Opioid Medication Safety-The Role of Naloxone
*Naloxone dispensing training does not substitute for the RN Dispensing Manual parts I and II training (available at publichealth.nc.gov). For a registered nurse to dispense naloxone in North Carolina health departments, he/she must have completed RN Dispensing training, parts I and II with live pharmacist training, in addition to naloxone training (part I addendum).
The Need

In North Carolina, in 2012, there were 1,101 people who died from unintentional poisonings, second only to 1,185 deaths due to motor vehicle crashes.

Since 1999, 10,952 North Carolina residents have lost their lives from unintentional poisonings; a nearly 300 percent increase, from 297 to 1,101 in yearly deaths, due to unintentional poisonings.
Figure 1: Poisoning Deaths by Intent: N.C. Residents, 1999-2012
The vast majority of unintentional deaths are drug or medication-related, occurring when people misuse or abuse prescription opioid medications (Fig.2).

Figure 2: Medication/Drug vs Non-Medication Types of Unintentional Poisonings: N.C. Residents, 2012

- Of these unintentional poisoning deaths, 91 percent are caused by drugs and medications (Over-the-counter, prescription and illicit) (Fig 2). Nine percent are toxins or chemicals (non-medication/non-drug).

- Prescription opioid analgesics, heroin and cocaine are the cause of death in over half (60%) of these poisoning deaths (Fig 2).
Opioid analgesics are now involved in more drug deaths than cocaine and heroin combined.
The Response

The “SB20 911 Good Samaritan/Naloxone Access law became effective April 9, 2013. It states that individuals who experience a drug overdose or persons who witness an overdose and seek help for the victim can no longer be prosecuted for possession of small amounts of drugs, paraphernalia, or underage drinking.

The purpose of the law is to remove the fear of criminal repercussions for calling 911 to report an overdose, and to instead focus efforts on getting help to the victim.”¹
“The Naloxone Access portion of SB20 removes civil liabilities from doctors who prescribe and bystanders who administer naloxone, or Narcan, an opiate antidote which reverses drug overdose from opiates, thereby saving the life of the victim.

SB20 also allows community based organizations to dispense Naloxone under the guidance of a medical provider.”¹
Recognizing that fatal and non-fatal overdoses from opioids play an increasing role in the mortality and morbidity of North Carolina residents, the NCDHHS approached the North Carolina Board of Pharmacy to implement new Naloxone Clinics in North Carolina, allowing RN naloxone dispensing in local health departments to provide wider access to patients at risk for an overdose.

The North Carolina Board of Pharmacy agreed to partially waive enforcement of 21 N.C.A.C. 46.2401 and .2403 to allow registered nurses to begin dispensing naloxone kits in a manner consistent with G.S. 96-106.2 (the “Good Samaritan/Naloxone” statute) and a standing order submitted to, and reviewed by, the Board at its January 2014 meeting.

**LHDs must use the standing order provided in the Dispensing Manual posted at [http://ncpublichealth.gov](http://ncpublichealth.gov) for RNs to dispense naloxone kits.**
ORDER OF THE BOARD

Pursuant to authority granted by 21 N.C.A.C. 46.2510, the Board of Pharmacy (“Board”) hereby partially waives enforcement of 21 N.C.A.C. 46.2401 and 21 N.C.A.C. 46.2403 as follows:

1. 21 N.C.A.C. 46.2510, promulgated by the Board pursuant to statutory authority, states that “Board may waive the enforcement of specific rules” under certain circumstances.

2. The North Carolina General Assembly has passed, and the Governor has signed into law, G.S. 96-106.2, which provides statutory authority for authorized practitioners to prescribe naloxone, an opioid antagonist medication, to a person at risk of experiencing an opiate-related overdose or to a family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

3. G.S. § 90-85.34A, authorizes registered nurses in a local health department to dispense prescription drugs and devices with certain conditions. Among them, the registered nurse may dispense “[o]nly prescription drugs and devices contained in a formulary recommended by the Department of Health and Human Services and approved by the Board.”
4. Acting State Health Director Robin Gary Cummings, M.D., has recommended that naloxone be added to the formulary from which health department registered nurses may dispense.

5. 21 N.C.A.C. 46.2401(a)(1) provides that a “registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions: (1) Drugs and devices may be dispensed only to health department patients.”

6. 21 N.C.A.C. 46.2401(a)(4) provides that “[o]nly the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse.” Neither naloxone specifically, nor opioid antagonist medications generally, are among the prescription drugs that may be dispensed pursuant to 21 N.C.A.C. 46.2403.

7. The Board partially waives enforcement of 21 N.C.A.C. 46.2401 to allow registered nurses in local health departments to dispense naloxone to a health department patient or to others as permitted by G.S. 90-106.2.

8. The Board partially waives enforcement of 21 N.C.A.C. 46.2403 to allow registered nurses in local health departments to dispense an opioid antagonist prescribed pursuant to G.S. 90-106.2.

9. The Board has determined that a partial enforcement waiver of 21 N.C.A.C. 46.2401 and .2403 will: (i) positively impact the delivery of pharmaceutical care; and (ii) will not compromise patient health and safety. 21 N.C.A.C. 46.2510(1), (2).
10. Any registered nurse at a local health department who chooses to dispense an opioid antagonist medication pursuant to this partial waiver of enforcement shall conform to the policies and procedures set forth in a naloxone standing order submitted to, and reviewed by, the Board on January 21, 2014. 21 N.C.A.C. 46.2510(3).

11. The partial enforcement waiver of 21 N.C.A.C. 46.2401 and .2403 is subject to continuing study by the Board. 21 N.C.A.C. 46.2510(4). The waiver shall continue until such time as the Board either promulgates amendments to 21 N.C.A.C. 46.2401 and .2403, or Board determines, after appropriate notice and hearing, that continuation of the waiver would no longer meet the standards of 21 N.C.A.C. 46.2510.

This is the 21st day of January, 2014.

NORTH CAROLINA BOARD OF PHARMACY

by:

[Signature]

Jack W. Campbell IV
Executive Director
What are opioids?

- chemicals derived from the opium poppy or are synthetically manufactured by pharmaceutical companies
- depressants that slow down the central nervous system
- opioid overdose occurs because the opioid is attached to the same receptor site in the brain that is responsible for breathing
Examples of Opioids

Prescription medications:

- codeine
- morphine
- hydromorphone
- methadone
- oxycodone
- hydrocodone
- meperidine
- propoxyphene
- fentanyl

Illicit medication

- heroin

*complete listing on National Institute on Drug Abuse website at www.drugabuse.gov.*
Naloxone

- **Naloxone** is an opioid antagonist - it displaces the opioid from the receptors in the brain.

- Usually acts dramatically, allowing slowed or absent breathing to resume.

- Is both safe and effective and has no potential for abuse.

- May work immediately, but can take up to 8 minutes to have the desired effect.
Naloxone

- effect of the naloxone will only last for about 30 to 90 minutes in the body

- most opioids last longer than 30 to 90 minutes

- Naloxone may wear off before opioid– overdose situation again

- **only effective when opioids are contributing to an overdose.** The more non-opioid substances that contribute to the overdose, the less effective naloxone will be.
Very important point:

Due to the complex nature of these medical emergencies, it further emphasizes the necessity of calling 911 in an overdose situation.

Stress calling 911 first- in patient education and training
Educate your patients on how to avoid an opioid overdose:

• take only medications prescribed for you and your condition

• take only as directed, never self-medicate

• never share medications

• tolerance to opioids will develop with chronic use

• talk with prescriber if adequate pain relief is not obtained with current dose

• Avoid mixing substances with opioids, such as alcohol and sedatives
In an opioid overdose

- the difference between surviving and dying depends on **breathing** and oxygen

- death is rarely instantaneous
The signs of an opioid overdose (what to look for):

- Blue skin tinge- usually lips and fingertips show first
- Body very limp
- Face very pale, skin clammy
- Pulse (heartbeat) slow, erratic, or not there at all
- Throwing up
- Passing out
- Choking sounds or a gurgling/snoring noise
- Breathing is very slow, irregular, or has stopped
- Unable to respond
How to respond to an opioid overdose

To determine if an individual is experiencing an overdose, the most important things to consider are presence of breathing and responsiveness to stimulation. Some relatively harmless ways to stimulate a person are:

1. Yelling their name, and if no response,
2. Rubbing knuckles over either the upper lip or up and down the front of the rib cage (sternal rub)

If the individual responds to these stimuli, they may not be experiencing an overdose at that time. It is best to stay with them to make sure they wake up.
If the individual does not respond to stimulation, it is important to:

1. **Call 911** to get help
2. Perform rescue breathing to provide oxygen (if the person is not breathing)
3. Administer naloxone
4. Stay with the person until help arrives
5. Once breathing, put the person in the **recovery position** (lying on side with body supported by bent knee, hand under head and face turned to the side)
What to say when calling 911

- important to say the victim’s breathing has slowed or stopped
- he or she is unresponsive
- the exact location of the victim.

If naloxone was given and did not work, this should be reported to the medical responders when they arrive.
Perform rescue breathing

When someone has stopped breathing and is unresponsive, rescue breathing should be done as soon as possible because it is the quickest way to get oxygen into the body.
Steps for rescue breathing

1. Place the person on his or her back and pinch their nose.

2. Tilt the chin up to open the airway. Check to see if there is anything in the mouth blocking the airway. If so, remove it.

3. Give 2 slow breaths.

4. Blow enough air into the lungs to make the chest rise.

5. Turn your head after each breath to ensure the chest is rising and falling. If not, tilt the head back more.

6. Breathe again every 5 seconds.
Administer naloxone

Naloxone may be administered by intramuscular injection or as a nasal spray, using different formulations. The standing order must state the administration route you will be using in your health department, per the local practitioner’s preference.

Intranasal naloxone

Intramuscular naloxone
To administer intranasal naloxone:

1. Remove the two yellow caps and one red (or purple) cap from the naloxone syringe and the plastic delivery device.
2. Hold the nasal atomizer device and screw it onto the top of the plastic delivery device.
3. Screw the naloxone syringe gently into the delivery device.
4. Spray half of the medicine up one side of the nose and half up the other side of the nose.
5. If there is no breathing, or very shallow breathing, continue to perform rescue breathing while waiting for the naloxone to take effect.
6. If no response in 3-5 minutes, repeat naloxone.
To administer intramuscular naloxone:

1. Remove the cap from the naloxone vial and the shield from the syringe.
2. Insert syringe into vial and draw up 1 ml of naloxone
3. If practical, don gloves and prepare injection site with alcohol pad.
4. Administer 1 ml of naloxone via intramuscular injection into upper arm, buttock, or thigh.
5. If there is no breathing, or very shallow breathing, continue to perform rescue breathing while waiting for the naloxone to take effect.
6. If no response in 3-5 minutes, repeat naloxone.
Continue to monitor the victim and wait for emergency responders.
How to Dispense Naloxone Kits

• naloxone is a prescription medication

• must be dispensed following all prescription medication rules and regulations

• all prescription labeling requirements - The NC Board of Pharmacy has specified that the prescription label should be affixed to the kit in a stable manner.

• naloxone inventory must be tracked and signed in and out of the pharmacy on a pharmacy log. Some sample pharmacy logs are available in the naloxone dispensing manual located at http://ncpublichealth.gov
All of the regulatory pharmacist oversight, patient counseling guidelines and prescription dispensing regulations must be observed as well, as listed in detail in the RN Dispensing Manual part I.
Naloxone kits may be dispensed by appropriately trained RNs to:

• clients at risk of experiencing an opiate-related overdose or who are in a position to assist a family member, friend or other person at risk of experiencing an opiate-related overdose

• clients who report no known sensitivity or allergy to naloxone

• clients who have been provided sufficient education regarding preventing, recognizing, and responding to a suspected opioid overdose

• clients following standing orders (recommended by Board of Pharmacy) and the NC Good Samaritan Law
The intramuscular kit should be assembled in appropriate packaging and contain at a minimum:

1. Prescription label
2. 2 vials of 0.4mg/ml naloxone
3. 2 syringes (3ml, 25G x 1”)
4. Alcohol swabs
5. Gloves
6. Disposable CPR shield
7. Instructions for use
8. Printed materials regarding overdose prevention and treatment, to include information regarding recognizing and responding to suspected opioid overdose and the importance of calling 911
The intranasal kit should be assembled in appropriate packaging and contain at a minimum:

1. Prescription label
2. 2 prefilled syringes of 2mg/2ml naloxone (with plastic delivery device)
3. Nasal atomizer piece
4. Disposable CPR shield
5. Instructions for use
6. Printed materials regarding overdose prevention and treatment, to include information regarding recognizing and responding to suspected opioid overdose and the importance of calling 911
Opioid Medication Safety
Helpful websites for overdose prevention and treatment materials (and videos for patient education):

http://projectlazarus.org  (336-667-8100) –Project Lazarus


http://prescribetoprevent.org

http://www.nchrc.org/harm-reduction/overdose-prevention/
Additional information:

Nasal Atomizer- Manufactured by Wolfe Tory Medical
website www.LMANA.com- MAD Nasal intranasal Mucosal Atomization Device

Naloxone 2mg/2ml  NDC 76329-3369-01 (syringe for intranasal use)
Naloxone 0.4mg/ml  NDC 00409-1215-01 (single dose vial for intramuscular use)

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