

OPIOID ANTAGONIST TRAINING FOR PHARMACISTS

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Tennessee Pharmacists Association Summer Meeting



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Shelly is the Manager of Pharmacy Patient Safety for The Kroger Co.'s Family of Pharmacies at General Office. She started with Kroger in 2003 as a pharmacy technician, became a pharmacy intern in 2005 and graduated with her PharmD from the University of Cincinnati in 2009. Shelly completed the Kroger/University of Cincinnati Community Pharmacy Residency Program in 2009-2010. She remained with Kroger after her residency and held several Pharmacy roles within the Division including Patient Care Pharmacist, Residency Preceptor, and Patient Care Coordinator. Shelly was promoted to her current role on the Corporate Pharmacy Regulatory Compliance team in October 2015.



Shelly has no conflicts of interest to disclose.



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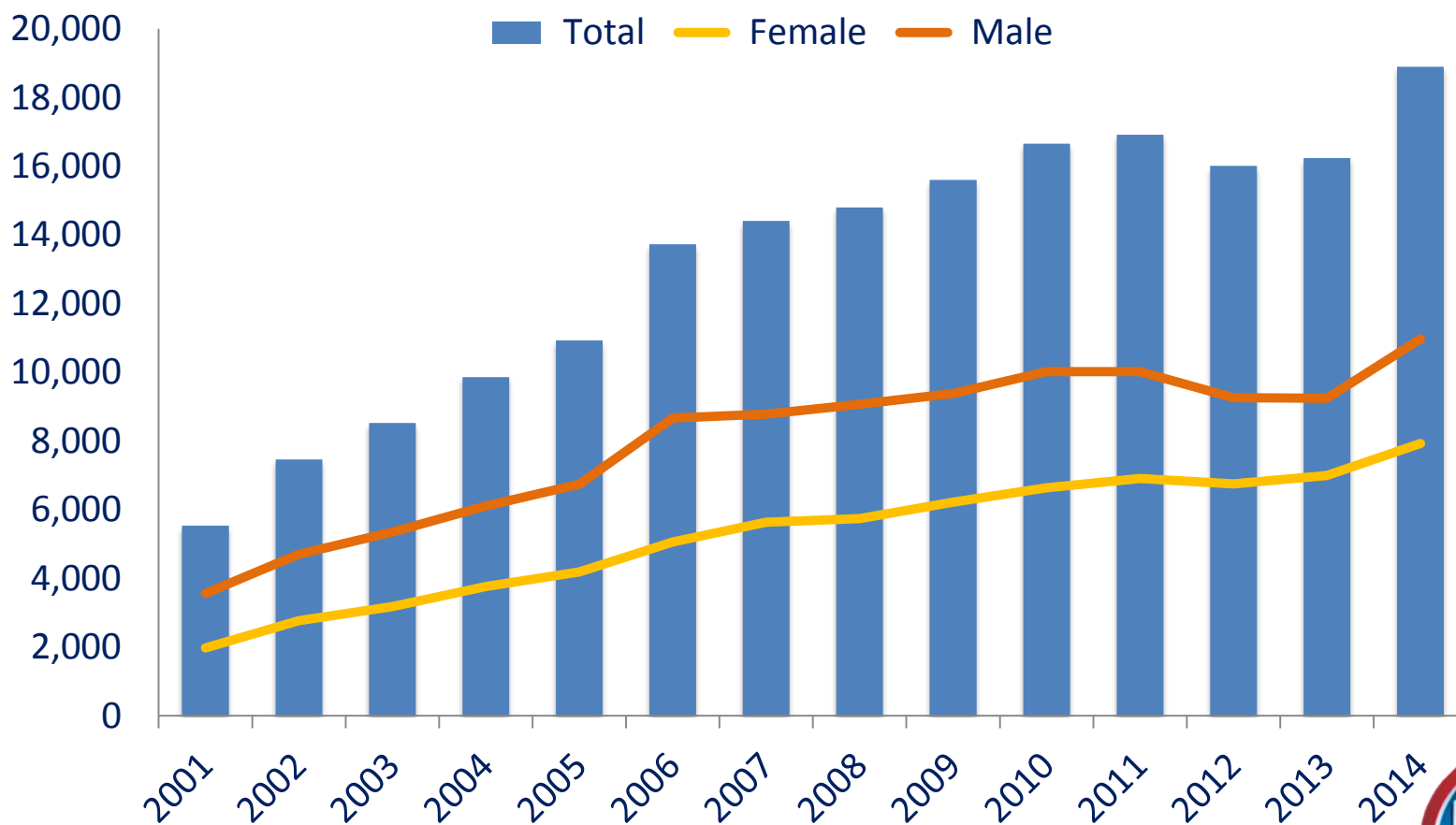
Objectives

- Discuss the epidemiology and pathophysiology of opioid addiction and overdose
- Identify risk factors for opioid overdose
- Explain how to recognize and respond to opioid overdose
- Demonstrate the proper administration of naloxone for opioid overdose in the community
- Describe the Tennessee state laws and regulations regarding naloxone access and distribution



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Deaths from Prescription Opioids in the US

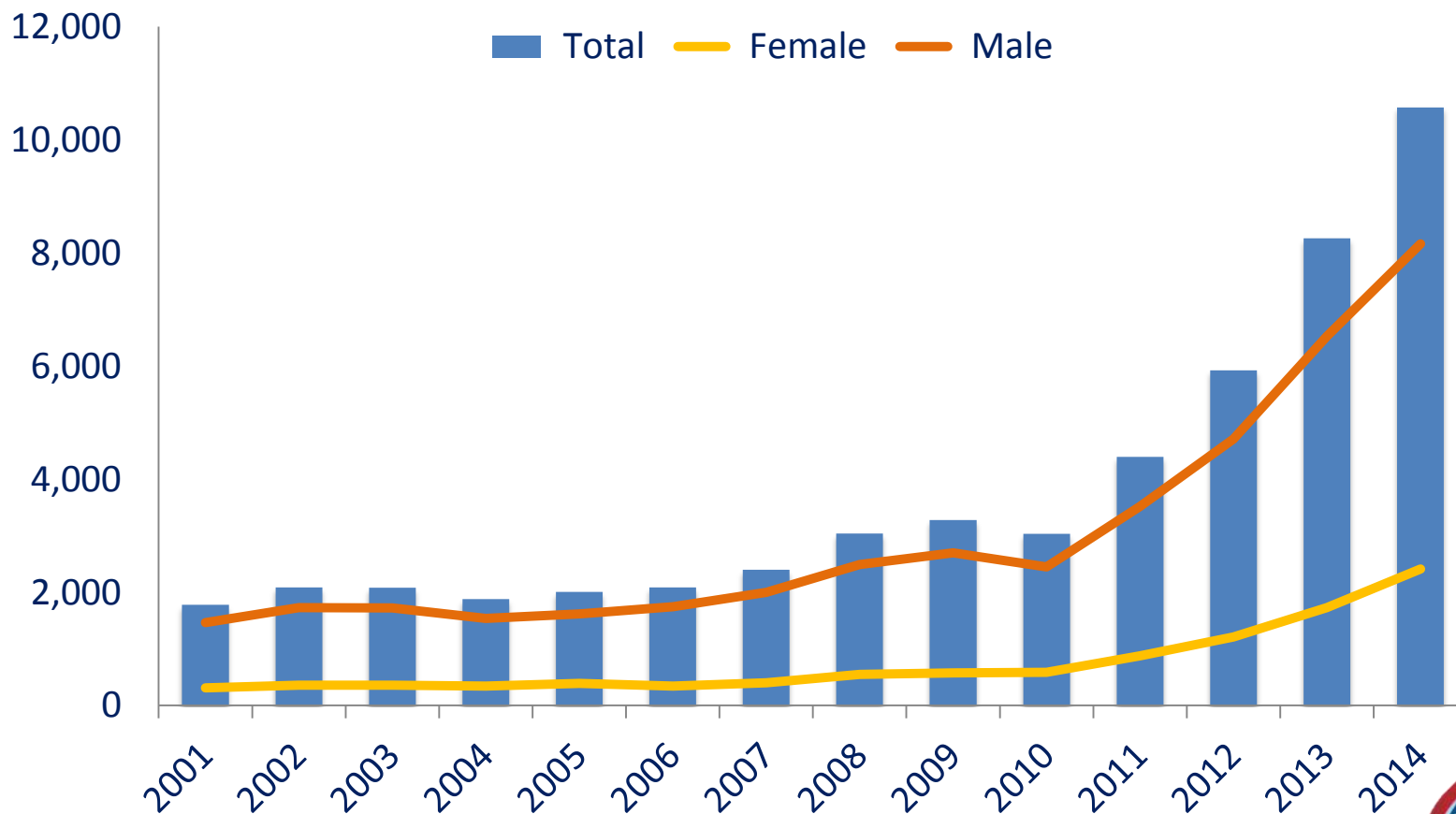


Source: National Center for Health Statistics, CDC Wonder



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Deaths from Heroin in the US

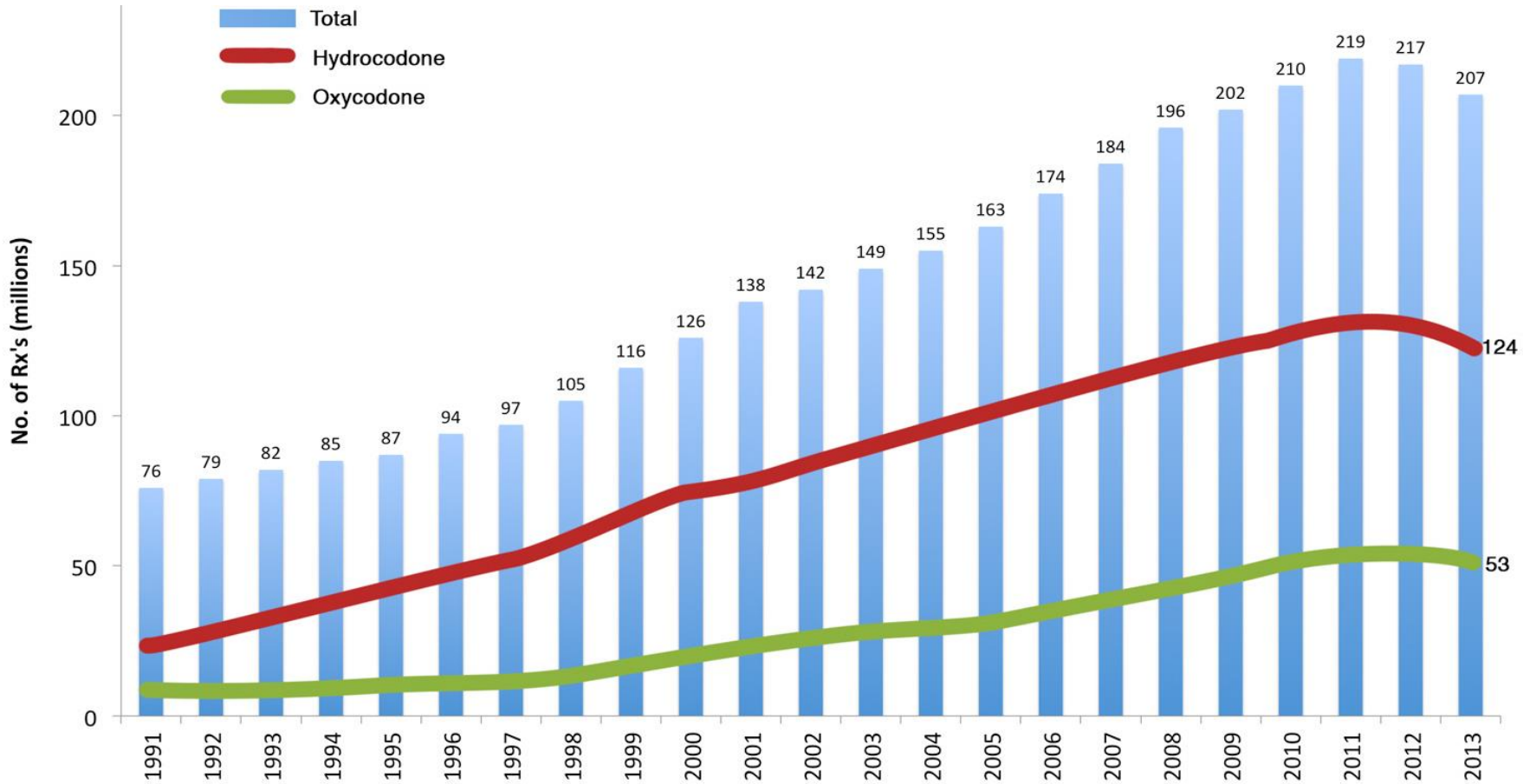


Source: National Center for Health Statistics, CDC Wonder



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Prescription Opioid Prescribing in the US



IMS Health, National Prescription Audit, Years 1997-2013, Data Extracted 2014.

Addiction

- A primary, chronic disease resulting in dysfunction in the circuits of the brain related to reward, motivation, and memory
- Characterized by
 - Drug craving
 - Impairment in control over efforts to abstain from drug use
 - Compulsive drug use despite negative consequences
- Distinct from tolerance and physical dependence
 - Addiction develops slower, lasts longer, and disrupts multiple brain processes



Addiction is a Chronic Disease

- Characterized by episodes of relapse and remission
- Genetic and environmental causes
- Can lead to disability or death, especially when left untreated
- Progressive and worsens over time
- Successful treatment involves development of self management skills, social support, and medications



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Brain Disease Model of Addiction

| Recurring Stages of Addiction | Neuroadaptations Lead to Disease Progression | | |
|---------------------------------------|--|----------------------------|--------------------------------------|
| Binge and intoxication | Feeling euphoric | Feeling good | Escaping dysphoria |
| Withdrawal and negative affect | Feeling reduced energy | Feeling reduced excitement | Feeling depressed, anxious, restless |
| Preoccupation and anticipation | Looking forward | Desiring drug | Obsessing and planning to get drug |

Addressing the Opioid Overdose Epidemic

Prevention & Training

- Guidelines on appropriate opioid use
- Increased use of PDMPs

Treatment

- Expanded access to medication-assisted treatment options

Harm Reduction

- Expanded access to and distribution of naloxone

Overdose Education and Naloxone Distribution (OEND)

- Most opioid overdoses are witnessed by others so expanding layperson access to naloxone is essential
- OEND is safe, effective, and cost-efficient
 - Over 25,000 documented reversals since 1996
- States with minimal or no layperson access to naloxone have more opioid overdose deaths
- Pharmacy-based naloxone (PBN) distribution can help to overcome barriers associated with community-based naloxone distribution

Bratberg JP and Jackson AN. Educating and empowering patients and caregivers: The pharmacist's role in reducing the risk of opioid overdose. <http://drugtopics.modernmedicine.com/drug-topics/news/part-ii-law-educating-and-empowering-patients-and-caregivers-pharmacist-s-role-reducing-risk-opioid-overdose>. Accessed April 7, 2016.



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Opioid Overdose

- Opioids bind to opioid receptors in the brain including the respiratory center located in the medulla
- Body becomes less sensitive to changes in oxygen and carbon dioxide saturation
- Decrease in sensitivity leads to respiratory depression and ultimately acute respiratory failure
- Generally occurs over 1-3 hours



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Risk Factors for Opioid Overdose

- Patients taking high-dose opioids or medications used for the treatment of opioid dependence
 - Opioid prescriptions \geq 100 morphine milligram equivalents (MME) per day
 - Buprenorphine/naloxone (Suboxone[®], Zubsolv[®], Bunavail[®])
 - Buprenorphine (Subutex[®])



Risk Factors for Opioid Overdose

- Patients receiving any opioid prescription for pain in addition to:
 - Concurrent prescription for a benzodiazepine or other CNS depressant
 - Concurrent prescription for an antidepressant
 - Concurrent alcohol use
 - Renal or hepatic dysfunction
 - Respiratory disease



Risk Factors for Opioid Overdose

- Patients on methadone
- Patients who rotate opioids or have recently switched from one opioid to another
- Personal history of substance use disorder
- Previous overdose
- Recent discharge from an abstinent environment
 - Detox, treatment center, incarceration, etc.



Overdose vs. Overmedication

| Signs/Symptoms of Overmedication | Signs/Symptoms of Overdose |
|--|--|
| <ul style="list-style-type: none">• Miosis• Drowsy but arousable; responsive to sternal rub• Slurred speech• Confusion• Reduced respiratory rate but > 8 breaths/minute | <ul style="list-style-type: none">• Miosis• Nonresponsive to sternal rub• Infrequent shallow respirations (< 8 breaths/minute)<ul style="list-style-type: none">○ Respirations could resemble sounds caused by choking, snoring, or gurgling• Dusky/cyanotic skin, lips, or fingertips• Hypotension and bradycardia |
| <p><i>ACTION:</i> Provide stimulation to keep patient responsive and monitor closely</p> | <p><i>ACTION:</i> Begin rescue breathing and administer naloxone</p> |

Responding to an Opioid Overdose

1 Check for signs/symptoms of opioid overdose

2 Give naloxone

3 Call 911

4 Start rescue breathing

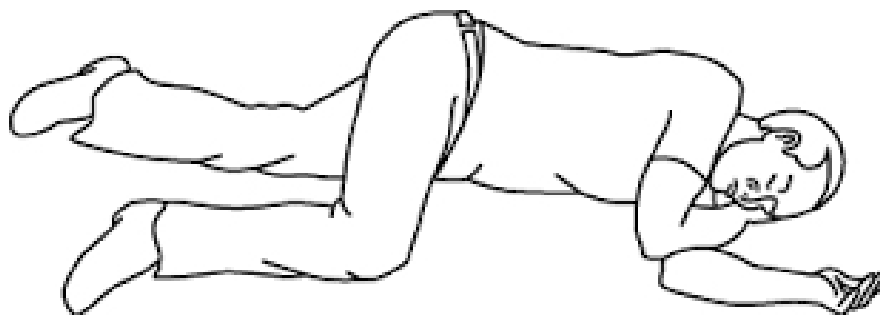
Responding to an Opioid Overdose

- Continue rescue breathing until emergency help arrives or person is able to breathe on their own
 - Make sure nothing is in the person's mouth
 - Tilt their head back, left chin, and pinch nose shut
 - Give 1 slow breath every 5 seconds until they start breathing again



Responding to an Opioid Overdose

- After they are able to breathe on their own again, put the person on their side so they do not choke (rescue/recovery position)
- **Stay with the person until emergency help arrives**



Naloxone

- Pure opioid antagonist that displaces exogenously administered opioids from their receptor sites
- Rapidly (but temporarily) reverses respiratory depression resulting from opioid overdose
 - Efficacy may be limited in patients who have ingested partial agonists or mixed agonist/antagonists (i.e. buprenorphine, pentazocine)
- Little to no pharmacologic activity in patients who have not taken opioids
- No potential for abuse

Naloxone

- **Contraindications**
 - Known hypersensitivity to naloxone or any of its inactive ingredients
- **Precautions**
 - Pregnant women who are opioid dependent
- **Onset and Duration of Action**
 - Generally begins to take effect in 2-5 minutes
 - Effects last for 30-90 minutes after which respiratory depression may return

Naloxone

- Adverse effects are primarily attributed to acute opioid withdrawal

| | | |
|--------------|---------------------------|------------------|
| Body aches | Restlessness/irritability | Nausea/vomiting |
| Fever | Tachycardia | Weakness |
| Piloerection | Sneezing | Abdominal cramps |
| Diarrhea | Yawning | Sweating |
| Runny nose | Shivering/trembling | ↑ blood pressure |

- Storage
 - Room temperature away from light
 - Do not assemble or prime prior to administration

Narcan[®] (naloxone) Nasal Spray

- 4 mg/0.1 mL (each spray contains 4 mg of naloxone)
- 2 doses/box
- Dosing
 - 1 spray in one nostril
 - May repeat after 2-3 minutes
 - Alternate nostrils with each dose
 - A new device must be used with each dose



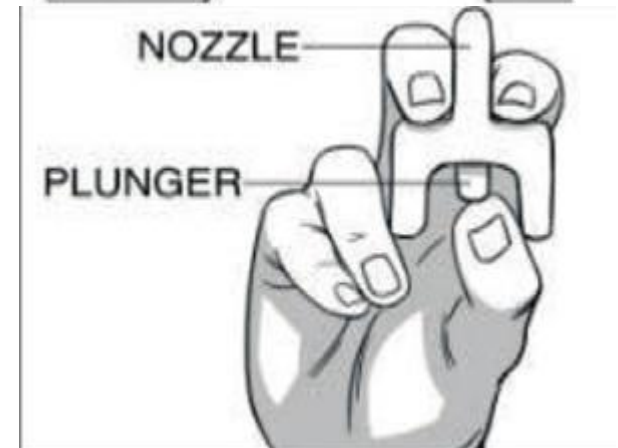
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Narcan[®] (naloxone) Nasal Spray Administration

1. Peel back the top of the package to remove the device



2. Place the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose

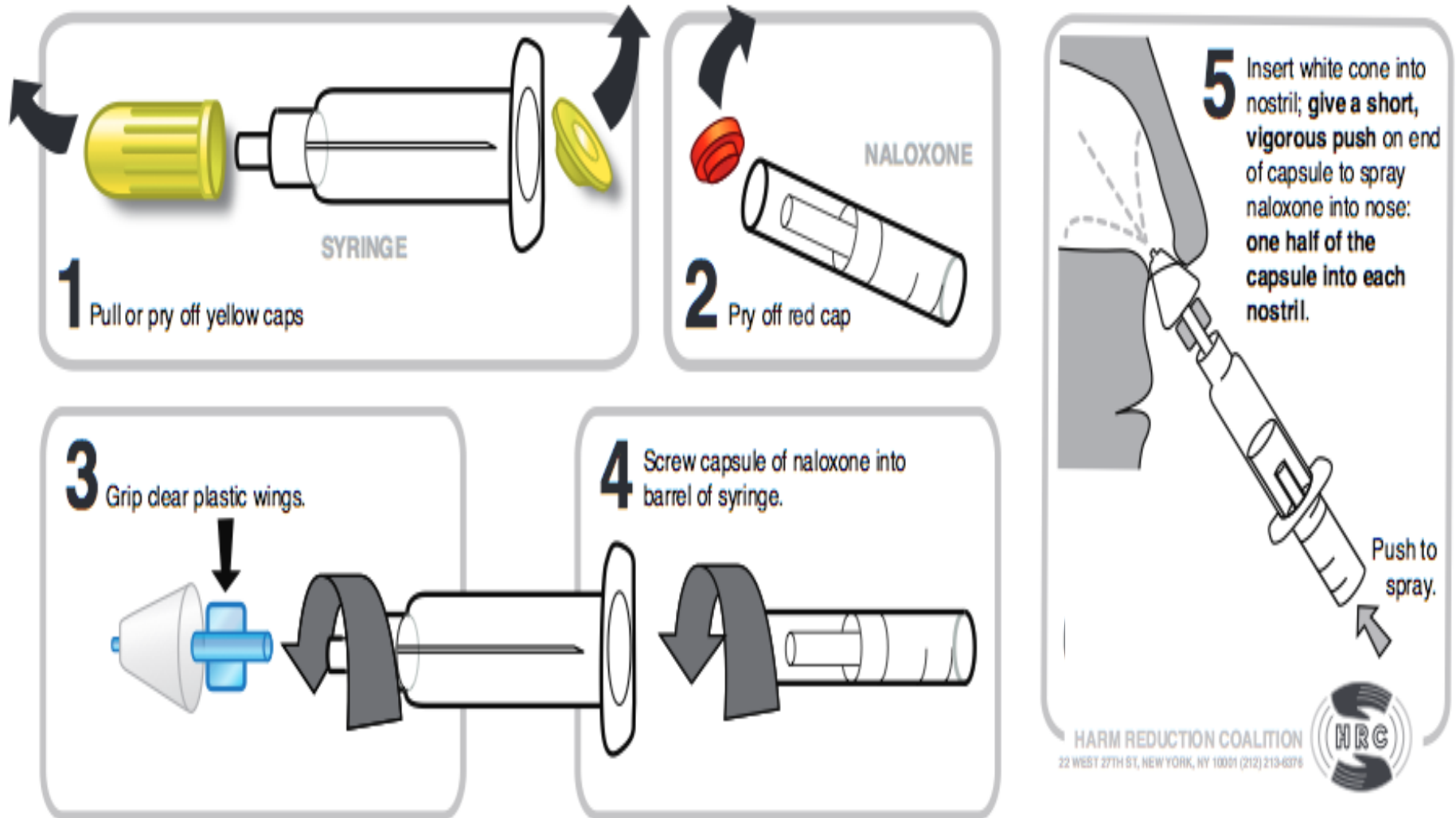


3. Press the plunger firmly to release the dose into the patient's nose

Naloxone 2 mg/2 mL Prefilled Syringe

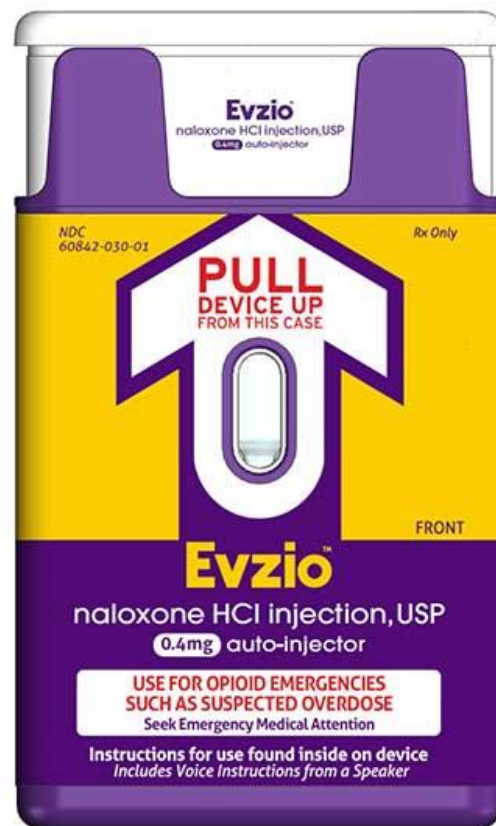
- Parenteral dosage form used off-label for intranasal administration
 - Must be used with a mucosal atomization device (MAD)
- Dosing
 - 1 mL in each nostril
 - May repeat after 3-5 minutes

Intranasal Naloxone Administration



Evzio[®] (naloxone) Auto-Injector

- 0.4 mg/0.4 mL (each dose delivers 0.4 mg of naloxone)
- Each box contains 2 doses + 1 trainer
- Provides voice instructions
- Dosing
 - Inject 1 dose (0.4 mg) into outer thigh and hold for 5 seconds
 - May repeat after 2-3 minutes
 - A new device must be used with each dose



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Naloxone 0.4 mg/mL

- Intended for intramuscular administration
- Dispense each dose with a syringe for administration
 - 23 gauge, 3 mL syringe with a 1 inch needle
- Dosing
 - Inject 1 mL intramuscularly into the deltoid or thigh
 - May repeat after 3 minutes

Naloxone Dispensing Considerations

- When deciding what dosage form to dispense, consider patient input, cost, and ease of administration
 - Take into account the cost of any additional required supplies (i.e. mucosal atomization device)
- 2 doses should be dispensed with each fill
- Follow all state laws and regulations in addition to any requirements listed in the collaborative practice agreement (CPA) under which you are practicing



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Patient Counseling Points

- How to recognize and respond to an opioid overdose
 - Importance of rescue breathing and calling 911
- Risk factors for and prevention of opioid overdose
- Dosing and administration specific to the naloxone product dispensed
- Adverse effects
- Storage
- Resources for opioid addiction



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Tennessee Code 63-1-101

- c) A licensed healthcare practitioner otherwise authorized to prescribe an opioid antagonist acting in good faith and exercising reasonable care may, directly or by standing order, prescribe an opioid antagonist to the following persons:
1. A person at risk of experiencing an opioid-related overdose, or
 2. A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose



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Tennessee Code 63-1-101

- d) In order to establish good faith, a licensed healthcare practitioner, prior to prescribing an opioid antagonist, may require receipt of a written communication that provides a factual basis for a reasonable conclusion that the person requesting the opioid antagonist is:
1. A person at risk of experiencing an opioid-related overdose, or
 2. A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose



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Tennessee Code 63-1-101

- e) A person who receives an opioid antagonist that was prescribed pursuant to subsection (c) may administer an opioid antagonist to another person if:
 1. The person has a good faith belief that the other person is experiencing an opioid-related drug overdose; and
 2. The person exercises reasonable care in administering the drug to the other person



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Tennessee Code 63-1-101

- f) Evidence of the use of reasonable care...shall include the receipt of basic instruction and information on how to administer the opioid antagonist, including successful completion of the online overdose prevention education program offered by the department of health
- Information on naloxone and the link to the online quiz can be found on the Tennessee Department of Health's website
 - <http://tn.gov/health/topic/information-for-naloxone>



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Tennessee Code 63-1-101

A licensed healthcare practitioner acting in good faith and with reasonable care, who prescribes or dispenses an opioid antagonist pursuant to subsection (c) is immune from:

- Civil liability
- Disciplinary or adverse administrative actions under title 63



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SB 2403/HB 2225

- Effective 3/10/16
- Authorizes the chief medical officer to implement a statewide collaborative pharmacy practice agreement (CPA) specific to opioid antagonist therapy with any pharmacist licensed in, and practicing in, the state
- Under this CPA, authorized pharmacists may dispense an opioid antagonist to:
 1. A person at risk of experiencing an opioid-related overdose, or
 2. A family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose



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SB 2403/HB 2225

- Prior to entering into this CPA, the pharmacist shall be able to provide documentation of completion of an opioid antagonist training program within the previous 2 years
- The training program shall include, but not be limited to, proper administration techniques, use, documentation, and quality assurance
- CPA must adhere to the requirements set forth in § 63-10-217 and be made available to the department of health upon request



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Tennessee Code 63-10-217

- Describes CPA requirements
- CPA shall be between ≥ 1 pharmacists and an individual prescriber or ≥ 1 prescribers in an organized medical group
 - Pharmacists and prescribers involved in the CPA must be licensed in the state
- CPA must define nature and scope of patient care services to be provided by the pharmacist(s)
 - These services must be within the scope of the authorizing prescriber(s)



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Tennessee Code 63-10-217

- Patient care services provided by pharmacist(s) pursuant to CPA shall be:
 - Documented in a patient record accessible by the pharmacist and the prescriber, OR
 - Communicated to the prescriber(s) within 3 business days
- A copy of the CPA shall be kept on file at the pharmacist's and prescriber's places of practice
- CPAs shall be reviewed and renewed biennially, at a minimum



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Assessment Questions

1. Which of the following statements are true regarding the disease of addiction?
 - a) It is a chronic disease
 - b) It occurs as a result of changes in the structure and function of the brain
 - c) It is distinct from tolerance and physical dependence
 - d) It is characterized by drug craving, inability to control efforts to abstain from drug use, and compulsive drug use despite negative consequences
 - e) All of the above



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Assessment Questions

2. All of the following are risk factors for opioid overdose, except:
- a) Taking a benzodiazepine in combination with an opioid
 - b) Opioid use in a patient with COPD
 - c) Opioid doses < 40 morphine milligram equivalents (MME) per day
 - d) Opioid use in a patient with renal dysfunction



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Assessment Questions

3. What is the appropriate action to take in a patient who is suspected of ingesting opioids and presents with the following signs/symptoms: miosis, nonresponsive to sternal rub, shallow/infrequent respirations (< 8 breaths/minute), and blue lips?
 - a) Provide stimulation to keep patient responsive and monitor closely
 - b) Begin rescue breathing and administer naloxone



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Assessment Questions

4. When counseling a patient on how to respond to an opioid overdose and how to administer naloxone, which of the following statements is incorrect:
- a) You don't need to call 911 after administering naloxone
 - b) Stay with the person until help arrives
 - c) The naloxone should take effect within 2-5 minutes
 - d) Store naloxone at room temperature away from heat and direct light



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Assessment Questions

5. Which of the following does SB 2403/HB 2225 address?
- a) Gives pharmacists prescriptive authority to prescribe and dispense opioid antagonists
 - b) Permits pharmacists to dispense opioid antagonists to law enforcement and pain management clinics
 - c) Authorizes the chief medical officer to implement a statewide collaborative pharmacy practice agreement (CPA) specific to opioid antagonist therapy with any pharmacist licensed in, and practicing in, the state



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