PRO-LIFE/PRO-NALOXONE: NALOXONE FOR OVERDOSE PREVENTION

OBJECTIVES
- Explain the purpose of naloxone for overdose prevention
- Review current naloxone for overdose prevention literature
- Describe recent regulatory changes affecting naloxone prescribing
- List and describe available naloxone formulations
- Identify appropriate candidates for take home naloxone
- Demonstrate ability to counsel patients and caregivers on naloxone use

OPIOID ANALGESICS
- Opioids continue to be a useful treatment option for patients in moderate to severe pain
- Chronic opioid therapy requires continued assessment of risk vs. benefits
- Safe use and rescue measures are now recommended by multiple agencies:
  - FDA
  - AMA
  - AAPM

OPIOID-INDUCED RESPIRATORY DEPRESSION (OIRD)
- Opioids depress the respiratory drive:
  - Slow breathing
  - Irregular breathing
- Mild OIRD is common and expected side effect
- Severe OIRD leads to hypoxia and hypercapnia
**LIFE THREATENING OIRD**

- Respiratory Depression
- Hypoxia
- Brain Damage
- Coma
- Death

**WHERE ARE OIRD EMERGENCIES OCCURRING**

- Home
- Witnessed

**TIME MATTERS**

- Brain cells begin to die within 4 minutes when deprived of oxygen
- The average EMS response time is 9 minutes

**NALOXONE**

- **MOA**
  - Competitive opioid antagonist with high affinity for the mu-opioid receptor
- **Indication**
  - Intended for emergency therapy in settings where opioids may be present
- **Availability**
  - IM/SC Auto-Injector (Evzio)
  - EN Kits

**PROJECT LAZARUS: COMMUNITY-BASED OVERDOSE PREVENTION IN RURAL NORTH CAROLINA**

- The Wilkes County unintentional poisoning mortality rate is quadruple that of North Carolina’s.
  - 46.6 vs. 11.0 per 100,000 population per year in 2009
- Top opioids
  - Fentanyl hydrocodone, methadone, oxycodone
  - Heroin is rarely suspected
- The average age of death = late 30s
- Use opioids for both medical and non-medical reasons
- Either directly or in combination with other substances

**Overdose prevention**

- Community organization and activation
- Prescriber education
- Supply reduction and diversion control
- Pain patient services and drug safety
- Drug treatment and demand reduction
- Harm reduction
- Community-based prevention education
COMMUNITY ORGANIZATION AND ACTIVATION

- Town hall meetings
- Specialized task forces
- Community-based leadership
- Coalition building
- “Managing Chronic Pain” tool kit

PRESCRIBER EDUCATION AND BEHAVIOR

- One-on-one prescriber education on pain management
- Continuing medical education sessions on pain management
- Licensing actions against prescribers by state medical board
- Promotion of prescription monitoring program (CSRS)

SUPPLY REDUCTION AND DIVERSION CONTROL

- Hospital ED opioid dispensing policy modified
  - Limits on amount dispensed at once
  - Required check of CSRS for hospital ED admissions
- Unused medication take-back events
- Fixed medicine disposal sites at law enforcement offices
- Hiring and training of drug diversion specialized law enforcement officers

PAIN PATIENT SERVICES AND DRUG SAFETY

- Medicaid policy change: mandatory use of patient–prescriber agreements and pharmacy home
- Support groups for pain patients
- ED case manager for Medicaid beneficiaries with chronic pain
- Vetting of local pain clinics and facilitation of specialized pain clinic referrals

DRUG TREATMENT AND DEMAND REDUCTION

- Drug detox program
- Negotiation and support for opening of satellite office-based drug treatment clinic with buprenorphine

HARM REDUCTION

- Naloxone prescription
COMMUNITY-BASED PREVENTION EDUCATION

- School-based education, including pledge cards
- Red Ribbon campaign—warnings not to share attached to dispensed prescription packages
- Billboard containing message against sharing medications
- Presentations at colleges, community forums, civic organizations, churches, etc.
- Radio and newspaper spots

RESULTS

WHO SHOULD RECEIVE OVERDOSE PREVENTION EDUCATION/NALOXONE

Everyone taking on opioid?

- Received care involving an overdose
- Suspected history of substance abuse or nonmedical opioid use
- Prescribed methadone or buprenorphine
- Higher-dose (>50 mg morphine equivalent/day) opioid prescription

CONCERNS

- Adverse reactions to Naloxone
- Patient’s won’t call EMS
- Patient’s will take greater risks

ADVERSE REACTIONS

- Low risk of serious ADRs
  - Seizures
  - Arrhythmia
- Common ADRs = Withdrawal symptoms
  - Confusion
  - N&V
  - HA
  - Aggressiveness
REFUSE EMS

- During a 5-year period in San Diego, 998 ambulatory patients received naloxone from EMS and refused transport, against medical advice
  - Reviews of medical examiner records found no instances of individuals dying of opioid poisoning within the 12 hours following naloxone administration
  - 592 patients
  - No patients who refused care died within 48 hours

PATIENT’S WILL TAKE GREATER RISKS

- “Studies evaluating the decade of naloxone distribution to heroin users in the United States have not revealed convincing evidence of risk compensation”
- "In cities with large-scale naloxone prescribing and dispensing programs for heroin users, opioid overdose mortality has consistently decreased after implementation, suggesting that naloxone distribution programs do not lead to increases in overdose deaths”

BEHAVIORAL IMPACT

- U.S. army base Fort Bragg in North Carolina averaged 8 overdoses per month
  - After initiating naloxone distribution
    - Overdose rate dropped to zero
    - No reported naloxone use

PATIENT CARE

- Increase communication, trust and openness between patients and providers
  - “I looked at different options, especially at my age”
  - “discuss the potential harms of opioids in a non-judgmental way”

EVZIO

- Take-home, hand-held, single-use auto-injector
- Quickly delivers 0.4 mg of naloxone
- Visual and voice instructions for guidance
- Retractable needle system helps prevent accidental needle exposure
- Prefilled 2mg/2ml naloxone needless syringe
- Mucosal atomization device
- Gloves
- CPR Face Shield
- Educational insert
**INTRANASAL VS. IM**

**Intranasal kits**
- Slower onset
- Milder withdrawal
- No needle stick risk
- No disposal concerns
- Low Cost

**IM Auto-injector**
- Fast onset
- Ease of use
- High cost
- Available

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**FLORIDA AND NALOXONE**

Senate Bill 758/House Bill 751: Emergency Treatment for Opioid Overdose Act
Signed by Governor Scott June 10, 2015

- Permits all first responders to possess, store, and administer naloxone
- Patients and caregivers are permitted to store and possess emergency opioid antagonists
- Patients and caregivers are authorized to administer an opioid antagonist to a person who is believed to be in an overdose situation
- Authorization applies in an emergency situation when a physician is not immediately available
- Authorizes health care practitioners to prescribe and pharmacists to dispense an emergency opioid antagonist to patients and caregivers
- Provides immunity from liability under the Good Samaritan Act
- Professional sanctions or disciplinary licensing actions related to prescribing or dispensing an opioid antagonist

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**CASE**

RK is a 59yo WM with prostate cancer. He reports increased back pain secondary metastatic disease

Current regimen:
- OxyContin 60mg 1 po Q12h
- Oxycodone IR 30mg Q6hr prn

Pt admits to taking extra oxycodone IR
Pt has a history of drinking alcohol while taking opioids

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**RISK FACTORS FOR OPIOID EMERGENCY**

1. High dose = 420me/day
2. History of medication over-use
3. Alcohol use

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**CASE**

Plan

- Increase OxyContin to 80mg 1 po Q12h
- Continue Oxycodone IR 30mg prn BTP
- Initiate take home Naloxone
  - PA for Evzio approved by Medicaid
- Education for patient and wife
SIGNS AND SYMPTOMS OF AN OPIOID EMERGENCY

- Unusual sleepiness - unable to awaken with a loud voice or rubbing firmly on the middle of their chest (sternum)
  
  WITH
  
  - Breathing problems - slow or shallow breathing, or they look like they are not breathing
  
  - "pinpoint pupils"

ADMINISTRATION

1. Pull from outer case
2. Pull off red safety guard
3. Place the black end against the middle of the patient's outer thigh
4. Press firmly and hold in place for 5 seconds
5. After using immediately seek emergency medical help
6. May repeat with additional injection if needed

"NOBODY DIES FROM NARCAN. THEY DIE FROM NOT GETTING NARCAN"

Dr. Mike Miller
Vice Speaker
Wisconsin Medical Society