

Reducing Opioid Overdose in NYC: Naloxone Non-Patient Specific Prescription and Dispensing for Pharmacists

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Objectives

Part A: Background

- Epidemiology of opioid overdose nationally and in NYC
- The role of naloxone in reducing opioid overdose mortality

Part B: Dispensing under non-patient specific prescription

- Citywide non-patient specific prescription and pharmacist dispensing protocol
- Patient education

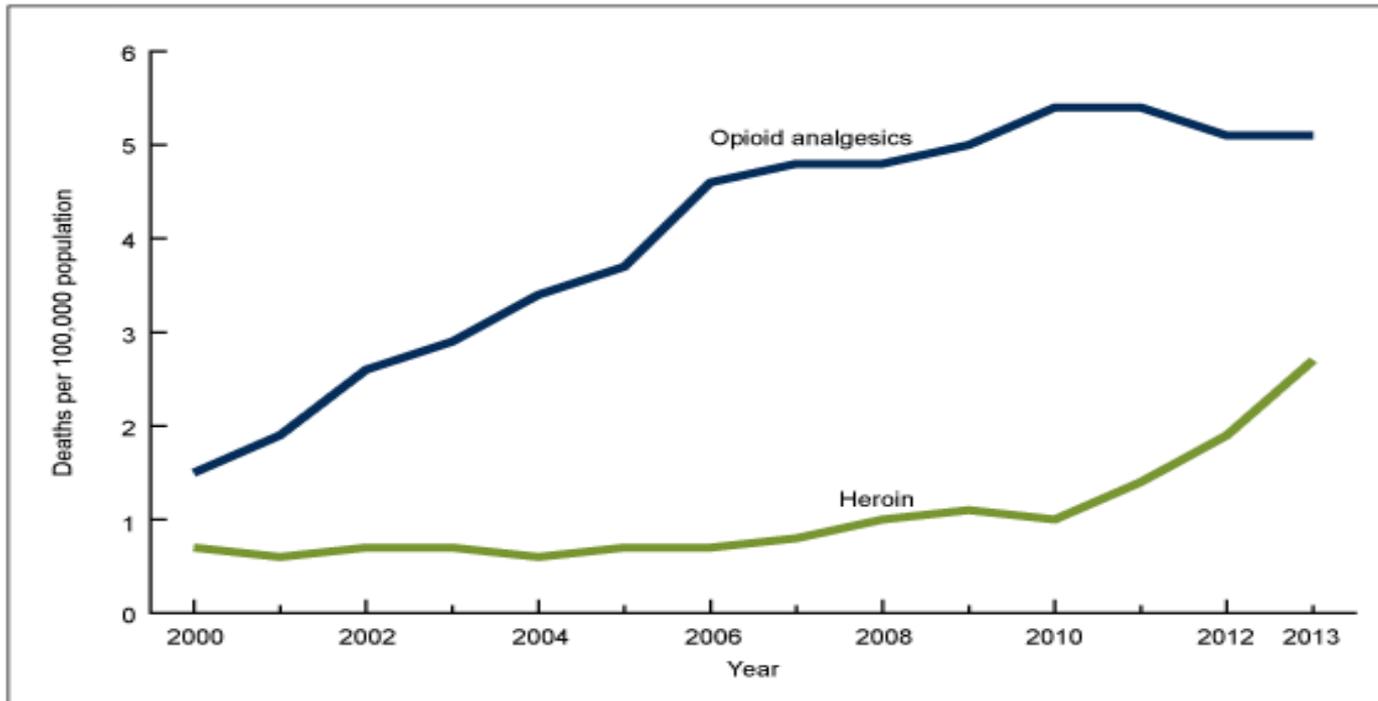
Part C: Resources

Part A: Background

EPIDEMIOLOGY OF OPIOID OVERDOSE NATIONALLY AND IN NYC

Opioid overdose rates in the US have increased steadily since 2000

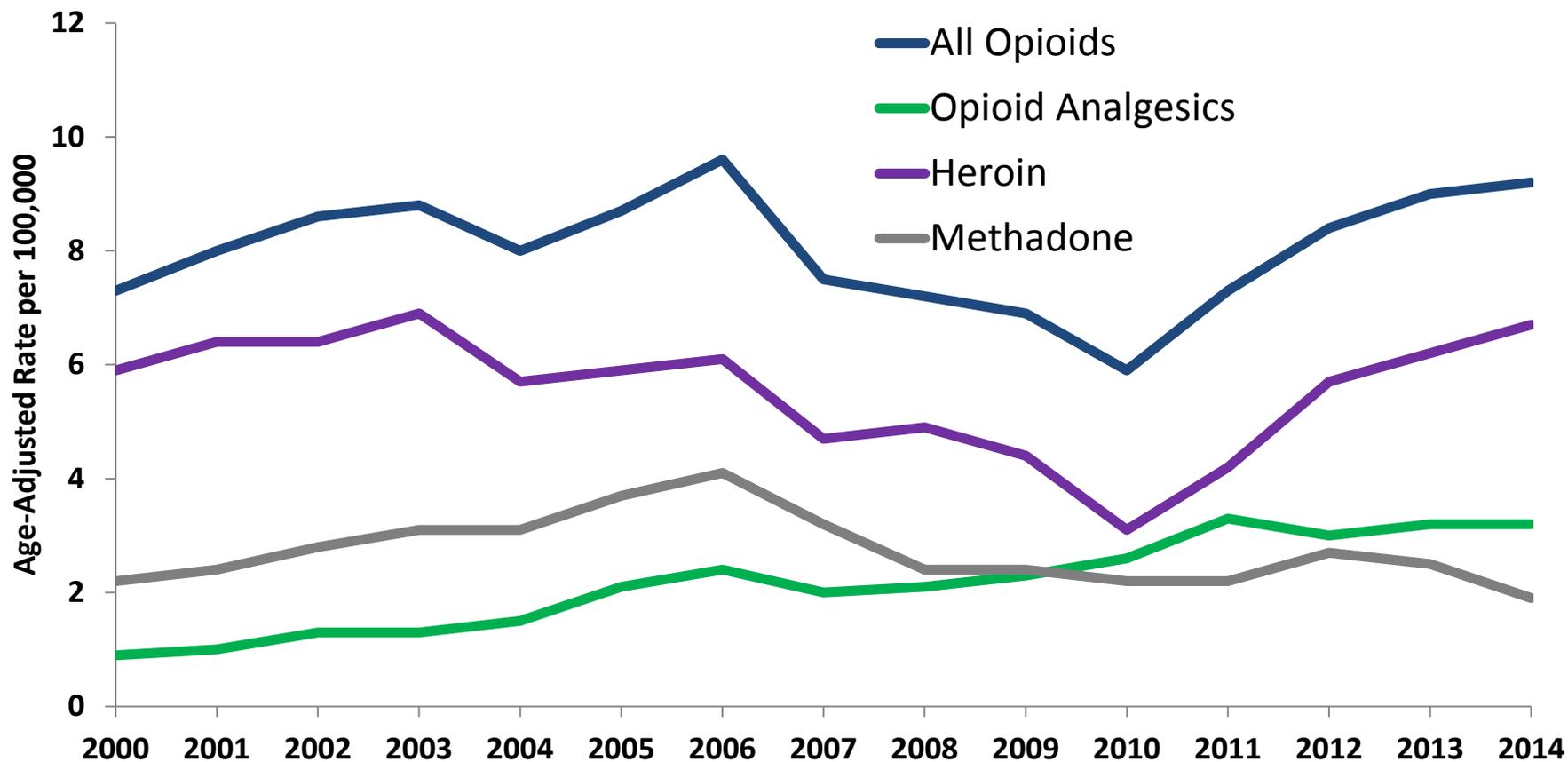
Figure 1. Age-adjusted rates for drug-poisoning deaths, by type of drug: United States, 2000–2013



NOTES: The number of drug-poisoning deaths in 2013 was 43,982, the number of drug-poisoning deaths involving opioid analgesics was 16,235, and the number of drug-poisoning deaths involving heroin was 8,257. A small subset of 1,342 deaths involved both opioid analgesics and heroin. Deaths involving both opioid analgesics and heroin are included in both the rate of deaths involving opioid analgesics and the rate of deaths involving heroin. [Access data table for Figure 1](#) [PDF - 86KB].
SOURCE: CDC/NCHS, National Vital Statistics System, Mortality.

Rate of unintentional drug poisoning deaths by drug type, NYC 2000-2014*

(Drugs not mutually exclusive)



*Data for 2014 are preliminary and subject to change.

Source: New York City Office of the Chief Medical Examiner &
New York City Department of Health and Mental Hygiene 2000-2014*

NYC Department of Health's multi-pronged approach to address opioid overdose

- Judicious opioid prescribing
 - Guidelines; prescriber detailing; prescription monitoring program
- Access to treatment for addiction
 - Treatment is effective, particularly with buprenorphine and methadone
- **Expand access to naloxone (opioid antagonist)**
 - Non-medically trained personnel (laypeople)
 - Law enforcement and first responders

NYS Public Health Law Section 3309

Created the NYS Opioid Overdose Prevention Program (OOPP), which allows:

- **Naloxone to be dispensed to laypeople by:**
 - Patient-specific prescription
 - Non-patient specific prescription (“standing order”)
- **Laypeople include:**
 - Individuals **at risk** of opioid overdose
 - Individuals **likely to witness** overdose and respond, such as family members or friends of person at risk

Opportunities for Pharmacists

- Until recently, naloxone has only been available in **community based settings** through the Opioid Overdose Prevention Program
- Pharmacists and pharmacy interns will be able to dispense naloxone through a NYC Health Department **citywide non-patient specific prescription**
- By **dispensing naloxone** to patients, pharmacists can **reduce morbidity and mortality** associated with **opioid overdose**

Part A: Background

**THE ROLE OF NALOXONE IN
REDUCING OPIOID OVERDOSE
MORTALITY**

Opioid analgesics include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin [®] , Lorcet [®] , Lortab [®] , Norco [®] , Zohydro [®]
Oxycodone	Percocet [®] , OxyContin [®] , Roxicodone [®] , Percodan [®]
Morphine	MS Contin [®] , Kadian [®] , Embeda [®] , Avinza [®]
Codeine	Tylenol [®] with Codeine (Tylenol [®] #3, Tylenol [®] #4)
Fentanyl	Duragesic [®]
Hydromorphone	Dilaudid [®]
Oxymorphone	Opana [®]
Meperidine	Demerol [®]
Methadone	Dolophine [®] , Methadose [®]
Buprenorphine	Suboxone [®] , Subutex [®] , Zubsolv [®] , Bunavail [®] , Butrans [®]

* **Heroin** is also an opioid.

Opioid Overdose

- Opioids are mu receptor agonists
 - Decreased respiratory frequency
- Clinical presentation of overdose includes:
 - Unresponsiveness
 - Miosis or pinpoint pupils
 - Blue or grey lips/nail beds

Overdoses can progress from minutes to hours – mortality is preventable with naloxone reversal.

Naloxone

- Mu opioid receptor antagonist
 - Displaces opioids from receptors
 - Reverses overdose and prevents fatalities
 - No clinical effect in absence of opioid agonists
- Hepatic metabolism; renal excretion
- **NOT** a controlled substance
 - Available by prescription only
 - Intranasal or injectable formulation (auto-injector available)

Naloxone

- Usually takes effect within **two to five minutes**
- Lasts for **30-90 minutes**
- Will **not** reverse overdoses caused by other substances
- Naloxone **cannot be misused or cause overdose**

Safety and Tolerability

- **Contraindications:** Known hypersensitivity to naloxone
- **Warnings:** Naloxone may cause withdrawal symptoms such as: anxiety, running nose and eyes, chills, muscle discomfort, disorientation, combativeness, nausea/vomiting and/or diarrhea

Indications for naloxone

Naloxone can be dispensed to anyone who **voluntarily requests** it. This may include:

- Any individual who is **at risk of experiencing** an opioid-related overdose
- Any **family member, friend or other person who may assist** an individual at risk for an opioid-related overdose

Who is at risk?

Pharmacist may **opt** to conduct risk assessment to identify additional patients to offer naloxone.

The following factors increase overdose risk and may serve as screening criteria in a pharmacy context:

- Taking opioid analgesics for more than three months
- Taking methadone or buprenorphine (aka Suboxone[®]) for the treatment of an opioid use disorder
- Having concurrent prescriptions for opioids and benzodiazepines
- Having experienced a previous non-fatal opioid overdose (if known)
- Having a family member or friend who meets any of the above

Part B: Dispensing under non-patient specific prescription

**CITYWIDE NON-PATIENT SPECIFIC
PRESCRIPTION AND PHARMACIST
DISPENSING PROTOCOL**

In *New York State*, prescribers can provide pharmacists with a **non-patient specific prescription** to make naloxone available to patients.

- Under the NYC Health Department's order, **pharmacists** and **pharmacy interns** can dispense naloxone in accordance with the outlined **protocol**

Naloxone products

INTRANASAL



Naloxone HCl 1 mg/mL
2 x 2mL as pre-filled Luer-Lock syringe

2 x Intranasal Mucosal Atomizing Device (MAD 300)

INTRAMUSCULAR



Naloxone HCl 0.4 mg/mL
2 x 1mL single-dose vials

2 x Intramuscular (IM) syringe, 3mL, 25G, 1 inch

EVZIO® AUTO INJECTOR



Evzio
0.4 mg/mL

1 x two-pack

Note: Several new products are under FDA review. Any future FDA approved products can also be dispensed.

Naloxone labels must include:

- Name of recipient/patient
- Prescriber name: Mary T. Bassett, MD
- Naloxone formulation and concentration
- Date dispensed
- Refills: 12 (recommended)
- The terms below:
 - “Dispensed per standing order”
 - “Use as directed”
 - “Trained opioid overdose responder”

Ordering naloxone

Naloxone can be ordered from suppliers listed below:

	Intranasal	Intramuscular	Auto-injector
Medication	NDC #76329-3369-01 Amphastar	NDC#00409-1215-01 Hospira	NDC#60842-030-01 Kaleo
Required devices	MAD300 (atomizer) nasal devices available from Teleflex 866-246-6990 or Safety Works Inc. 800-723-3892	3ml 25G 1" syringes	N/A

Billing

- Some insurance plans cover naloxone
- Check the patient's coverage and dispense naloxone formulation **based on coverage and patient preference**

If a patient cannot afford the naloxone and/or copay, direct to listing of Opioid Overdose Prevention Programs in NYC, where naloxone can be accessed free of charge:

www.health.ny.gov/overdose

Reporting requirements

For **each dose** of naloxone dispensed under non-patient specific prescription, pharmacy must **maintain in records**, per standard practice:

- Name of patient
- Name of pharmacist
- Date dispensed

The **number of doses** of each naloxone formulation/product dispensed, indicating the **number of refills**, must be submitted to the NYC Health Department **quarterly**:

- Report is due every January 31st, April 30th, July 31st, October 31st
- Reporting forms are available online by visiting nyc.gov/health and searching for “Pharmacy Naloxone”. There is a web-based form for electronic submission or it can be downloaded and sent to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax)

Reversal reporting

- If a patient comes in for a refill, ask if naloxone was used
- If a patient has used naloxone, submit a Pharmacy Overdose Reversal Reporting Form
 - A web-based form is available for electronic submission by visiting nyc.gov/health and searching for “Pharmacy Naloxone”
 - Forms can be also be downloaded and sent to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax)
- Repeat patient training is not necessary to refill naloxone if the patient demonstrates knowledge of overdose prevention and naloxone administration
 - Confirm knowledge of key points in patient handout: *Opioid Safety and How to Use Naloxone*

Part B: Dispensing under non-patient specific prescription

PATIENT EDUCATION

Patient education

- Per NYS law, **patient education is required**
- Pharmacist or pharmacy intern **must** review a **patient handout** with patients, and **include a written copy** with the naloxone
- Pharmacists can create their own patient handout as long as it covers all required topics. The NYC Health Department handout may be used as-is or adapted with permission.
- Patient **must be provided with OASAS' hotline information**: OASAS HOPEline: call 1-877-8-HOPENY (1-877-846-7369), text HOPENY (467369) or visit <http://www.oasas.ny.gov/accesshelp/>

Required elements for patient education

Patients **MUST** receive education on:

- 1. Naloxone** overview
- 2. Risk factors** for opioid overdose
- 3. Signs** of opioid overdose
- 4. Overdose response** steps
- 5. Additional** information

The following slides provide information about each area.

1) Naloxone overview

- Naloxone **blocks** the effects of **opioids**
- Lasts for **30-90 minutes**
- Usually takes effect within **two to five minutes**
- **Safe**: no effect if opioids are not present
- Will **not** reverse overdoses caused by other substances
 - If unsure what substances were used, administer naloxone

2) Risk factors for opioid overdose

- **Use of ANY opioids** can slow breathing and put individuals at risk for overdose
- Risk for overdose may be increased by:
 - **Changes in tolerance:** Patient should be careful if they take a break, miss a dose or take more opioids than they are used to
 - **Mixing opioids with other drugs or medications** such as alcohol or benzodiazepines as well as cocaine
- **Taking opioids when alone** increases the risk of fatal overdose because nobody is around to help

3) Signs of opioid overdose

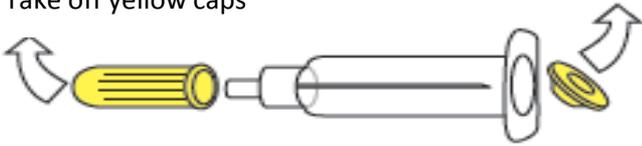
- Person may be **unresponsive and will not wake up** even when shaken
 - *Try to wake the person by rubbing your knuckles up and down the front of rib cage (sternal rub)*
- **Breathing slows** or even stops
- Lips and/or fingernails turn **blue, pale or gray**

4) Overdose response steps

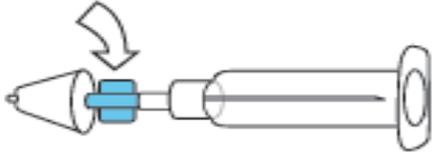
1. **Call 911.** Follow 911 dispatcher instructions.
2. **Administer naloxone** (*refer to patient handout for instructions*) If there is no reaction in three minutes, give a second dose
3. **After naloxone.** Stay with the person for as long as you can or until help arrives. Discourage use of more opioids. If person is still unresponsive, lay on side to prevent choking and wait for help.

Nasal spray naloxone

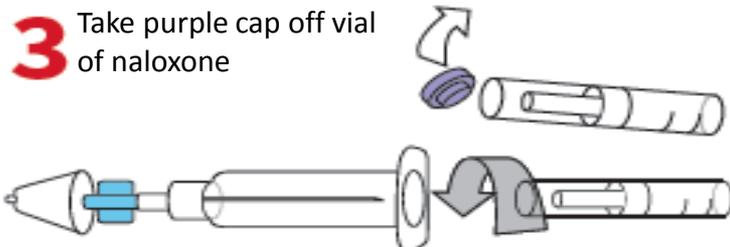
1 Take off yellow caps



2 Screw on white cone



3 Take purple cap off vial of naloxone



4 Gently screw vial of naloxone into barrel of syringe



5 Insert white cone into nostril; **give a short, strong push** on end of vial to spray naloxone into nose: **ONE HALF OF VIAL INTO EACH NOSTRIL**

Push to spray

6 If no response in three minutes, give second dose

Injectable naloxone

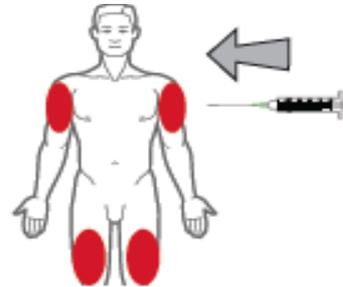
1 Remove caps from naloxone vial and needle



2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up entire contents.



3 Inject whole vial into upper arm or thigh muscle



4 If no response in three minutes, give second dose

Auto-injector

The naloxone auto-injector has voice instructions for injecting the naloxone into the outer thigh, through clothing if needed. There is also a training device for practice included with each kit.

5) Additional Patient Information

- **Share information** about naloxone, including where it will be kept and how to use, with friends and family
- Patients should be instructed to **ask for a refill** of naloxone if it is used, lost/damaged, or nearing expiration
 - If naloxone was used, patient should **inform pharmacist**
- **Store naloxone** at room temperature and out of direct light if possible
- **911 Good Samaritan Law** provides substantial protection for individuals when calling 911 to save a life even if drugs are present

If time permits, provide the following information:



- If the person isn't breathing, do rescue breathing or CPR, if you know how
- Instructions for administering rescue breathing:
 - Place the person on his or her back and tilt chin up to open airway. *Check to see if there is anything in the mouth blocking airway.*
 - Pinch nose closed with one hand, make a seal between your lips and theirs, and give two even, regular-sized breaths. Blow enough air into their lungs to make their chest rise.
 - Give one breath every five seconds until help arrives or until the person resumes breathing.

Part C: Resources

Summary of forms

All forms available by visiting nyc.gov/health and searching for “Pharmacy Naloxone”

- **Non-Patient Specific Prescription and Pharmacist Dispensing Protocol, NYC**
 - Supervising pharmacist must sign and return to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax) to initiate pharmacy dispensing of naloxone. Authorizing health department signatures will be added and form will be returned for pharmacy records.
- **Pharmacy Overdose Reversal Reporting Form**
 - Submit report using web based submission or to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax) on downloaded form for any reported usage of naloxone by patients. Ask if naloxone was used when dispensing refill.
- **Quarterly Pharmacy Naloxone Dispensing Report**
 - Submit data using web based submission or by sending the downloaded form to pharmacynaloxone@health.nyc.gov or 347-396-8889 (fax) on: January 31st, April 30th, July 31st, October 31st

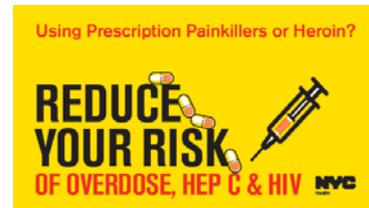
Additional resources

Available by visiting nyc.gov/health and searching for “Pharmacy Naloxone”

- **Training Webinar:** *Reducing Opioid Overdose in New York City: Naloxone Non-Patient Specific Prescription and Dispensing for Pharmacists* (available for CE credit)
- **Patient Handout:** *Opioid Safety and How to Use Naloxone*
 - Include a patient handout with naloxone
- **Pharmacist Checklist:** *Dispensing Naloxone: New York City Department of Health and Mental Hygiene Standing Order*
- **List of participating pharmacies**

Additional Information

- New York City Health Department website:
Visit www.nyc.gov/health and search for “Prevent Overdose”
- New York State Health Department website:
www.health.ny.gov/overdose
- You can order overdose prevention materials from 311:



Contact Information

Contact us at:

pharmacynaloxone@health.nyc.gov or

347-396-8889 (fax) with questions about:

- NYC citywide non-patient specific prescription, pharmacist dispensing protocol, training or forms
- Naloxone
- Overdose prevention
- Related issues

Acknowledgments

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