ruthless dealers turn to violence to feed the nation's growing hunger for narcotic painkillers.

From Redmond, Wash., to St. Augustine, Fla., criminals are holding pharmacists at gunpoint and escaping with thousands of powerfully addictive pills that can sell for as much as $80 apiece on the street.
PHARMACIES ARE IDEAL LOCATIONS FOR PUBLIC HEALTH SERVICES

- Geography
- Hours
- Quantity
- Identity
- Marketing
- Greater access, especially vulnerable populations
Essential Services of Public Health

- Assure a competent workforce
- Evaluate health services
- Research
- Develop policies and plans
- Enforce laws and regulations
- Link people to needed services / assure care
- Monitor health status
- Diagnose and investigate
- Inform, educate, and empower
- Mobilize community partnerships
• Self-identified barriers to the provision of health-promotion and preventive services in current pharmacy practice

Six pharmacists from community- and clinic-based (HIV, substance abuse, pain) pharmacies interviewed

Seattle, Boston, Pittsburgh

Prescribers approached pharmacists

Naloxone prescribing, dispensing and billing

Public health model (no billing)

Patients targeted

- High-dose opioids for pain
- High risk of overdose from rx/heroin

EXISTING PARTNERSHIPS PHARMACISTS

- Education “paramount”
- Caregiver competency in naloxone administration undefined
- Reimbursement more difficult than provider/patient acceptance
  - Public health – grant funding
  - Clinics sometimes charged for service
  - Best practice Medicaid coverage
  - No coverage for atomizer as drug
- Prescription processing best at one pharmacy

## PHARMACIST ROLES DIFFER BY POSITION

### National
- Association leadership
- Pharmacy Benefit managers
- Corporate community pharmacy leadership
- Veteran’s Affairs

### State
- Association leadership
- Pharmacists at third-party payers
- Universities/colleges of pharmacy
- Health department

### Local
- Health department
- Hospital leadership
- Hospital pharmacy specialists (ID, pain, substance abuse, ED, psychiatric)
- Clinic pharmacists
- Veteran’s Affairs
- Community independent pharmacists/owners
- Community corporate pharmacists
UTILIZE PRESCRIBING PATHWAYS

Prescriber-Patient
- Rational opioid prescribing
- Pain contracts
- Naloxone co-prescribing
- OD education
- Addiction treatment referral
- Opioid substitution therapy
- Mental health referral
- EMR prompts / apps

Patient
Prescriber
Pharmacist
Pharmacist-Patient

- Risk recognition (PMP)
- Harm reduction
  - Replacement needles
  - OD education
  - Opioid substitution therapy
- Drug interactions
- Disease interactions
- Initiate naloxone (CPAN)
- EMR prompts / apps

UTILIZE PRESCRIBING PATHWAYS
UTILIZE PRESCRIBING PATHWAYS

Prescriber-Pharmacist
- PMP communication
- Collaborative practice agreement for naloxone (CPAN)
- Stock naloxone kits
- Collaborate
  - Insurance coverage
  - Advocacy
  - Education
  - Awareness
RI PHARMACISTS OPINIONS OF NALOXONE AND OVERDOSE

- Feasibility of pharmacy-based naloxone intervention
- 21 pharmacy staff (technicians and pharmacists) interviewed from Rhode Island
  - Independent owner (n=2)
  - Chain manager (n=4)
  - Independent community pharmacist (n=3)
  - Corporate community pharmacist (n=6)
  - Pharmacy technician (n=6)
- Pharmacy-based naloxone could dramatically increase access to this life-saving intervention
- Qualitative results presented

Pharmacists not aware of overdose prevalence

Fatal overdoses are likely intentional – technician

Pharmacists thought they stocked naloxone
  - Was naltrexone

Staff interviewed thought that naloxone would increase risk behaviors, “build up resistance” to naloxone

Overall supported the intervention

“...it’s one way to stop the cycle, even if one person out of 1000 that actually could actually help maybe prevent an OD...it would be worth it. And to be honest, I think it could be, depending on what programs, could be helpful to [employer] financially, too...” – 29 yo corporate pharmacy manager

Pharmacists interviewed compared intervention to existing antidotes dispensed

- Glucagon for families of patients with diabetes
- Epinephrine auto-injector for caregivers of allergic patients

Intervention could be de-stigmatized if naloxone provided to both injection drug and prescription opioid users
INTEGRATE NALOXONE INTO OPIOID PRESCRIBING CULTURE

- Make the public aware
  - Seatbelts
  - Fire safety
  - Helmets
- Implement best practices
  - Immunization
  - Herd immunity
  - HIV/HCV testing/screening
- Maximize technology
- Make it routine, systematic, de-stigmatized
NALOXONE: STOCKING
An ANTIDOTE for OPIOID overdose

Naloxone is an opioid receptor antagonist at mu, kappa, and delta receptors

Works at the opioid receptor to displace opioid agonists

Shows little to no agonist activity

Shows little to no pharmacological effect in patients who have not received opioids
ONSET AND DURATION OF ACTION

- Naloxone takes effect in 3 to 5 minutes
  - If patient is not responding in this time a second dose may need be administered

- Naloxone wears off in 30 to 90 minutes
  - Patients can go back into overdose if long acting opioids were taken (fentanyl, methadone, extended release morphine, extended release oxycodone)
  - Patients should avoid taking more opioids after naloxone administration so they do not go back into overdose after naloxone wears off
  - Patients may want to take more opioids during this time because they may feel withdrawal symptoms

- The shelf-life of naloxone is 12-18 months – store at room temperature to minimize degradation
## NALOXONE: STOCKING

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<tr>
<th>Admin</th>
<th>Manufacturer</th>
<th>NDC</th>
<th>Strength</th>
<th>Total volume</th>
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<td>2 mg / 2 ml</td>
<td>Box of 10 Luer-Jet™ prefilled glass syringes</td>
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<td></td>
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</tbody>
</table>
NALOXONE: STOCKING

- Most major wholesalers carry naloxone formulations
- CAUTION: Assembly prior to use
  - Do NOT draw up into syringes or screw glass vial into syringe
  - Expiration date becomes 14 days instead of date on vials
- Storage
  - IM - Store at 20° to 25°C (68° to 77°F); Protect from light
  - IN - Store at 15° to 30°C (59° to 86°F); Protect from light
  - Auto-IM – Store at 15° to 25°C (59° to 77°F)
- Mucosal atomizer devices (MAD) for intranasal administration
  - Atomizes to particles 30-100 microns in size for mucosal absorption
  - MAD300 - LMA® MAD Nasal™ Intranasal Mucosal Atomization Device without Syringe
  - 25 devices/box
  - Order: 1.866.246.6990 or 1.888.788.7999
  - Teleflex/LMA America – Lmaems.com; Cardinal Health
  - No NDC – durable medical equipment (DME)
INTRAMUSCULAR NALOXONE RESCUE KIT
Naloxone for Overdose Prevention

Are they breathing?
Signs of an overdose:
- Slow or shallow breathing
- Gasping for air when sleeping or weird snoring
- Pale or bluish skin
- Slower heart rate, weak good resuscitation:
  - We arouse them with pinprick (not an address)

Call 911 for help
All you have to say: “Someone is unresponsive and not breathing”
Give clear address and location.

Airway
Make sure nothing is inside the person’s mouth.

Rescue breathing
Oxygen saves lives. Breathe for them.
One hand on chin, tilt head back, pinch nose closed.
Make a seal over mouth & breathe in
1 breath every 5 seconds
Chest should rise, not stomach

Evaluate
Are they any better? Can you get naloxone
and prepare it quickly enough that they won’t
for too long without your breathing assistance?

Prepare naloxone
- Remove cap from naloxone and uncover needle
- Insert needle through rubber plug, with bottle upside down
- Pull back on plunger and take up 1 cc into the syringe
- Don’t worry about air bubbles (they aren’t dangerous in muscle injections)

Muscular injection
Inject 1cc of naloxone into a big muscle (shoulder or thigh)

Evaluate + support
- Continue rescue breathing
- Give another shot of naloxone in 3 minutes if no or minimal breathing
  or response versus
  - Naloxone wears off in 30-90 minutes
  - Comfort them: withdrawal can be unpleasant
  - Get them medical care and help them not use more opiate right away
  - Encourage survivors to seek treatment if they feel they have a problem

How to Avoid Overdose
- Only take medicine prescribed to you
- Don’t take more than instructed
  - Call a doctor if your pain gets worse
- Never mix pain meds with alcohol
- Avoid sleeping pills when taking pain meds
- Dispose of unused medications
- Store your medicine in a secure place
- Learn how to use naloxone
- Teach your family and friends how to respond to an overdose

For More Info
PrescribeToPrevent.com

Poison Center
1-800-222-1222
(free & anonymous)
INTRANASALNALOXONE RESCUE KIT
IM NALOXONE: PRESCRIBING
NALOXONE PRESCRIPTION INSTRUCTIONS

### Intramuscular
- **Rx:** Naloxone 0.4 mg/mL
- **Quantity:** 2-4 single-use 1 mL vials or 1 X 10 mL multi-use vial
- **Sig:** For suspected opioid overdose, inject 1 mL in shoulder or thigh. Repeat after 3 minutes if no or minimal response.
- **Refills:** prescriber preference

### Intra-Nasal
- **Rx:** Naloxone 1mg/1mL
- **Quantity:** 2-4 x 2 mL prefilled Luer-Jet™ Luer-Lock needleless syringe
- **Sig:** For suspected opioid overdose, spray 1 mL (half of the syringe) into each nostril. Repeat after 3 minutes if no or minimal response.
- **Refills:** prescriber preference

### Auto-IM
- Use as directed.
EVZIO AUTO-INJECTOR

- **EVZIO**
  - Speaker
  - LEDs
  - Base
  - Safety Guard
  - Viewing Windows

- **Outer Case**
  - Outer Case

Instructions for use found inside on device. Includes voice instructions from a speaker.
EVZIO ADMINISTRATION INSTRUCTIONS

- EVZIO is user actuated and may be administered through clothing [e.g., pants, jeans, etc.] if necessary.
- Inject EVZIO while pressing into the anterolateral aspect of the thigh. In pediatric patients less than 1 year of age, pinch the thigh muscle while administering EVZIO.
- Upon actuation, EVZIO automatically inserts the needle intramuscularly or subcutaneously, delivers the naloxone, and retracts the needle fully into its housing. The needle is not visible before, during, or after injection.
- Each EVZIO can only be used one time.
- If the electronic voice instruction system on EVZIO does not work properly, EVZIO will still deliver the intended dose of naloxone hydrochloride when used according to the printed instructions on its label.
- The electronic voice instructions are independent of activating EVZIO and are not required to wait for the voice instructions to be completed prior to moving to the next step in the injection process.
EVZIO ADMINISTRATION INSTRUCTIONS

- Post-injection, the black base locks in place, a red indicator appears in the viewing window and electronic visual and audible instructions signal that EVZIO has delivered the intended dose of naloxone hydrochloride.
- EVZIO’s red safety guard should not be replaced under any circumstances. However, the trainer is designed for re-use and its red safety guard can be removed and replaced.
- It is recommended that patients and caregivers become familiar with the training device provided and read the Instructions for Use; however, untrained caregivers or family members should still attempt to use EVZIO during a suspected opioid overdose while awaiting definitive emergency medical care.
- Periodically visually inspect the naloxone solution through the viewing window. If the solution is discolored, cloudy, or contains solid particles, replace it with a new EVZIO.
- Replace EVZIO before its expiration date.

NALOXONE: BILLING
Most major public and private insurers cover naloxone formulations
- Prior authorization may be required
- Pharmacists perform real-time claim submission to determine coverage
- Patients without insurance can buy prescribed naloxone
  - 2 X 0.4 mg/ml single-use vials: ~$60 (May 2014)
  - 2 X 2 mg/2ml single-use Luer-lock syringes ~ $80 (May 2014)
- State vary in regard to over-the-counter IM syringe availability and quantity for purchase
- Mucosal atomizer devices
  - Cost ~$5 each
  - Billed as DME only
  - Mechanism not usual practice
CPAN OVERVIEW
COLLABORATIVE PRACTICE AGREEMENTS

Definition: “A formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.”

- Also called Collaborative Drug Therapy Management (CDTM)
- Not associated with reimbursement
- Some agreements permit “initiation,” most permit “modify”
Patient care services provided by pharmacists can reduce fragmentation of care, lower health care costs, and improve health outcomes.

A 2010 study found that patient health improves significantly when pharmacists work with doctors and other providers to manage patient care.
Figure 1. Map of States with Laws Explicitly Authorizing Pharmacist Collaborative Practice Agreements, 2012

Note: Physician delegation is considered permissive in MI and WI, allowing physicians and pharmacists to enter into CPAs.
RI CPAN STEPS
“Epidemiologic Trends in Rx Opioid Abuse and Unintentional Opioid Poisoning: Pharmacy-Based Interventions for Patient Safety”

Traci Green, Msc, PhD

~70 pharmacists attended
CPAN IMPLEMENTATION STEPS  
AUGUST 2012

- “Rhode Island Overdose Death Prevention: Naloxone Access and Distribution Strategy Day” Jenny Arnold, PharmD, BCPS
- Washington State Naloxone Collaborative Practice Agreement

The Washington State Pharmacist Perspective

Jenny Arnold, PharmD, BCPS
Director of Pharmacy Practice Development
Washington State Pharmacy Association
University of Rhode Island College of Pharmacy Student Tara Thomas ’13 develops 1-hour online Continuing Professional Education (CPE) Program with URI CPE Office

“Opioids: Addiction, Overdose Prevention (Naloxone) and Patient Education.”

Corporate pharmacy managers are approached, Walgreens agrees to participate

Four locations are selected as CPA pilot sites located near clusters of opioid overdose death reports

RI Pharmacy Foundation funds ten pharmacists at those stores to complete online CE for Naloxone CPA participation after “initiation” waiver approved by Board of Pharmacy
Rhode Island Board of Pharmacy unanimously approves waiver to permit “initiation” of naloxone by pharmacists trained using URI CE program, recognizing the epidemic of overdose deaths as a public health emergency.

Jeff Bratberg of URI and others from Miriam Hospital/Lifespan gave a presentation to the Board seeking a collaborative practice agreement in which several community pharmacies would serve as pilot sites to dispense Naloxone to patients or their caregivers who are at risk of opioid overdose. A motion was made by Chris Albanese and seconded by Robert Iacobucci to approve the establishment of a practice pilot program to dispense naloxone to those at risk of opioid overdose by way of collaborative practice agreement. The motion passed unanimously.
Walgreen’s corporate legal department approves CPA

Nov 2013: Naloxone shortage

Ten pharmacists complete online training

IM and IN naloxone formulations and mucosal atomizer devices stocked at pharmacies

CPA is signed by Jody Rich, MD and all pharmacists

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### CPAN IMPLEMENTATION STEPS

**NOV-FEB 2013**

### NALOXONE PROTOCOL

**A COLLABORATIVE PRACTICE AGREEMENT FOR OPIOID OVERDOSE PREVENTION AND RESPONSE**

**Purpose:** To reduce morbidity and mortality from opioid overdose.

**Policy:** Under this collaborative practice agreement, eligible pharmacists who have completed certificate training program in opioid overdose prevention (CE program) and are CPR certified, may initiate naloxone and educate patients based on the criteria below.

**Continuing Education (CE) in the area of practice covered by the agreement may include any of the following areas related to the safe prescribing of opioids:**
- Opioid overdose prevention
- Reducing the risk of prescription opioid abuse
- The safe use of opioids for the management of chronic pain
- The use of screening tools to detect opioid abuse or dependency, specialist referrals and management of difficult patients
- Preventing diversions of prescribed opioid medications
- Treating patients with pain and addiction
- Naloxone administration technique
- Review of collaborative practice agreement

**Procedure:**

1. **Pharmacists listed below** will identify patients eligible for participation, meeting any of the criteria of overdose risk:
   - a. Voluntary request
   - b. Recipient of emergency medical care for acute opioid poisoning
   - c. Suspended illicit or nonmedical opioid user
   - d. High-dose opioid prescription (>100 morphine equivalence per day)
   - e. Any methadone prescription to opiate naïve patient
   - f. Any opioid prescription and smoking/COPD or other respiratory illness or obstruction
   - g. Any opioid prescription for patients with renal dysfunction or hepatic disease
   - h. Any opioid prescription and known or suspected concurrent alcohol use
   - i. Any opioid prescription and concurrent benzodiazepine prescription
   - j. Any opioid prescription and concurrent SSRI or TCA anti-depressant prescription
   - k. Release prisoner from correctional facilities
   - l. Release from opioid detoxification and maintenance abstinence program
   - m. Patients entering methadone maintenance treatment programs (for addition or pain)
   - n. Patients may have difficulty accessing emergency medical services

2. **Pharmacists will be allowed to initiate naloxone prescriptions if patient meets criteria above:**
   - a. Naloxone HCl (Narcan® or generic equivalent) will be dispensed for intramuscular administration (standard naloxone concentration of 0.4mg/mL).
     - i. The preferred container type is 1mL single-dose flip-top vials, but 10mL multi-dose flip-top vial, or 2mL Carpuject® Lock-glass syringes without needles may also be dispensed.
     - ii. If int. vials or Carpuject® Lock-glass syringes are dispensed, the patient should receive a total of at least 2mL, strongly recommended a total of 4mL.
     - iii. The total amount of naloxone dispensed per patient is not to exceed 10mL.
   - b. In appropriate amount in use at own disposal of the patient.

3. **Both parties shall maintain a copy of licensing and liability insurance information in their respective records for both the pharmacist and physician named below.**

4. **Either party may cancel the agreement by written notification.**

5. **This policy and procedure shall remain in effect until rescinded or for 2 years after the effective date.**

**Effective date of implementation:** 1/1/13

**Signatures:**

- **Physician or Medical Provider**

**Date:** 1/1/13
Michael Botticelli, Deputy Director of the White House Office of National Drug Control and Prevention (ONDCP), holds overdose prevention roundtable in Woonsocket, RI in response to 14 acetyl fentanyl heroin overdose deaths between Feb-May (MMWR 2013;62:703-4.) CPA extended to fifth Walgreen’s store in Woonsocket and then to all 26 RI locations after Board of Pharmacy approval.

**Notes from the Field**

**Acetyl Fentanyl Overdose Fatalities — Rhode Island, March—May 2013**

In May 2013, the Rhode Island State Health Laboratories noticed an unusual pattern of toxicology results among 10 overdose deaths of suspected illicit drug users that had occurred during March 7–April 11, 2013. An enzyme-linked immunosorbent assay (ELISA) for fentanyl in blood was positive for fentanyl in all 10 cases, but confirmatory gas chromatography/mass spectrometry (GC/MS) did not detect fentanyl. The mass spectrum was instead consistent with acetyl fentanyl, a fentanyl analog. Acetyl fentanyl, a synthetic opioid, has not been documented in illicit drug use or overdose deaths, and is not available as a prescription drug anywhere. Animal studies suggest that acetyl fentanyl is up to five times more potent than heroin as an analgesic (1).

During May 14–21, 2013, CDC and Rhode Island public health officials conducted a field investigation to determine whether this cluster of 10 deaths represented an increase in the typical number of overdose deaths and what role might have been played by acetyl fentanyl. Data on illicit drug (cocaine, heroin, synthetic cathinones [bath salts], gamma-hydroxybutyric acid, and methamphetamine) overdose deaths during March 1, 2012–March 31, 2013 were abstracted from the Rhode Island Office of State Medical Examiners database and examined using Poisson regression. Data also were abstracted from autopsy reports, toxicology results, and medical records relating to the 10 deaths that were preliminarily positive for acetyl fentanyl. The state health laboratories performed all toxicology testing for acetyl fentanyl.

Investigators found that the number of illicit drug overdose deaths in Rhode Island was significantly higher in March 2013 (21, including 10 attributed to acetyl fentanyl), compared with the monthly average during March 2012–February 2013 (8.9; p<0.001). During the field investigation, two additional acetyl fentanyl overdose deaths were confirmed (dates of death: March 20 and May 16, 2013), bringing the total number of acetyl fentanyl deaths to 12. Among the 12 acetyl fentanyl decedents, ages ranged from 19 to 57 years, and eight were male. All but one of the deaths occurred in northern Rhode Island; six occurred in the same small city and none in the capital city, Providence. Evidence suggested that acetyl fentanyl was administered intravenously in at least four (33%) of the deaths. The cause of acetyl fentanyl administration was undetermined for the remaining eight decedents.

The GC/MS toxicology results for 10 of the 12 decedents showed, in addition to acetyl fentanyl, various mixtures of other drugs, including cocaine (58%), other opioids (33%), ethanol (25%), and benzodiazepines (17%). None of the decedents tested positive for fentanyl by GC/MS. Toxicology results for one decedent showed only acetyl fentanyl. Since completion of the field investigation, two persons using acetyl fentanyl together died on May 26, 2013, increasing the number of acetyl fentanyl deaths to 14. Acetyl fentanyl overdose deaths have recently been confirmed in Pennsylvania (2). If states observe clusters or increases in illicit opioid-related overdoses above expected levels, acetyl fentanyl could be involved and confirmatory testing will be needed. CDC encourages public health officials and laboratories, when feasible, to use an ELISA test to screen specimens from suspected illicit, nonpharmaceutical opioid overdose deaths. If an ELISA test is positive for fentanyl, CDC recommends laboratories conduct confirmatory testing by GC/MS; if no fentanyl is detected by GC/MS, then fentanyl analogs should be suspected, and subsequent testing should be considered.

Naloxone is an opioid antagonist that can reverse potentially fatal opioid-induced respiratory depression and is used as part of the initial treatment of suspected opioid overdose. Because of the increased potency of acetyl fentanyl, larger doses of naloxone might be needed to achieve reversal (3); health-care providers who administer naloxone in emergencies might consider increasing the amount they keep on hand. In addition, expansion of community-based programs that provide opioid-overdose prevention services, including distribution of and training in the use of naloxone, might be an effective strategy to help reduce opioid-related overdose deaths (4).

**Reported by**

Laura O’Gorman, MD, Rhode Island State Health Laboratories; Christina Stanley, MD, Rhode Island Office of State Medical Examiners, Lauren Lewis, MD, Div of Environmental Hazards and Health Effects, National Center for Environmental Health; Molly Boyd, MD, Div of Toxicology and Human Health Sciences, Agency for Toxic Substances & Disease Registry; Matthew Larson, PhD, EIS officer, CDC. **Corresponding contributor:** Matthew Larson, Woonsocket, RI. E-mail: laraa@yms.com; cdc.gov 770-480-7974
Aug 2013 SAMSHA Opioid Overdose Prevention Toolkit released, RI CPA solution cited

79 Walgreens pharmacists from 26 stores complete online CE training

Nov 2013 ~100 Connecticut pharmacists trained in Opioid Overdose certification program
Rhode Island Opioid overdose death rate doubled

Media attention magnified

State health department recommends patient and caregivers go to Walgreens to receive naloxone and overdose education

February 2014 - Health department emergency regulations released requiring behavioral health staff and patients to be trained on and dispensed naloxone
More emergency regulations released with Board consultation giving all pharmacists the ability to prescribe naloxone and prescribers to dispense naloxone

Front-page Sunday Providence Journal story on naloxone and pharmacy access

Insurers, pharmacists, prescribers meet to discuss naloxone reimbursement

CT stakeholder meeting
Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents

1. APhA supports education for pharmacists and student pharmacists to address issues of pain management, palliative care, appropriate use of opioid reversal agents in overdose, drug diversion, and substance-related and addictive disorders.

2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient’s conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.

Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents

3. APhA supports pharmacists’ access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.

4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.

5. 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.
Health Department recommends all pharmacies stock naloxone and atomizers.

Board of Pharmacy approves CVS/Caremark CPA waiver:
- Naloxone initiation
- Participation of pharmacists with < 2 years of work experience
- One credit of CPE/year required to maintain CPA instead of five
- Walgreens renews CPA with same terms
Unintentional drug poisoning (overdose) deaths, Rhode Island 2009-2014*

*Projected for 2014 based on data as of May 2014. Graph courtesy Traci Green, PhD/RI Medical Examiners office.
Increase in Fentanyl-Related Overdose Deaths — Rhode Island, November 2013–March 2014

Melissa C. Mercado-Crespo, PhD1, Steven A. Sumner, MD1, M. Bridget Spelke2, David E. Sugerman, MD2, Christina Stanley, MD3 (Author affiliations at end of text)

During November 2013–March 2014, twice as many all-intent drug overdose deaths were reported in Rhode Island as were reported during the same period in previous years. Most deaths were among injection-drug users, and a large percentage involved fentanyl, a synthetic opioid that is 50–100 times more potent than morphine (1). Clusters of fentanyl-related deaths have been reported recently in several states. From April 2005 to March 2007, time-limited active surveillance from CDC and the Drug Enforcement Administration identified 1,013 deaths caused by illicit fentanyl use in New Jersey; Maryland; Chicago, Illinois; Detroit, Michigan; and Philadelphia, Pennsylvania (2). Acetyl fentanyl, an illegally produced fentanyl analog, caused a cluster of overdose deaths in northern Rhode Island in 2013 (3).

The Rhode Island Department of Health (RIDOH) requested CDC’s assistance in describing and determining risk factors for recent fentanyl-related overdose death cases. CDC abstracted records from RIDOH’s Office of State Medical Examiners, Division of Vital Records, and Prescription Monitoring Program, with the assistance of local staff members. A fentanyl-related overdose death was defined as a death that occurred during November 2013–March 2014 in which fentanyl was listed as the official cause of death, a contributor to the cause of death, or in which toxicology reports identified fentanyl levels above the detection limit (≥2 ng/mL) by enzyme-linked immunosorbent assay.

Preliminary analyses show that fentanyl-related overdose deaths accounted for 52 (31.5%) of the 165 unintentional overdose deaths reported during November 2013–March 2014. Most decedents did not have active fentanyl prescriptions; the fentanyl appeared to originate from illicit sources and was not acetyl fentanyl–related. Although fentanyl-related overdose deaths were widespread in Rhode Island, most cases occurred in Providence and surrounding urban areas. CDC is currently conducting additional data analyses to determine whether the prescription monitoring program records or medical records of the decedents might help identify others at high risk for similar outcomes.

CDC collaborated with RIDOH to develop an emergency regulation that requires all Rhode Island emergency departments to report fatal and nonfatal opioid overdose cases within 48 hours to RIDOH. CDC recommended that RIDOH continue and expand its efforts to make naloxone, a prescription drug that helps reverse the effects of opioids, accessible for prior drug overdose patients and their families.

1EIS officer, CDC; 2Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC; 3Office of the State Medical Examiners, Rhode Island Department of Health (Corresponding author: Melissa C. Mercado-Crespo, mm mercado-crespo@cdc.gov, 770-488-4713)

References

KEY ELEMENTS OF CPAN
ELIGIBLE PATIENTS TO PARTICIPATE:

- Voluntarily requesting
  - Does not have to be someone at risk of overdose - can be a friend, family member, etc.

- Recipient of emergency medical care for acute opioid poisoning

- Suspected illicit or nonmedical opioid user

- High dose opioid prescription (>100 morphine mg equivalents daily)

- Methadone prescription to opioid naïve patient
ELIGIBLE PATIENTS TO PARTICIPATE:

- Opioid prescription and:
  - history of smoking
  - COPD
  - Respiratory illness or obstruction
  - renal dysfunction or hepatic disease
  - Known or suspected concurrent alcohol abuse
  - Concurrent benzodiazepine prescription
  - Concurrent SSRI or TCA anti-depressant prescription
ELIGIBLE PATIENTS TO PARTICIPATE:

- Recently released prisoners from a correctional facility
- Released from opioid detoxification or mandatory abstinence program
- Patients entering a methadone maintenance treatment program - for addiction or pain
- Patients that may have difficulty accessing emergency medical services
The pharmacist shall initiate a naloxone prescription pursuant to the protocol described, and issue that prescription in the name of the collaborating medical provider participating in this CPA.

The pharmacist shall contact the physician entered in the CPA in the event that medical consultation is required for a particular patient.
Prior to providing services to patients pursuant to this CPA, the pharmacy will obtain informed consent from each patient, which shall include:

- A signed authorization for the release of protected health information by and between the pharmacy and the Collaborating Physician
- A provision allowing the patient to withdraw at any time from the collaborative practice described in this CPA
- An acknowledgment that patient has been offered the education and training
- Pharmacy will retain a copy of the informed consent
Before receiving naloxone patients must have overdose prevention, identification, and response training

- Purpose for naloxone
- Correct naloxone administration
- Precautions regarding interacting medications
- Identifying and avoiding high risk situations for overdose
- Risk reduction strategies
- Opioid overdose response
PROTOCOL: EDUCATION

- Opioid overdose response
  - How to identify an overdose
  - How to respond in an overdose
    - Rescue breathing
    - Calling 9-1-1
  - How to administer naloxone (IM or IN)
  - What to do and expect after naloxone administration
    - Withdrawal
    - Rescue position
    - Repeat naloxone
  - Stay with the patient
Naloxone

What is naloxone?
Naloxone is an antidote for opioid overdose. In an overdose, opioids can cause difficulty breathing, sedation, and death. Naloxone is a medication that reverses these effects.

Naloxone only works if opioids are present in the body, and has no effect if they are not. It does not work on other drugs or alcohol. Naloxone usually takes effect in 3 to 5 minutes and lasts 60 to 90 minutes.

Who should take naloxone?
Naloxone should be given to someone experiencing an opioid overdose. Overdose death can occur over one to three hours. This gives time to take saving actions.

Overdose most often occurs when people take a large or increased amount of opioids, mix opioids with alcohol or other drugs, or have had recent changes in tolerance levels.

If a person is not responding, not breathing, or is struggling to breathe, they may be experiencing an overdose and it is time to begin the steps of naloxone administration.

How to Respond in an Overdose:

Step 1: IDENTIFY OVERDOSE
Opioids can be dangerous because they suppress the body’s urge to breathe, which can possibly lead to death. If someone is not breathing or is struggling to breathe try calling their name and rubbing your knuckles on their chest. If they are still unresponsive they may be experiencing an overdose. Other signs that may help you identify an overdose are:
- blue or pale skin color
- small pupils
- low blood pressure
- slow heart beat
- slow or shallow breathing
- snoring sound
- gasping for breath

Step 2: CALL 9-1-1
After identifying an overdose it is very important to get help as quickly as possible. Call 9-1-1. Make sure to say the person is unresponsive and not breathing or struggling to breathe. Give a clear address and location.

Step 3: GIVE RESCUE BREATHS
Giving oxygen can save a life in an overdose.
- Make sure nothing is in the person’s mouth blocking their breathing.
- Place one hand on the chin and tilt the head back. With the other hand pinch the nose closed.
- Administer two slow breaths and look for the chest to rise.
- Continue administering 1 breath every 5 seconds until the person starts breathing on their own. Continue this for at least 30 seconds. If the person is still unresponsive, you can give naloxone.

Examples of Opioids:
- MORPHINE (MS Contin®)
- CODEINE
- HYDROCODONE (Vicodin®, Norco®)
- HYDROMORPHONE (Dilaudid®)
- OXYCODONE (Percocet®, OxyContin®)
- OXYMORPHONE (Opana®)
- FENTANYL (Duragesic®)
- BUPRENORPHINE (Subutex®)
- METHADONE
- HEROIN

The RI Good Samaritan Overdose Prevention Act prevents anyone in a drug overdose or anyone seeking medical help for them from being charged or prosecuted for certain crimes related to drugs if the evidence for the charge was gained as a result of the overdose and the need for medical help.

Step 4: GIVE NALOXONE
Naloxone is available as an injection and as a nasal spray. Follow the instructions on what form you have. While getting ready to give naloxone, make sure you are not going too long without giving rescue breaths. Store naloxone in an easy to reach place in case of emergency. Make sure you and your family know where it is stored.

Injection into the Muscle
Open the cap of the naloxone vial. Remove the cap of the needle, and insert into the vial. With the vial upside down, pull back the plunger and draw up 1mL (1cc) of naloxone. Your naloxone vial may only have one dose, or may be a multi-dose vial. Using a needle at least 1 inch long, inject into the muscle in the upper arm.

Nasal Spray
When using the nasal spray you will have three pieces: the nasal adapter, the applicator, and the prefilled naloxone syringe. Remove the yellow caps from the ends of the applicator. Twist the nasal adapter on the tip of the applicator until it is tight. Take the red cap off of the naloxone syringe and insert in the other side of the applicator and twist in until tight. Push 1mL (1cc) of naloxone into each nostril. The naloxone vial contains 2mL, so you are administering one half in one nostril and one half in the other nostril.

After giving naloxone continue rescue breathing with 1 breath every 5 seconds. If they are still not responding in 3 to 5 minutes you can give a second dose of naloxone. Continue rescue breathing until emergency responders arrive.

Step 5: STAY UNTIL HELP ARRIVES
It is important to stay with someone after giving naloxone. Naloxone can reverse an overdose, but can also make someone enter withdrawal.

After someone is given naloxone, make sure they do not take any more opioids because they could go back into overdose after the naloxone wears off. They can also go back into overdose if they took a long-acting opioid. In these situations, repeat doses of naloxone may be needed.

Get medical help immediately if after naloxone administration someone experiences rapid or irregular heart beat, chest pain, seizures, sudden stopping of the heart, hallucinations, or loss of consciousness.

RECAP: Steps for Responding in Overdose:
1) Identify overdose
2) Call 9-1-1
3) Give rescue breaths
4) Give naloxone
5) Stay until help arrives

More Questions?
In an emergency call 9-1-1 for questions or help with life saving steps.

For more information on naloxone call your pharmacy.

Poison Center: 1-800-522-1222
Alert the physician entered into the collaborative practice agreement via fax when naloxone is dispensed within 7 days

 Maintain records for minimum of 5 years
  - Informed consent
  - Re-fill form
  - Log of monthly activity
  - Staff / CPA prescriber will review monthly

 Licensing and liability insurance information of participating pharmacist(s) and prescriber (s) will be maintained
HOW TO PREVENT OVERDOSE

- Only take prescription opioids that are prescribed to you and only take them as directed
- If you are addicted to opioids seek treatment
- If you are on prescription opioids, make sure your doctor knows of any other medications you are on
- Don’t mix opioids with other drugs or alcohol
- Store medication in a safe and secure place and dispose of unused medication
- Understand that not taking opioids for a period may change your tolerance level and you may need to restart at a lower dose
- Teach your friends a family how to respond to an overdose and the role of naloxone in an overdose
June 2014 – A pharmacist may furnish naloxone in accordance with standardized procedures or protocols

- Education provided: opioid overdose prevention, recognition, and response, safe administration of naloxone, potential side effects or adverse events, and seek emergency medical care
- Drug treatment program education
- PCP should be notified
- Consultation required by the board and the Medical Board of California cannot be waived
- One hour of approved continuing education on the use of naloxone hydrochloride required
- Does not expand the authority of a pharmacist to prescribe any prescription medication
Signed into law June 23, 2014 by Governor Cuomo

“Improved Accessibility to Naloxone Anti-Overdose Kits to Help Save Lives”

- Requires that every naloxone anti-overdose kit include informational cards with the important information on how to recognize symptoms of an overdose; what steps to take, including calling first responders; and how to access services through OASAS

- Health care professionals can now prescribe this life saving medicine by non-patient-specific prescription

- Pharmacists, using their professional expertise, will also be able to dispense naloxone to anyone who needs it
OVERDOSE PREVENTION
Overdose is more likely when:
- You use by yourself
- You mix opioids with alcohol or other drugs
- Your tolerance is low because you haven’t used recently
- You have a chronic disease (HIV/AIDS, HepC, COPD) or an acute illness (pneumonia, flu).

OVERDOSE RECOGNITION
Signs of overdose include:
- Can’t be woken up
- Slow or no breathing
- Limp body
- Fingernails or lips turning blue
- Unable to speak/incoherent
- Vomiting or gurgling noises

OVERDOSE RESPONSE
1. Call 911 - tell them someone is not breathing
2. Rescue breathing
3. Give naloxone (Narcan)
4. Stay until help arrives, roll the person on their side if you have to leave
- Naloxone starts working in 3-5 minutes and lasts 30-90 minutes
- Keep rescue breathing until naloxone starts to work.
- If there is no improvement in 5 minutes, give another dose.
- Naloxone may cause withdrawal symptoms - DO NOT let person use more opioids

**INJECTABLE NALOXONE**

1. Remove cap from naloxone and syringe.
2. Insert needle through rubber plug.
3. Pull back on plunger until there is 1cc in the syringe.
4. Inject into a large muscle (thigh or upper arm).

**NASAL NALOXONE**

1. Remove all caps.
2. Screw glass vial into plastic tube.
3. Screw nasal atomizer into plastic tube.
4. Inject half of vial into each nostril.
WEBSITES AND OTHER MATERIALS

- Prescribetoprevent.org
- Stopoverdose.org
- nopeRI.org
- Opioids: Addiction, Overdose Prevention (Naloxone) and Patient Education
- web.uri.edu/pharmacy/2014/02/14/opioidsaddiction
PARTNERING WITH PHARMACISTS: NALOXONE PRESCRIBING AND DISPENSING TO PREVENT OVERDOSE DEATHS (AOAAM)

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