Hospitals’ Role in Addressing the Opioid Crisis

Webinar 2: Naloxone Prescribing and Dispensing

July 11, 2017
Agenda

• Naloxone and the Maryland Overdose Response Program (ORP)
  ▪ Kirsten Forseth, Health Policy Analyst, Overdose Prevention Office, Maryland Department of Health

• The UMMC Emergency Department Experience: Take Home Naloxone
  ▪ R. Gentry Wilkerson, M.D., Director of Clinical Research/Assistant Residency Program Director, University of Maryland School of Medicine, Department of Emergency Medicine
  ▪ Christopher Welsh, M.D., Medical Director-UMMC Substance Abuse Consultation Service; Medical Director-UMMC Comprehensive Recovery Program
Naloxone and the Maryland Overdose Response Program (ORP)

Kirsten Forseth, MPH
Overdose Prevention Policy Analyst
Department of Health
Context: Nationwide Increase in Opioid-Involved Overdose Deaths

The number of opioid-involved drug overdose deaths more than tripled from 2000 to 2014.

210% increase in the age-adjusted death rate from 2000 to 2014.

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2014 on CDC WONDER Online Database, released 2015. Data for 2000 to 2014 were extracted by ONDCP on December 29, 2015.
Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2007-2016

- Total
- Opioid-related
- Not opioid-related


Number of deaths:
- Total: 815, 694, 731, 649, 671, 799, 858, 1041, 1259, 2089
- Opioid-related: 500, 500, 500, 500, 500, 500, 500, 500, 500, 500
- Not opioid-related: 315, 194, 231, 149, 171, 149, 158, 175, 175, 175
Figure 7. Number of Opioid-Related Deaths Occurring in Maryland by Substance, 2007-2016.

### Number of deaths

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*Total opioids include heroin, prescription opioids, and illicit forms of fentanyl.*
Figure 18. Number of Fentanyl-Related Deaths Occurring in Maryland by Place of Occurrence, 2016.
About Fentanyl

• Synthetic opioid
  – Much more potent than heroin
  – Used medically as an analgesic and anesthetic

• Non-pharmaceutical fentanyl
  – Illicitly produced, often mixed with heroin and/or cocaine—
    with or without the user’s knowledge
  – Pill form packaged to look like prescription medications,
    powder form looks similar to heroin
  – Deaths related to fentanyl are the result of illicitly
    manufactured fentanyl
Backdrop of Prescription Opioid and Heroin Use

In 1991, health professionals wrote 76 million opioid prescriptions in the U.S. In 2011, they wrote 219 million.

In 12 states, the number of prescriptions written for painkillers exceeded the number of people in the state.

Meanwhile, Mexican heroin production increased from 8 metric tons to 50 metric tons between 2005 and 2009. Source: National Institute on Drug Abuse.
How Do We Address the Harms Associated with Drug Use?

Public Health: Prevention

Law Enforcement: Arrest/Incarceration

Public Health: Harm Reduction

Public Health: Treatment
Harm Reduction Approach

- Harm Reduction: a practical set of strategies that aim to reduce the risks associated with drug use.

- Harm reduction interventions accept that people may continue to use drugs and does not require abstinence as a prerequisite for engagement.

- Harm reduction approaches:
  - Are rooted in a commitment to public health & human rights
  - Combat stigma
  - Empower people who use drugs
  - Meet people where they are
  - Aim to attain any positive change
Behavioral Health Continuum

Assessment

Recovery Support

Engagement

Continuing Care

Treatment

Harm Reduction

[Image of the Behavioral Health Continuum with steps: Assessment, Recovery Support, Engagement, Continuing Care, Treatment, and Harm Reduction.]
• History:
  – Overdose education and naloxone distribution (OEND) has been part of the harm reduction landscape for decades.
  – OEND was originally provided through syringe exchange programs.

• OEND provides vital education on overdose risk.
• Naloxone is an empowerment tool for individuals and communities.
## Evidence Base for OEND

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| OEND is feasible in many settings. | Walley et al. JSAT 2013; 44:241-7  
Piper et al. Subst Use Misuse 2008: 43; 858-70 |
| Participants demonstrate knowledge and skills after training.  
Green et al. Addiction 2008: 103;979-89  
| Naloxone does not lead to an increase in risky use, but does lead to an increase in drug treatment. | Seal et al. J Urban Health 2005:82:303-11  
Walley et al. BMJ 2013; 346: f174  
Goal: Provide a means of authorizing non-medical individuals to:
- Receive training on opioid recognition & response w/ naloxone
- Acquire, possess & administer naloxone to someone experiencing suspected opioid overdose when emergency services not immediately available

DHMH authorizes entities to train individuals
Trainees may be prescribed/dispensed naloxone & administer it in emergency situation
Legal protections for naloxone prescribers/dispensers & individuals who administer naloxone

Authorized by law in 2013: Article-Health-General, Title 13, Subtitle 31, Annotated Code Maryland, §§13-3101 – 3109
Regulations: COMAR 10.47.08.01-.11 (3/3/14)
Key Elements: Naloxone Distribution

- Community-based outreach programs: Naloxone provided at the time of training
- Medical settings
- Pharmacy distribution
  - Statewide standing order

Naloxone can be provided by a physician to any patient at risk for overdose or likely to witness and respond to an opioid overdose.
Goals of Maryland Overdose Education and Naloxone Distribution

Reduce overdose death by targeting individuals at risk for overdose and their friends and family through:

- Outreach model
- Peer-delivered training
- Detention center training and dispensing
- Pharmacy-based distribution
- Emergency department bedside dispensing
- Opioid treatment programs
- Syringe services programs

...to achieve community saturation.
Overdose Education Content

Patient education for naloxone should include:

1. When to administer naloxone (recognizing the signs & symptoms of opioid overdose)
2. How to administer naloxone (including demonstration)
3. Informing patients to alert others about the medication, how to use it and where it’s kept, as it is generally not self-administered

Optional topics:
- Overdose risk factors and overdose prevention tips
- Good Samaritan Law
- Reporting naloxone use and obtaining a refill
HOPE Act: Summary of ORP-Related Changes

- Fewer statutory requirements on ORPs will allow for streamlined operations/reduced admin burden
- Standing orders may allow pharmacists to dispense to anyone, not just ORP certificate holders
- All licensed healthcare providers w/ prescribing authority may Rx naloxone to anyone, not just ORP certificate holders or their patients
- Criminal and civil immunity protections expanded to include all individuals prescribed/dispensed in accordance w/ law
- Civil and disciplinary immunity protections extended to all healthcare providers w/ prescribing authority
(c) An individual is not required to obtain training and education on opioid overdose recognition and response from a private or public entity under subsection (b) of this section in order for a pharmacist to dispense naloxone to the individual.
What the HOPE Act *DOES NOT* Do

- Completely remove “training requirement”
  - All available naloxone products available by Rx only, per FDA
  - Rx status presumes use under medical direction
  - Prescriber (& dispenser) have legal obligations to provide drug recipient w/ info/education/training/counseling to ensure use in medically appropriate manner

- Make naloxone “over the counter”
  - There are no FDA-approved OTC naloxone products
  - As Rx drug, naloxone cannot be sold on retail shelf next to aspirin, etc.
  - Pharmacist must still dispense, even if person-specific paper or electronic Rx not required
  - Stating naloxone now “OTC” could give false impression of ease of access; pharmacists/pharmacies still must be educated & comfortable w/ dispensing under standing orders
Billing and Insurance Coverage

Billing for Patient Counseling:
According to the SAMHSA Opioid Overdose Toolkit: Information for Prescribers, the codes for Screening, Brief Intervention, and Referral to Treatment (SBIRT) can be used to bill time for counseling a patient about how to recognize overdose and how to administer naloxone.

Insurance Coverage for Naloxone:
• Any Maryland Medicaid preferred naloxone product, including NARCAN® nasal spray and generic naloxone (0.4mg/mL single dose vials and 2mg/2mL prefilled syringe), is covered through the Pharmacy Program with a $1 copay. The EVZIO® 2mg/0.4mL auto-injector requires prior authorization and a $3 copay.
• The atomizer is covered through the Durable Medical Equipment/Disposable Medical Supplies (DME/DMS) Program.
• Commercial insurance carriers vary in their policies related to pharmacy coverage of naloxone.
Key Considerations

The ED is an opportunistic setting for preventing opioid overdose deaths through overdose education and provision of take-home naloxone at the time of an ED visit.

Key considerations for any program include:

• Naloxone purchasing and reimbursement
• Creation of an electronic medical record order set
• Provider education
• Patient education
• Referral to Peer Recovery Specialist or other treatment and recovery resources
“A client who received Evzio through our program saw a group of people carrying someone out of an abandoned condominium near his home. Coincidentally, it was his neighbor who was being carried to the apartment building. His friends were planning to abandon him. When the client realized it was someone overdosing, he ran to his apartment to retrieve his Evzio. After carrying the neighbor to the apartment, the client administered his Evzio and the neighbor awoke within a minute! He was agitated at the time, and was transported to the emergency department nearby. Two days later, the neighbor came to the client's apartment and thanked him for saving his life. The client took the opportunity to refer him to the treatment program where he received the Evzio. Both the client and the neighbor are now in treatment together.”
Resources

• BHA Naloxone website: naloxonemd.org
• Prescribetoprevent.org
• Harmreduction.org

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The UMMC Emergency Department Experience:
Take Home Naloxone

R. Gentry Wilkerson, MD
Assistant Professor in Emergency Medicine
Director of Clinical Research
Assistant Residency Program Director
Department of Emergency Medicine
University of Maryland School of Medicine
Background

• July 2016 – Approach to Take Home Naloxone (THN) from the ED was not standardized nor consistent
• Support from ED leadership
• Collaboration with ED pharmacists
• Research
ORP Application

- General Information
- Provider Oversight
- Prescribing & Dispensing Naloxone
- Training Materials
- Records Maintenance
• November 2016
• Approved by Maryland Dept of Health and Mental Hygiene
• Initially limited to 4 trainers:
  – 1 MD, 2 ED Pharmacists and 1 Research Associate
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DENTISTRY • LAW • MEDICINE • NURSING • PHARMACY • SOCIAL WORK • GRADUATE STUDIES

Davidge Hall is the historical symbol of the University of Maryland School of Medicine - America’s oldest public medical school, founded in 1807.
## Records Maintenance

- Google Sheets
- Google Forms
- HIPAA Compliant using em.umaryland.edu

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### Naloxone Training Log

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• January 2017
  - Email sent to Faculty, residents, nurse practitioners and nurses
  - 2 faculty, 2 chief residents, 13 residents trained as certifiers
• Improvised Intranasal Kit
  – Cartridge
  – Syringe
  – Nasal Atomizer
• Not FDA Approved
• Widespread use in THN programs
  – No other products on market prior to 2014
• Evzio Autoinjector
• FDA Approved in April 2014 as 0.4 mg dose
• 2 mg dose approved in October 2016
• Major price increase in 2016
• Includes training device
• Narcan Nasal Spray
• FDA Approved in Nov 2015 as 4 mg dose
• 2 mg dose approved in Jan 2017
• No trainer device yet
Emergency Opiate Overdose Kit Instructions

This Kit contains:
- 2 naloxone (2 mg/2 ml) in prefilled needless syringes

VS

Evzio
naloxone HCl injection, USP
0.4 mg auto-injector

USE FOR OPIOID EMERGENCIES SUCH AS SUSPECTED OVERDOSE
Seek Emergency Medical Attention

Instructions for use found inside on device
Includes Voice Instructions from a Speaker
Champion

• Identify a champion for program among MDs, RNs and midlevels

• Engage pharmacy
Overdoses in the ED
Questions?
## Schedule of Webinars

<table>
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<th>Topic</th>
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<td>June 28</td>
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<tr>
<td>July 11</td>
<td>Naloxone Prescribing and Dispensing</td>
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<tr>
<td>September 12</td>
<td>Alcohol and Drug Use Screening</td>
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<tr>
<td>October 11</td>
<td>Overdose Survivors Outreach Project</td>
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<td>November 14</td>
<td>Buprenorphine in the Emergency Department</td>
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Materials will be posted at: [http://www.mhaonline.org/resources/opioid-resources-for-hospitals](http://www.mhaonline.org/resources/opioid-resources-for-hospitals)

All webinars are 8:30 – 9:30 a.m.