OPIOIDS: ADDICTION, OVERDOSE PREVENTION (NALOXONE) AND PATIENT EDUCATION

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Continuing Professional Education

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- Tara Thomas, PharmD, '13, for taking on this project!

OVERVIEW

- Opioid abuse and overdose is a growing problem in the United States and in Rhode Island
- Pharmacists can play a role in ensuring the safe use of opioids and preventing opioid overdose
- Naloxone is an antidote for opioid overdose
- A collaborative practice agreement that allows pharmacists to initiate naloxone therapy could prevent opioid overdose death

OBJECTIVES

- Explain the neurobiology of **ADDICTION** and the spectrum of opioid addiction
- Discuss **OPIOID OVERDOSE** and the epidemic on a national and state level
- Identify the role **NALOXONE** has in opioid overdose prevention
- Describe the contents of the **COLLABORATIVE PRACTICE AGREEMENT**
- List three ways to best **EDUCATE PATIENTS & CAREGIVERS on overdose management**

ADDICTION

Understanding Addiction

Risk Factors

Neurobiology

Spectrum of Opioid Addiction

LANGUAGE

- The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine developed a universal agreement on the definition of language that is often **misused and misunderstood**

Savage SR, Joranson DE, Covington EC, et al. Definitions related to the medical use of opioids: Evolution towards universal agreement. J Pain Symptom Manage 2003;26:655–667.

LANGUAGE

- Addiction:
  - A primary, chronic, neurobiologic disease, with **genetic**, **psychosocial**, and **environmental** factors influencing its development and manifestations
  - Characterized by behaviors that include one or more of the following
    - Impaired control over drug use
    - Compulsive use
    - Continued use despite harm
    - Craving

Savage SR, Joranson DE, Covington EC, et al. Definitions related to the medical use of opioids: Evolution towards universal agreement. J Pain Symptom Manage 2003;26:655–667.

LANGUAGE

- Physical Dependence
  - A state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist

- Tolerance
  - A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time

Savage SR, Joranson DE, Covington EC, et al. Definitions related to the medical use of opioids: Evolution towards universal agreement. J Pain Symptom Manage 2003;26:655–667.

UNDERSTANDING ADDICTION

- Why do people misuse drugs?
  - TO FEEL GOOD:
    - Euphoria is felt after taking most drugs
    - When taking opioids it is usually a feeling of relaxation and satisfaction
  - TO FEEL BETTER:
    - Taking drugs can relieve stress or depression
  - CURIOSITY:
    - Adolescents are especially vulnerable to peer pressure
  - DEPENDENCE:
    - People can unintentionally become physically dependent on drugs, and continue to take drugs to avoid withdrawal symptoms

National Institute on Drug Abuse. Drugs, Brains, and Behavior: The Science of Addiction. Available at: http://www.drugabuse.gov/publications/science-addiction/drug-abuse-addiction. Accessed Sept 26, 2012.

UNDERSTANDING ADDICTION

- After continued drug use tolerance starts to develop people may need to take drugs just to feel normal, or may need to take higher and more frequent doses to get a high

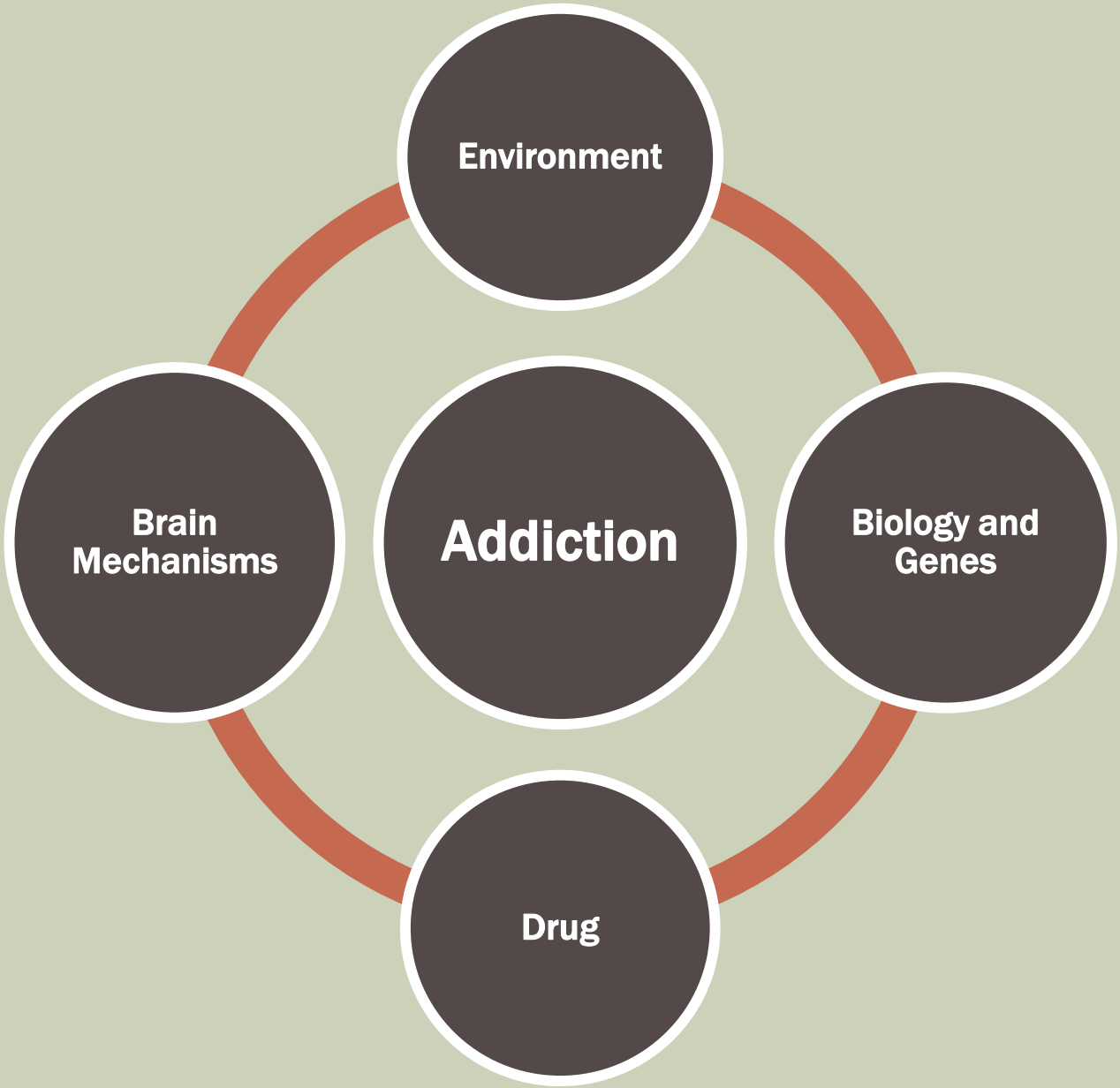
- Addiction is a chronic, relapsing neurological disease
  - Drugs change the structure and functioning of the brain

National Institute on Drug Abuse. Drugs, Brains, and Behavior: The Science of Addiction. Available at: http://www.drugabuse.gov/publications/science-addiction/drug-abuse-addiction. Accessed Sept 26, 2012.

UNDERSTANDING ADDICTION

- Addiction is characterized by **compulsive** drug seeking and using
- When people become addicted they will seek drugs, often despite any **consequences**
- **Self-control** can often be lost during drug addiction, and continued drug abuse may not feel like voluntary behavior
- **Many factors** play a role in addiction, not everyone who takes drugs will go on to continued abuse and addiction

National Institute on Drug Abuse. Drugs, Brains, and Behavior: The Science of Addiction. Available at: http://www.drugabuse.gov/publications/science-addiction/drug-abuse-addiction. Accessed Sept 26, 2012.



National Institute on Drug Abuse. Drugs, Brains, and Behavior: The Science of Addiction. Available at: http://www.drugabuse.gov/publications/science-addiction/drug-abuse-addiction. Accessed Sept 26, 2012.

RISK FACTORS

- Biology and Genes
  - Genetics: can account for 40-60% of a person's vulnerability to addiction
  - Mental disorders, gender, and ethnicity may influence risk for drug abuse and addiction

- Environment
  - Home life and abuse: most important in childhood
  - Parental attitudes: parents who use drugs can increase child's risk of developing drug addiction
  - Peer influences: greatest in adolescence
  - Community attitudes
  - Socioeconomic status

National Institute on Drug Abuse. Drugs, Brains, and Behavior: The Science of Addiction. Available at: http://www.drugabuse.gov/publications/science-addiction/drug-abuse-addiction. Accessed Sept 26, 2012.

RISK FACTORS

- Route of administration: smoking a drug or injecting it into a vein increases likelihood of addiction
  - Quick onset of action
  - Short duration of action
- This brings someone back down quickly after a high
  - Wanting to restore the high leads to repeated drug use
- Early use: the earlier a person starts using drugs the more likely they are to continue to abuse
- Ease of availability and cost of a drug

National Institute on Drug Abuse. Drugs, Brains, and Behavior: The Science of Addiction. Available at: http://www.drugabuse.gov/publications/science-addiction/drug-abuse-addiction. Accessed Sept 26, 2012.

NEUROBIOLOGY

Brain Mechanisms

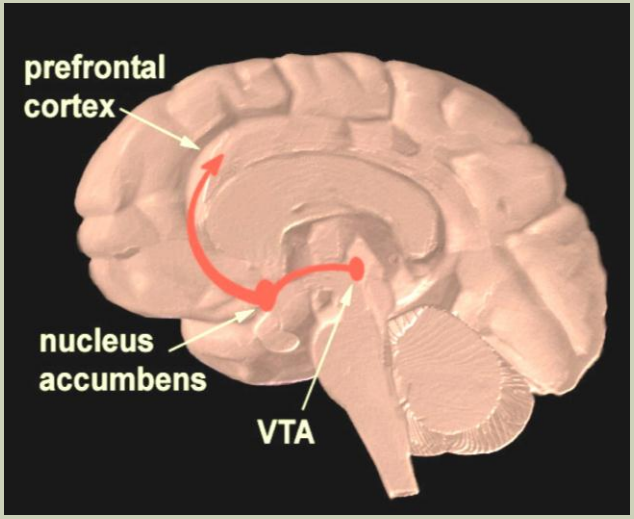
- Opioids work by over stimulating the reward pathway of the brain
- The reward pathway in the brain is activated by natural rewards like food, water, and sex

- By activating the pathway, we feel pleasure and learn to repeat these life-sustaining activities
- This feeling then motivates repetition of the behavior

National Institute on Drug and Abuse: DrugFacts: Prescription and Over-the-Counter Medication. Available at: http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications. Accessed Sept 26, 2012.

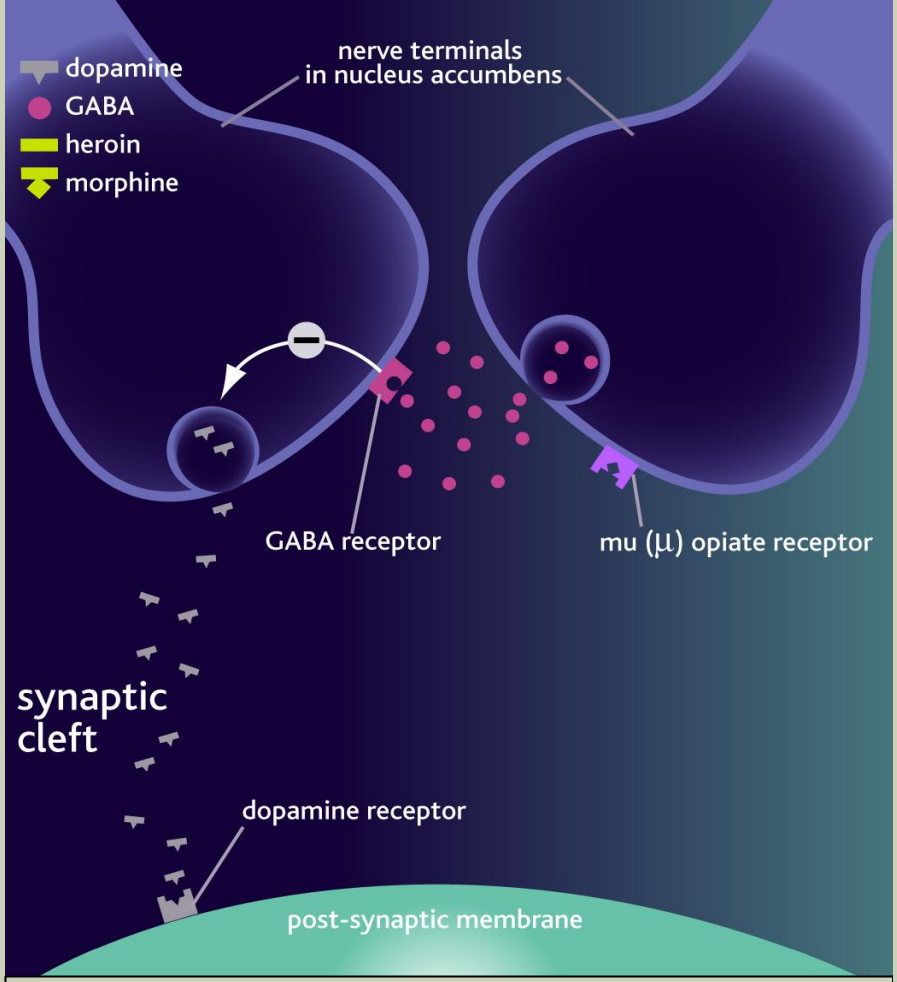
NEUROBIOLOGY

- The "reward pathway" is the **mesolimbic pathway**
  - Starts in the ventral tegmental area
  - Connects to the limbic system, including the nucleus accumbens
  - Dopaminergic



  - Releasing an increased amount of dopamine causes euphoria
  - Addictive drugs over stimulate this pathway
  - Opioids cause the release of more dopamine than natural rewards

National Institute on Drug Abuse: The Neurobiology of Drug Addiction. Available at: http://www.drugabuse.gov/publications/teaching-packets/neurobiology-drug-addiction/section-ii-reward-pathway-addiction/3-reward-pathway. Accessed Sept 26, 2012.



- Dopamine is released from nerve terminals in nucleus accumbens
- Activates dopamine receptor on post-synaptic membrane
- GABA acts to inhibit release of dopamine, exhibiting negative control

Lundbeck Institute. The mechanism of action of heroin at the mu (m) opiate receptors. Available at: http://www.cnsforum.com/imagebank/item/moa_heroin_mu/default.aspx. Acessed: Sept 26, 2012.

THERE IS A SPECTRUM OF OPIOID ADDICTION

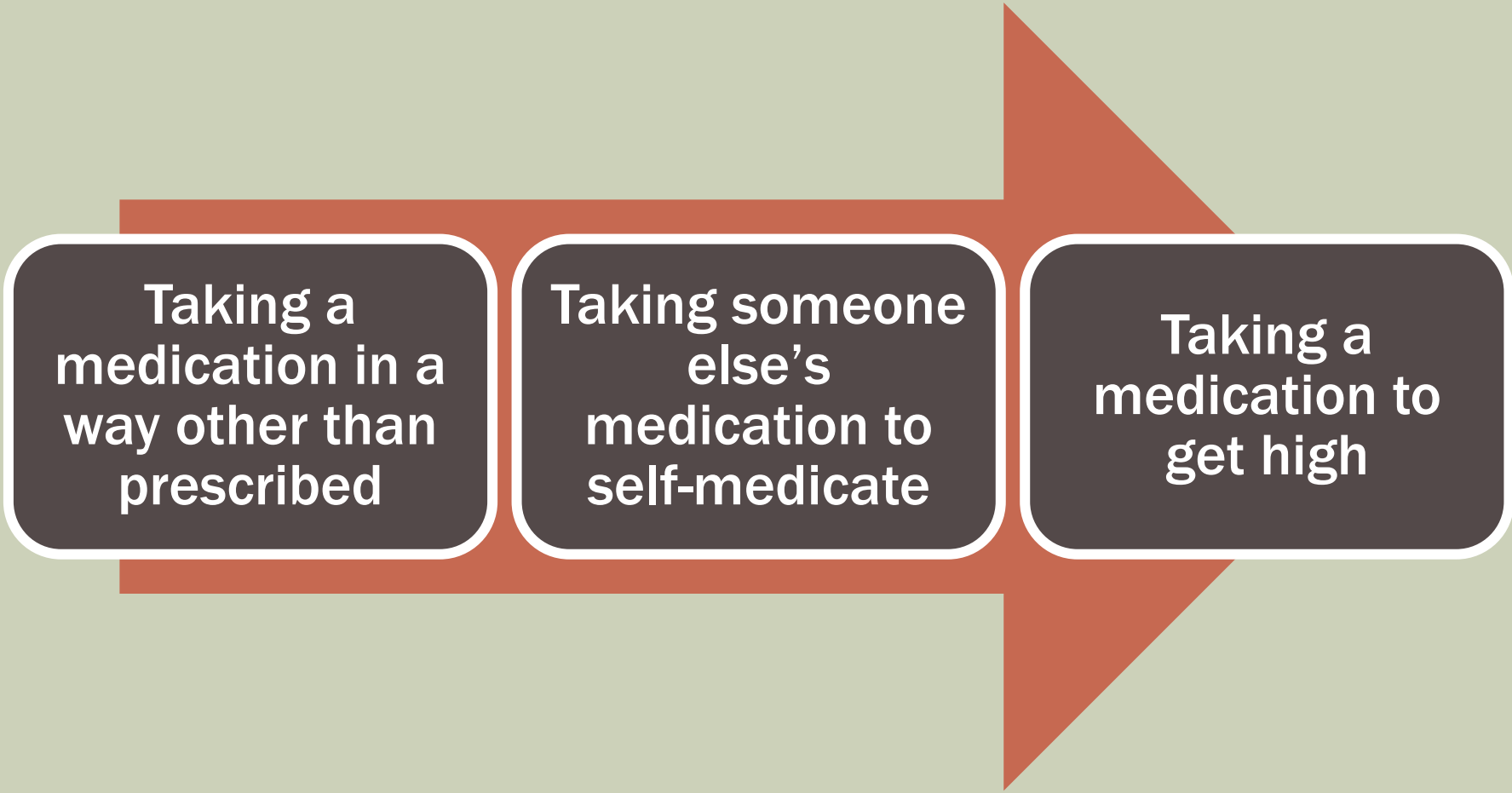
- Prescription opioids are generally used to treat pain
- Prescription opioid addiction can begin with recreational use
- Can also begin when someone receives a prescription for a legitimate medical condition

- In these situations it is possible for dependence to develop
- Taking a medication other than it is directed, like at higher dose, is prescription opioid abuse
- Both dependence and abuse can lead to addiction

PAINKILLER ADDICTION

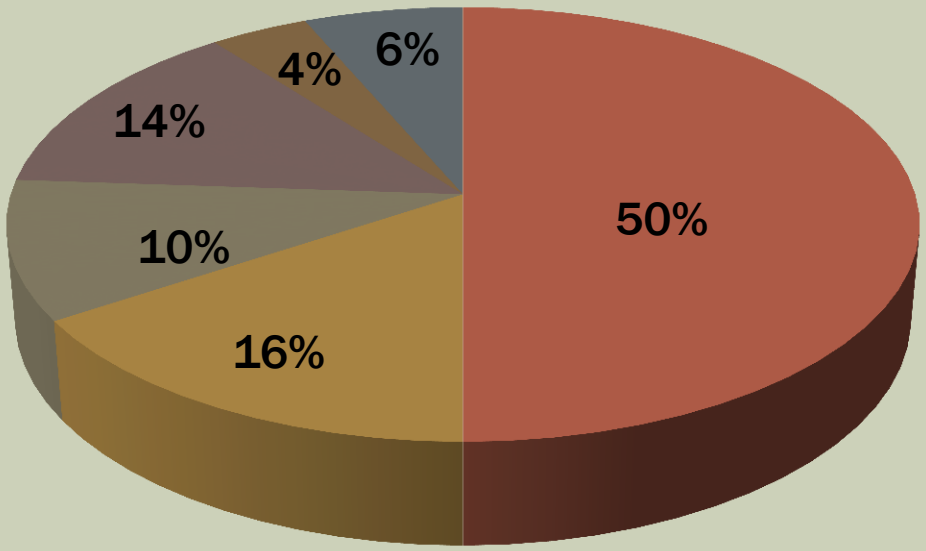
- If someone has **multiple** opioid prescriptions from different doctors and different pharmacies this can indicate opioid abuse and possible opioid addiction
- Prescription opioids can be **crushed and snorted** for a stronger high, but certain manufacturers of long acting opioids, like OxyContin®, have made special formulations to prevent or make crushing tablets harder
- One criticism- this just causes a **shift** of drug addicts to use heroin instead

PRESCRIPTION MISUSE AND ABUSE SPECTRUM



National Institute on Drug and Abuse: DrugFacts: Prescription and Over-the-Counter Medication. Available at: http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications. Accessed Sept 26, 2012.

WHERE DO PEOPLE GET PRESCRIPTION DRUGS?



- Obtained free from friend or relative
- Prescribed by one doctor
- Bought from friend or relative
- Took from friend or relative without asking
- Got from drug dealer or stranger
- Other

Most people don't get prescription drugs from drug dealers or strangers

http://www.cdc.gov/HomeandRecreationalSafety/images/poisoning/rxbrief/sources_300w.png

- Heroin is also an opioid, but unlike prescription opioids it a schedule 1 drug:
  - No medical use, high potential for abuse, not safe under medical supervision
- Heroin is usually injected so there is a risk of injection drug related comorbidities- hepatitis B, HIV, endocarditis

- Once heroin enters the body it is converted to morphine and works on the same receptors as prescription opioids
- Because it can be injected it has a different effect than taking opioid pills
- There is a quicker rush, but it can be a shorter high, which leads to repeated use

- Methadone is used for both pain and to treat heroin addiction
- Taking it for either indication can lead to abuse, dependence, and addiction

- People addicted to prescription opioids, heroin, and methadone may represent different populations
- When dealing with all aspects of opioid addiction it is important to remember the broad spectrum and treat every situation individually

OPIOID OVERDOSE

The biology of overdose

The opioid overdose epidemic

Rhode Island

OPIOIDS

- Opioids:
  - Prescription opioids (morphine, oxycodone, hydrocodone, etc.)
  - Illegal drugs (heroin)

- When prescription opioids are used therapeutically they bind to and activate the opioid receptors, usually to treat pain

OPIOID RECEPTORS

- Mu:
  - Analgesia
  - Sedation
  - Euphoria
  - Respiratory depression
  - Constipation
  - Physical Dependence
- Kappa:
  - Mild analgesia
  - Less respiratory depression
- Delta:
  - Mild analgesia

OVERDOSE

- Opioid receptors are found in the brain, including in the respiratory center in the medulla

- Opioid overdose causes:
  - Reduced sensitivity to changes in O_2 and CO_2 outside of normal ranges
  - Changes in tidal volume and respiratory frequency

White JM, Irvine RJ. Mechanism of fatal opioid overdose. *Addiction*. 1999 Jul;94(7):961-72.

OVERDOSE

- An acute condition due to excess intake of opioids
- Overdose death usually occurs over 1 to 3 hours
- Opioids cause death by:
  - Acute respiratory failure
  - Hypoventilation
  - Increased CO_2
  - Decreased oxygen

OVERDOSE

- Risk factors for overdose:
  - Intake of a large or increased amount of opioids
  - Mixing opioids with other drugs or alcohol
  - Recent changes in tolerance levels
    - Recently leaving a correctional facility or drug treatment center
  - Overdosing alone leads to an increased risk of fatal overdose

OPIOID OVERDOSE: TOXIDROME

- Decreased blood pressure
- Decreased heart rate
- Decreased respiratory rate
- Decreased body temperature
- Miosis
- Blue lips and nails

PRESCRIPTION OPIOID OVERDOSE EPIDEMIC

- **14,800 deaths** in the US in 2008 from opioids
  - This is more than triple the deaths from 1999 data
  - Continuing to rise today
  - CDC has declared this an epidemic

Centers for Disease Control and Prevention. Prescription Painkiller Overdoses in the US. Available at: http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html. Accessed Sept 25, 2012.

PRESCRIPTION OPIOID OVERDOSE EPIDEMIC

- In 2010: **12 million** Americans age 12 or older reported nonmedical use of prescription opioids in the *past year*[1]
- In 2011: **4.5 million** (1.7%) Americans age 12 or older were *current* nonmedical users of pain relievers[2]
- In 2011: Nonmedical pain reliever use in past month
  - 2.3% in youths 12-17
  - 3.6% in adults 18+

1)Centers for Disease Control and Prevention. Prescription Painkiller Overdoses in the US. Available at: http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html. Accessed Sept 25, 2012.

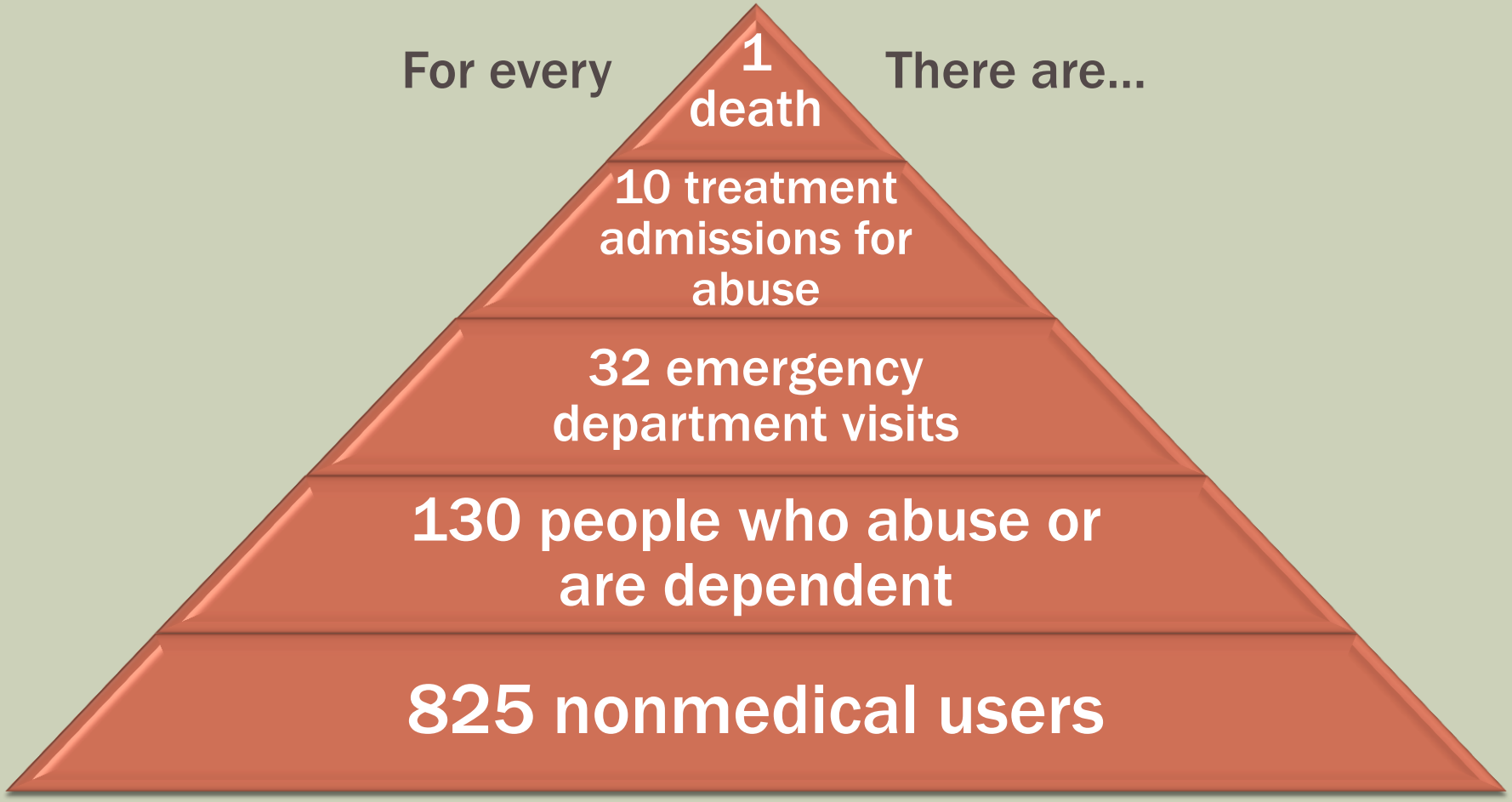
2) U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration Center for Behavioral Health Statistics and Quality. Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings. Available at: http://store.samhsa.gov/product/Results-from-the-2011-National-Survey-on-Drug-Use-and-Health-NSDUH-/SMA12-4713

PRESCRIPTION OPIOID OVERDOSE EPIDEMIC

- The overdose epidemic encompasses more than overdose death:
  - In 2009 there were nearly **500,000** emergency department visits from opioid misuse or abuse
  - Opioid abuse and misuse costs health insurers up to **$72.5 billion** annually in direct health care costs

Centers for Disease Control and Prevention. Prescription Painkiller Overdoses in the US. Available at: http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html. Accessed Sept 25, 2012.

PRESCRIPTION OPIOID DATA (2008)



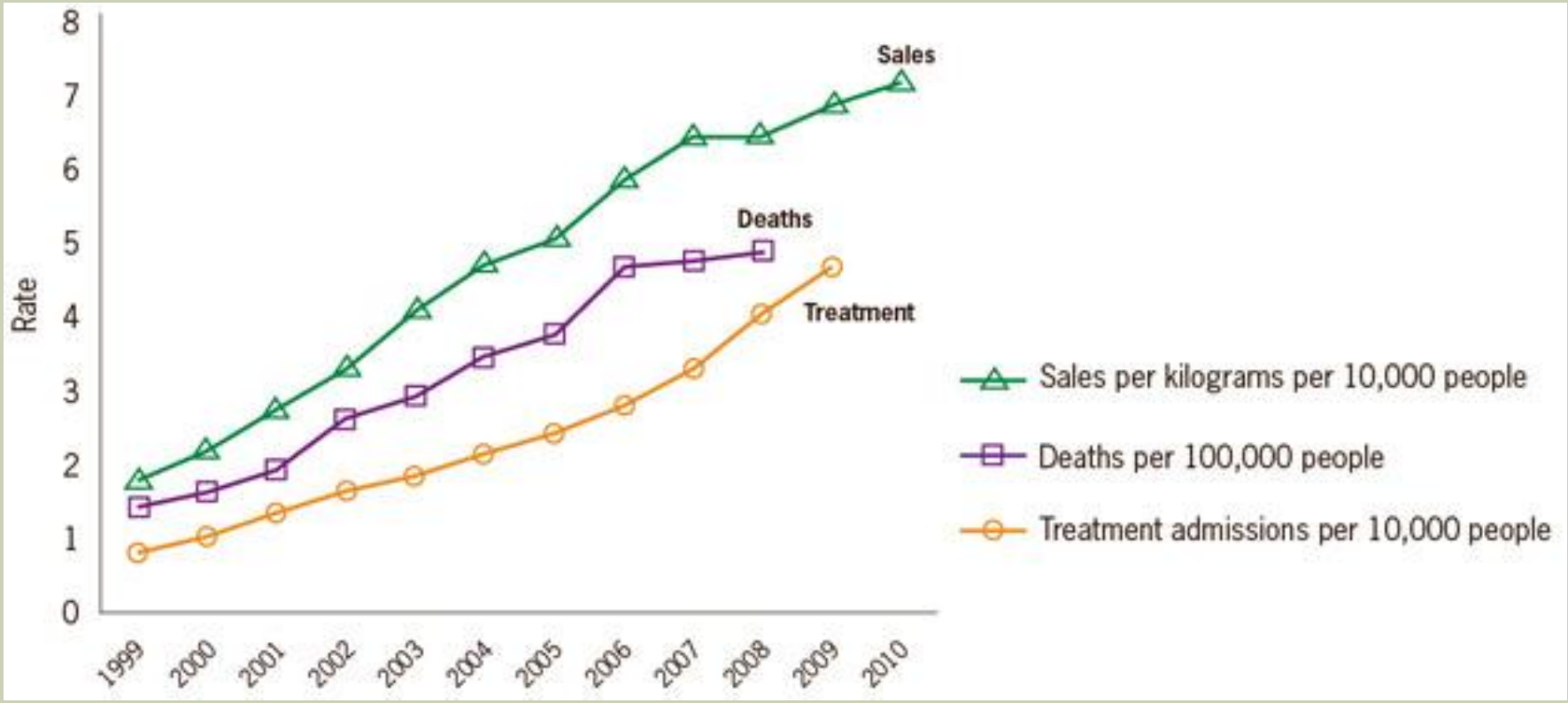
Centers for Disease Control and Prevention. Prescription Painkiller Overdoses Policy Impact Brief. Available at: http://www.cdc.gov/homeandrecreationalsafety/rxbrief/. Accessed: Sept 25, 2012.

EPIDEMIOLOGY- RX OPIOID OVERDOSE

- More men then women die of overdose from prescription opioids
- People in rural counties are more likely to overdose than people in big cities
- About one-half of prescription painkiller deaths involve **at least one other drug**, including benzodiazepines, cocaine, and heroin

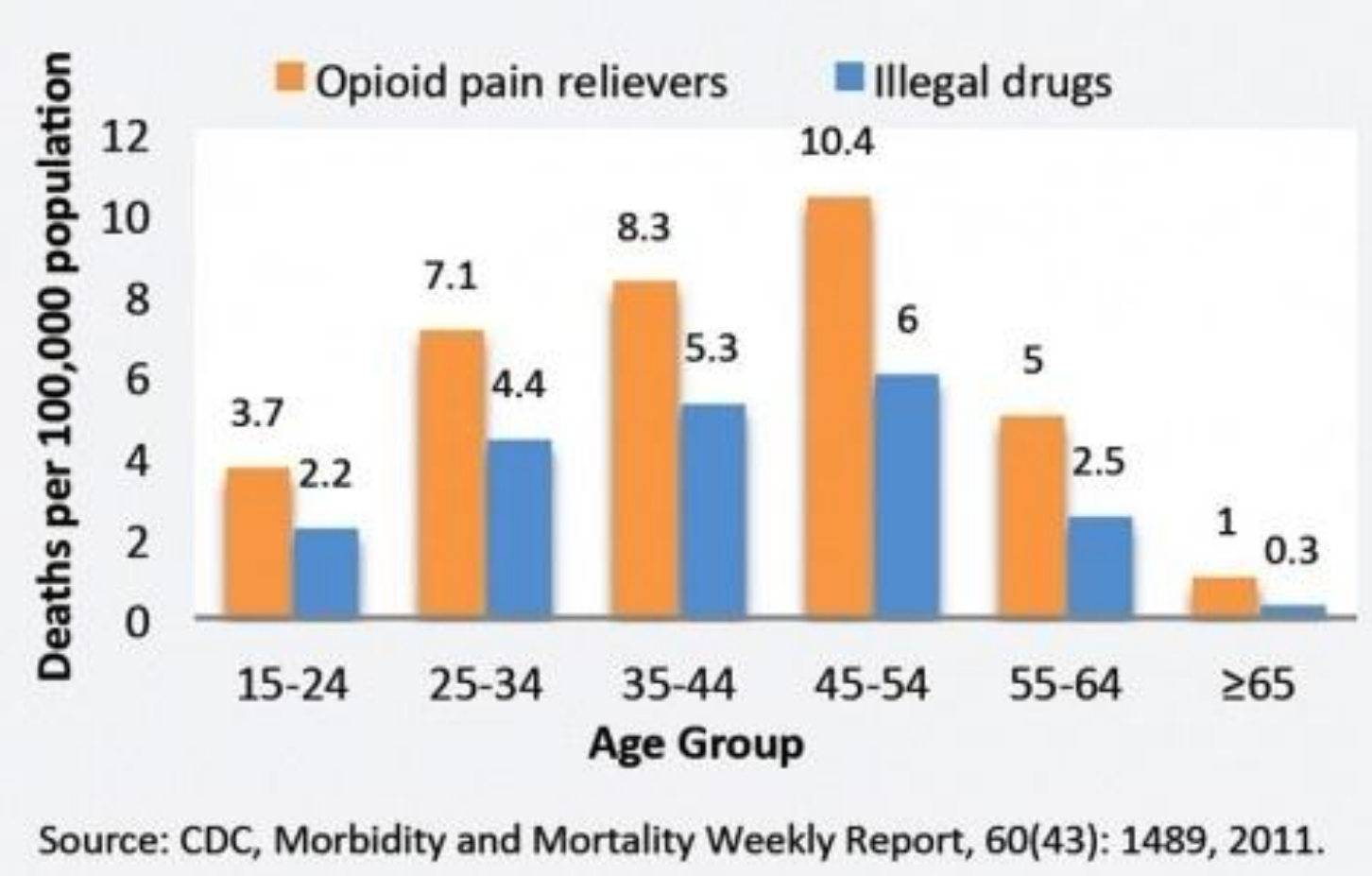
Centers for Disease Control and Prevention. Prescription Painkiller Overdoses in the US. Available at: http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html. Accessed Sept 25, 2012.

RATES OF PRESCRIPTION OPIOID SALES, DEATHS AND SUBSTANCE ABUSE TREATMENT ADMISSIONS (1999-2010)



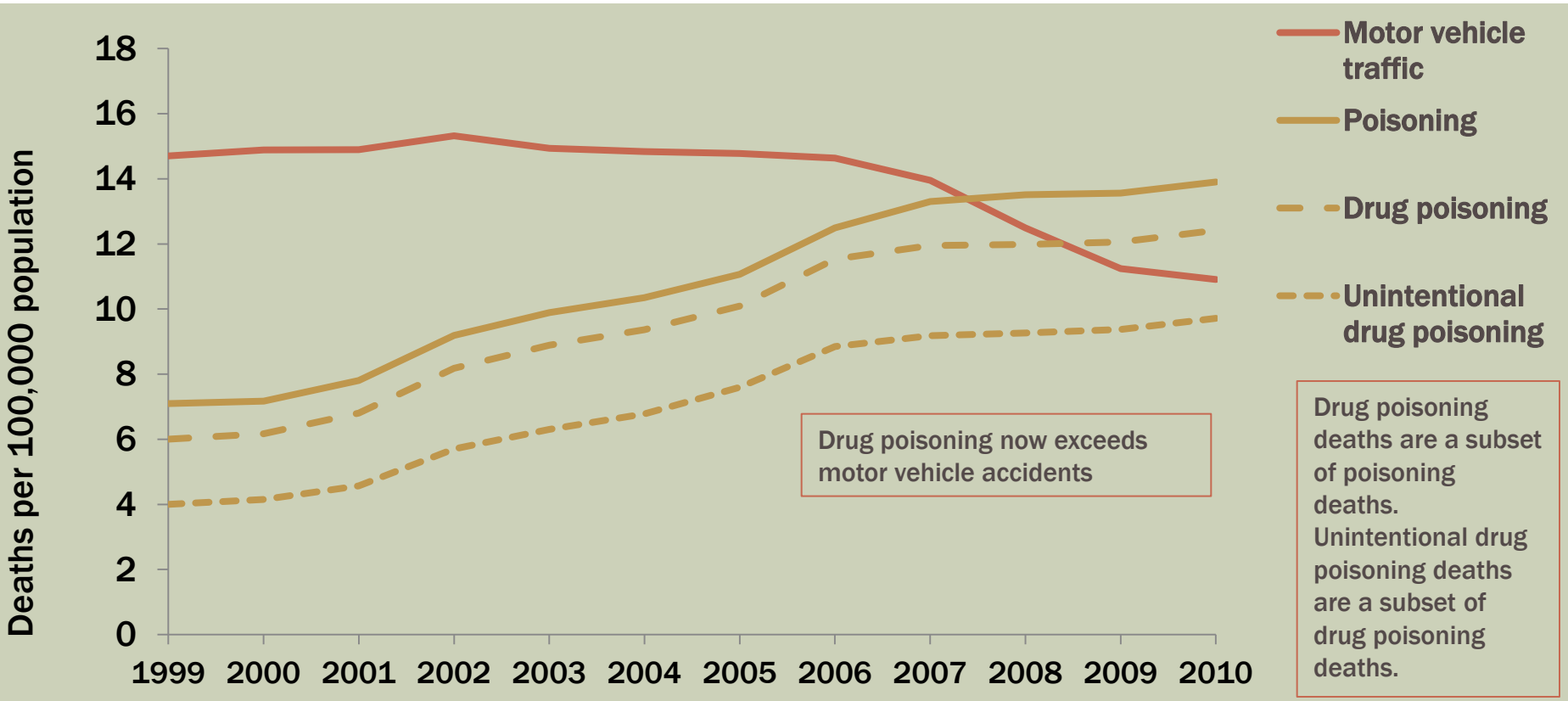
National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

DEATHS FROM OPIOID PAIN RELIEVERS EXCEED THOSE FROM ALL ILLEGAL DRUGS



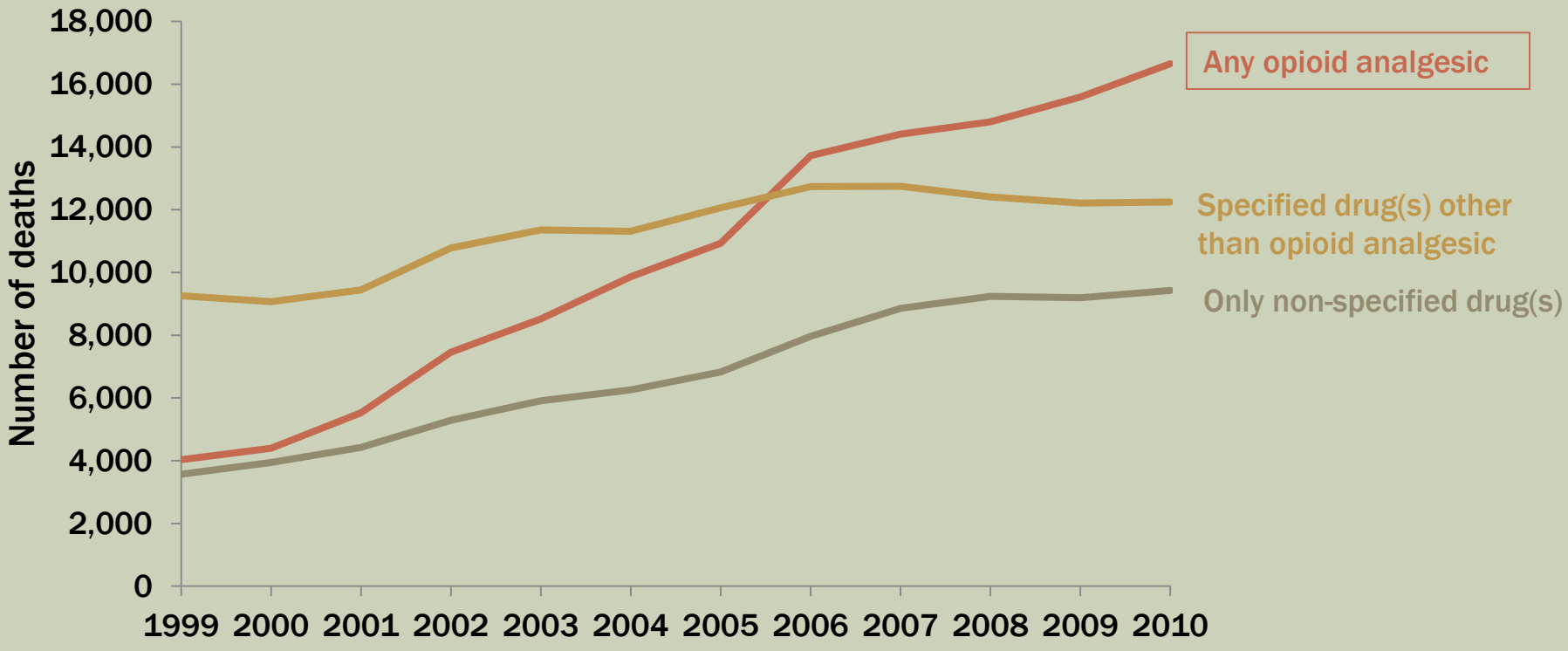
National Institute on Drug and Abuse: DrugFacts: Prescription and Over-the-Counter Medication. Available at: http://www.drugabuse.gov/publications/drugfacts/prescription-over-counter-medications. Accessed Sept 26, 2012.

DEATH RATES: UNITED STATES, 1999--2010



Updates to NCHS Drug Poisoning Data Brief 2010 mortality data. CDC/NCHS, National Vital Statistics System; and Warner M, Chen LH, Makuc DM, Anderson RN, Miniño AM. *Drug poisoning deaths in the United States, 1980–2008*. NCHS data brief, no 81. Hyattsville, MD: National Center for Health Statistics. 2011. Available at: http://www.cdc.gov/nchs/data/databriefs/db81.htm

NUMBER OF DRUG POISONING DEATHS: UNITED STATES, 1999--2010



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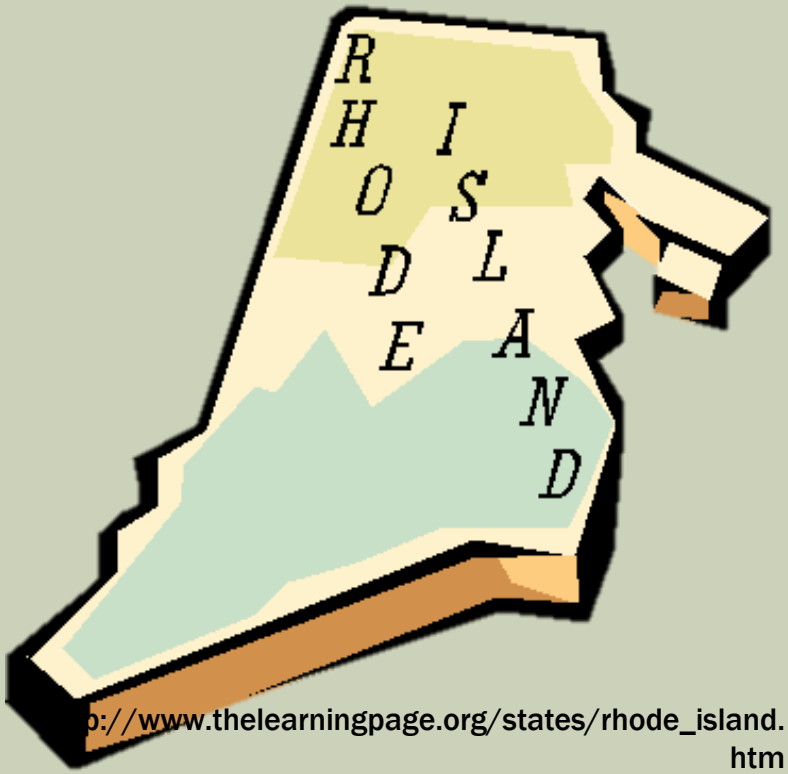
RHODE ISLAND

- 17.2 drug overdose death rate per 100,000 people in 2008[1]
  - **7th highest state**
- A quality-of-life survey in Rhode Island found that 88.5% of drug users were willing to administer naloxone to prevent an overdose fatality[2]



p://www.thelearningpage.org/states/rhode_island.htm

1) Centers for Disease Control and Prevention. Prescription Painkiller Overdoses Policy Impact Brief. Available at: http://www.cdc.gov/homeandrecreationalsafety/rxbrief/. Accessed: Sept 25, 2012.
2) Kim D, Irwin KS, Khoshnood K. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. *Am J Public Health*. 2009 March; 99(3): 402–407.

RHODE ISLAND (2008) IS RANKED IN THE TOP 10 STATES WITH THE HIGHEST RATES OF:

Measure	Age Groups
Past Month Illicit Drug Use	12+, 18-25
Past Month Marijuana Use	All Age Groups
Past Year Marijuana Use	All Age Groups
Least Perception of Risk Associated with Smoking Marijuana Once a Month	All Age Groups
Past Month Use of an Illicit Drug Other Than Marijuana	12+, 18-25
Past Year Cocaine Use	12+, 18-25, 26+
Past Year Nonmedical Use of Pain Relievers	18-25
Past Month Alcohol Use	All Age Groups
Past Month Binge Alcohol Use	12+, 18-25, 26+

Substance Abuse and Mental Health Services Administration. Rhode Island: States in Brief, Substance Abuse and Mental Health Issues At-A- Glance. December, 2008.

RHODE ISLAND (2009-2010 DATA) PERCENTAGES, BY AGE GROUP

- Past *Month* Illicit Drug Use

AGE GROUP:	12+	12-17	18-25	26+	18+
PERCENT:	13.21%	12.85%	32.35%	9.64%	13.24%

SAMHSA, Center for Behavioral Health Statistics and Quality. State Estimates of Substance Use and Mental Disorders from the 2009-2010 National Surveys on Drug Use and Health: Illicit Drug Use. Available at: http://www.samhsa.gov/data/NSDUH/2k10State/NSDUHsae2010/NSDUHsaeCh2-2010.htm.

RHODE ISLAND (2009-2010 DATA) PERCENTAGES, BY AGE GROUP

- Past *Year* Nonmedical Use of Pain Relievers

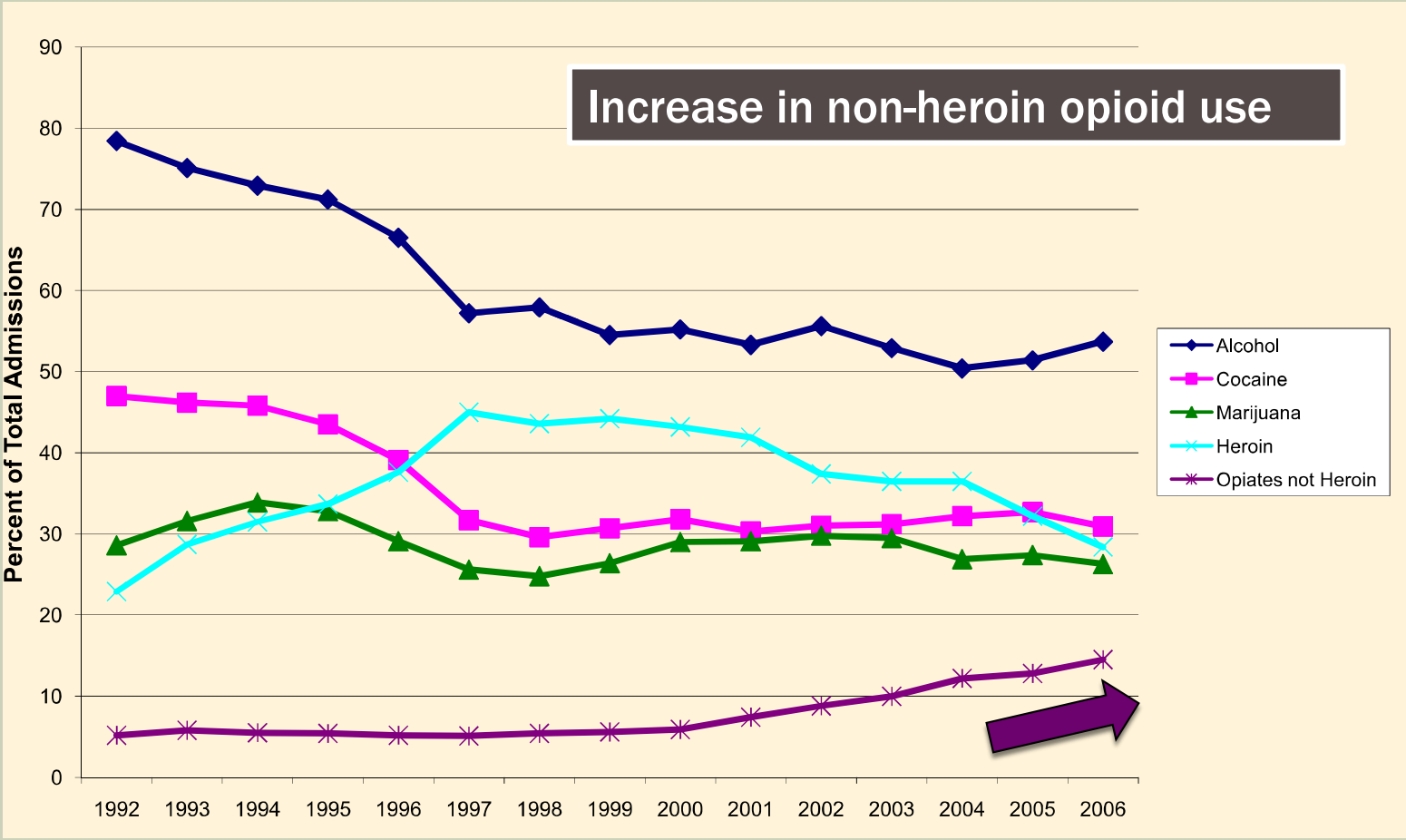
AGE GROUP:	12+	12-17	18-25	26+	18+
PERCENT:	5.93%	6.29%	14.64%	4.24%	5.89%

Compared to a national rate of 4.9%

RI has **higher** past year nonmedical use of pain relievers than national rates

SAMHSA, Center for Behavioral Health Statistics and Quality. State Estimates of Substance Use and Mental Disorders from the 2009-2010 National Surveys on Drug Use and Health: Illicit Drug Use. Available at: http://www.samhsa.gov/data/NSDUH/2k10State/NSDUHsae2010/NSDUHsaeCh2-2010.htm.

DRUGS MENTIONED AT TREATMENT ADMISSION IN RI



Substance Abuse and Mental Health Services Administration. Rhode Island: States in Brief, Substance Abuse and Mental Health Issues At-A- Glance. December, 2008.

NALOXONE

Naloxone's Role in Opioid Overdose

Opioid Withdrawal

NALOXONE

- 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

NALOXONE

Naloxone is an antidote for opioids only:

- fentanyl
- morphine
- buprenorphine
- codeine
- hydromorphone
- hydrocodone
- oxymorphone
- methadone
- oxycodone
- heroin

NALOXONE

- Intramuscular form (IM)
  - Available as 0.4mg/ml solution for injection in 1ml and 10 ml vials
- Intranasal form (IN)
  - Available as 2mg/2ml prefilled syringes
  - Compatible with a mucosal automation device for nasal delivery
- Intravenous form (IV)
  - Standard antidote used by EMS for diagnosing and treating opioid overdose

WHY USE NALOXONE

- Not scheduled or controlled
  - Fewer barriers to access
- Cannot be abused
  - No euphoria from naloxone
  - No effect if opioids are not present
- Effective, inexpensive, easy to administer
- Naloxone has shown success in take-home programs facilitated by community outreach programs in various states

PHARMACOLOGY

- Reverses clinical and toxic effects of opioid overdose
  - Reverses respiratory depression, hypotension, sedation
  - Restores breathing
  - Reverses analgesia
  - Patients can enter withdrawal after naloxone administration

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

OPIOID WITHDRAWAL

- Opioids act in the locus ceruleus to suppress the release of norepinephrine
- During withdrawal there is a rebound release of norepinephrine leading to:
  - Tachycardia
  - Tremor
  - Anxiety
  - Hypertension

Doering PL. Substance-Related Disorders: Overview and Depressants, Stimulants, and Hallucinogens. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, et al. Pharmacotherapy: A Pathophysiologic Approach. 8th ed. New York: McGraw-Hill Medical; 2012.

OPIOID INTOXICATION AND WITHDRAWAL

	Intoxication	Withdrawal
Symptoms	Euphoria, dysphoria, apathy, sedation, attention impairment	Piloerection, insomnia, muscle aches, yawning, diarrhea, nausea, vomiting
Signs	Motor retardation, slurred speech, miosis	Fever, lacrimation, diaphoresis, mydraisis, rhinorrhea

Doering PL. Substance-Related Disorders: Overview and Depressants, Stimulants, and Hallucinogens. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, et al. Pharmacotherapy: A Pathophysiologic Approach. 8th ed. New York: McGraw-Hill Medical; 2012.

OPIOID WITHDRAWAL

- Withdrawal can be described as a severe case of influenza
- Non-life threatening unless there is a concurrent life threatening condition
- Onset of withdrawal:
  - Can be a few hours after stopping a drug (ex. heroin)
  - Can be a few days after stopping a drug (ex. methadone)
- Duration can last 3 days to 2 weeks

Doering PL. Substance-Related Disorders: Overview and Depressants, Stimulants, and Hallucinogens. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, et al. Pharmacotherapy: A Pathophysiologic Approach. 8th ed. New York: McGraw-Hill Medical; 2012.

NALOXONE COLLABORATIVE PRACTICE AGREEMENT

COLLABORATIVE PRACTICE AGREEMENT

- The Collaborative Practice Agreement allows pharmacists to initiate naloxone therapy

- This is the first program that would allow naloxone to be dispensed from a pharmacy without a prescription to anyone that meets the criteria outlined in the protocol

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 >100mg equivalents morphine daily
- Methadone prescription to opioid naïve patient

ELIGIBLE PATIENTS TO PARTICIPATE:

- Opioid prescription with history of smoking, COPD, respiratory illness, or obstruction
- Opioid prescription to patient with renal dysfunction or hepatic disease
- Opioid prescription with known or suspected concurrent alcohol abuse
- Opioid prescription and concurrent benzodiazepine prescription

ELIGIBLE PATIENTS TO PARTICIPATE:

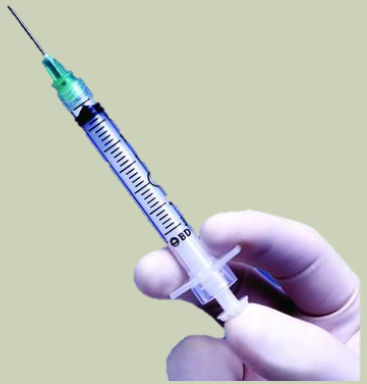
- Opioid prescription and concurrent SSRI or TCA prescription
- Recently released prisoners from a correctional facility
- Released from opioid detoxification or mandatory abstinence program
- Patients entering a methadone maintenance treatment program- for addiction or pain
- Patients that may have difficulty accessing emergency medical services

PROTOCOL: DISPENSING

- Naloxone HCl is the only medication that will be dispensed to patients under this agreement
- Volumes up to **10ml** per patient may be dispensed at a single time
- Naloxone must have a shelf life of at least **12 months** when it is dispensed to the patient

PROTOCOL: DISPENSING

- IM syringes 1- 1.5-inch must be sold with the naloxone vials for intramuscular administration



- A nasal mucosal automation device must be dispensed with the Luer-Jet syringes **without** needles for intranasal use

http://www.cardinalhealth.com/us/en/distributedproducts/ASP/BF305269.asp?cat=med_surg
http://www.lmana.com/pwpcontrol.php?pwpID=8159

PROTOCOL: INFORMED CONSENT

- Before receiving naloxone patients must provide **informed consent** for the release of all medical information:
  - from the prescribing health care provider or physician to the pharmacist
  - from the pharmacist to the prescribing health care provider or physician in accordance with the collaborative practice agreement
- Pharmacy will **retain a copy** of the informed consent

Authorization for Release of Protected Health Information

Patient Name: _____ Phone Number: _____

Date of Birth:_____ Record Number: _____

Address:_____

1. I authorize **Josiah Rich, MD, MPH , The Miriam Hospital, Providence, RI** to disclose and obtain my health information specific to the following dates and/or time period:

_____

2. Walgreens, Inc. pharmacist(s) authorized to receive and disclose my health information:

_____

3. This information is being disclosed in accordance with a collaborative pharmacy practice agreement between providers at the named institutions.

4. Information to be disclosed may include my consent form, medical enrollment form, the certificate of training and/or re-fill form.

5. I understand that my records are protected under the federal privacy laws and regulations and under the general laws of Rhode Island, and cannot be disclosed without my written consent except as otherwise specified by law.

6. I understand that if person(s) or entity(ies) that receive the information is not a health care provider or health plan covered by federal privacy regulations, the information described above may be re-disclosed and is not longer protected by those regulations. Therefore I release _____, it's employees, and my physicians from all liability arising from this disclosure of my health information.

7. It is my understanding that this authorization will not expire. I understand that I may revoke this authorization, or withdraw from collaborative practice at any time by notifying, in writing, the issuing hospital or medical practice. I understand that any previously disclosed information would not be subject to my revocation request.

THIS FORM MUST BE FULLY COMPLETED BEFORE SIGNING

_____ _____ _____

Signature of Patient or Patient's Legal Representative | Date | Print Patient's Name

_____ _____ _____

Print Name of Legal Representative (if applicable) | Date | Relationship to Patient

PROTOCOL: EDUCATION

- Patients may have received previous training on naloxone and overdose at another location, like a community outreach program
- Previous training at another location is **not required** to receive naloxone
- It is the responsibility of the pharmacist to educate or verify the education of **all patients** that come in to make sure they understand the steps for overdose prevention and naloxone administration

PROTOCOL: EDUCATION

- Before receiving naloxone patients must have overdose prevention, identification, and response training
  - Purpose for naloxone
  - Identifying and avoiding high risk situations for overdose
  - Risk reduction strategies
  - Opioid overdose response
- Refresh patients on indications for use and naloxone administration upon refill

PROTOCOL: EDUCATION

- Opioid overdose response includes:
  - How to identify an overdose
  - How to respond in an overdose
    - Rescue breathing, calling 9-1-1
  - How to administer naloxone (either IM or IN)
  - What to do and expect after naloxone administration (withdrawal, rescue position)

PROTOCOL

- This information will be included on a Patient Information Handout, but before dispensing naloxone make sure-
  - The patient received the Patient Information Handout
  - They are comfortable with and understand the material
  - Any questions they have are answered
  - They understand how to prepare the naloxone for use (either drawing up IM dose or putting together nasal device)

PROTOCOL: PROCEDURE

- Pharmacists participating in the collaborative will:
  - Contact the physician entered in the collaborative practice agreement in the even that medical consultation is required for a particular patient
  - Allow the physician to override a collaborative practice decision made by the pharmacist, if appropriate and/or in the best interest of the patient

PROTOCOL: DOCUMENTATION

- Pharmacist will retain a **dispensing log** and document:
  - Date
  - Patient name and DOB
  - The number of doses and volume dispensed
  - NDC, lot number, expiration date
  - Refill number
  - Pharmacist will sign that patient has received the proper education

PROTOCOL: DOCUMENTATION

- Alert the physician entered into the collaborative practice agreement via fax when naloxone is dispensed
- Provide naloxone use reports upon request to the the physician entered into the collaborative practice agreement via fax

WHEN DISPENSING NALOXONE-

1) Patient signed **informed consent** form for the release of medical information, and a copy of this consent is retained in the pharmacy

1) Patient received **Patient Information Handout** containing educational information

3) The patient was **educated** on naloxone in the following areas. Even if dispensing a refill, or the patient presents a certificate of training from another site, the pharmacist must check that the patient was educated in the following areas:

- How naloxone works
- How to identify an overdose
- How to respond in an overdose
- How to administer naloxone (IM or IN)
- What to do and what to expect after naloxone administration
- How to identify and avoid his risk overdose situations

4) **Dispensing log** was filled out- with date, patient name and DOB, NDC, volume and number of doses dispensed, lot number, expiration date, refill number, and pharmacist verification that patient received education- and this is retained in the pharmacy

5) The physician entered into the collaborative practice agreement is **notified** via fax when naloxone is dispensed.

PATIENT EDUCATION

Educating Your Patients On:

How to respond in an overdose

How to administer naloxone

How to prevent overdose

HOW TO RESPOND IN AN OVERDOSE

1) Identify Overdose
2) Call 9-1-1
3) Give Rescue Breaths
4) Give Naloxone
5) Stay Until Help Arrives

1) IDENTIFY OVERDOSE

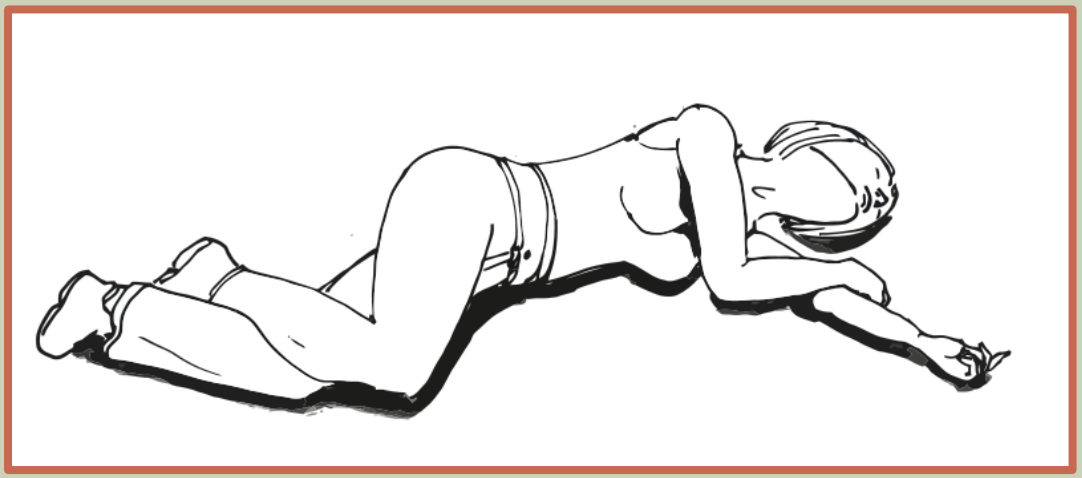
- Make sure patients know how to identify an overdose
- If a person is not breathing or is struggling to breath call out their name and rub knuckles of a closed fist over the sternum
  - If they are not responding they may be experiencing an overdose
- Use instinct, if something doesn't look right call 911

1) IDENTIFY OVERDOSE

- Other signs that may help to identify an overdose:
  - Blue or pale skin color
  - Small pupils
  - Low blood pressure
  - Slow heart beat
  - Slow or shallow breathing
  - Gasping for breath or a snoring sound

RESCUE POSITION

- Make sure the patient understands that if they have to leave at anytime- to call 911 or to get naloxone ready- to use the **rescue position**
- Put them on their side with their top leg and arm crossed over their body
- This makes it difficult for them to roll over and lessens the chance they will choke on vomit



2) CALL 9-1-1

- It is important to get emergency help as soon as possible
- Reassure patients that medical help is crucial to saving lives
- Reinforce that after identifying an overdose, call 9-1-1 immediately, **do not wait until after** administering naloxone
- When calling 9-1-1 all that needs to be said is:
  - Someone is unresponsive and not breathing or struggling to breath
  - Give a clear address and location

2) CALL 9-1-1

- People may be scared to call 911 in the case of an overdose for a variety of reasons
  - Police are normally notified of a 911 call involving an overdose an often come to the scene
  - People may be hesitant to call if they are on parole, have outstanding arrest warrants, etc.
  - Lack of education on overdose or denial overdose is occurring
  - Home remedies are used instead
- Calling 911 is estimated to occur only 10-56% of the time
- Improve this by educating patients on the RI Good Samaritan Overdose Prevention Act

Kim D, Irwin KS, Khoshnood K. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. *Am J Public Health*. 2009 March; 99(3): 402–407.

RI GOOD SAMARITAN OVERDOSE PREVENTION ACT: PASSED JUNE 2012

- A person may administer an opioid antagonist to another person if:
  - They believe the other person is experiencing a drug overdose
  - They act with reasonable care in administering the drug
- They will not be subject to civil liability or criminal prosecution as the result of administration of the drug

RI House Bill 7248- 2012 Regular Session. Available at: http://legiscan.com/gaits/text/619399

RI GOOD SAMARITAN OVERDOSE PREVENTION ACT: PASSED JUNE 2012

- A person either experiencing a drug overdose or a person seeking medical assistance for a drug overdose or drug-related medical emergency shall not be charged or prosecuted for any crime related to
  - possession or delivery of controlled substance or drug paraphernalia
  - the operation of drug-involved premises
- If the evidence for the charge was gained as a result of seeking medical assistance

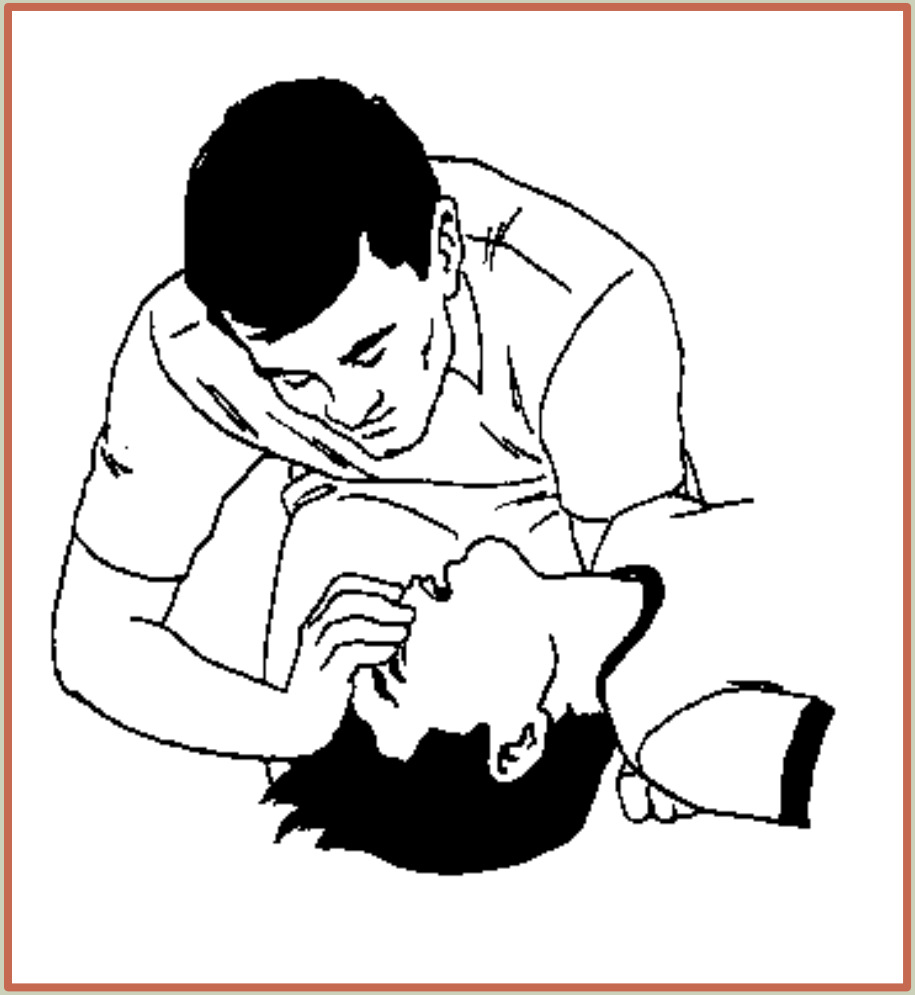
RI House Bill 7248- 2012 Regular Session. Available at: http://legiscan.com/gaits/text/619399

3) GIVE RESCUE BREATHS

- During an overdose respiratory depression occurs, and **lack of oxygen** is the major concern
- Giving oxygen can save a life in an overdose
- All patients receiving naloxone should be educated on how to administer rescue breathing
- Make sure patients don't think they can skip this step

3) GIVE RESCUE BREATHS

- Make sure the airway is clear and remove anything in their mouth
- Place 1 hand on the chin and tilt head back to open airway
- Pinch the nose closed
- Give 2 slow rescue breaths into the mouth



3) GIVE RESCUE BREATHS

- Make sure the chest is rising with the breaths
- Give 1 breath every 5 seconds until the person can breath on their own
- If they are still unresponsive after 30 seconds and you have naloxone available, consider getting it at this time if you do not have to leave the person alone long enough without giving rescue breaths

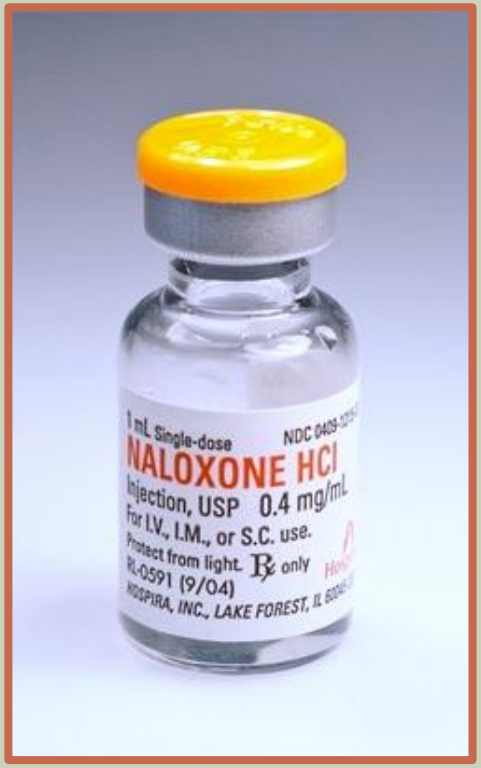
4) GIVE NALOXONE

- Naloxone is available intramuscularly (IM) and intranasally (IN)
- When dispensing naloxone to a patient, make sure they know how administer the dosage form of naloxone that they receive

4) GIVE NALOXONE: IM

- When injecting into the muscle:
  - Remove the cap of the naloxone vial
  - Remove the cap of the needle and insert into vial
  - Hold the vial upside down
  - Pull back the plunger and draw up 1ml of naloxone (0.4mg)
  - Patients will either have a multi dose vial (10ml vial) or will draw up the entire vial (1ml vial)

NDC 00409-1219-01 for 10mL multi-dose vial
NDC 00409-1215-01 for 1mL single dose vial



Hospira: Naloxone Hydochloride Injection, USP 0.4mg/ml

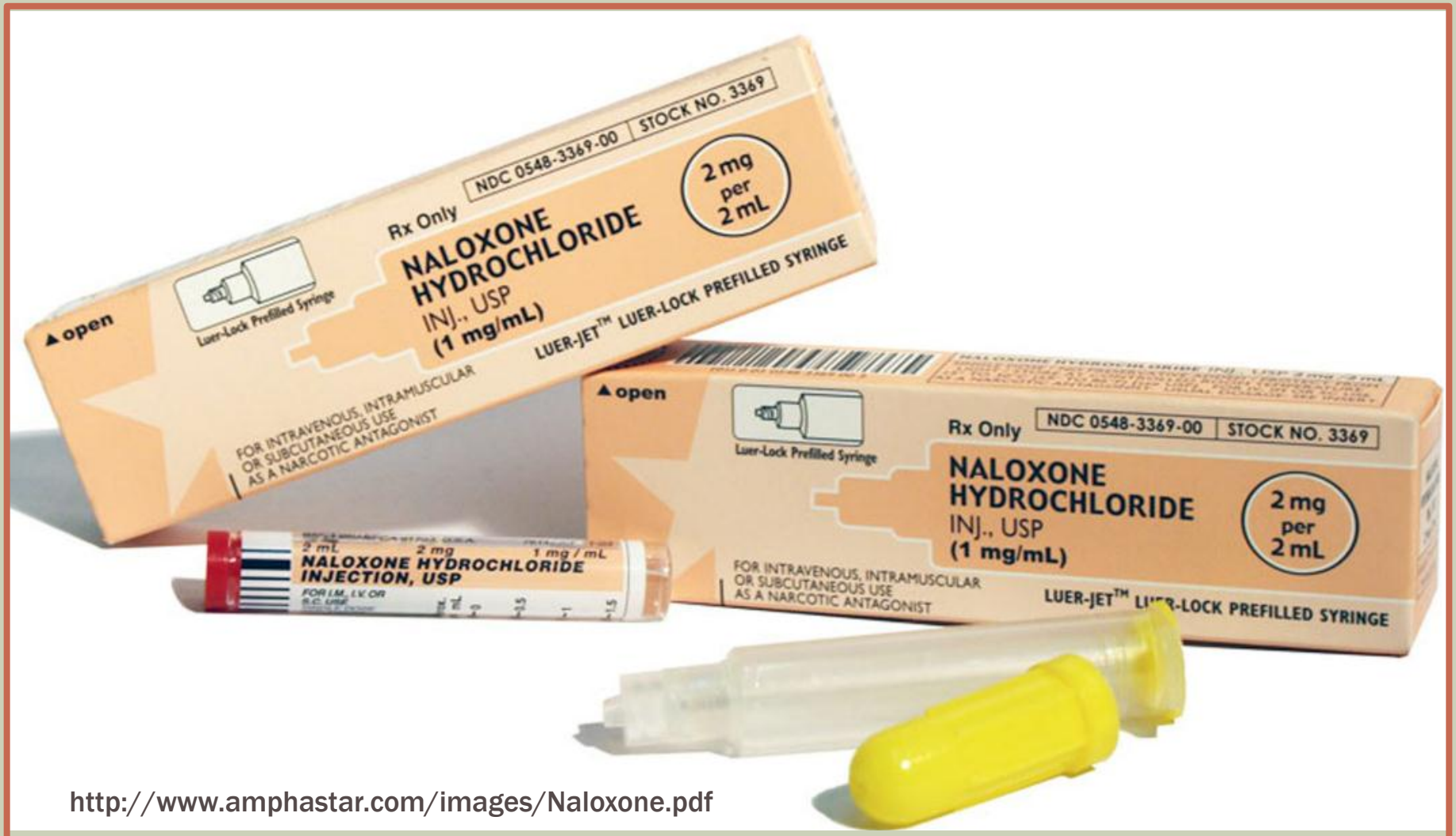
4) GIVE NALOXONE: IM

- Using a needle at least 1 inch long, instruct patients to inject into a muscle
- It is may be safest and easiest to instruct patients to inject into the deltoid muscle
- Recommended needle to dispense: 1inch, 3ml, 25 gage
- Recommend retractable needles

Safety Syringe. Available at :http://www.youtube.com/watch?v=1CbkirLZjpo

4) GIVE NALOXONE: IN

- The intranasal naloxone needs to be dispensed with the mucosal automation device
- The patient will have three parts
  - Nasal Adaptor
  - Applicator
  - Naloxone prefilled syringe
- The applicator comes with the Luer-Jet Luer-Lock Prefilled Syringe of naloxone



http://www.amphastar.com/images/Naloxone.pdf

NDC 76329-3369-10 for 2mg/2ml naloxone prefilled syringe without needle
(NDC pictured no longer active)

4) GIVE NALOXONE: IN

http://www.lmana.com/pwpcontrol.php?pwpID=8159

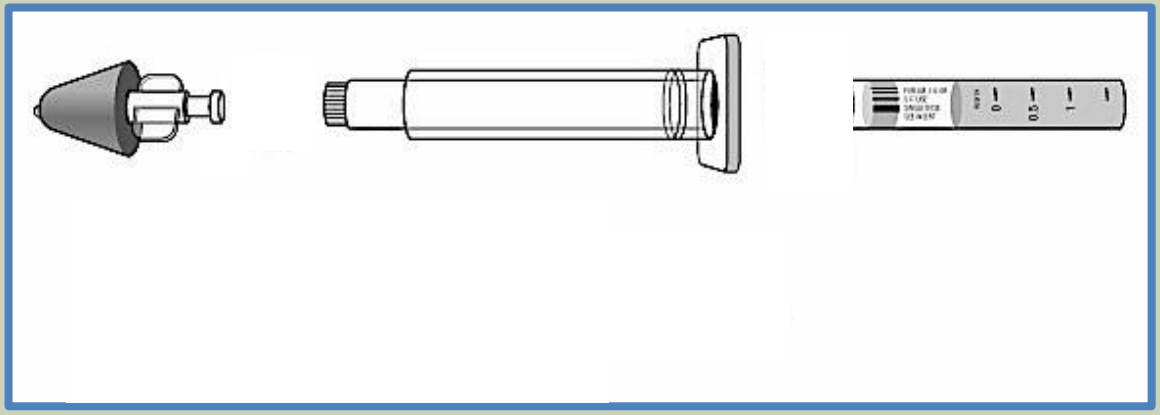
- The nasal adapter allows for needleless delivery
- Naloxone absorbed directly into the blood stream through absorption in the nasal epithelium
- Achieves medication levels comparable to injections

- Advantage: no concern about needle sticks or proper needle disposal
- Intranasal naloxone is not FDA approved

LMA MAD Nasal. Intranasal Mucosal Atomization Device. Available at: http://www.lmana.com/pwpcontrol.php?pwpID=6359.

4) GIVE NALOXONE: IN

- Remove the yellow caps from the ends of the applicator (1)
- Twist the nasal adapter onto the tip of the applicator (2)
- Remove the red cap from the naloxone (3)
- Twist the naloxone on the other side of the applicator (4)



4) GIVE NALOXONE: IN

- Push 1ml (1mg) of naloxone into each nostril
- Administer the entire contents of the 2ml syringe with approximately one half (1ml) administered in each nostril
- Administering one half in each nostril maximizes absorption

4) GIVE NALOXONE

- After giving naloxone- either IM or IN:
  - Continue rescue breathing with 1 breath every 5 seconds
  - Continue rescue breathing until emergency responders arrive
  - If patient is still unresponsive after 3-5 minutes another dose of naloxone may be administered

5) STAY UNTIL HELP ARRIVES

- **Do not leave** someone alone after giving naloxone
- Make sure they do not take any more opioids
- If someone takes more opioids because of withdrawal symptoms, it is possible they will go back into overdose when the naloxone wears off
- It is possible they could go back into overdose if they took a long acting opioid that is still around to bind to opioid receptors after the naloxone wears off

5) STAY UNTIL HELP ARRIVES

- Get medical help immediately if the naloxone does not work to restore breathing and responsiveness

- Get medical help immediately if something seems wrong after administering naloxone:
  - Rapid or irregular heart beat
  - Chest pain
  - Seizures
  - Sudden stopping of the heart
  - Hallucinations
  - Lost of consciousness

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

RISK BENEFIT ANALYSIS

- Some concerns have been raised with increasing the availability of naloxone:
  - Unsafe administration
  - Lack of follow up care
  - Additional opioids will be used to counter the withdrawal effects
  - Persons administering naloxone may be intoxicated themselves
  - Seizures and arrhythmias possible in patients with preexisting heart disease
  - Availability may encourage more frequent or higher volume drug use
- Many of these concerns have been disproven from data from various community outreach program
- It is still important to understand the possible risks of naloxone dispensing. This is a relatively new idea and data should be continuously collected

Kim D, Irwin KS, Khoshnood K. Expanded Access to Naloxone: Options for Critical Response to the Epidemic of Opioid Overdose Mortality. *Am J Public Health*. 2009 March; 99(3): 402–407.

SUMMARY

- Opioid abuse and overdose is a growing problem in the United States and in Rhode Island
- Pharmacists can play a role in ensuring the safe use of opioids and preventing opioid overdose
- Naloxone is an antidote for opioid overdose
- A collaborative practice agreement that allows pharmacists to initiate naloxone therapy could prevent opioid overdose death

SELF-ASSESSMENT QUESTIONS

- 1. Which of the following brain receptors are involved in drugs of addiction?
  - A. Dopamine
  - B. Serotonin
  - C. Norepinephrine
  - D. Vasopressin

SELF-ASSESSMENT QUESTIONS

- 2. Which of these is NOT a type of opioid addiction?
  - A. Prescription painkiller (OxyContin®) addiction
  - B. Methadone addiction
  - C. Methamphetamine addiction
  - D. Heroin Addiction

SELF-ASSESSMENT QUESTIONS

- 3. Which of these does NOT indicate opioid overdose?
  - A. Decreased blood pressure
  - B. Decreased heart rate
  - C. Miosis
  - D. Diaphoresis

SELF-ASSESSMENT QUESTIONS

- 4. Which statement about naloxone is TRUE?
  - A. Naloxone has partial agonist activity
  - B. Naloxone is safe if opioids are not present in the body
  - C. Naloxone is a controlled substance
  - D. Naloxone only reverses toxic effects of opioids, it does not reverse clinical effects

SELF-ASSESSMENT QUESTIONS

- 5. What is the purpose for a naloxone collaborative practice agreement in RI?
  - A. To better educate patients who bring in a prescription for naloxone
  - B. To expand naloxone access by allowing pharmacists to initiate therapy with naloxone
  - C. To give patients the skills they need to respond to an overdose without having to call 911
  - D. To reduce the frequency of infections passed through the use of unclean needles

SELF-ASSESSMENT QUESTIONS

- 6. Which of the following is NOT one of the opioid overdose management steps to educate patients about?
  - A. Identify overdose
  - B. call 9-1-1
  - C. Give rescue breaths
  - D. Call the police