Candidates for Naloxone: What the Data Tell Us

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U.S. Centers for Disease Control and Prevention

High Risk Groups

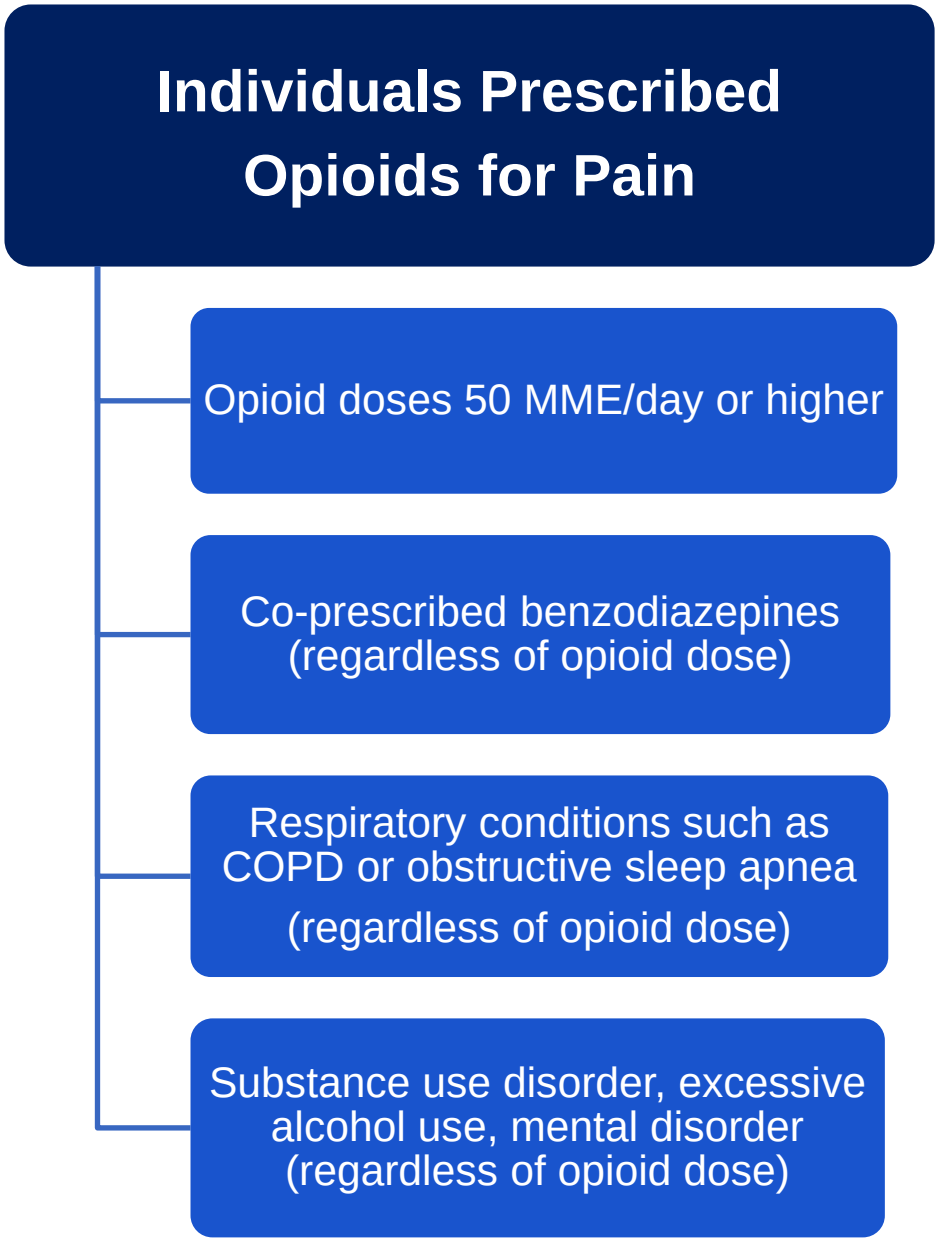
Individuals Prescribed Opioids for Pain

- Opioid doses 50 MME/day or higher
- Co-prescribed benzodiazepines (regardless of opioid dose)
- Respiratory conditions such as COPD or obstructive sleep apnea (regardless of opioid dose)
- Substance use disorder, excessive alcohol use, mental disorder (regardless of opioid dose)

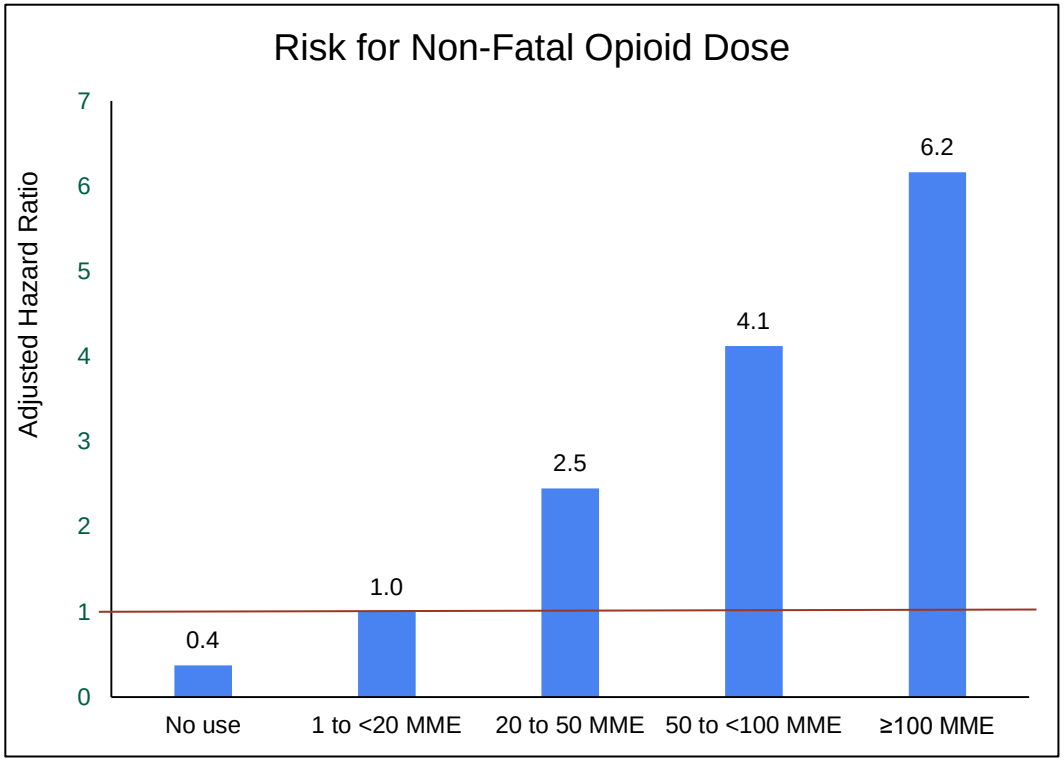
Individuals at High-Risk for Opioid Overdose

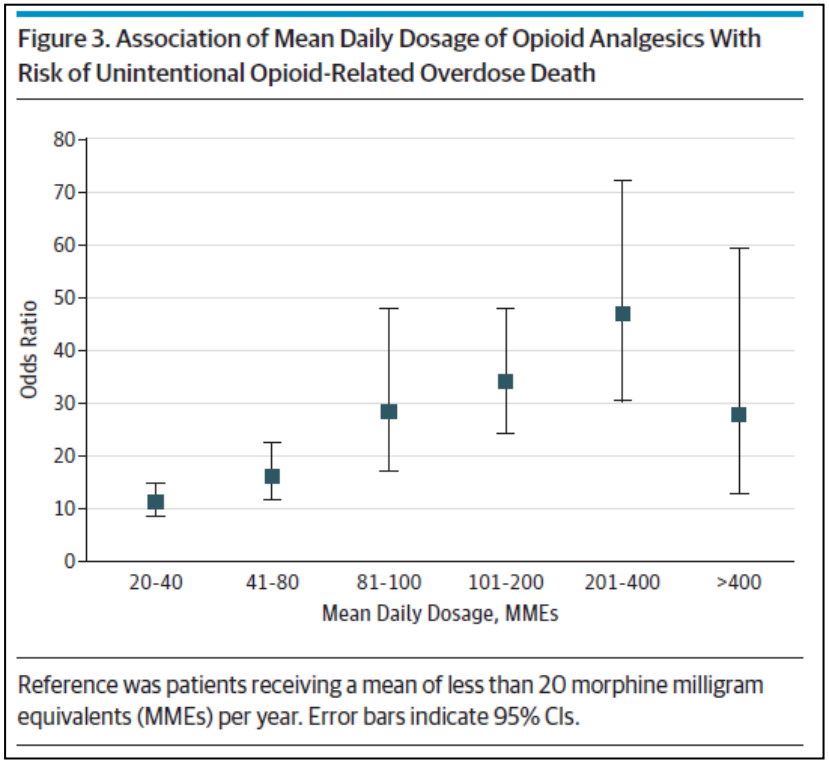
- Using heroin or synthetic opioids or misusing Rx opioids
- Using methamphetamine, cocaine, other drugs potentially contaminated with illicit synthetic opioids
- Receiving treatment for OUD, including medication-assisted treatment
- Released from incarceration or other controlled setting and history of opioid misuse

High Risk Groups



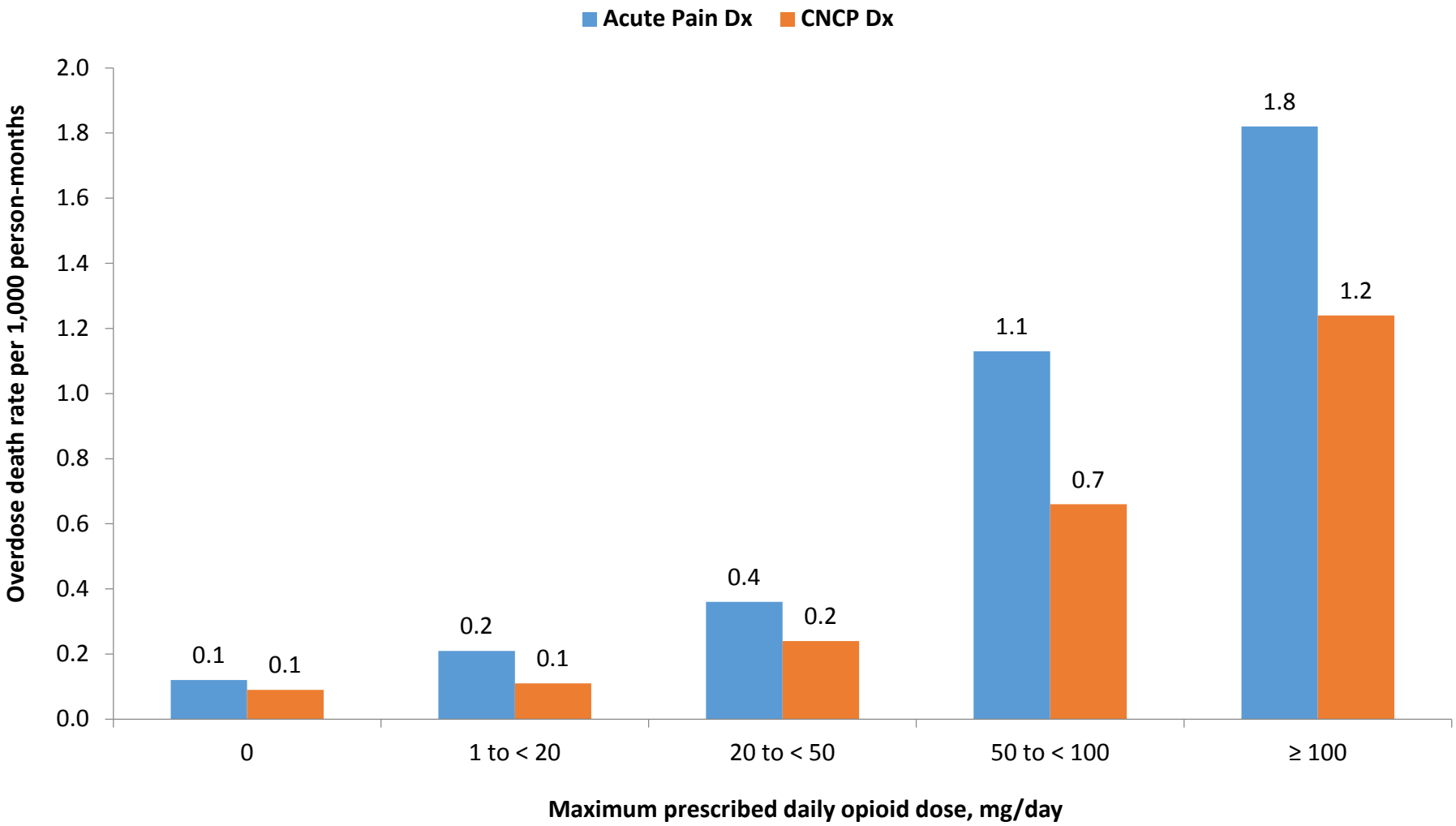
Patients Receiving Opioid Doses of 50 MME or Higher





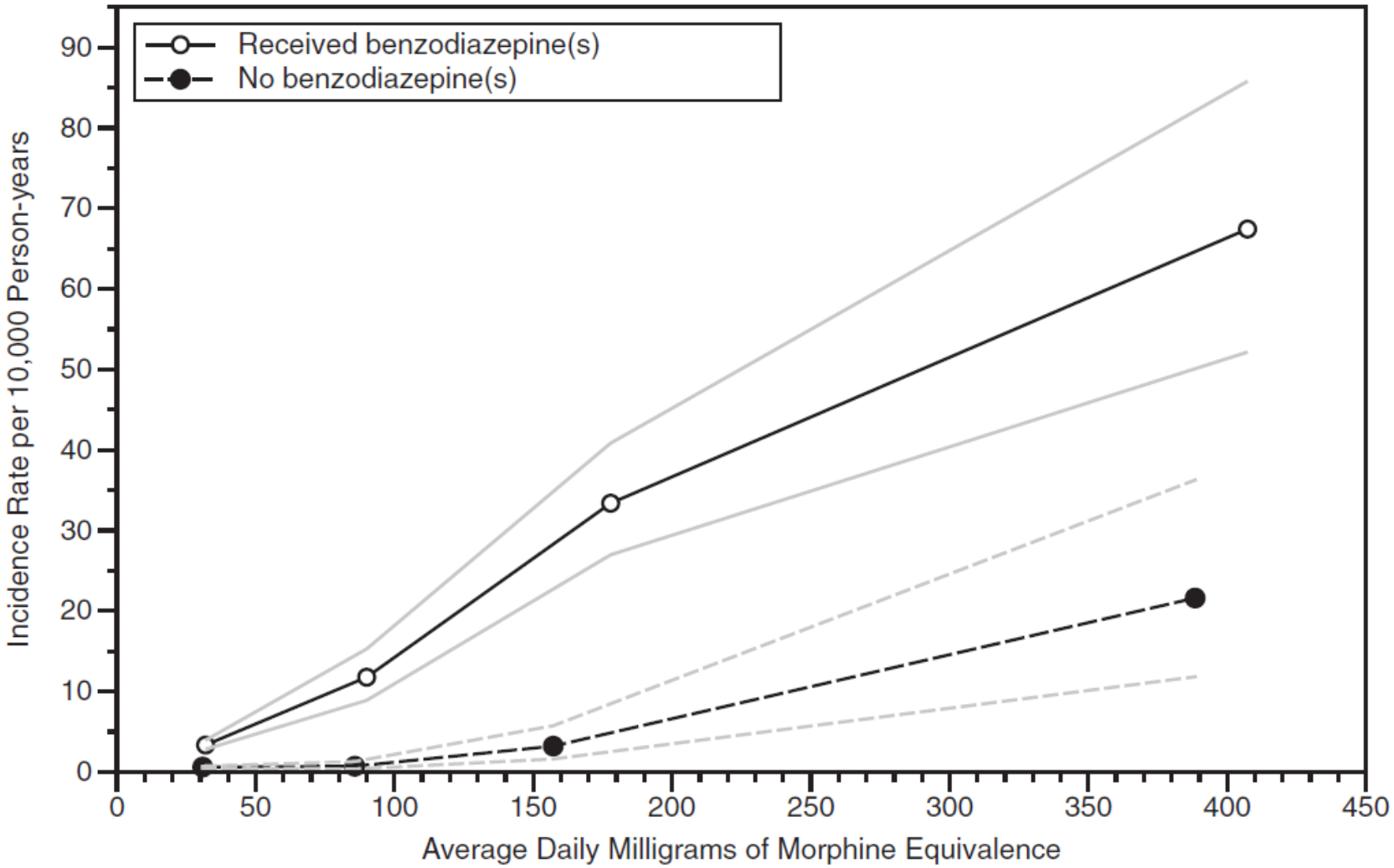
Source: Campbell et al., Preventive Medicine, 2018; Baumblatt et al., JAMA IM. 2014.

Patients Receiving Opioid Doses of 50 MME or Higher



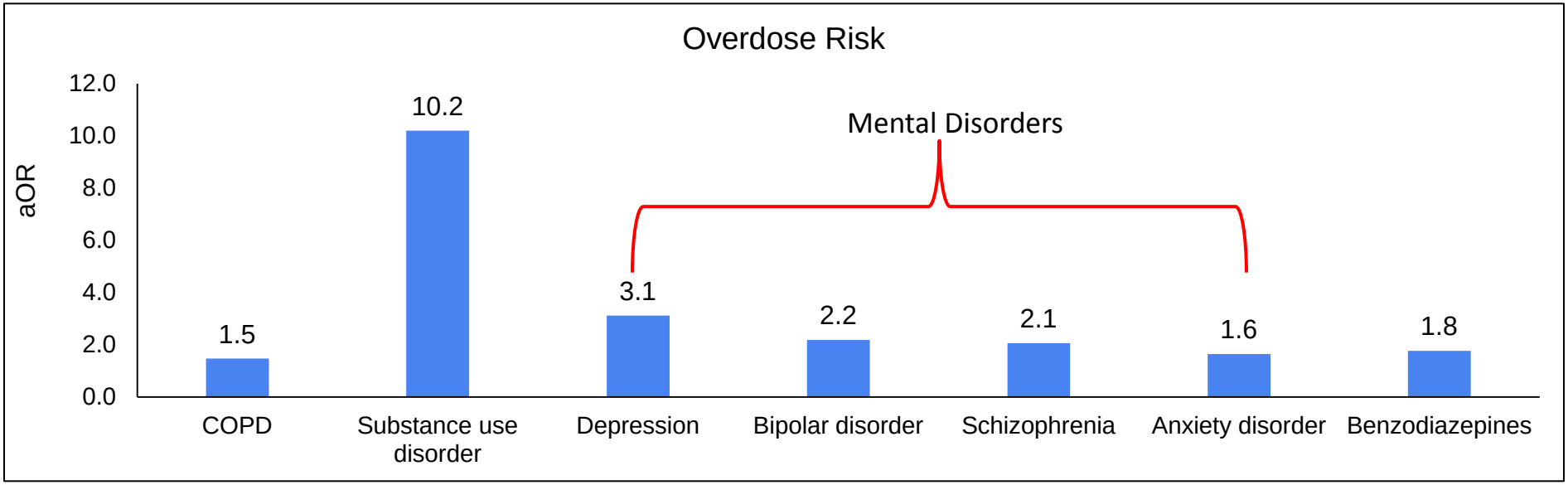
Source: Bohnert et al, JAMA, 2011

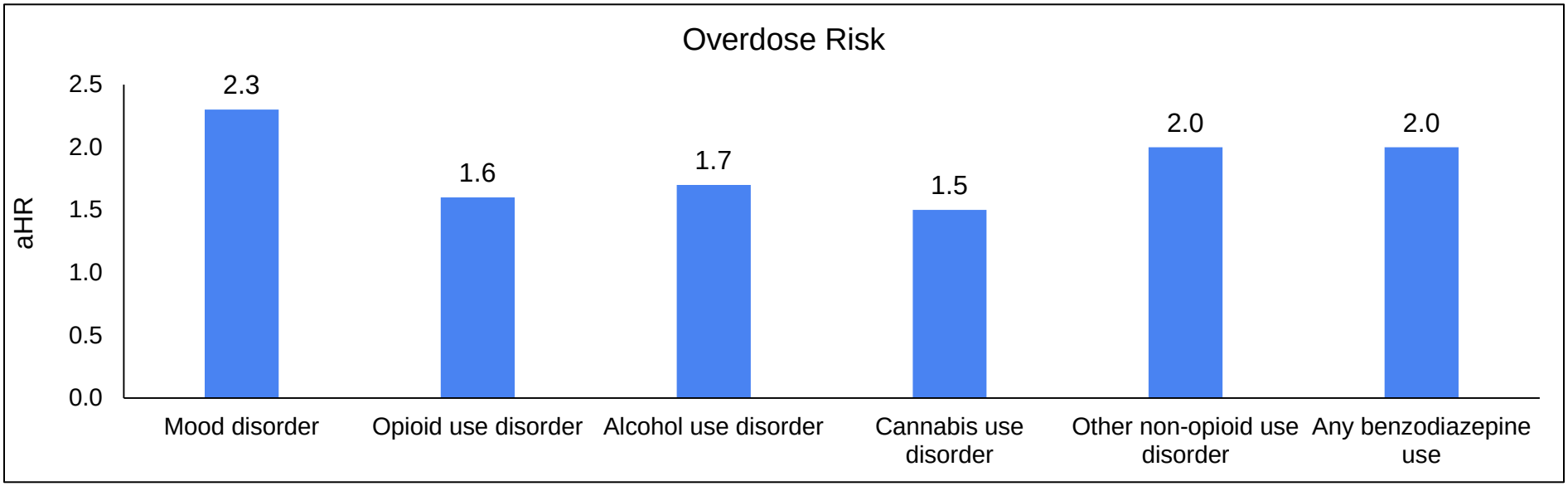
Patients Receiving Opioids and Benzodiazepines



Source: Dasgupta et al., Pain Med, 2015

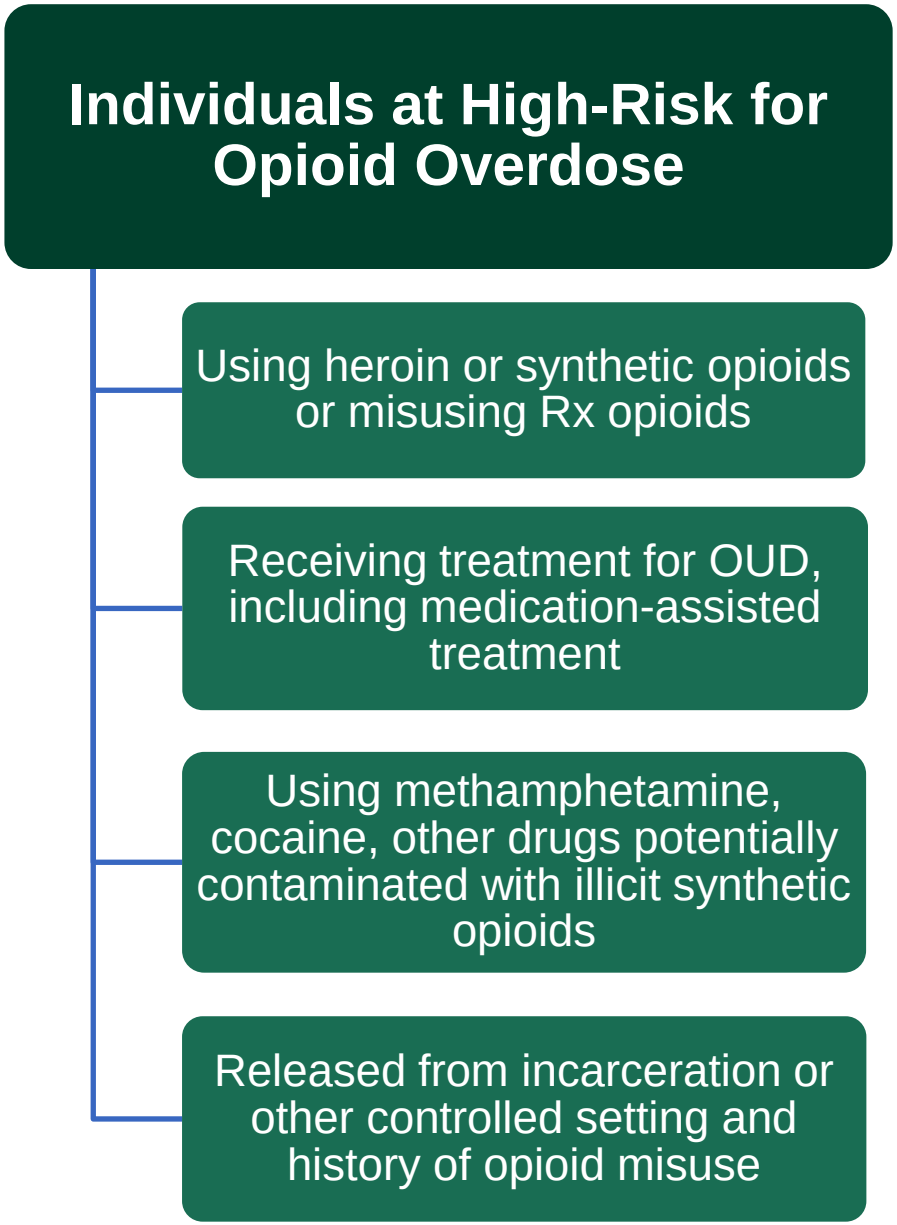
Patients Receiving Opioids with Other Co-Morbidities





Source: Nadpara et al., Pain Med, 2018; Campbell et al., Preventive Medicine, 2018

High Risk Groups



Fentanyl Contamination of the Illicit Drug Supply Expanding Population At-Risk for Opioid Overdose

Counterfeit Norco Poisoning Outbreak — San Francisco Bay Area, California, March 25–April 5, 2016

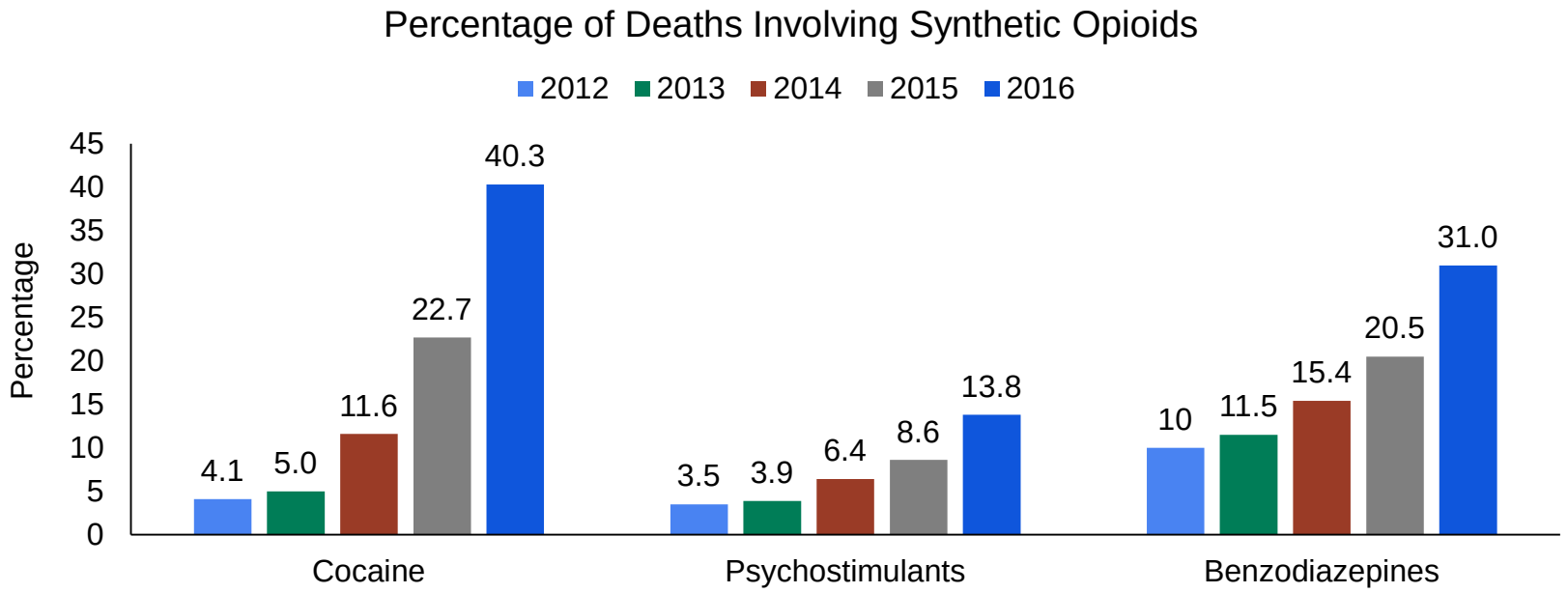
Kathy T. Vo, MD[1,2]; Xander M.R. van Wijk, PhD[3]; Kara L. Lynch, PhD[3]; Alan H.B. Wu, PhD[3]; Craig G. Smollin, MD[1,2]

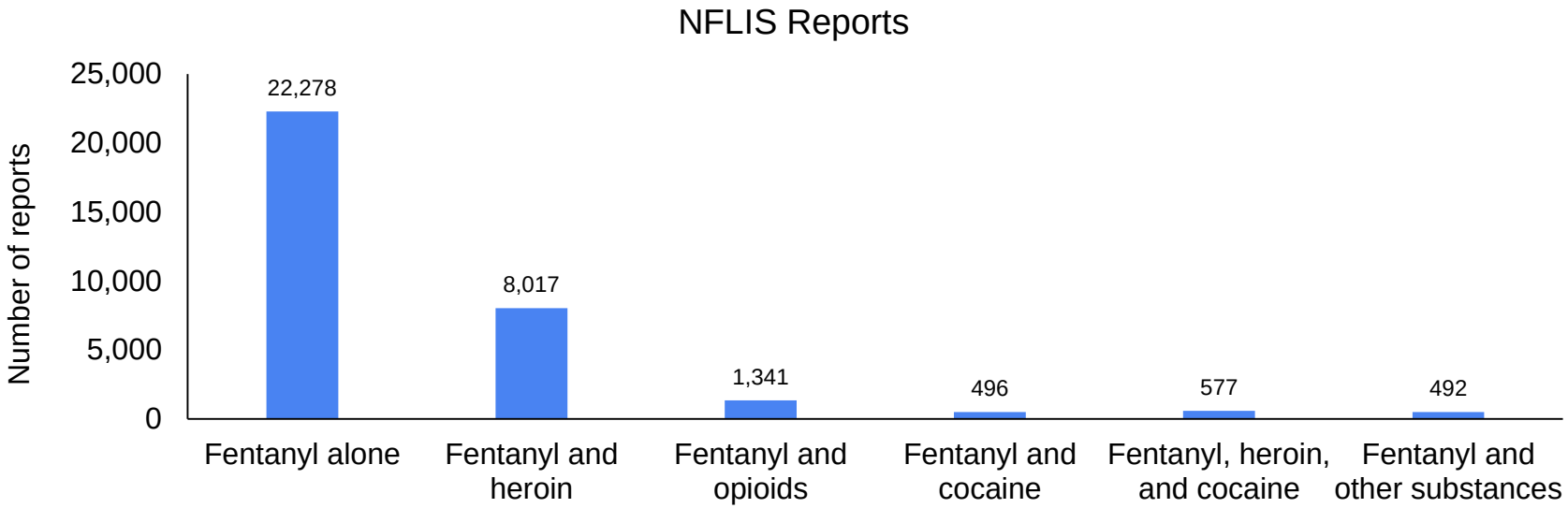

Figure 3: Counterfeit 30 Milligram Oxycodone Pills Containing Fentanyl.

Furanyl-Fentanyl Overdose Events Caused by Smoking Contaminated Crack Cocaine — British Columbia, Canada, July 15–18, 2016

Salman A. Klar, MPH[1]; Elizabeth Brodkin, MD[1]; Erin Gibson[1]; Shovita Padhi, MD[1]; Christine Predy[2]; Corey Green, MHSc[1]; Victoria Lee, MD[1]

People Using Other Illicit Drugs

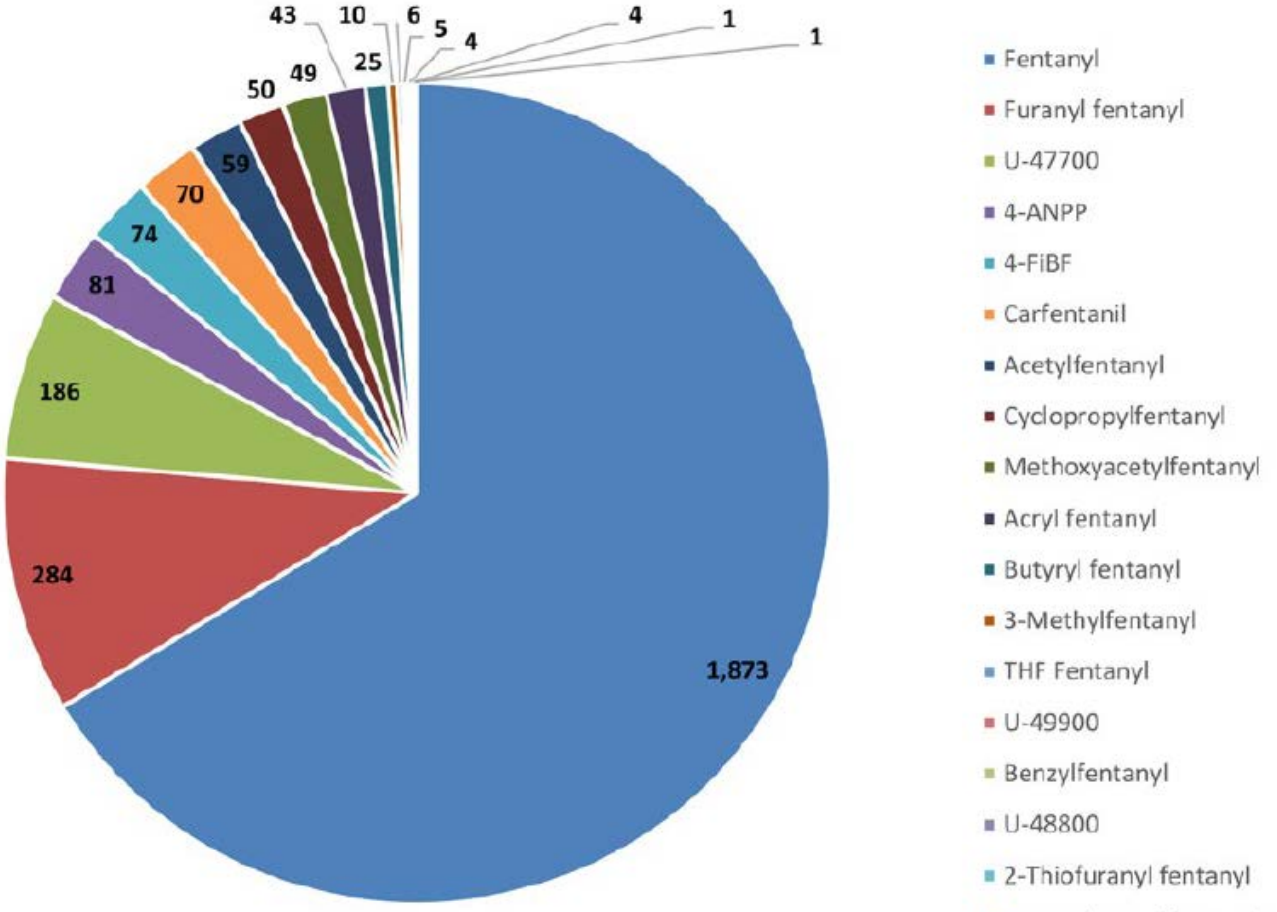




Source: Jones et al., JAMA, 2018; DEA National Drug Threat Assessment, 2018

Proliferation of Fentanyl Analogs and Other Illicit Synthetic Opioids

Figure 29. Identifications of Fentanyl, Fentanyl Related Substances, Fentanyl Precursors, and Other Synthetic Opioids, CY 2017.

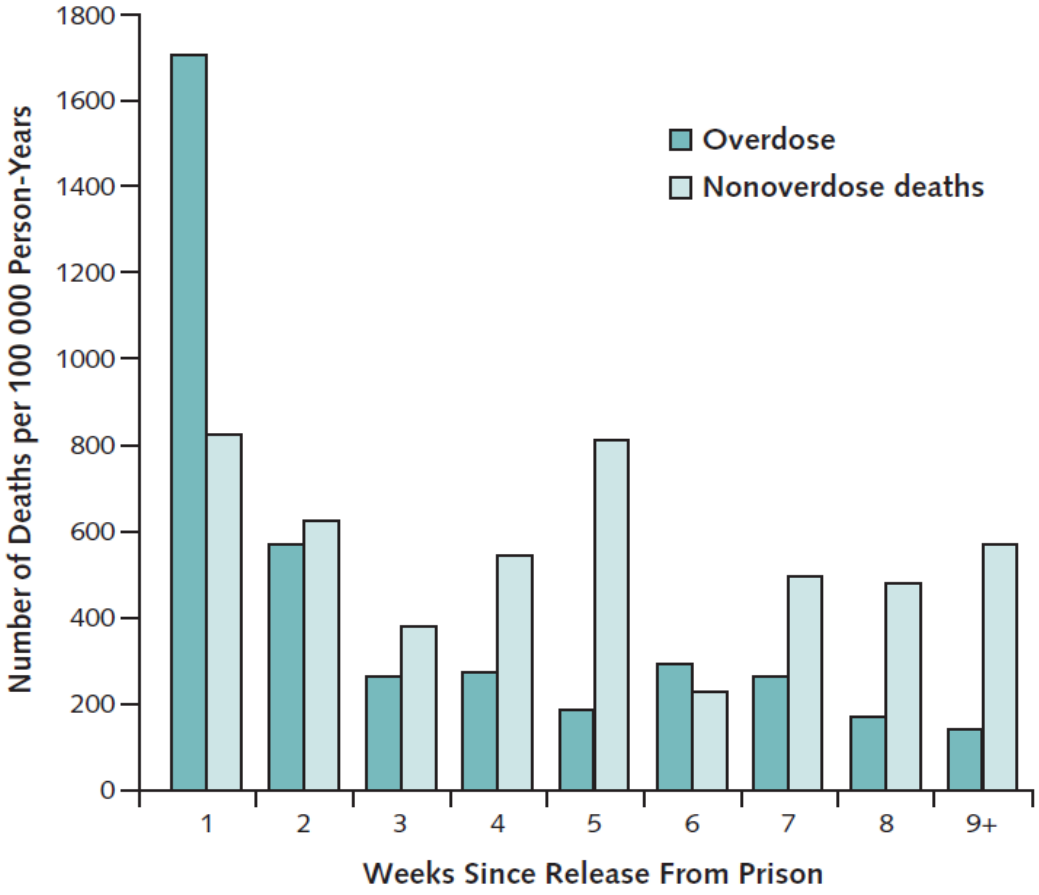


Source: DEA

Source: DEA National Drug Threat Assessment, 2018

Released from incarceration or other controlled setting

Figure. Mortality rate, by week since release, for overdose and all other (nonoverdose) causes of death.



Source: Binswanger et al., AIM, 2013

fjr0@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

U.S. Department of Veterans Affairs

Opioid Overdose Education and Naloxone Distribution (OEND) Within the Veterans Health Administration

Elizabeth Oliva, PhD

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VA Program Evaluation and Resource Center

VA Office of Mental Health and Suicide Prevention

Investigator

VA Center for Innovation to Implementation

VA Palo Alto Health Care System

AADPAC/DSARM

December 2018

ACKNOWLEDGMENTS

- Veterans Health Administration
  - Staff across the country getting lifesaving OEND to Veterans!
  - VA OEND National Support & Development Workgroup; VA OEND Spanish Translation Workgroup
  - Pharmacy Benefits Management Services (PBM); PBM Academic Detailing Services
  - Office of Mental Health and Suicide Prevention
  - Homeless Programs
  - Office of Nursing Services
  - Specialty Care Services (Pain Management; Emergency Medicine; Enterprise Opioid Strategy team)
  - Patient Care Services (Primary Care, Social Work)
  - Employee Education System
  - Diffusion of Excellence, National Center for Patient Safety, Office of Security & Law Enforcement
  - Health Services Research & Development (IIR 16-078); Quality Enhancement Research Initiative (RRP 13-446)
- Community
  - Eliza Wheeler and Sharon Stancliff
  - Alexander Walley
  - Phillip Coffin
  - Maya Doe-Simkins
  - Corey Davis
  - Traci Green
  - Jeffrey Bratberg
  - Robert Childs
  - Andrew McAuley

WHAT IS OEND?

- Risk mitigation initiative that aims to prevent opioid-related overdose deaths
  - **One of many risk mitigation strategies** employed by VA to minimize risk of opioid-related adverse events
  - **Target patient populations***
    - Patients with opioid use disorder
    - Patients prescribed opioids
- **Opioid Overdose Education (OE)**
  - Provide patient education on how to ***prevent, recognize, and respond*** to an opioid overdose
- **Naloxone Distribution (ND)**
  - Provide patient with ***naloxone***
    - Train patient and potential bystanders on how to use naloxone

*VA Clinical Guidance: "***Offer*** naloxone rescue to Veterans prescribed or using opioids who are at increased risk for opioid overdose or whose provider deems, based on their clinical judgment, that the Veteran has an indication for ready naloxone availability"

VIEWPOINT

Addressing the Opioid Epidemic in the United States

Lessons From the Department of Veterans Affairs

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Over the past 15 years, more than 165 000 people in the United States have died from overdoses related to prescription opioids,[1] and millions more have suffered adverse consequences.[2,3] The misuse and abuse of prescription opioids have contributed to a precipitous increase in heroin and fentanyl overdoses.[1]

Patients treated in the health care system of the Department of Veterans Affairs (VA) are part of this epidemic. Chronic pain impacts half of veterans using the VA, co... of psychiatric comorbidities ... traumatic stre... offi... tic... op... n... ment's data capabi... tives reduced the use of opioid me... proved the safety of opioid prescribing, while expandi... alternative pain therapies (**Figure**). By mid-2016 compared with mid-2012, the number of veterans dispensed an opioid each quarter had decreased by 172 000, or about 25%. Moreover, there were 57 000 (47%) fewer patients receiving concomitant opioids and benzodiazepines and 22 000 (36%) fewer patients receiving daily opioid dosages of more than 100 morphine-milligram equivalents, both measures of potentially unsafe opioid use. Between 2010 and 2015, the rate of

Strategies to Address the Opioid Epidemic

The VA has employed 4 broad strategies to address the opioid epidemic: education, pain management, risk mitigation, and addiction treatment (eTable in the Supplement).

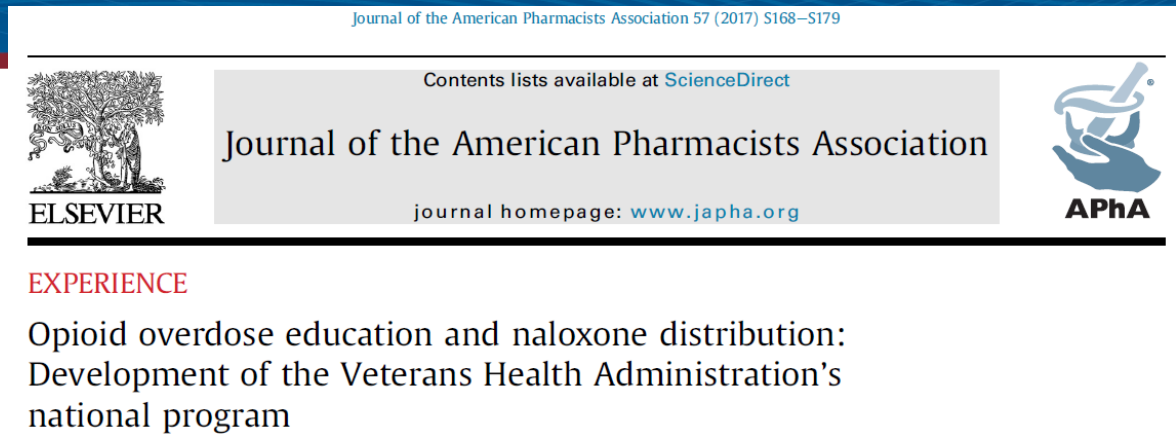
pharmacists engage directly with opioid prescribers, similar to detailing by pharmaceutical representatives. The VA detailers use sophisticated dashboards with real-time prescriber-level data to engage clinicians in adopting best practices around opioid prescribing. This focus is not simply on reducing opioid medications, but rather on improving the safe use of opioids. Beyond detailing, the VA developed an overdose education and naloxone distribution system that has distributed tens of thousands of naloxone doses and developed standardized patient and provider education to comple... broader educational efforts outside of the VA that ...scribing.

macologic ... expanded mini-residency ... consult capabilities for primary care clinic... prove their management of pain.

Risk Mitigation

The VA implemented several strategies to support and track risk mitigation activities for opioid therapy (eTable in the Supplement). A key component of the Opioid

NATIONAL VA OEND PROGRAM



- In 2014, VA established a national OEND program
  - Informed by pilot VA OEND programs
  - Developed by national, cross-program office workgroup
    - Composed of representatives from pharmacy, mental health, pain management, nursing, primary care, emergency medicine, and employee education
    - National workgroup members facilitated presentations to program offices to garner leadership and staff buy-in
- Major innovations
  - Policy and clinical guidance
  - Educational resources
  - Implementation and evaluation resources
  - Pharmacy-driven

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington, DC 20420

IL 10-2014-12
Reply to: 10P4

May 13, 2014

UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

IMPLEMENTATION OF OPIOID OVERDOSE EDUCATION AND NALOXONE DISTRIBUTION (OEND) TO REDUCE RISK OF OPIOID-RELATED DEATH

4. VA providers should consider providing OEND to Veterans who are at significant risk of opioid overdose. Clinical judgment about risk/benefit and patient-centered care involving Veterans and their significant others in shared decision-making should guide decisions on provision of OEND.

- Naloxone layperson formulations added to National Drug File
- "Free-to-Facilities" Naloxone Initiative
  - VA Pharmacy Benefits Management Services (PBM) has provided funding for naloxone to be dispensed to VA patients without the medical center incurring the cost of naloxone
  - To allow the initiative to last as long as possible, funds go to purchasing the nasal spray (the current preferred option when clinically appropriate)
- CARA *Section 915. ELIMINATION OF COPAYMENT REQUIREMENT FOR VETERANS RECEIVING OPIOID ANTAGONISTS OR EDUCATION ON USE OF OPIOID ANTAGONISTS*
  - Exempts copays for naloxone as well as training on naloxone (when visit is solely for naloxone)
- Recommendations for Issuing Naloxone (July 2017; RFU)

Naloxone Rescue: Recommendations for Issuing

Naloxone Rescue [Naloxone HCl nasal spray (Narcan®) or Naloxone HCl autoinjector (Evzio®)] for the VA Opioid Overdose Education and Naloxone Distribution (OEND) Program

July 2017

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives
in collaboration with the VA OEND National Support and Development Work Group

Assess the risk of opioid-related adverse events***. Discuss*** the provision of naloxone rescue as an opioid risk mitigation option with patients and/or family/carers. ***Offer*** naloxone rescue to Veterans prescribed or using opioids who are at increased risk for opioid overdose or whose provider deems, based on their clinical judgment, that the Veteran has an indication for ready naloxone availability. ***Educate*** patients and carers on the proper use and storage of naloxone rescue medications. ***Document*** OEND-related discussions and opioid overdoses in patients' medical records and through appropriate diagnostic coding, including documenting any reversal events with VA naloxone rescue medications using a nationally recommended and standardized note template (see VA National OEND SharePoint for more information).

- ***Assess*** risk
- ***Discuss*** naloxone as an option
- ***Offer*** naloxone
- ***Educate*** patients and caregivers
- ***Document*** OEND-related discussions and opioid poisonings and overdoses (including reversal events)

EVOLUTION OF NALOXONE WITHIN VHA

VA Intranasal Naloxone Kit

- 2 mucosal atomizer devices
- 2 Luer-lock prefilled syringe naloxone 1 mg/mL (2mL)
- 1 Laerdal face shield
- 1 pair nitrile gloves
- 1 opioid safety brochure
- 1 intranasal naloxone kit brochure
- 1 blue zippered pouch

VA Intramuscular Naloxone Kit

- Two 3 ml, 25g, 1-inch syringes
- 2 vials naloxone 0.4 mg/mL (1 mL) injection
- 1 Laerdal face shield
- 1 pair nitrile gloves
- 2 alcohol pads
- 1 opioid safety brochure
- 1 intramuscular naloxone kit brochure
- 1 black zippered pouch

Naloxone Nasal Spray (4 mg)

Carton/box contains:

- Two 4 mg naloxone nasal sprays (each spray includes a Quick Start Guide)
- 1 prescribing information and patient instructions for use

Naloxone Auto-Injector (2 mg)

Carton/box contains:

- 1 auto-injector trainer
- 2 naloxone 2 mg auto-injectors
- 1 prescribing info
- 2 instructions for use

VA TECHNICAL ASSISTANCE

- **VA National OEND SharePoint (internal VA site)** Step-by-step instructions for implementation; Quick Guide; **TWO** VA Patient Education Brochures (English and Spanish): (1) patients with opioid use disorder and (2) patients prescribed opioids; Posters; "Program Models"
- **VA OEND Videos (links to all videos)**
  - Intro for People with Opioid Use Disorders https://youtu.be/-qYXZDzo3cA
  - Intro for People Taking Prescribed Opioids https://youtu.be/NFzhz-PCzPc
  - How to Use the VA Naloxone Nasal Spray https://youtu.be/0w-us7fQE3s
  - How to Use the VA Auto-Injector Naloxone Kit https://youtu.be/-DQBCnrAPBY
- **VA Academic Detailing**
  - Patient education brochures, "Kit" brochures, DVDs for providers and patients (VA staff can order through depot)
- **Panel Management Tools**
  - OEND Patient Risk Dashboard; Stratification Tool for Opioid Risk Mitigation; Opioid Therapy Risk Reduction Report
- **VA Monthly OEND Call**
- **Accredited TMS training:** VA TMS trainings 27440 and 27441
  - Available outside VA on www.train.org: https://www.train.org/main/course/1064943
- **Opioid Safety Initiative (OSI) & Psychotropic Drug Safety Initiative (PDSI)**

VA Academic Detailing OEND SharePoint (internal site)

Provider Materials

Quick Reference Guide

IB#: 10-788 | Order

Preventing Rx Overdoses

Centers for Disease Control

Opioid Overdose Toolkit

SAMHSA

Patient Materials

Naloxone Instructions

Naloxone Nasal Spray

IB#: 10-926 | Order

Naloxone Auto-injector

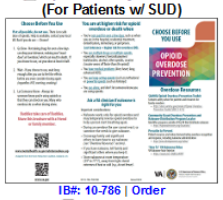
IB#: 10-780 | Order

Brochures & Handouts

Opioid Safety Brochure (For Patients on Opioids)

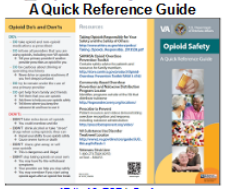
IB#: 10-784 | Order
Spanish: View | IB#: 10-783 | Order

Opioid Safety Brochure (For Patients w/ SUD)



IB#: 10-786 | Order
Spanish: View | IB#: 10-785 | Order

Opioid Safety Brochure A Quick Reference Guide



IB#: 10-787 | Order

Am I At Risk? Brochure

IB#: 10-921 | Order
508 Version: View

Order DVDs

Patient (IB#: 10-769) | Provider (IB#: 10-770)

Academic Detailing Service Data Resources

Available Tools and When to Use Them

Do I Have Access? | Do Others Have Access?

Risk Dashboard

Data: VISN/Facility/Provider Scores
Target Audience: Admin/Leadership

Priority Panel Report

Data: Provider Panel Opportunities
Target Audience: Academic Detailers

Trend Reports

National | VISN | Facility | Prescriber
Target Audience: Admin/Leadership

Patient Risk Report

Data: Patient Information
Target Audience: Clinicians

Detailed Patient Report

Data: Patient Information
Target Audience: Clinicians

Daily Appointment Report

Data: Clinic & Patient Information
Target Audience: Clinicians

Implementation Status Report

Data: National/VISN/Facility Summaries
Target Audience: Admin/Leadership

Naloxone Rx Release Report

Data: Patient Information
Target Audience: Supervisors/Clinicians

Additional Data Resources

Distribution Report

Data: VISN/Facility Summary
Target Audience: Admin/Leadership

STORM

Data: Summary & Patient Data
Target Audience: All Users

OTRR

Data: Patient Information
Target Audience: PACT & BHIP Teams
Special Access Required

VA Patient Education Brochure: Patients with Opioid Use Disorder (English/Spanish)

Choose Before You Use

If at all possible, do not use. There is no safe dose of opioids. Help is available, contact your local VA. But if you do use—Choose!

1. Go Slow - Not taking drugs for even a few days can drop your tolerance, making your "usual dose" an "overdose," which can result in death. If you choose to use, cut your dose at least in half.

2. Wait - If you choose to use, wait long enough after you use to feel the effects before you even consider dosing again *(regardless if IV, snorting, smoking)*.

3. Let Someone Know - Always let someone know you're using opioids so that they can check on you. Many who overdose do so when dosing alone.

Buddies take care of Buddies.
Share this brochure with a friend or family member.

www.mentalhealth.va.gov/substanceabuse.asp

(Adapted from the Harm Reduction Coalition, Oakland, CA)

www.va.gov

You are at higher risk for opioid overdose or death when

- You've not used for even a few days, such as when you are in the hospital, residential treatment, detoxification, domiciliary, or jail/prison.
  Lost tolerance = higher risk for overdose (OD).
- You use multiple drugs or multiple opioids, especially: downers/ benzodiazepines/ barbiturates, alcohol, other opioids, cocaine *(cocaine wears off faster than the opioid)*.
- You have medical problems *(liver, heart, lung, advanced AIDS)*.
- You use long-acting opioids *(such as methadone)* or powerful opioids *(such as fentanyl)*.
- You use alone, and don't let someone know you are using opioids.

Ask a VA clinician if naloxone is right for you

Important considerations:

- Naloxone works only for opioid overdose and may temporarily reverse opioid overdose to help a person start breathing again.
- During an overdose the user cannot react, so someone else needs to give naloxone.
- Encourage family and significant others to learn how to use naloxone *(see "Overdose Resources" section)*.
- If you have naloxone, tell family and significant others where you keep it.
- Store naloxone at room temperature (59^0 to 77^0 F), away from light. Avoid extremes of heat or cold *(e.g., do not freeze)*.

Overdose Resources

SAMHSA Opioid Overdose Prevention Toolkit
Contains safety advice for patients and resources for family members
- *http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742*

Community-Based Overdose Prevention and Naloxone Distribution Program Locator
Identifies programs outside of the VA that distribute naloxone
- *http://hopeandrecovery.org/locations/*

Prescribe to Prevent
Patient resources and videos demonstrating overdose recognition and response, including naloxone administration
- *http://prescribetoprevent.org/video/*

"How To" VA Naloxone Video
VA Naloxone Nasal Spray:
- *https://youtu.be/0w-us7fQE3s*

VA Naloxone Auto-Injector Kit:
- *https://youtu.be/-DQBCnrAPBY*

IB 10-786, P96788 Revised: 09/16

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Employee Education System

Signs of Overdose

Signs of an Overdose*

Check: Appears sleepy, heavy nodding, deep sleep, hard to arouse, or vomiting

Listen: Slow or shallow breathing *(1 breath every 5 seconds)*; snoring; raspy, gurgling, or choking sounds

Look: Bluish or grayish lips, fingernails, or skin

Touch: Clammy, sweaty skin

- If the person shows signs of an overdose, see next section "Responding to an Overdose"

* *Even if the person responds to an initial safety check, bystanders should continue to monitor any person with these signs constantly to make sure the person does not stop breathing and die.*

Resources

Consider seeking long-term help at your local VA substance use disorder treatment program

Help on the Web

» VA Substance Use Disorder Program Locator: *www2.va.gov/directory/guide/SUD.asp*

» Substance Use Disorder Treatment Locator for non-Veterans: *https://findtreatment.samhsa.gov/*

» VA PTSD Programs: *www.va.gov/directory/guide/PTSD.asp*

Help is Available Anytime

» **Local Emergency Services: 911**

» **National Poison Hotline: 1-800-222-1222**

» **Veterans Crisis Line: 1-800-273-TALK (8255), or text – 838255**

Responding to an Overdose

1. Check For A Response

- Lightly shake person, yell person's name, firmly rub person's sternum *(bone in center of chest where ribs connect)* with knuckles, hand in a fist
- If person does not respond—**Give Naloxone, Call 911**

Rub Sternum

2. Give Naloxone, Call 911

- If you have naloxone nasal spray, DO NOT PRIME OR TEST the spray device. Gently insert the tip of the nozzle into one nostril and press the plunger firmly to give the entire dose of naloxone nasal spray.
- If you have the naloxone auto-injector, pull device from case and follow voice instructions.
- When calling 911, give address and say the person is not breathing.

Nasal Spray (4 mg)

OR

Auto-injector

3. Airway Open

Rescue Breathing *(if overdose is witnessed)*

- Place face shield *(optional)*
- Tilt head back, lift chin, pinch nose
- Give 1 breath every 5 seconds
- Chest should rise

Chest Compressions *(if collapse is unwitnessed)*

- Place heel of one hand over center of person's chest *(between nipples)*
- Place other hand on top of first hand, keep elbows straight, shoulders directly above hands
- Use body weight to push straight down, at least 2 inches, at rate of 100 compressions per minute
- Place face shield *(optional)*
- Give 2 breaths for every 30 compressions

Rescue Breathing *(if overdose is witnessed)*

OR

Chest Compressions *(if collapse is unwitnessed)*

4. Consider Naloxone Again

- If person doesn't start breathing in 2-3 minutes, or responds to the first dose of naloxone and then stops breathing again, give second dose of naloxone
- Because naloxone wears off in 30 to 90 minutes be sure to stay with the person until emergency medical staff take over or for at least 90 minutes in case the person stops breathing again

5. Recovery Position

- If the person is breathing but unresponsive, put the person on his/her side to prevent choking if person vomits

VA Patient Education Brochure: Patients Prescribed Opioids (English/Spanish)

What are Opioids?

Opioids are a type of drug found in some pain or other prescription medications, and in some illegal drugs of abuse *(e.g., heroin)*. In certain situations, opioids can slow or stop a person's normal breathing function.

Opioid harms

- Taking too much opioids can make a person pass out, stop breathing and die.
- Opioids can be addicting and abused.
- Tolerance to opioids can develop with daily use. This means that one will need larger doses to get the same effect.
- If a person stops taking opioids, he/she will lose tolerance. This means that a dose one takes when tolerant could cause overdose if it is taken again after being off of opioids.
- An opioid dose a person takes could cause overdose if shared with another person. Another person may not be tolerant.

Share this brochure with a friend or family member.

www.va.gov

Safe Use of Opioids

Safe use of opioids prevents opioid harms from happening to not only you, but also to family, friends and the public.

To use opioids safely

- Know what you're taking *(e.g., color/shape/size/name of medication)*
- Take your opioid medication exactly as directed
- Review the booklet *Taking Opioids Responsibly for Your Safety and the Safety of Others* with your provider
- DON'T mix your opioids with:
  - » Alcohol
  - » Benzodiazepines *(Alprazolam/Xanax, Lorazepam/Ativan, Clonazepam/Klonopin, Diazepam/Valium)* unless directed by your provider
  - » Medicines that make you sleepy

Ask a VA clinician if naloxone is right for you

Important considerations:

- Naloxone works only for opioid overdose and may temporarily reverse opioid overdose to help a person start breathing again.
- During an overdose the user cannot react, so someone else needs to give naloxone.
- Encourage family and significant others to learn how to use naloxone *(see "Overdose Resources" section)*.
- If you have naloxone, tell family and significant others where you keep it.
- Store naloxone at room temperature (59^0 to 77^0 F), away from light. Avoid extremes of heat or cold *(e.g., do not freeze)*.

Resources

Local Emergency Services: 911
National Poison Hotline: 1-800-222-1222
Veterans Crisis Line: 1-800-273-TALK (8255), or text – 838255

Taking Opioids Responsibly for Your Safety and the Safety of Others
- *http://www.ethics.va.gov/docs/policy/Taking_Opioids_Responsibly_2013528.pdf*

VA Substance Use Disorder Treatment Locator
- *www2.va.gov/directory/guide/SUD.asp*

VA Posttraumatic Stress Disorder (PTSD) Treatment Locator
- *www.va.gov/directory/guide/PTSD.asp*

"How To" VA Naloxone Video
- *VA Naloxone Nasal Spray: https://youtu.be/0w-us7fQE3s*
- *VA Auto-Injector Naloxone Kit: https://youtu.be/-DQBCnrAPBY*

IB 10-784, P96786

Revised: 09/16

U.S. Department of Veterans Affairs
Veterans Health Administration
Employee Education System

Opioid Overdose

Opioid overdose occurs when a person takes more opioids than the body can handle, passes out and has no or very slow breathing *(i.e., respiratory depression)*.

» Overdose can occur seconds to hours after taking opioids and can cause death

Signs of an Overdose*

Check: Appears sleepy, heavy nodding, deep sleep, hard to arouse, or vomiting

Listen: Slow or shallow breathing (1 breath every 5 seconds); snoring; raspy, gurgling, or choking sounds

Look: Bluish or grayish lips, fingernails, or skin

Touch: Clammy, sweaty skin

- If the person shows signs of an overdose, see next section "Responding to an Overdose"

* *Even if the person responds to an initial safety check, bystanders should continue to monitor any person with these signs constantly to make sure the person does not stop breathing and die.*

Overdose Resources

SAMHSA Opioid Overdose Prevention Toolkit
Contains safety advice for patients and resources for family members

- *http://store.samhsa.gov/product/Opioid-Prevention-Toolkit/SMA13-4742*

Community-Based Overdose Prevention and Naloxone Distribution Program Locator
Identifies programs outside of the VA that distribute naloxone

- *http://hopeandrecovery.org/locations/*

Prescribe to Prevent
Patient resources and videos demonstrating overdose recognition and response, including naloxone administration

- *http://prescribetoprevent.org/video/*

Responding to an Overdose

1. Check For A Response

- Lightly shake person, yell person's name, firmly rub person's sternum *(bone in center of chest where ribs connect)* with knuckles, hand in a fist
- If person does not respond—**Give Naloxone, Call 911**


Rub Sternum

2. Give Naloxone, Call 911

- If you have naloxone nasal spray, DO NOT PRIME OR TEST the spray device. Gently insert the tip of the nozzle into one nostril and press the plunger firmly to give the entire dose of naloxone nasal spray.
- If you have the naloxone auto-injector, pull device from case and follow voice instructions.
- When calling 911, give address and say the person is not breathing.


Nasal Spray (4 mg)

OR


Auto-injector

3. Airway Open

Rescue Breathing
(if overdose is witnessed)

- Place face shield *(optional)*
- Tilt head back, lift chin, pinch nose
- Give 1 breath every 5 seconds
- Chest should rise

Chest Compressions
(if collapse is unwitnessed)

- Place heel of one hand over center of person's chest *(between nipples)*
- Place other hand on top of first hand, keep elbows straight, shoulders directly above hands
- Use body weight to push straight down, at least 2 inches, at rate of 100 compressions per minute
- Place face shield *(optional)*
- Give 2 breaths for every 30 compressions


Rescue Breathing
(if overdose is witnessed)

OR


Chest Compressions
(if collapse is unwitnessed)

4. Consider Naloxone Again

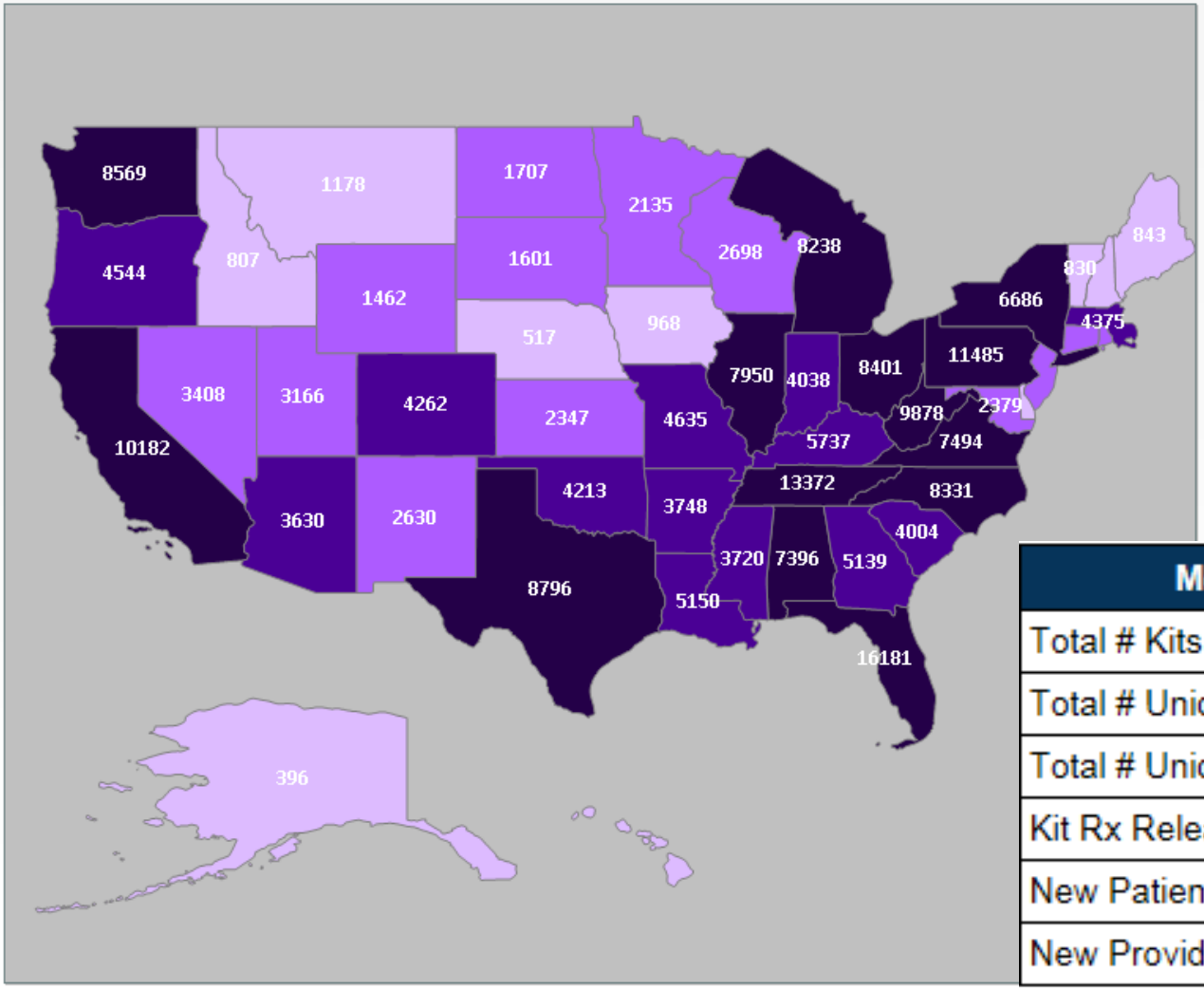
- If person doesn't start breathing in 2-3 minutes, or responds to the first dose of naloxone and then stops breathing again, give second dose of naloxone
- Because naloxone wears off in 30 to 90 minutes be sure to stay with the person until emergency medical staff take over or for at least 90 minutes in case the person stops breathing again

5. Recovery Position

- If the person is breathing but unresponsive, put the person on his/her side to prevent choking if person vomits

VHA Naloxone Distribution (12/6/18)

Naloxone Kit Prescription Fills by State



State	Kit Rx Fill Count
DE	1,267
NJ	1,549
Manila	14
Puerto Rico	768
RI	1,529

Metric Name	Metric Value
Total # Kits Rxs Released	225,109
Total # Unique Veterans	158,753
Total # Unique Prescribers	17,175
Kit Rx Releases (Past Week)	2,179
New Patients (Past Week)	1,226
New Providers (Past Week)	96

OEND National Trends

Feedback

Definitions

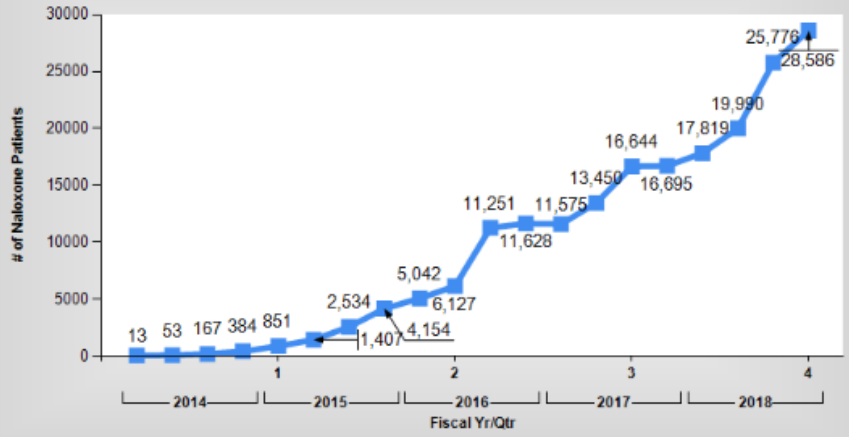
AD Visits (Salesforce) Last Update:	11/7/2018

Go to:

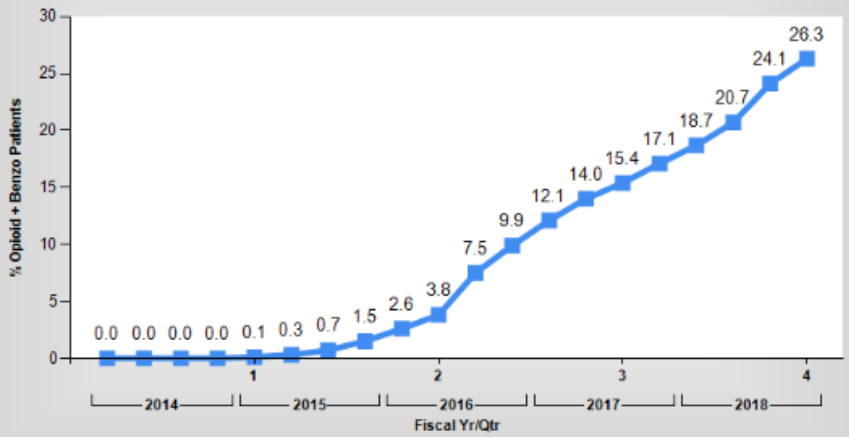
[General Trends](#) • [RIOSORD Trends](#) • [Risk Group Trends](#)

General Information / Trends

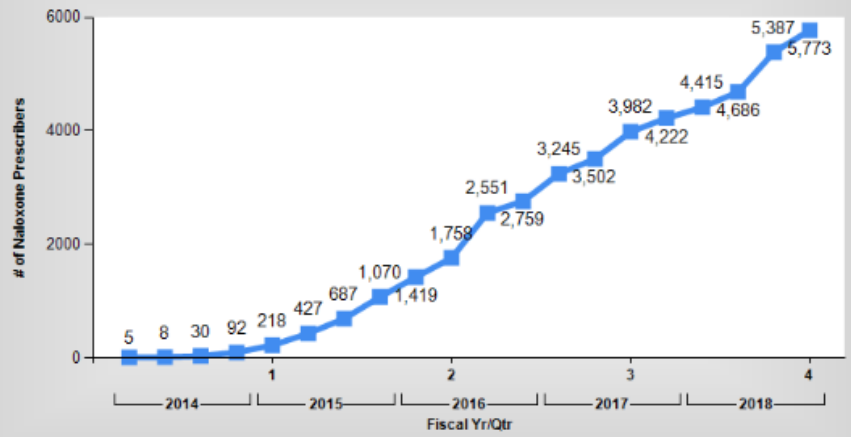
Patients w/ Naloxone Fill by Quarter



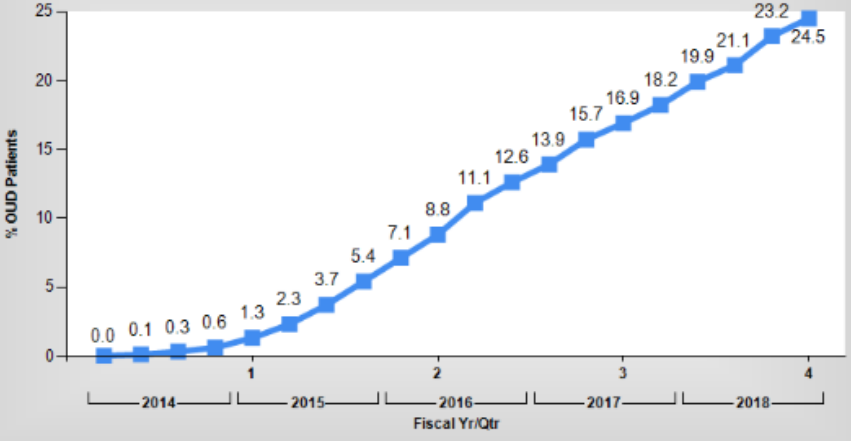
% Opioid + Benzo Patients w/ a Naloxone Fill in the Previous Year



Naloxone Prescribers by Quarter



% OUD Patients w/ a Naloxone Fill in the Previous Year



KEY IMPLEMENTATION CONSIDERATIONS

- Provider Education
- Patient Identification
- Patient Education
- Post-Overdose Care

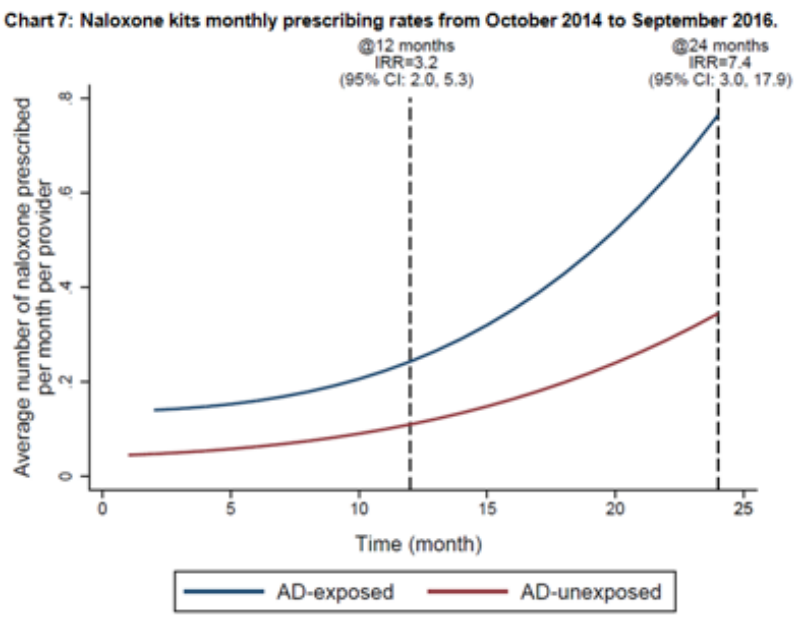
PROVIDER EDUCATION

- In-person training
  - Academic Detailing
- Web-based training
  - Available outside VA on www.train.org: https://www.train.org/main/course/1064943
- Monthly national call
- Address stigma and misperceptions (e.g., risk compensation)

Academic Detailing Services resulted in 7 times greater prescribing rate of Naloxone to Veterans at risk of overdose at 24 months

From October 2014 to Sept 2016, detailed providers had prescribing rate of naloxone >3 times higher than non detailed providers 1 year after first OEND-related AD visit, and >7 times greater at 2 years.

Moreover, the average rate of increase in naloxone prescribing was 7.1% greater in the AD-exposed versus the AD-unexposed providers (95% CI: 2.0%, 12.5%)



Bounthavong et al., 2017

KEY IMPLEMENTATION CONSIDERATIONS

- Provider Education
- **Patient Identification**
- Patient Education
- Post-Overdose Care

VA Academic Detailing OEND Risk Dashboard (internal site)

OEND Dashboard

Definitions | Export | Feedback

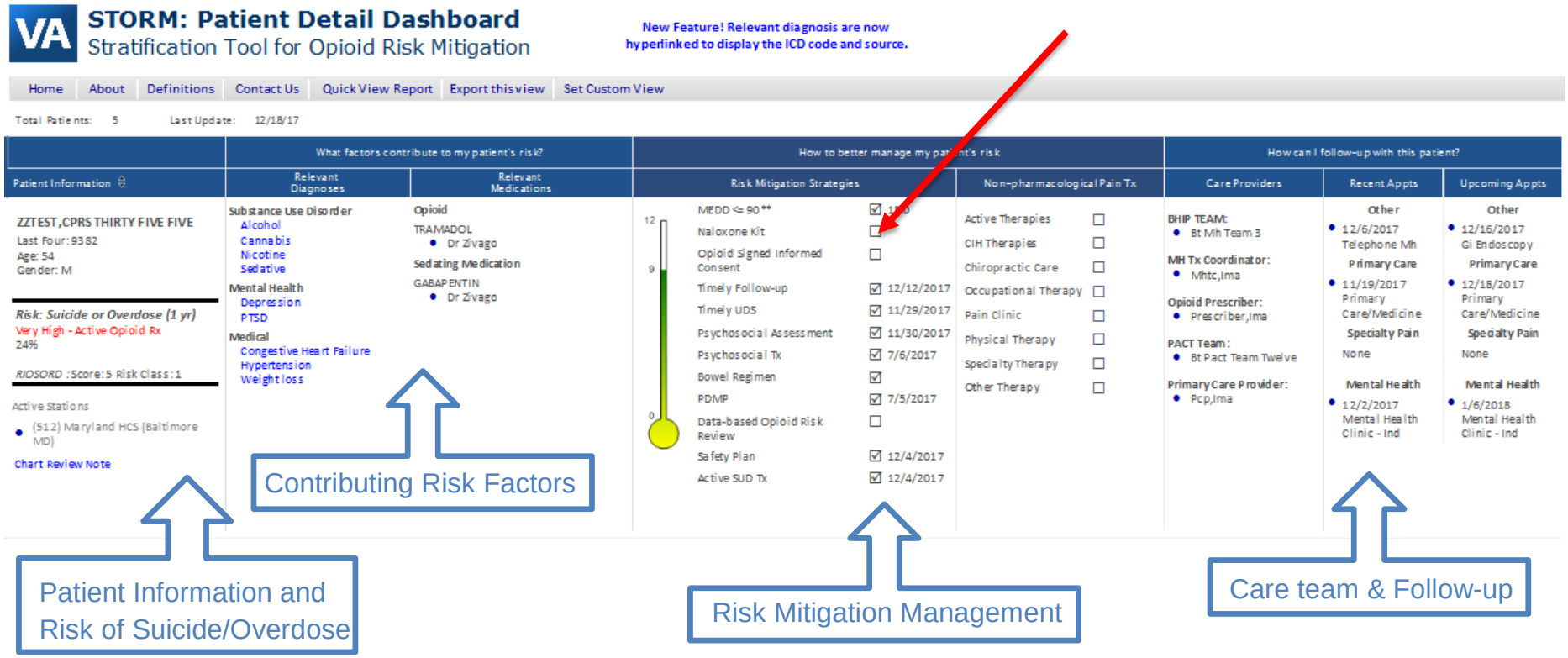
Update Status:	In Process
Last Updates:	12/5/2018

Location/Prescriber	# Naloxone Fills	% Nasal Fills (90d)	% Auto-Inj. Fills (90d)	% IM Fills (90d)	# Naloxone Patients	#Naloxone Prescribers	# Naloxone Uses
National	224,757	100.0%	0.0%	0.0%	158,545	17,159	286

		Naloxone Rx Released to Patient (1 year) / Total Patient Cohort			
Location / Prescriber	Potential Risk Factor	Patient Cohort	Score	National Score	⊞ Patients w/ No Fill
Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)		**RIOSORD Cohort Inclusive of All Opioid, OUD, and OAT Risk Group Patients**			
National	RIOSORD Risk Class (View Publication)	All Patients	36.0%	36.0%	281,888
		⊞ Risk Class ≥ 8	54.4%	54.4%	2,684
		⊞ Risk Class 5-7	43.3%	43.3%	9,512
		⊞ Risk Class ≤ 4	22.7%	22.7%	269,692
Opioid Pharmacotherapy					
National	Opioid + Benzodiazepine	All Patients	31.8%	31.8%	12,552
	MEDD ≥ 50 (Last 30 days)	All Patients	38.1%	38.1%	31,096
	MEDD ≥ 90 in Past Year w/ No Fill in the Past 90 Days	All Patients	17.8%	17.8%	8,011
	Methadone (Outpatient Rx or Active Non-VA Medication)	All Patients	30.6%	30.6%	11,824
OUD & OAT Pharmacotherapy					
National	OUD Diagnosis	All Patients	23.0%	23.0%	72,464
	Possible Overdose (3 Years)	All Patients	35.3%	35.3%	6,366
	Buprenorphine SL (Outpatient Rx or Active Non-VA Medication)	All Patients	41.6%	41.6%	9,115
	Naltrexone (Outpatient Rx, Active Non-VA, or Recent Clinic Order)	OUD Patients	38.8%	38.8%	1,804
	OUD-Related Fee Basis	All Patients	34.1%	34.1%	2,250

VA Stratification Tool for Opioid Risk Mitigation (internal site)

➢ Main Page



Opioid Therapy Risk Report - Panel

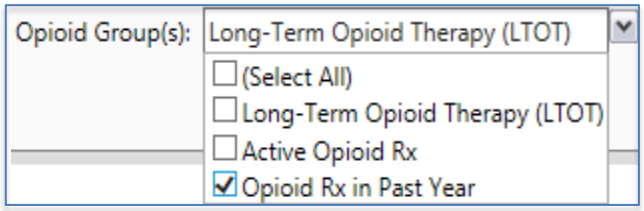
→ Create Panels by **Provider**, **Prescriber**, & **Teams**

→ Choose Opioid Group(s)

Any Opioid in Past Year

Long-Term Opioid Therapy

Active Rx



VSSC

Current As Of: 11/16/2018

ALL OPIOIDS
PATIENT LIST

For: [redacted]

Double Asterisk identifies values evaluated for past two years

Data Definitions Updated 04/27/2017

VSSC Help Desk | VHA Pain Mgt Site

Opioid OEND | PDMP Resources

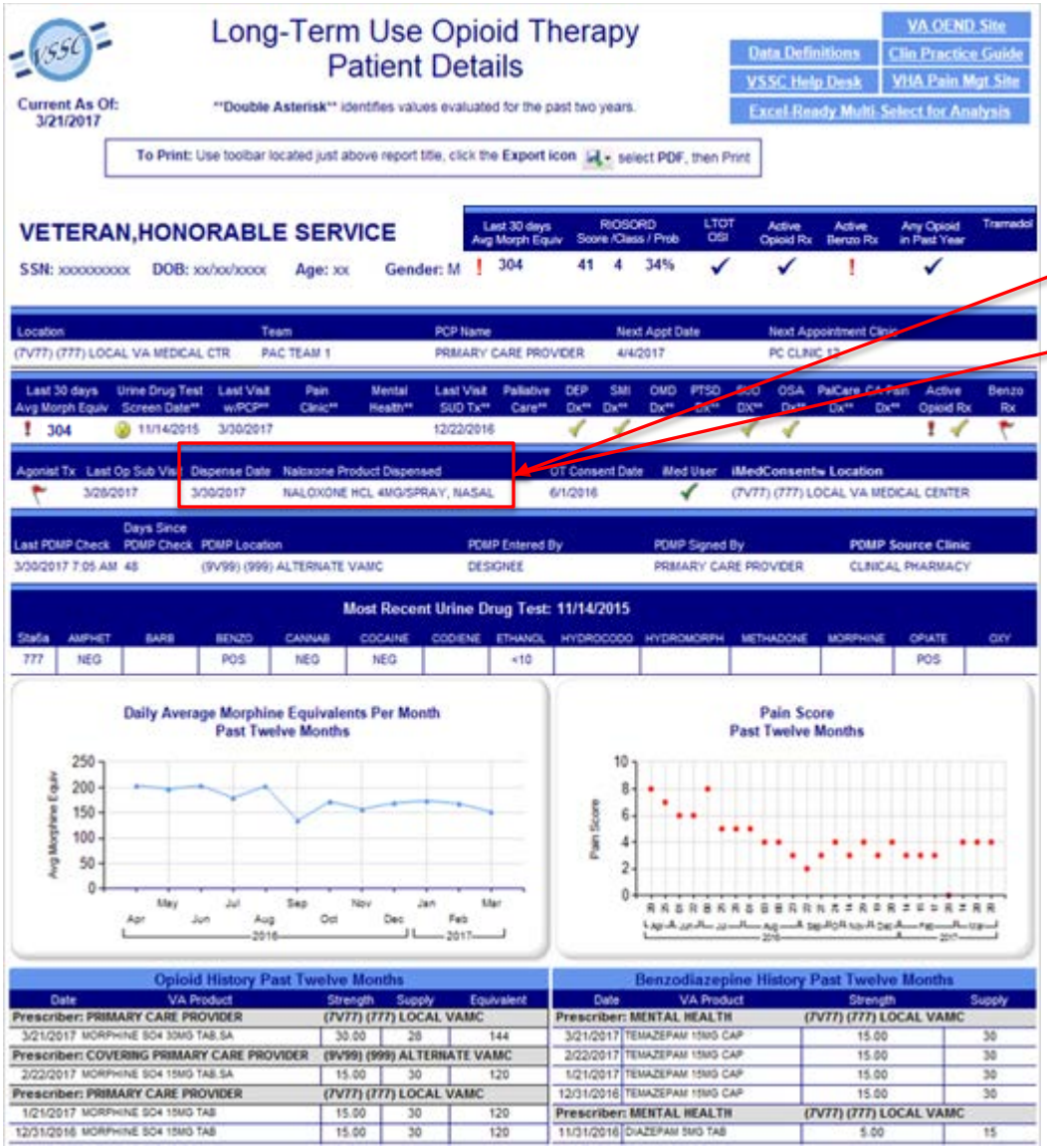
OTRR - Analyst MultiSelect
Use to Export Entire Pt List to Excel

Naloxone Dispense Date

Patient Name	PatientSSN	Date of Birth	Age	Gender	Last 30 Days Avg Morph Equiv	RIOSORD Score /Class / Prob			Last PDMP Check	Days Since PDMP	Last Urine Drug Test**	Entry Date National OT Consent	Signed by IMED USER	Long-Term Opioid Therapy	Active Opioid Rx	Active Benzo Rx	Last Naloxone Dispensed	Last Visit w/PCP**
[redacted]	[redacted]	[redacted]	[redacted]	M	182	35	3	24%	10/30/2018	18	9/7/2018	2/22/2018	✓	✓	✓		9/7/2018	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	M	113	25	2	14%	10/31/2018	17	8/31/2018	3/14/2018	✓	✓	✓		3/27/2018	[redacted]

★ Veteran-Focused ★ Actionable

Opioid Therapy Risk Report (OTRR)

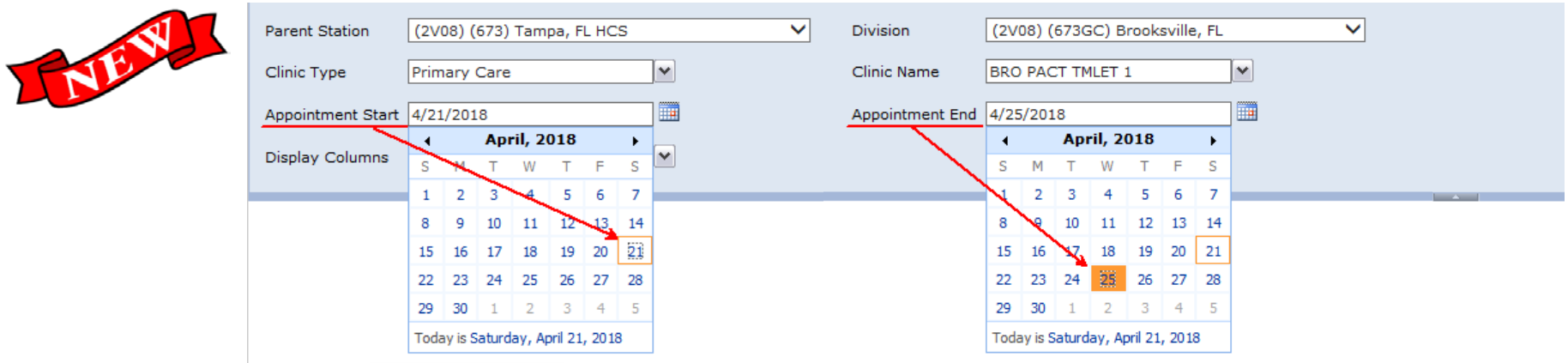


Veteran Details

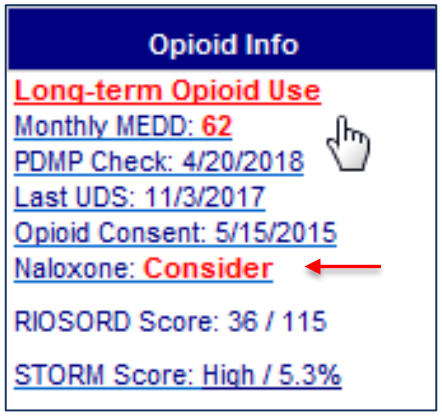
- All data **refreshed daily**
- Naloxone **Dispense Date**
- Naloxone **Product Dispensed**
- Quickly determine which patients require **proactive clinical action**
- Check recent **interactions w/other VA health providers**
- Latest information from across the VA **regardless of location**
- One Year history of Prescribed **Opioids**, **Benzos**, & **Pain Scores**

★ Veteran-Focused ★ Actionable

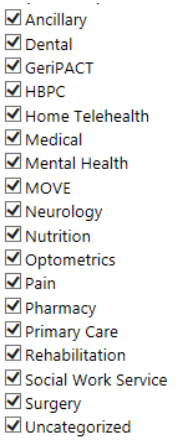
Clinic Huddle Patient Appointments Planning Tool



Appointment Info	Patient	Opioid Info	Diagnoses	Med Info	Labs	Screening	Prevention	Behavioral Health Scores	Care Coordination
04/25/2018 @ 10:00 AM (30 min) Est Patient CID/PID: 04/25/2018 (Wait: 0 days) Scheduled on: 03/17/2018 By: SCHEDULER 1 Comments: MOVED TO NEW CLINIC NoShow Count: 7 Miles to Clinic: NA	Patient, Number 4 SSN: 000000004 DOB: 5/22/1946 (72) Gender: M Disruptive Behavior: N Phone: 555-555-55555	Long-term Opioid Use Monthly MEDD: 62 PDMP Check: 4/20/2018 Last UDS: 11/3/2017 Opioid Consent: 5/15/2015 Naloxone: Consider RIOSORD Score: 36 / 115 STORM Score: High / 5.3%	CAN 90 day: 90 ACSC rank: 95 COPD DEPRESSION DIABETES HTN OBESITY HxTOBACCO	Active Meds: 18 Non-Supply: 15 Supply: 3 Controlled-Sub: 1 Last PDMP Check: 4/20/2018	BP: 152/86 (4/17/2018) A1c: 10.2 (3/6/2018) LDL: 73 (3/6/2018) eGFR: 75 (4/20/2018) SCr: 1.0 (4/20/2018)	CRC Screening: Reminder: GAP: Action Now Action Type: Recommendation or Clinical Endpoint Needed Action Due: 4/26/2018	Flu: 10/31/2017 PPSV23: 11/20/2014 PCV13: 12/15/2017 Other: 1/1/2006 PNEUMOCOCCAL, UNSPECIFIED FORMULATION Td: 1/15/2011 Tdap: 1/19/2012 Shingles:	AUDC: 1 (9/15/2017) PHQ-2: 0 (6/8/2017) PHQ-9: None in past year PC PTSD: 0 (10/27/2015)	Last PC Visit: 01-25-2018 Last Clinic: PACT CLINIC ALPHA # VA ED/UC Visits Past 12 Mo: 0 # VA Discharges Past 12 Mo: 1 Pending Labs: 16 Open Consults: 1

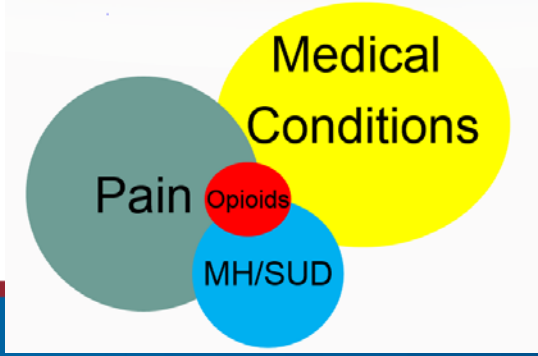


- **Actionable, Time-Sensitive, Cross-functional**
  - Address issues essential to veteran health & well-being
  - Efficient, Consistent
  - Pulls data from across the VA into one place
  - Select specific clinics by Name & Date Range
  - Links directly to full details

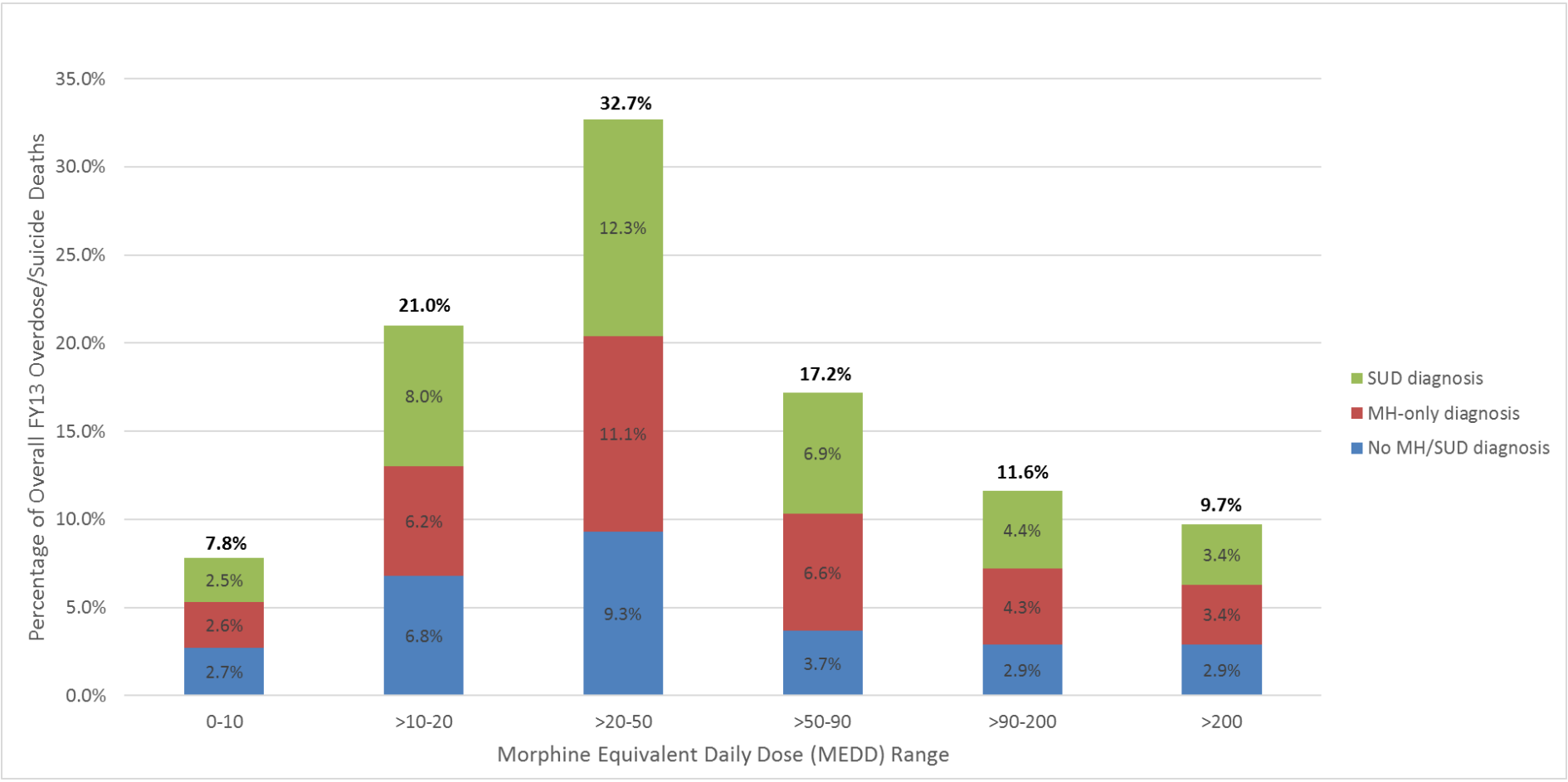


MOVING BEYOND MEDD AND OPIOIDS TO ADDRESS OPIOID CRISIS

- Among patients prescribed opioids, those at greatest risk for overdose tend to be complex patients with multiple comorbidities in addition to pain
- Comorbidities account for more risk compared to opioids across multiple predictive risk models (Glanz et al., 2018; Oliva et al., 2017; Zedler et al., 2015, 2018)
- Patient-centered risk mitigation addressing comorbidities is important *for all patients*, regardless of MEDD threshold, naloxone prescribing, or if opioids are no longer part of the patient's treatment plan

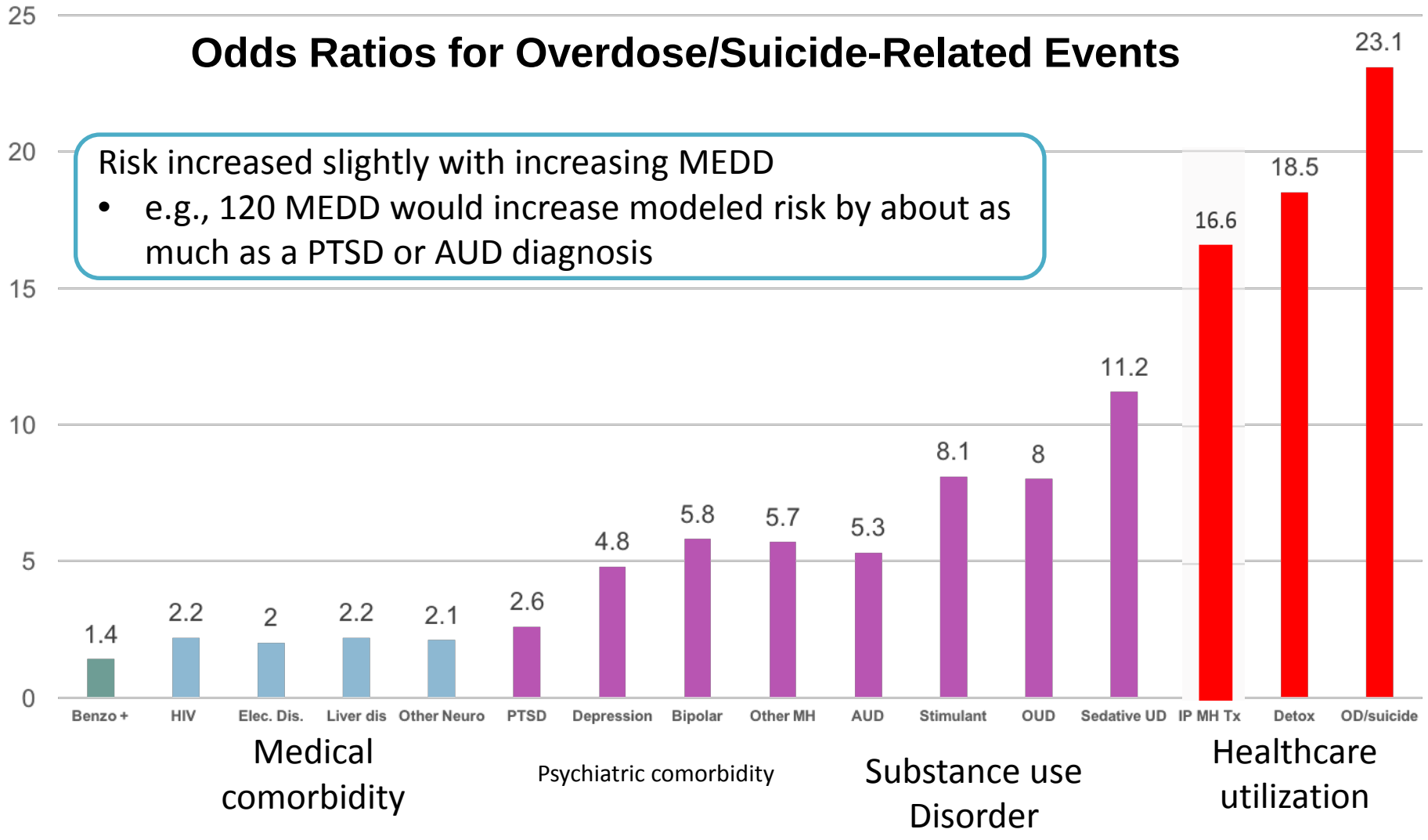


FY2013 OVERDOSE/SUICIDE MORTALITY--VHA



- Almost 4 out of every 5 patients who died from overdose/suicide were prescribed doses < 90 MEDD
- Almost 3 out of every 4 overdose/suicide deaths were among patients with MH/SUD diagnoses
- More than 1 out of every 2 deaths were among patients with MH/SUD diagnoses prescribed < 90 MEDD

MH/SUD AND NON-OPIOID RELATED FACTORS HAVE HIGHER ODDS RATIOS THAN OPIOID-RELATED FACTORS IN PREDICTIVE MODEL



Oliva et al., Psychol Serv 2017

KEY IMPLEMENTATION CONSIDERATIONS

- Provider Education
- Patient Identification
- **Patient Education**
- Post-Overdose Care

PATIENT EDUCATION: A FEW EXAMPLES

Targeted Outreach

- Patients prescribed opioids
  - Various efforts using MEDD (<50 or 100); Co-Rx benzodiazepines; Intrathecal pump patients
  - Primary care, Pain clinics, Pharmacy
- Patients with opioid use disorder
  - Substance Use Disorder Treatment programs (including Medication Assisted Treatment; Residential treatment); detoxification; inpatient; emergency department

Increasing Awareness

- "Am I At Risk?" brochure
- E-board
- Buttons

Educational Efforts

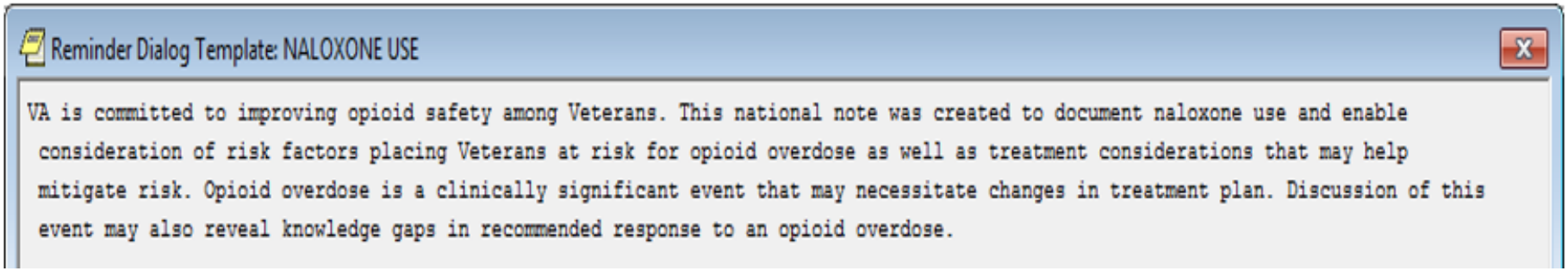
- Individual and group visits in primary care and pain clinics
  - Schedules "scrubbed" daily for same-day education opportunities
  - Phone-outreach by care team with educational materials mailed and discussed via phone and/or in a group visit
- Residential treatment
  - Initial assessment/evaluation; Upon admission and at discharge; classes for all residents; ensure naloxone can be kept on person and taken on passes
- Medication Assisted Treatment Programs
  - Offered upon enrollment; during medication management visits
- Pharmacy
  - Window dispensing; Consult Service; Residency projects
- Electronic Medical Record
  - Standardized notes for OEND
  - Health factor added to opioid refill note
  - Included in order sets
- Letter-based

Images from Mendes, 2/22/17 presentation

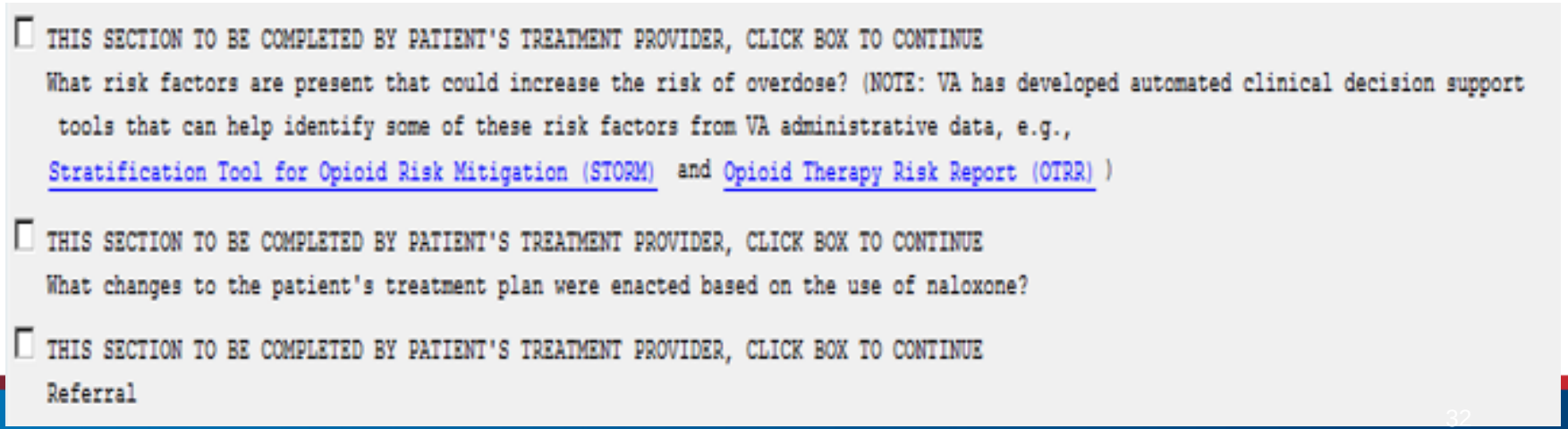
KEY IMPLEMENTATION CONSIDERATIONS

- Provider Education
- Patient Identification
- Patient Education
- **Post-Overdose Care**

VA National Naloxone Use Note



- Improve care post-overdose
- Cover sheet reminder component if patient's treatment provider does not complete sections of the note specified for patient's treatment provider



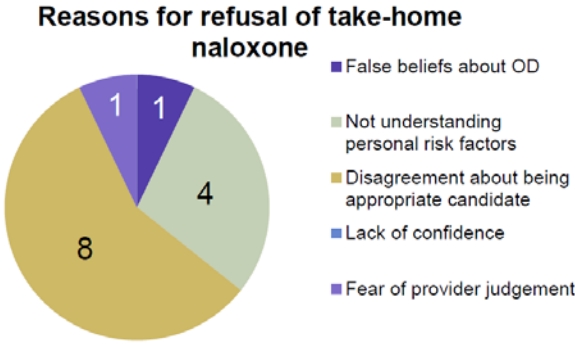
HEALTHCARE SYSTEM CONSIDERATIONS

- One tool in clinical armamentarium—not a panacea, not just about naloxone!
- Numerous levers—policy, funding, technical assistance
  - Coordination across program offices
  - Academic Detailing can help support implementation
- Patient Identification
  - Patients prescribed opioids
  - Patients with opioid use disorder
- Provider and Patient Education
  - Provide patient education on how to ***prevent, recognize, and respond*** to an opioid overdose
    - **A few minutes of training that could save a life!**

CLINICAL CONSIDERATIONS

- Medication Assisted Treatment (MAT) for Opioid Use Disorder (OUD)
  - OEND lifesaving; MAT lifesaving and life-transforming
- Post-overdose care
  - Non-fatal overdose—critical juncture
    - OEND and MAT
    - Standardize response (e.g., national note templates)
- Consider comorbidities and ANY history of opioid use
  - Even if opioids are no longer being taken (prescribed or illicit) high risk patients are still at-risk; naloxone is still needed + risk mitigation targeting comorbidities
    - Patients with OUD, even if in treatment
    - Patients with past chronic opioid therapy; even if opioids are no longer prescribed; also need to address pain and other risk factors!!

RELEVANT CONSIDERATIONS



- Patient refusal of naloxone
  - More effective methods for explaining risk
  - Recommendations for patients who live alone
    - Emphasize OE part of OEND
  - Recommendations for patients in recovery
  - Strategies to decrease stigma
- Letter-Based approaches
  - Involvement of provider/treatment team (do not want to undermine patient-provider relationship)
  - Opt-in versus Opt-out
    - "Why you may be denied life insurance for carrying naloxone" (WBUR)
  - Training considerations

"I feel that whether or not you say that it isn't held against us, it still feels that way"

Images from Valentino, 5/31/17 presentation

VHA Rapid Naloxone Initiative

The program increases the availability of naloxone in the following ways:

VA Police Naloxone

Equips VA police with naloxone and trains them in its use

Naloxone-stocked in AED cabinets

Stocked in areas such as cafeterias, substance use disorder treatment programs, and primary care clinics

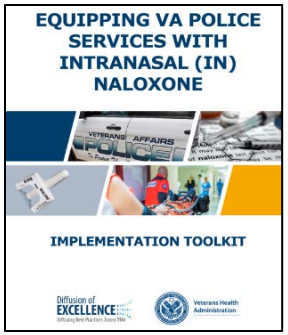
Opioid Overdose Education and Naloxone Distribution (OEND)

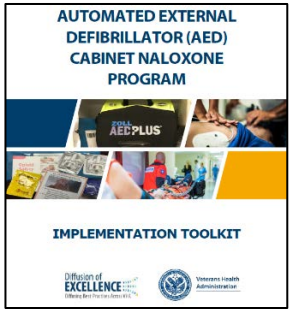
Educates at-risk patients and their families in how to *prevent, recognize, and respond to an overdose,* including how to respond with naloxone

The Impact

Making naloxone more readily available will increase the likelihood of successful overdose reversal, potentially saving hundreds of Veteran lives.

VA Boston Healthcare System implementation of all three elements resulted in 132 opioid overdose reversals.





- Implementation to date
  - OEND in all VA facilities
  - VA Police Naloxone (109 facilities implementing)
  - AED Cabinet Naloxone (95 facilities implementing)
- Media
  - Diffusion of Excellence Gold Status Practice (medium.com; VAntage Point)
  - Ted-style Talk on VA gold status practice that inspired this initiative
  - NPR feature
- Questions about the initiative can be sent to VHARapidNaloxoneNaloxone@va.gov

FUTURE RESEARCH

- Effectiveness of a Rescue Medication in Preventing Opioid Overdose in Veterans (PI: Oliva; VA HSR&D Grant; Beginning this winter)
  - Aim 1: Characterize naloxone distribution within VA and patient-, prescriber-, and setting-related factors associated with distribution.
  - Aim 2: Assess whether naloxone distribution to at-risk Veterans compared to similar at-risk Veterans who did not receive naloxone is associated with reduced fatal and non-fatal opioid overdose.
- VHA Rapid Naloxone Initiative Partnered Evaluation: Improving Implementation to Save Lives and Transform Post-Overdose Care (PIs: Bounthavong & Oliva; submitted grant)
  - Aim 1: Identify barriers and facilitators of VHA Rapid Naloxone Initiative adoption to inform the development of an enhanced implementation strategy.
  - Aim 2: Test the effectiveness of the enhanced implementation strategy using a cluster randomized stepped wedge trial and identify effective elements of the enhanced implementation strategy.
  - Aim 3: Characterize opioid overdose across VHA reporting systems and ways to improve post-overdose care via interviews with VHA staff who have reported an opioid overdose, VHA patients who have experienced a non-fatal opioid overdose, and concerned others of VHA patients who have experienced a non-fatal opioid overdose.

U.S. Department of Veterans Affairs

THANK YOU!!!

Elizabeth.Oliva@va.gov

U.S. Department of Veterans Affairs

Addendum Slides

VA MONTHLY OEND CALL SAMPLE TOPICS

- Identifying high risk patients for OEND
- OEND Research
- Using Motivational Interviewing in OEND
- Strategies for managing patients after non-fatal overdose
- Innovative approaches to OEND expansion (VA Police, AED Cabinets)
- Models of OEND Implementation in Primary Care
- Getting OEND to Patients with OUD and Patients Prescribed Opioids: Strategies and Lessons Learned from VA's High Performing Facilities
- Letter-Based Approaches to OEND: Comparing and Contrasting Different Strategies
- VA Pharmacy Resident OEND Innovations—Increasing access to OEND, Improving Veterans' comfort with OEND, and Understanding why Veterans refuse naloxone
- VA National Naloxone Use Note and Emergency Department Model of OEND

VA National Naloxone Use Note

☑ THIS SECTION TO BE COMPLETED BY PATIENT'S TREATMENT PROVIDER, CLICK BOX TO CONTINUE

What risk factors are present that could increase the risk of overdose? (NOTE: VA has developed automated clinical decision support tools that can help identify some of these risk factors from VA administrative data, e.g., Stratification Tool for Opioid Risk Mitigation (STORM) and Opioid Therapy Risk Report (OTRR))

☑ Previous overdose Comment:

☐ Discuss circumstances surrounding current and previous overdoses to identify potential patterns and ways to mitigate risk and improve patient safety

☑ Periods of abstinence from opioids (e.g., detoxification, inpatient or residential treatment, incarceration)

☐ Discuss how periods of abstinence can decrease tolerance and increase risk for overdose as well as strategies to decrease risk

☑ Opioid tapering

☐ Discuss how opioid tapering can decrease tolerance and increase risk for overdose as well as strategies to decrease risk (e.g., slow taper, 5-20% reduction every 4 weeks; see Opioid Taper Decision Tool)

☑ Substance use disorder (SUD, including opioid use disorder and alcohol use disorder)

Plan: Consider SUD treatment, including medication and counseling for opioid use disorder and alcohol use disorder

☐ SUD being addressed in treatment plan

☐ Referral for SUD treatment

☐ Discussed with the patient and the patient declined SUD treatment/referral

☑ Mental health (e.g., PTSD, depression, anxiety, schizophrenia, bipolar disorder)

Comment: *

☐ Mental health being addressed in treatment plan

☐ Referral for mental health treatment

☐ Discussed with the patient and the patient declined mental health treatment/referral

VA National Naloxone Use Note

- [x] Use of sedatives (e.g., benzodiazepines) Comment:
  - [ ] Discuss risks associated with use of sedatives
  - [ ] Discuss alternative treatments
  - [ ] Discuss tapering/discontinuation
- [x] Use of non-prescribed opioids Comment:
  - [ ] Discuss risks associated with use of non-prescribed opioids and ways to mitigate risk and improve patient safety
- [x] Use of prescribed opioids
  - (•) Opioids prescribed only from the VA
    - [ ] Discuss how there is no safe dose of opioids and that risk increases with increased dose and other co-morbidities
    - [ ] Ask the patient to consider strategies to improve opioid safety, including alternative pain management approaches

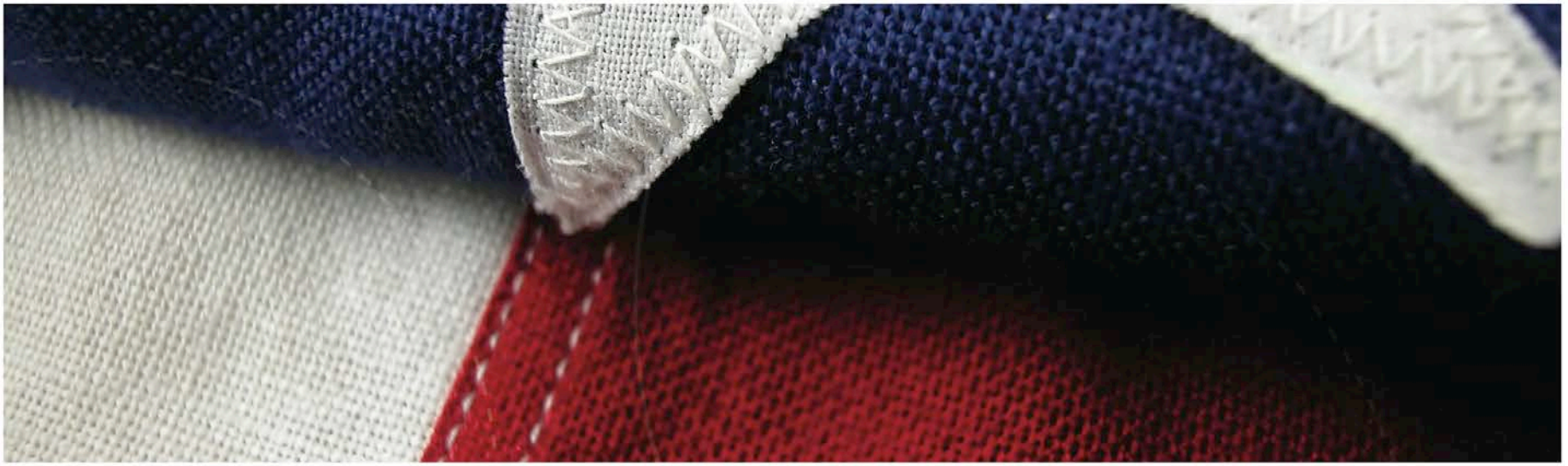
    Treatment Considerations (Check each treatment that will be recommended)
      - [ ] Consider non-opioid treatments for pain
      - [x] Change in opioid treatment plan
        - [ ] Slow taper (e.g., 5-20% reduction every 4 weeks; see Opioid Taper Decision Tool)
        - [ ] Other:
      - [ ] No change in opioid treatment plan

  - ( ) Opioids prescribed only from non-VA sources
    - [ ] Discuss how there is no safe dose of opioids and that risk increases with increased dose and other co-morbidities
    - [ ] Ask the patient to consider strategies to improve opioid safety, including alternative pain management approaches

    Treatment Considerations (Check each treatment that will be recommended)
      - [ ] Discuss overdose with outside provider and ways to improve patient safety
      - [ ] Consider non-opioid treatments for pain

CINCINNATI VA STUDIES (7% FEMALE)
(TIFFANY ET AL., 2015; WILDER ET AL., 2015)

- **90 Veterans receiving opioids for ≥ 3 months**
  - 52 Opioid Substitution Clinic (OSC); 38 Pain Management Clinic (PMC)
  - High risk→Average risk factors for opioid overdose—6 PMC, 8 OSC
- **Perception of risk**
  - ~70% believed their overdose risk was BELOW that of the average American adult
- **Opioid overdose experience**
  - **52%** of OSC and **21%** PMC Veterans had **experienced** an opioid overdose
  - **83%** of OSC and **50%** PMC Veterans had **witnessed** an opioid overdose
- **Knowledge about and interest in naloxone**
  - ~1/3 had heard of naloxone (46% OSC, 18% PMC); none had a kit
  - **After a brief explanation, 73% of OSC and 55% of PMC Veterans wanted a kit**
  - NOTE: Among patients NOT interested in naloxone kits—23% were using benzos and 23% were using additional opioids NOT prescribed by the VA (**other risk mitigation strategies are also needed**)



Saving Veterans Lives through Implementation of Opioid Overdose Education and Naloxone Distribution (OEND)

Elizabeth M. Oliva, PhD

VA National Opioid Overdose Education and Naloxone Distribution (OEND) Coordinator

VA Program Evaluation and Resource Center

Office of Mental Health Operations

Investigator

VA Center for Innovation to Implementation

VA Palo Alto Health Care System

July 1, 2015

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

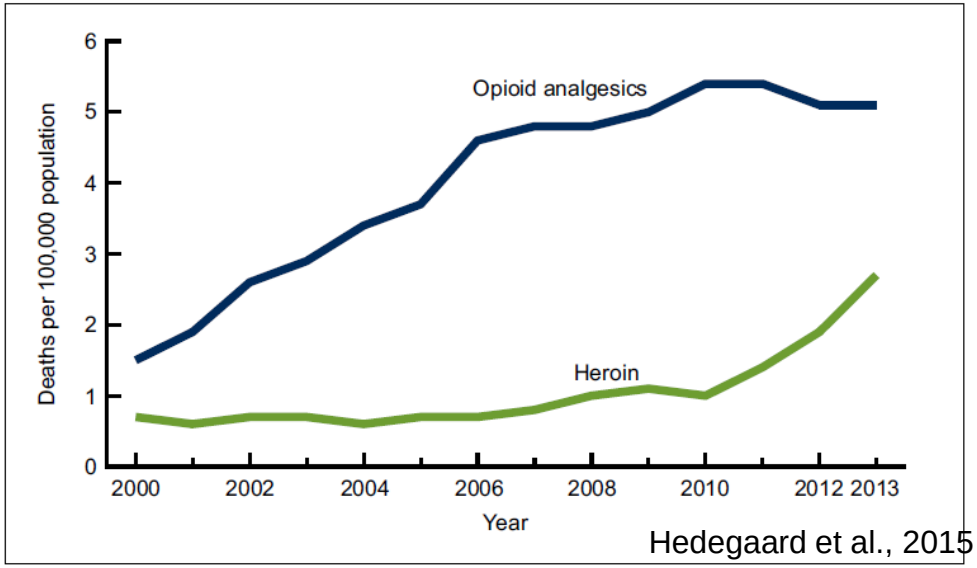
Report No. 14-00895-163

Healthcare Inspection - VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy

VA Need for OEND

- Opioid overdose epidemic
  - Veterans **twice** as likely to die from accidental overdose compared to non-Veterans (Bohnert et al., 2011)
- Successful VA pilots
  - In fall 2013 Cleveland VA was first to implement OEND; inspired VISN 10 to implement OEND in *every facility* in FY14 as part of a phased roll-out
  - Overwhelmingly positive response

Figure 1. Age-adjusted rates for drug-poisoning deaths, by type of drug: United States, 2000–2013



Hedegaard et al., 2015

OEND SAVES LIVES!

- **5400+ kits dispensed from 115 VA facilities with 79 reported opioid overdose reversals (as of 6/23/15)**

Medical News & Perspectives

JAMA February 12, 2014 Volume 311, Number 6

Back From the Brink

Groups Urge Wide Use of Opioid Antidote to Avert Overdoses

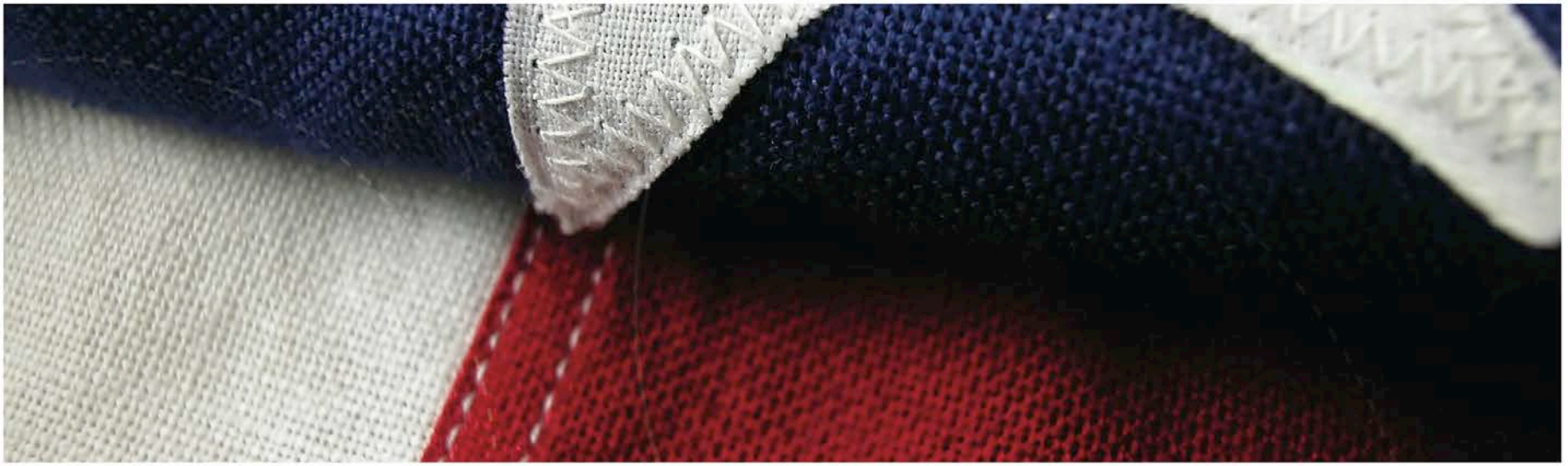
Bridget M. Kuehn, MSJ

Oliva, July 2015, *Exploring Naloxone Uptake and Use,* Interagency Scientific Workshop

VA OEND Implementation: Zeitgeist

- Holidays 2011—Concern surrounding OEF/OIF overdoses; Blue ribbon panel
- February 2012—CDC MMWR article (Wheeler et al.)
- April 2012—FDA, Office of the Assistant Secretary for Health, NIDA, and CDC public workshop: "Role of Naloxone in Opioid Overdose Fatality Prevention"
- January 2013—Mortality and cost-effectiveness (Walley et al.; Coffin & Sullivan)
- April 2013—Cleveland VA champions OEND
- May-July 2013—Other VAs interested; VA/DoD CPG for patients at risk for suicide
- August 2013—**Cleveland VA dispenses 1st VA naloxone kit**; SAMHSA toolkit release
- November 2013—PBM endorses request for National OEND program
- December 2013—Establish VA OEND National Support & Development Workgroup
- February 2014—VA Leadership support for OEND implementation
- March-May 2014—develop standard VA naloxone rescue kits; add to National Drug File; centralize distribution through CMOP; **dispense 1st VA national kit May 2014**

Oliva, July 2015, *Exploring Naloxone Uptake and Use,* Interagency Scientific Workshop



Moving Beyond MEDD and Opioids to Address the Opioid Crisis*

Elizabeth M. Oliva, PhD
VA National Opioid Overdose Education and Naloxone Distribution (OEND) Coordinator
VA Program Evaluation and Resource Center
VA Office of Mental Health and Suicide Prevention

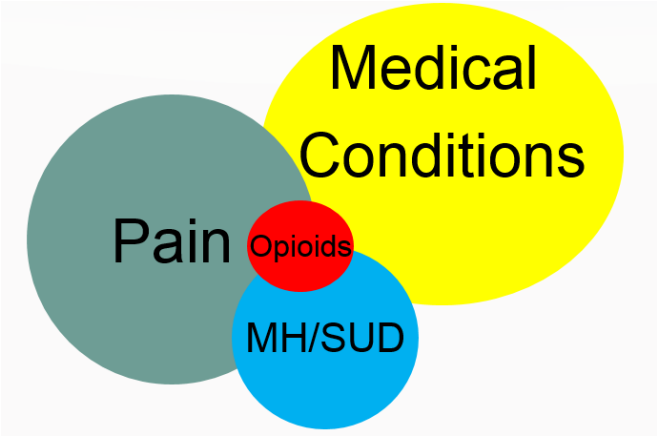
UCSF-Gladstone Center for AIDS Research (CFAR) Symposium on Opioids and HIV
May 11, 2018

*This is an abbreviated version of a 2018 National Rx Drug Abuse & Heroin Summit presentation (Kertesz, Manhapra, Oliva, & Sandbrink)

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Clinical Considerations in Addressing Overdose and Suicide Among Patients Prescribed Opioids

- Moving beyond Morphine Equivalent Daily Dose (MEDD) and opioids
  - Based on previous observational research, many assume that overdose is mostly an opioid dose-related event
  - Re-examining data from these studies suggests that:
    - Most patients who die are below commonly recommended MEDD thresholds
    - MH/SUD diagnoses and other comorbidities play just as critical a role, and in some cases an even more critical role than opioids, in overdose and/or suicide outcomes



Review of Risk Factors for Overdose and OUD

Risk factors are related to:

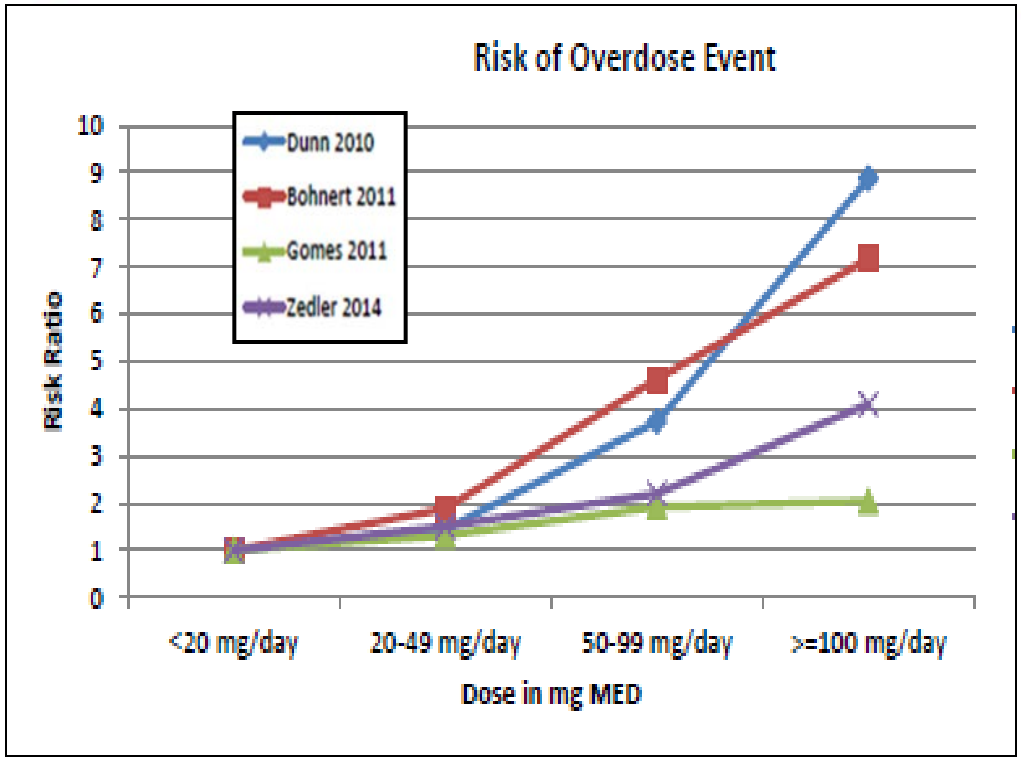
- Opioid prescribing
- Interaction with other medication/drugs
- Medical comorbidities
- Mental health comorbidities

"Opioid dosage was the factor most consistently analyzed and also associated with increased risk of overdose. Other risk factors include concurrent use of sedative hypnotics, use of extended-release/long-acting opioids, and the presence of substance use and other mental health disorder comorbidities."

Park et al., J Addict Med 2016

Review of 15 articles published between 2007 and 2015 that examined risk factors for fatal and nonfatal overdose in patients receiving opioid analgesics

Higher Dosage Associated with Increased Risks from Opioids



Hazard Ratios(HR):

Mortality (all causes):

HR 1.64 for LA opioids

Overdose deaths (unintentional)

HR 7.18-8.9 for MME > 100 mg/d

Opioid use disorder

on long-term opioids (> 90 d)

HR 15 for 1-36 mg/d MME

HR 29 for 36-120 mg/d MME

HR 122 for > 120 mg/d MME

Edlund et al., 2014

Most Opioid Overdoses In Patients with No or Lower Dose Opioids (Bohnert et al, JAMA 2011)

Table 2. Unadjusted Rate of Prescription Opioid Overdose Death by Opioid Dose and Fill Type

	Overdose Deaths, No.	Person-Months	Overdose Death Rate per 1000 Person-Months (95% CI)
Patients With Chronic Noncancer Pain Diagnoses			
Maximum prescribed daily opioid dose, mg/d			
0	243	2 729 022.7	0.09 (0.08-0.10)
1-<20	44	395 205.0	0.11 (0.08-0.15)
20-<50	108	458 296.2	0.24 (0.19-0.28)
50-<100	86	129 491.6	0.66 (0.53-0.82)
≥100	125	100 479.3	1.24 (1.04-1.48)
Patients With Acute Pain Diagnoses			
Maximum prescribed daily opioid dose, mg/d			
0	97	786 769.5	0.12 (0.10-0.15)
1-<20	17	81 006.8	0.21 (0.12-0.34)
20-<50	34	95 109.1	0.36 (0.25-0.50)
50-<100	33	29 080.7	1.13 (0.78-1.59)
≥100	41	22 537.9	1.82 (1.31-2.47)
Patients With Substance Use Disorder Diagnoses			
Maximum prescribed daily opioid dose, mg/d			
0	159	378 244.9	0.42 (0.36-0.49)
1-<20	24	44 630.0	0.54 (0.34-0.80)
20-<50	42	53 584.0	0.78 (0.56-1.06)
50-<100	27	17 019.2	1.59 (1.05-2.31)
≥100	44	14 809.2	2.97 (2.16-3.99)

79%

81%

85%

Most Overdose/Serious Opioid-Induced Respiratory Depression In Patients with No or Lower Dose Opioids

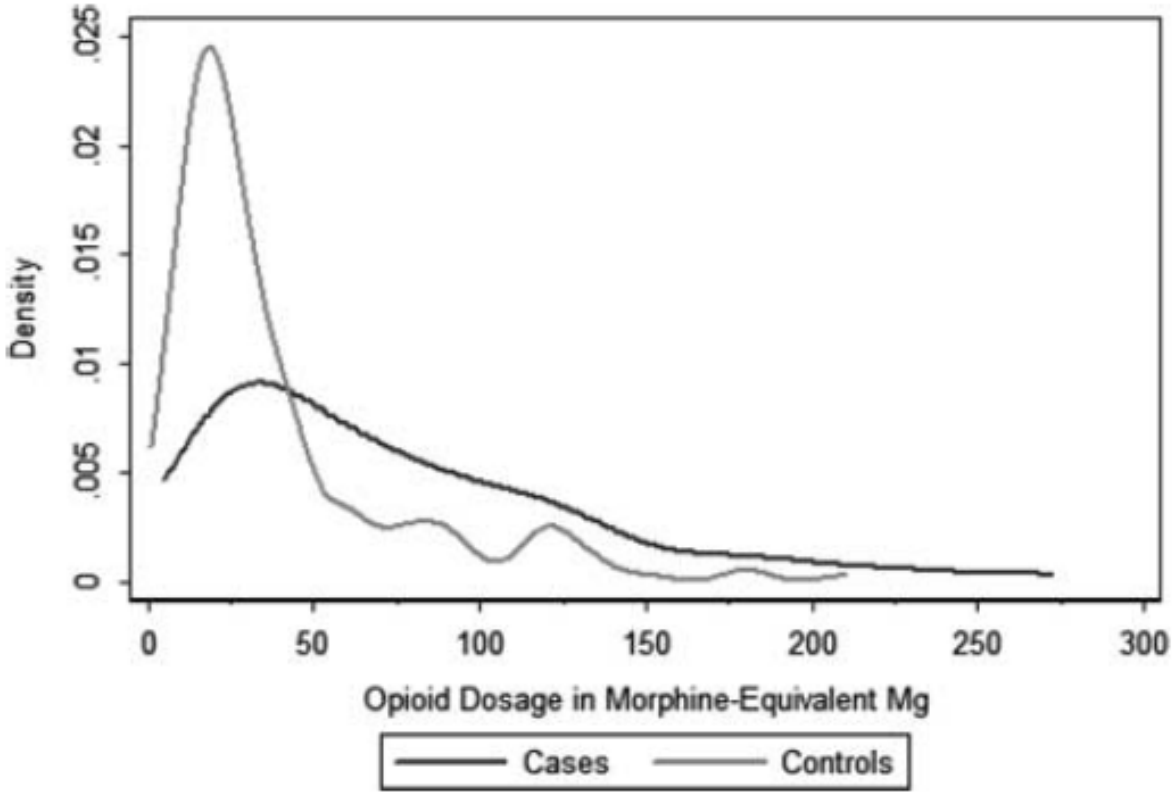
Table 1 *Continued*

Characteristics	Cases ($n = 817$) n (%)	Controls ($n = 8,170$) n (%)	P Value
MAXIMUM PRESCRIBED DAILY MED (mg), Mean (SD)	98.7 (122.1)	24.2 (48.4)	<0.001
Maximum Prescribed Daily MED Group			
1–<20	35 (4.3)	1,331 (16.3)	<0.001
20–<50	227 (27.8)	2,614 (32)	
50–<100	163 (20)	718 (8.8)	
≥100	268 (32.8)	273 (3.3)	
TOTAL	**693 (84.9%)**	**4,936 (60.4%)**	
Missing	**124 (15.1%)**	**3,234 (39.6%)**	

67%

Zedler et al., Pain Med 2015

No Clear Cut-Point to Distinguish Opioid Overdose Cases; Majority of Opioid Overdose Deaths Among Patients Below 100 MEDD



Average opioid dosages

Cases (overdose deaths):
98.1 MEDD (SD 112.7)

Controls:
47.7 MEDD (SD 65.2)

- Median dosage for patients with opioid overdose was 60 MEDD; i.e., vast majority below 100 MEDD

Bohnert et al., Med Care 2016

MH/SUD-related Factors Account for Similar OSORD Risk as Opioid-related Factors in VHA Sample

Table 3 Risk index for overdose or serious opioid-induced respiratory depression (RIOSORD)*

Question	Points for Yes Response
In the past 6 months, has the patient had a healthcare visit (outpatient, inpatient or ED) involving any of the following health conditions?†	
Opioid dependence?‡	15
Chronic hepatitis or cirrhosis?	9
Bipolar disorder or schizophrenia?	7
Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)?	5
Chronic kidney disease with clinically significant renal impairment?	5
An active traumatic injury, excluding burns (e.g., fracture, dislocation, contusion, laceration, wound)?	4
Sleep apnea?	3
Does the patient consume:	
An extended-release or long-acting (ER/LA) formulation of any prescription opioid?§ (*e.g., OxyContin, Oramorph-SR, methadone, fentanyl patch*)	9
Methadone? (*Methadone is a long-acting opioid so also check "**ER/LA formulation**" [9 points]*)	9
Oxycodone? (*If it has an ER/LA formulation [e.g., OxyContin] also check "**ER/LA formulation**" [9 points]*)	3
A prescription antidepressant? (*e.g., fluoxetine, citalopram, venlafaxine, amitriptyline*)	7
A prescription benzodiazepine? (*e.g., diazepam, alprazolam*)	4
Is the patient's current maximum prescribed opioid dose#:	
≥100 mg morphine equivalents per day?	16
50–<100 mg morphine equivalents per day?	9
20–<50 mg morphine equivalents per day?	5
In the past 6 months, has the patient:	
Had one or more emergency department (ED) visits?	11
Been hospitalized for one or more days?	8
Total point score (maximum 115)	

- MH/SUD-related factors 29% of index
- Model ORs:
  Opioid dep=4.5
  Bipolar/SZ=1.9
  Benzo=1.5
  Antidep=2.0

- Opioid-related factors 32% of index
- Model ORs:
  ER/LA=2.5
  Methadone=2.4
  ≥100 MEDD=5.0

Zedler et al., Pain Med 2015

MH/SUD-related Factors Account for Similar OSORD Risk as Opioid-related Factors in US Commercial Health Plan Sample

Table 3 CIP-based risk index for serious opioid-induced respiratory depression (RIOSORD)

Question*	Points for "yes" response
In the past 6 months, has the patient had a health care visit (outpatient, inpatient, or ED) involving any of the following health conditions?†	
• Substance use disorder (abuse or dependence)? (This includes alcohol, amphetamines, antidepressants, cannabis, cocaine, hallucinogens, opioids, and sedatives/anxiolytics)	25
• Bipolar disorder or schizophrenia?	10
• Stroke or other cerebrovascular disease?	9
• Kidney disease with clinically significant renal impairment?	8
• Heart failure?	7
• Nonmalignant pancreatic disease (e.g., acute or chronic pancreatitis)?	7
• Chronic pulmonary disease (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis)?	5
• Recurrent headache (e.g., migraine)?	5
Does the patient consume:	
• Fentanyl?	13
• Morphine?	11
• Methadone?	10
• Hydromorphone?	7
• An extended-release or long-acting formulation of any prescription opioid?‡	5
• A prescription benzodiazepine?	9
• A prescription antidepressant?	8
Is the patient's current maximum prescribed opioid dose ≥100 mg morphine equivalents per day? (Include all prescription opioids consumed on a regular basis)	7
Total point score (maximum = 146)	

- MH/SUD-related factors 36% of index
- Model ORs:
  SUD=12.7
  Bipolar/SZ=2.8
  Benzo=2.3
  Antidep=2.2

- Opioid-related factors 36% of index
- Model ORs:
  Fentanyl=3.7
  Methadone=2.8
  ER/LA=1.7
  ≥100 MED=2.0

Zedler et al., Pain Med 2018

MH and SUD Diagnoses Were Largest Predictors of Opioid Overdose in Kaiser Predictive Model

Table 3 Unadjusted and Adjusted (final) Cox Regression Models for Predicting 2-Year Overdose Risk for Patients Prescribed Chronic Opioid Therapy at the Derivation Site

Characteristic	Unadjusted model	Adjusted model*	
	Hazard ratio (95 CI†)	β coefficient	Hazard ratio (95 CI†)
Age (per year)	0.93 (0.88–0.98) ‡	−0.06915	0.93 (0.89–0.98)
Age-squared	1.00 (1.00–1.00) ‡	0.0005626	1.00 (1.00–1.00)
Mental health diagnosis§	4.18 (2.88–6.07)	1.22076	3.39 (2.32–4.96)
Psychotropic prescription	2.82 (1.88–4.25)		
Substance abuse/dependence diagnosis‖	6.01 (4.03–8.96)	1.24387	3.47 (2.25–5.36)
Tobacco use or tobacco abuse/dependence diagnosis¶	2.31 (1.60–3.32)	0.42788	1.53 (1.03–2.28)
History of opioid prescriptions in the year prior to initiating chronic opioid therapy	1.43 (1.00–2.05)		
Long-acting or extended-release opioid formulation	2.47 (1.25–4.87)	0.68552	1.99 (1.00–3.93)
Daily opioid dose (per 10 mg morphine equivalents)**	1.01 (0.99–1.03)		
Hepatitis C diagnosis††	2.82 (1.04–7.63)		

Glanz et al., JGIM 2018

MH and SUD Diagnoses Account for More Opioid Overdose Risk than Opioids

Table 5 Point-Based System* to Calculate 2-Year Risk of Opioid Overdose Based on Model Coefficients

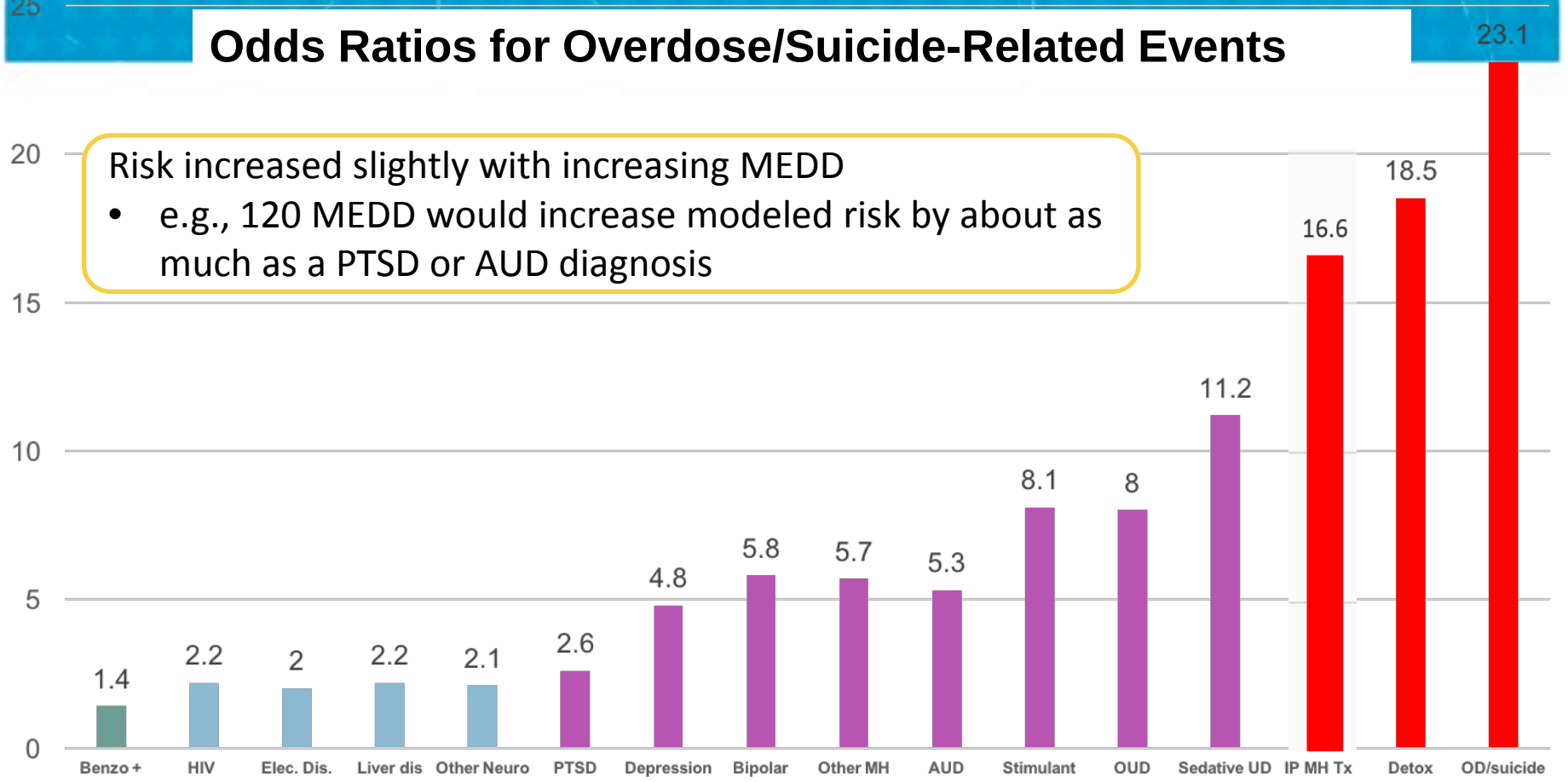
Characteristic	Number of points
Age (years)	
18–25	98
26–30	94
31–35	91
36–40	88
41–45	85
46–50	84
51–55	83
56–60	82
61–65	83
66–70	84
71–75	84
76–80	86
81–85	87
86–90	89
91–95	92
96–100	96
Mental health diagnosis	22
Substance abuse/dependence diagnosis	22
Tobacco use or tobacco abuse/dependence diagnosis	8
Long-acting or extended-release opioid formulation	12

Scores of summed points, based on patient characteristics, indicate low (≤ 85), medium (86–103) or high risk (≥104)

- MH/SUD diagnoses 27% of max points; 69% of non-age related points
- Opioid-related factor 7% of max points; 19% of non-age related points

Glanz et al., JGIM 2018

MH/SUD and Non-Opioid Related Factors Have Higher Odds Ratios than Opioid-Related Factors in VHA Predictive Model

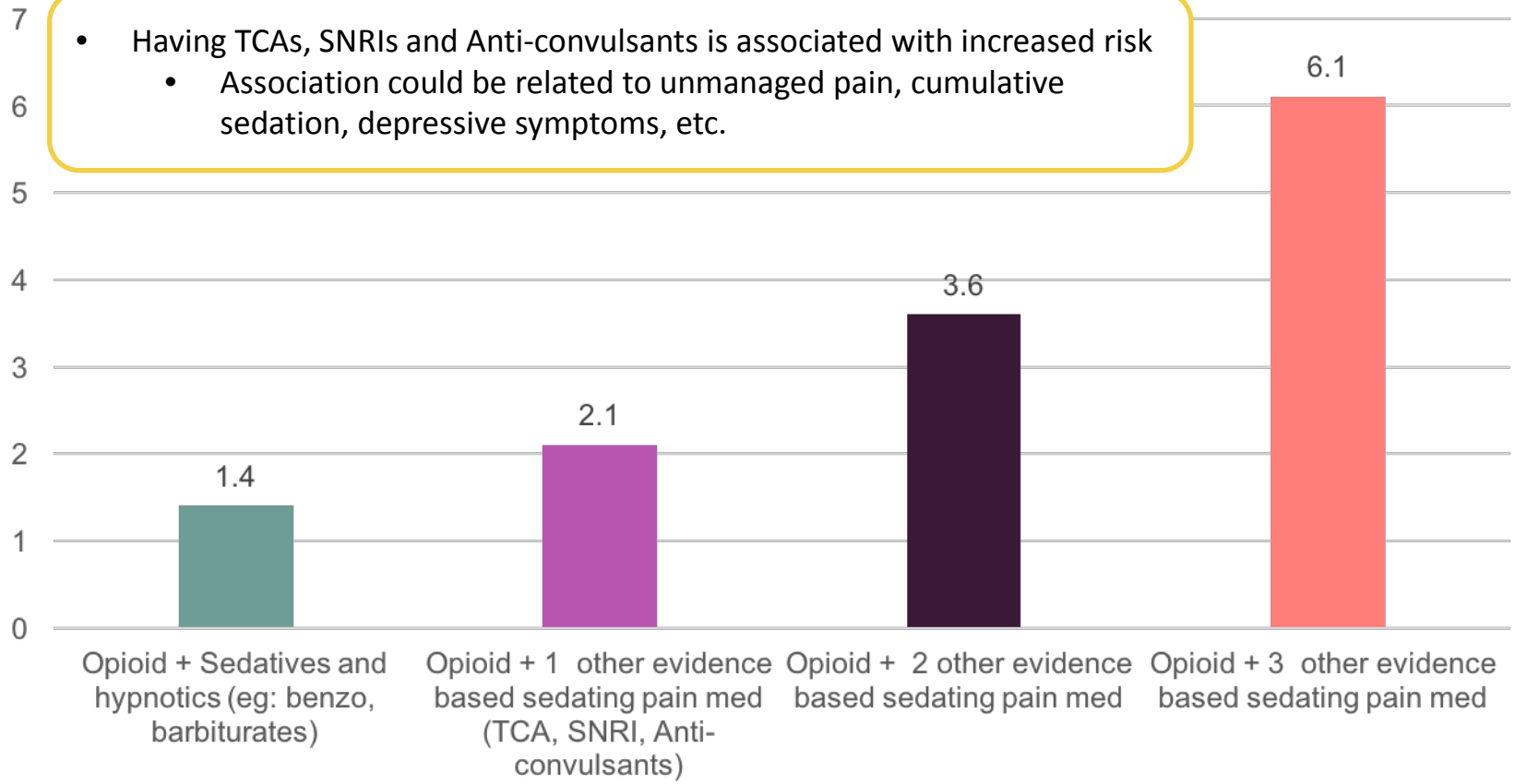


Oliva et al., Psychol Serv 2017

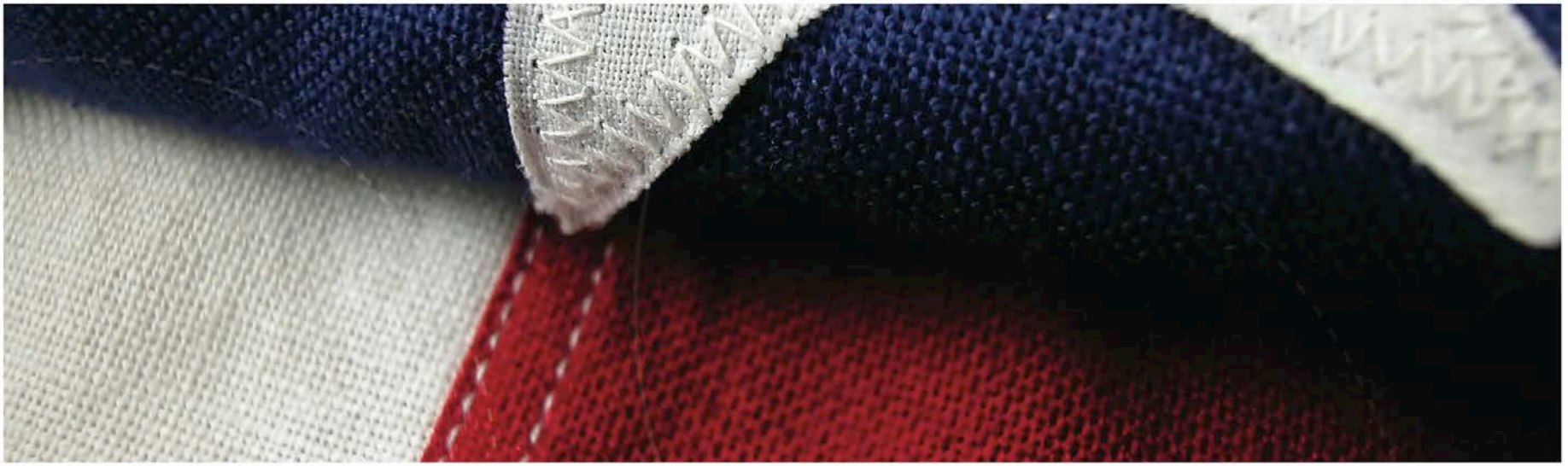
High Odds Ratios for Other Evidence-Based Sedating Pain Medications

Odds Ratios for Overdose/Suicide-Related Events

- Having TCAs, SNRIs and Anti-convulsants is associated with increased risk
  - Association could be related to unmanaged pain, cumulative sedation, depressive symptoms, etc.



Oliva et al., Psychol Serv 2017



Healthcare System-Based Implementation of Opioid Overdose Education and Naloxone Distribution (OEND) in the Veterans Health Administration: Strategies and Lessons Learned from the First Nationwide Program in the United States

Elizabeth M. Oliva, PhD[1] and Julianne Himstreet, PharmD, BCPS[2]

[1]VA National OEND Coordinator, VA Program Evaluation and Resource Center, VA Office of Mental Health Operations

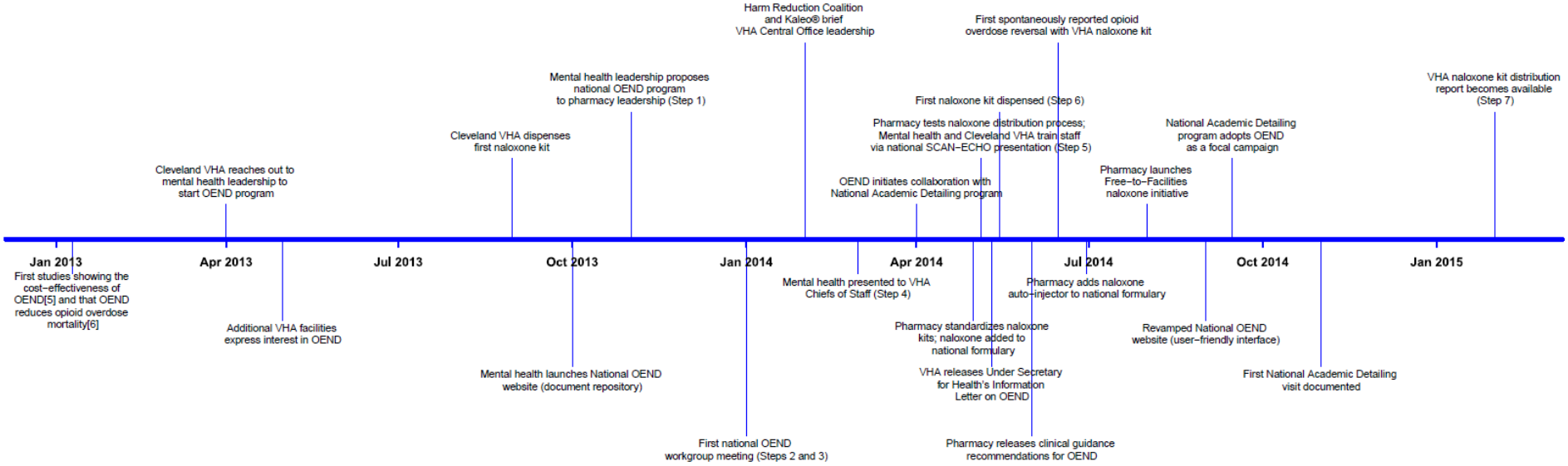
[2]National Program Manager, VA Academic Detailing Services, VA Pharmacy Benefits Management Services

National Rx Drug Abuse & Heroin Summit

April 19, 2017

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

VA OEND Implementation Timeline



E.M. Oliva et al. / Journal of the American Pharmacists Association 57 (2017) S168–S179

- April 2013—VA facility interest in OEND
- August 2013—Cleveland VA implements first OEND program
- January 2014—VA National OEND workgroup's first meeting
- May 2014—VA national program launched, first kit dispensed
- November 2015—OEND implemented in every VA facility
- As of March 16, 2017—68,141 naloxone prescriptions dispensed
  - 172 spontaneously reported opioid overdose reversals with VA naloxone (2/2/16)

Reversal of overdose on fentanyl being illicitly sold as heroin with naloxone nasal spray: A case report (Fareed et al., 2015)

- Atlanta VA—One of the early adopters of OEND
- Describes reversal of fentanyl overdose with naloxone nasal spray
  - Patient was unaware that fentanyl was being sold as heroin
  - Required 2 doses
- Implemented OEND in Evaluation, Stabilization and Placement (ESP) substance abuse outpatient assessment clinic
  - Provided educational sessions for 63 Veterans and their families
  - Prescribed 41 naloxone kits
  - 3 reports of opioid overdose reversals
- Strongly advocate for dissemination of OEND
  - Easily implemented and low cost

Cincinnati VA studies
(Tiffany et al., 2015; Wilder et al., 2015)

- 90 Veterans receiving opioids for ≥ 3 months
  - 52 Opioid Substitution Clinic (OSC); 38 Pain Management Clinic (PMC)
  - High risk→Average risk factors for opioid overdose—6 PMC, 8 OSC
- Perception of risk
  - ~70% believed their overdose risk was BELOW that of the average American adult
- Opioid overdose experience
  - **52%** of OSC and **21%** PMC Veterans had **experienced** an opioid overdose
  - **83%** of OSC and **50%** PMC Veterans had **witnessed** an opioid overdose
- Knowledge about and interest in naloxone
  - ~1/3 had heard of naloxone (46% OSC, 18% PMC); none had a kit
  - **After a brief explanation, 73% of OSC and 55% of PMC Veterans wanted a kit**
  - NOTE: Among patients NOT interested in naloxone kits—23% were using benzos and 23% were using additional opioids NOT prescribed by the VA (**other risk mitigation strategies are also needed**)

Patient perspectives on VA OEND (Oliva et al., 2016)

Method

- 4 focus groups conducted with 21 patients in VA residential tx
  - 6 month program for Homeless Veterans, 3 month substance use disorder tx program

Results

- Benefits
  - Training is interesting, novel, and empowering; **Kits will save lives**
- Concerns
  - Legal and liability issues; Challenges of involving family in training; Kits may contribute to relapse (among non-opioid users NOT opioid users; opioid users—kits not a relapse trigger)
    - **"Whether it increases, decreases or triggers someone to go out and use it, at least we have a means to save a life"**
- Suggestions for improvement
  - **Increasing OEND awareness and access to OEND**
  - Active learning (hands-on practice)

Legal Regimes: Naloxone Access

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Outline

- Legal Concerns
  - Prescriber
  - Patient/Bystander/Lay administrator
- Aims of Legislation
  - Naloxone Access Laws
  - Good Samaritan Laws
- Statewide Legislation
  - Comparison
  - Nuances
  - Summary
- Impact of Legislation

Legal Concerns[1]

Prescriber

- Criminal prosecution
  - "Aiding and abetting" unauthorized practice of medicine*
  - Absent practitioner-patient relationship*
- Civil prosecution
  - Damages from prescribing/dispensing
  - Injury/death/loss from act or omission

Patient/Bystander/Lay Administrator

- Criminal prosecution
  - Unlawful possession of a legend drug
  - Controlled substance/paraphernalia possession
  - Violation of probation/parole/restraining order
- Civil prosecution
  - Injury/death/loss from act or omission

*Cause for professional sanctions by licensing board

Aims of Legislation: Naloxone Access Laws[1-3]

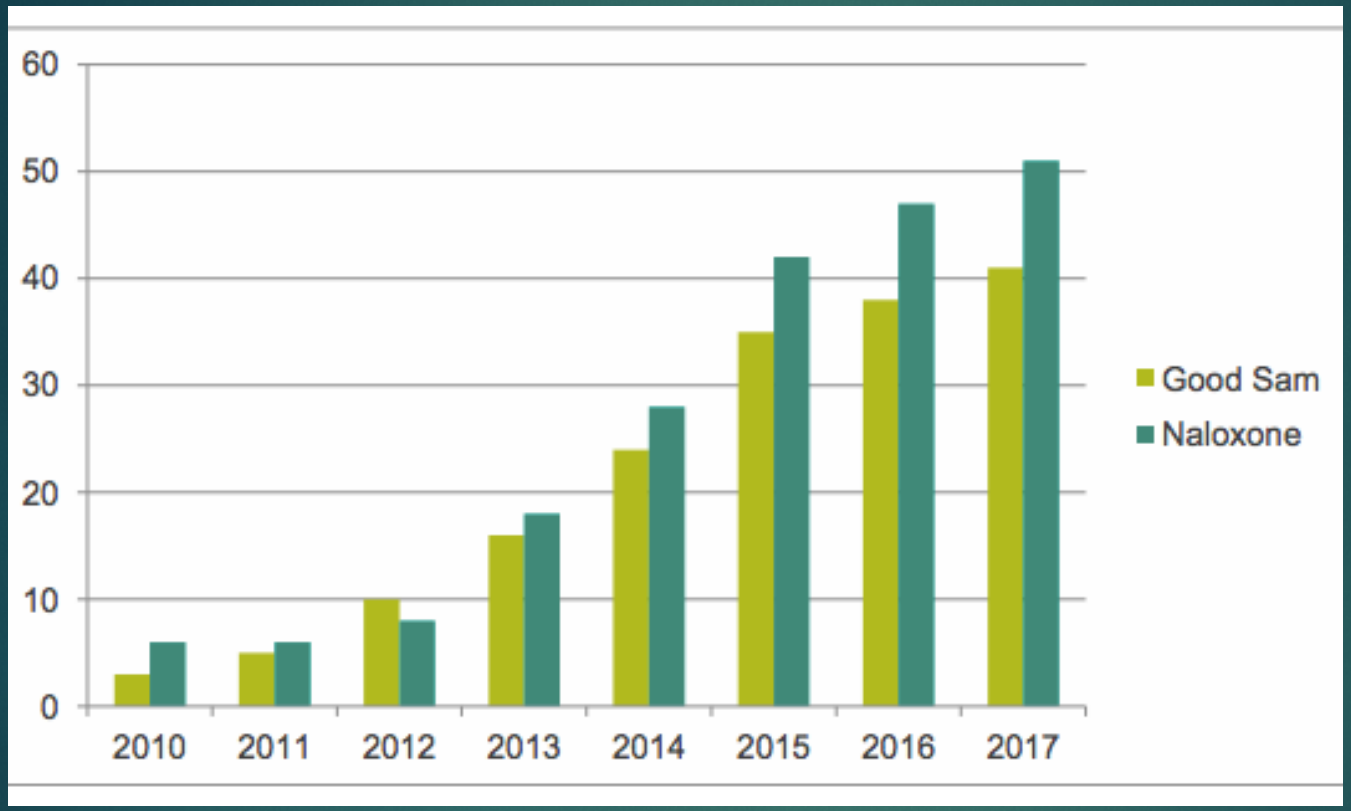
- Expand Access
  - Third-party prescribing
  - Distribution
    - Standing order
    - Protocol order
    - Collaborative practice agreement
    - Direct authorization by legislature
  - Pharmacist prescriptive authority
- Promote Education/Training
- Provide Legal Immunity
  - Prescriber
  - Dispenser
  - Patient/Lay administrator

Aims of Legislation: Good Samaritan Laws[1,2]

- Promote Use of Emergency Services
- Provide Legal Immunity
  - Possession of controlled substance
  - Possession of drug paraphernalia
  - Other violations[a]
  - Other protections[b]

[a] Violation of protective/restraining order; pretrial, probation, or parole conditions; other controlled-substance crimes
[b] Reporting mitigating factor; civil forfeiture

Statewide Legislation[2]



Adoption of legislation by states over time

Comparison of Legislation[4-14]

	NAL	CRIM (PRESC)	CIV (PRESC)	THIRD PARTY	DISTR	CRIM/CIV (ADMIN)
ALABAMA	X[a]	X	X	X	X	X
ALASKA	X		X	X	X	CIV ONLY
ARIZONA	X[a,b]	X		X	X	
ARKANSAS	X[a]	X	X	X	X	X
CALIFORNIA	X	X	X	X	X	X
COLORADO	X[a]	X	X	X	X	X
CONNECTICUT	X[c]	X	X	X	X	X
DELAWARE	X[a,b]	X	X	X	X	
DIST OF COLUMBIA	X[c]	X	X	X	X	X

[a] Includes pharmacist protections
[b] Includes professional/disciplinary immunity
[c] Includes pharmacist prescriptive authority

NAL=naloxone access law; CRIM (PRESC)=criminal immunity for prescriber; CIV (PRESC)=civil immunity for prescriber; DISTR=naloxone distribution; CRIM/CIV (ADMIN)=criminal/civil immunity for administrator

Comparison of Legislation[15-25]

	NAL	CRIM (PRESC)	CIV (PRESC)	THIRD PARTY	DISTR	CRIM/CIV (ADMIN)
FLORIDA	X[a,b]	X	X	X	X	CIV ONLY
GEORGIA	X[a,b]	X	X	X	X	X
HAWAII	X[b,c]	X	X	X	X	X
IDAHO	X[c]	X	X	X		X
ILLINOIS	X[a,b]	X		X	X	X
INDIANA	X[a]		X	X	X	CRIM ONLY
IOWA	X		X	X	X	CIV ONLY
KANSAS	X[a]	X	X	X	X	X
KENTUCKY	X[a,b]			X	X	X

[a] Includes pharmacist protections
[b] Includes professional/disciplinary immunity
[c] Includes pharmacist prescriptive authority

NAL=naloxone access law; CRIM (PRESC)=criminal immunity for prescriber; CIV (PRESC)=civil immunity for prescriber; DISTR=naloxone distribution; CRIM/CIV (ADMIN)=criminal/civil immunity for administrator

Comparison of Legislation[26-34]

	NAL	CRIM (PRESC)	CIV (PRESC)	THIRD PARTY	DISTR	CRIM/CIV (ADMIN)
LOUISIANA	X[a,b]	X	X	X	X	X
MAINE	X[a,b,c]	X	X	X	X	X
MARYLAND	X[b]		X	X	X	CIV ONLY
MASSACHUSETTS	X[a,b]	X	X	X	X	X
MICHIGAN	X[a]		X	X	X	X
MINNESOTA	X	X	X		X	X
MISSISSIPPI	X[b]	X	X	X	X	X
MISSOURI	X[a]	X	X	X	X	X
MONTANA	X[b]	X	X	X	X	X

[a] Includes pharmacist protections
[b] Includes professional/disciplinary immunity
[c] Includes pharmacist prescriptive authority

NAL=naloxone access law; CRIM (PRESC)=criminal immunity for prescriber; CIV (PRESC)=civil immunity for prescriber; DISTR=naloxone distribution; CRIM/CIV (ADMIN)=criminal/civil immunity for administrator

Comparison of Legislation[35-44]

	NAL	CRIM (PRESC)	CIV (PRESC)	THIRD PARTY	DISTR	CRIM/CIV (ADMIN)
NEBRASKA	X	X		X		CRIM ONLY
NEVADA	X[a,b]	X	X	X	X	X
NEW HAMPSHIRE	X[b]	X	X	X	X	X
NEW JERSEY	X[a,b]	X	X	X	X	X
NEW MEXICO	X[a,b]			X	X	X
NEW YORK	X			X	X	X
NORTH CAROLINA	X[a]	X	X	X	X	X
NORTH DAKOTA	X[a,b]	X	X	X	X	X
OHIO	X[a,b]	X	X	X	X	X

[a] Includes pharmacist protections
[b] Includes professional/disciplinary immunity
[c] Includes pharmacist prescriptive authority

NAL=naloxone access law; CRIM (PRESC)=criminal immunity for prescriber; CIV (PRESC)=civil immunity for prescriber; DISTR=naloxone distribution; CRIM/CIV (ADMIN)=criminal/civil immunity for administrator

Comparison of Legislation[45-56]

	NAL	CRIM (PRESC)	CIV (PRESC)	THIRD PARTY	DISTR	CRIM/CIV (ADMIN)
OKLAHOMA	X[c]		*	X	X	*
OREGON	X[c]		X	X		CIV ONLY
PENNSYLVANIA	X[a,b]	X	X	X	X	X
RHODE ISLAND	X			X	X	X
SOUTH CAROLINA	X[a,b]	X	X	X	X	X
SOUTH DAKOTA	X	X	X	X	X	
TENNESSEE	X[a]		X	X	X	CIV ONLY
TEXAS	X[a,b]	X	X	X	X	X
UTAH	X[a]	*	X	X	X	CIV ONLY

[a] Includes pharmacist protections
[b] Includes professional/disciplinary immunity
[c] Includes pharmacist prescriptive authority

NAL=naloxone access law; CRIM (PRESC)=criminal immunity for prescriber; CIV (PRESC)=civil immunity for prescriber; DISTR=naloxone distribution; CRIM/CIV (ADMIN)=criminal/civil immunity for administrator

Comparison of Legislation[57-63]

	NAL	CRIM (PRESC)	CIV (PRESC)	THIRD PARTY	DISTR	CRIM/CIV (ADMIN)
VERMONT	X[a]	X	X	X	X	X
VIRGINIA	X		X	X	X	CIV ONLY
WASHINGTON	X[a,b]	X	X	X	X	X
WEST VIRGINIA	X[a]	X	X	X	X	X
WISCONSIN	X[a,b]	X	X	X	X	X
WYOMING	X[a,b,c]	X	X	X	X	X

[a] Includes pharmacist protections
[b] Includes professional/disciplinary immunity
[c] Includes pharmacist prescriptive authority

NAL=naloxone access law; CRIM (PRESC)=criminal immunity for prescriber; CIV (PRESC)=civil immunity for prescriber; DISTR=naloxone distribution; CRIM/CIV (ADMIN)=criminal/civil immunity for administrator

Nuances of Legislation

- Civil/Criminal Protections
  - Conditions for immunity
    - Education/training program participation
    - Acting with reasonable care
- Third Party Prescribing
  - Definition (family, caregiver, “any” person)
  - Education/training program participation
- Distribution
  - Standing order/protocol/collaborative practice agreement
  - Developed by physician/public health department/board of pharmacy/board of medicine
  - Distributed by/to first responders, community-based overdose prevention programs, opioid treatment facilities, correctional facilities, school districts, laypersons
  - Training requirements for patient/distributor

Nuances of Legislation[19,64-68]

- California
  - Grant program for at-risk populations
    - Overdose education and naloxone provision
- Connecticut
  - Prior authorization not required
- Hawaii
  - Covered drug under Medicaid
- Illinois
  - Covered drug by insurance and state medication assistance program
  - Grants and drug overdose prevention program

Nuances of Legislation[69-73]

- Indiana
  - Requires syringe exchange programs to provide overdose response/naloxone education
- Maryland
  - Establishment of guidelines for co-prescribing
- Massachusetts
  - Municipal Naloxone Bulk Purchase Trust Fund
  - Pharmacies in high risk areas to maintain stock
- Minnesota
  - Naloxone education by state-operated opioid treatment programs

Nuances of Legislation[38,40,41,74]

- Nevada
  - Grants per Department of Health and Human Services
  - Opioid informed consent to include naloxone
- New Jersey
  - Grants per Commissioner of Human Services
- New York
  - Pharmacy with ≥20 locations to have dispensing protocol or register as opioid overdose prevention program
  - Detailed requirements for operation of opioid overdose prevention programs

Nuances of Legislation[51,75-78]

- North Carolina
  - Syringe exchange programs shall provide access to naloxone
- Oklahoma
  - Naloxone dispensed/sold by pharmacist without prescription or protocol
- Oregon
  - Prescription monitoring program for dispensed naloxone
- Rhode Island
  - Collection of electronic dispensing data for naloxone
  - Establishment of best practices for co-prescribing
  - Covered drug by insurance

Nuances of Legislation[56,57,79]

- Utah
  - Opiate Overdose Outreach Pilot Program Grants
  - Establishment of co-prescribing guidelines by physician licensing boards
- Vermont
  - Statewide opioid antagonist pilot program
- West Virginia
  - Community Overdose Response Demonstration Pilot Project
  - Data collection for naloxone prescription/dispensing/administration

Summary of Legislation[2,4-79]

Naloxone Access Law[a]

- 51 states
- Criminal Protections (Prescriber)
  - 37 states
- Civil Protections (Prescriber)
  - 43 states
- Third Party Prescribing
  - 50 states
- Distribution
  - 48 states
- Criminal/Civil Protections (Layperson)
  - 47 states
- Pharmacist Prescriptive Authority
  - 8 states
- "Any" Person To Possess
  - 7 states

Good Samaritan Law[b]

- 41 states

[a]As of November 2018
[b]As of July 2017

Impact of Legislation

Naloxone dispensing

Opioid Overdose Education and Naloxone Distribution (OEND) program implementation

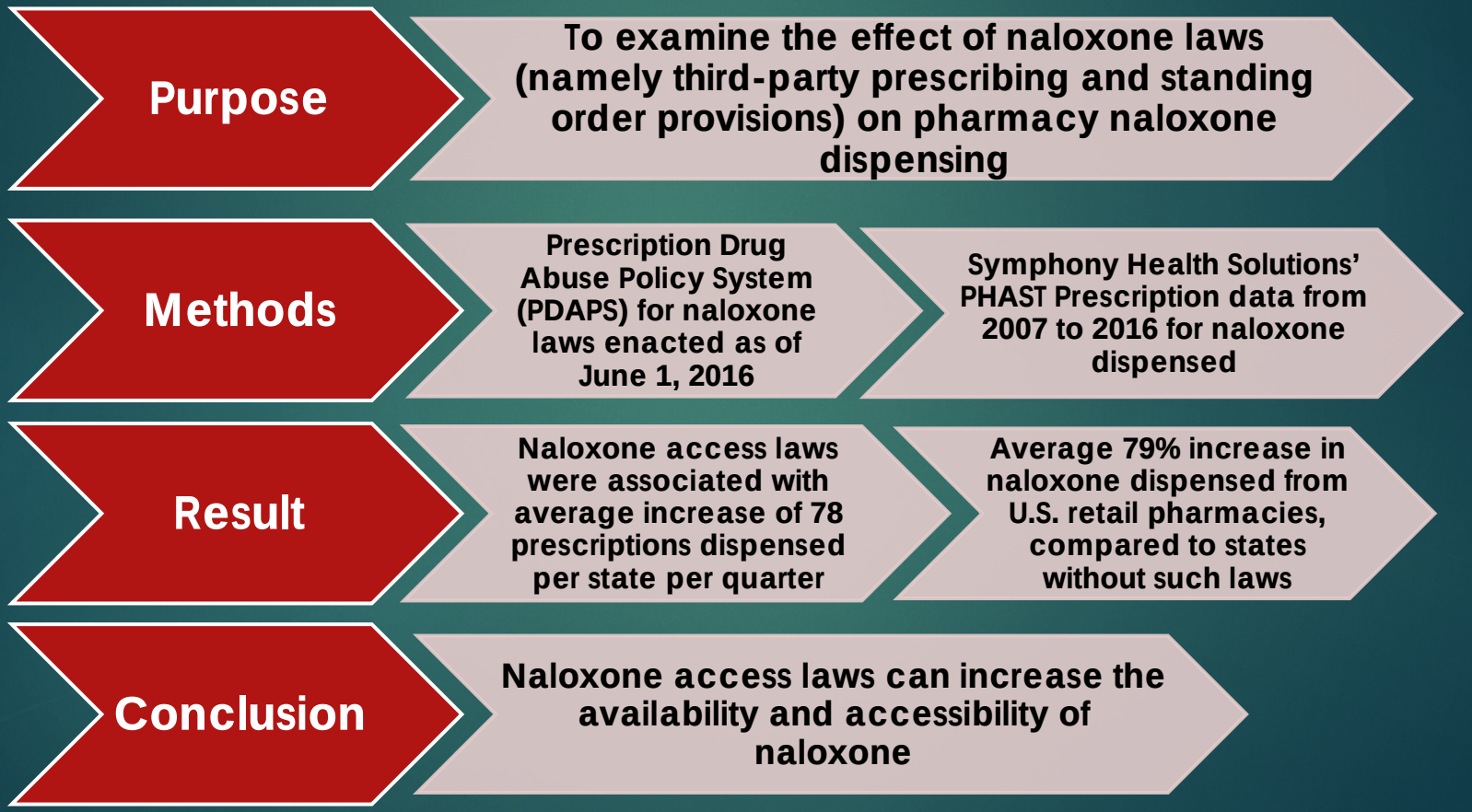
Layperson emergency response

Opioid misuse

Opioid-related mortality

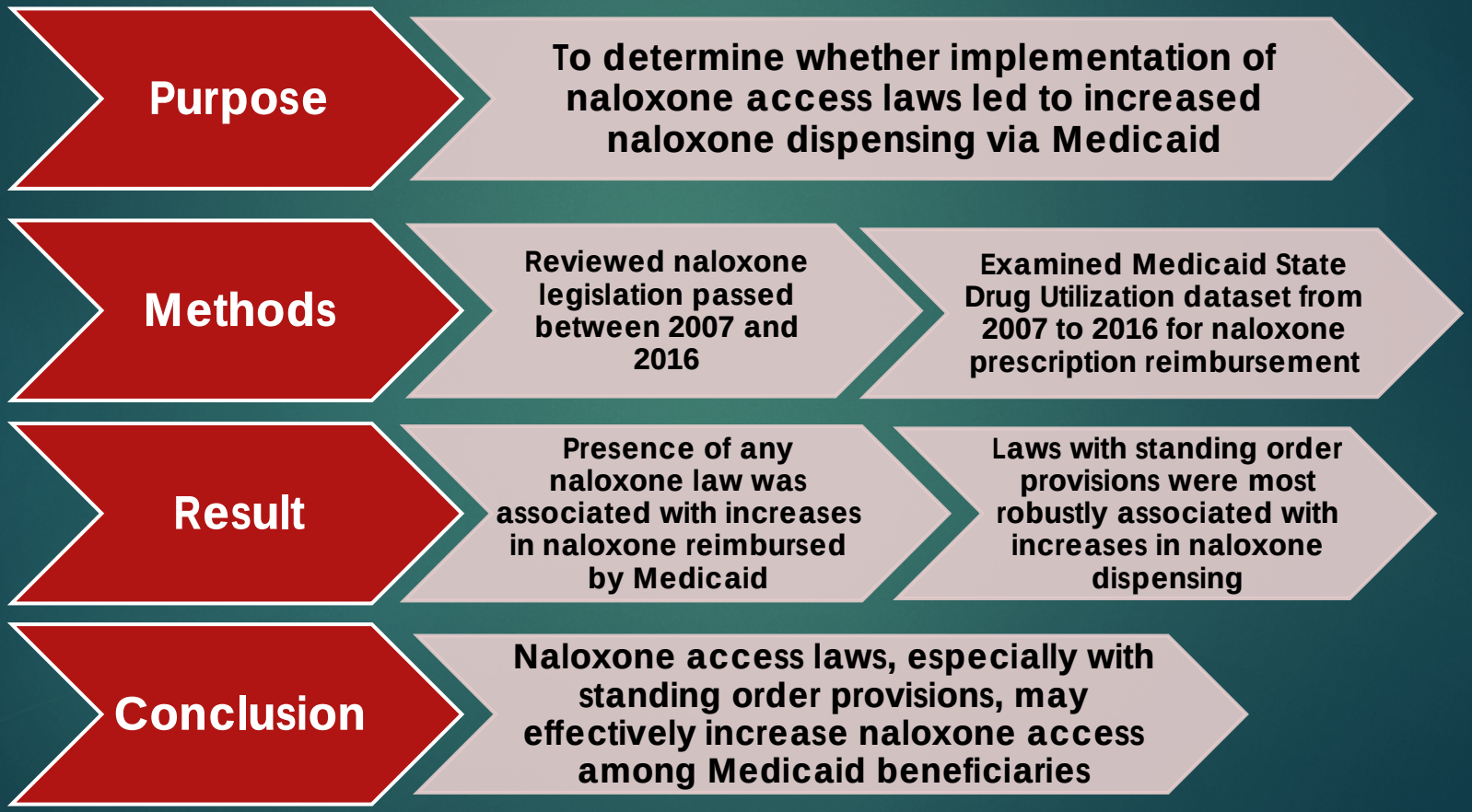
Impact of Legislation[80]

Xu J, et al.



Impact of Legislation[81]

Gertner AK, et al.



Impact of Legislation[82]

Lambdin BH, et al.

Purpose

To assess whether state-level naloxone laws and provisions stimulated the implementation of OEND programs

Methods

Reviewed Westlaw legal database, Prescription Drug Abuse Policy System, Harm Reduction Coalition OEND database, National Center of Health Statistics, and United States Census from 2000 to 2014

Result

By end of 2014, 259 (8%) counties had OEND programs

Counties within states that had a naloxone law had 28-fold increased odds of OEND program implementation

Conclusion

Naloxone laws facilitated OEND implementation, but future studies should investigate strategies to improve OEND implementation

Impact of Legislation[83]

Watson DP, et al.

Purpose

To examine attitudes and knowledge among lay responders who received naloxone kits from 20 local health departments across Indiana

Methods

Postcard surveys distributed inside naloxone kits in 20 Indiana counties

Collected demographic information, overdose experiences, use of 911, knowledge of Good Samaritan laws

Result

77.4% of 217 respondents indicated knowledge of Indiana's Good Samaritan protections

Those with knowledge of protections were more likely to have called 911 (84.7 vs. 15.3%; $p = .048$)

Conclusion

Strengthening Good Samaritan laws, educating lay persons about protections, and improving police interactions at an overdose scene are likely to improve outcomes of naloxone distribution

Impact of Legislation[84]

McClellan C, et al.

Purpose

To assess the relationship of naloxone access and Good Samaritan laws with opioid overdose mortality and non-medical opioid use

Methods

Reviewed National Vital Statistics System data, National Survey on Drug Use and Health data, and primary datasets of naloxone access and Good Samaritan laws

Result

Data from 2000-2014, indicate states with naloxone access or Good Samaritan laws had a 14% (p=-.033) and 15% (p=0.050) lower incidence of opioid overdose mortality, respectively

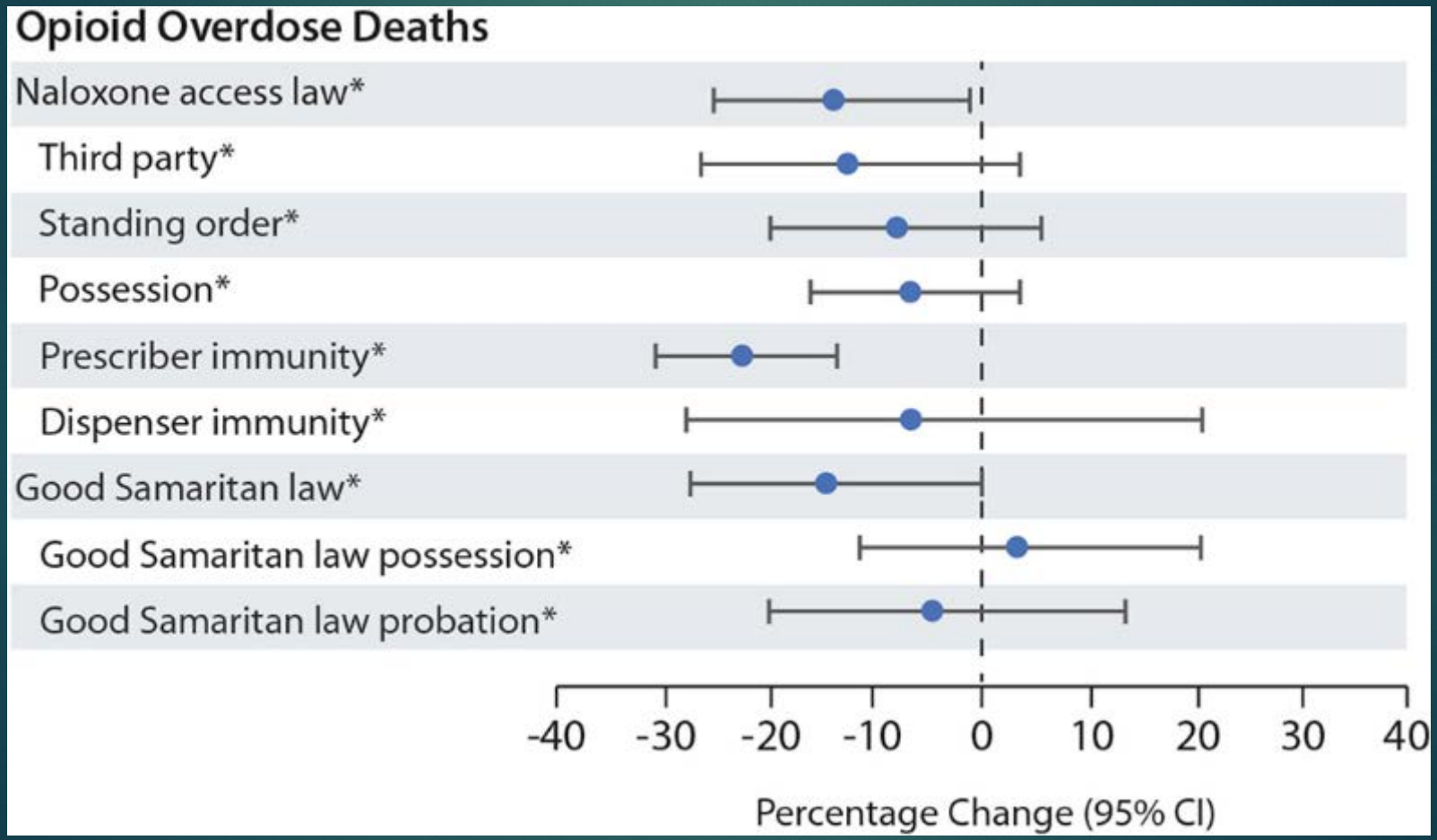
Conclusion

Laws were associated with reduced opioid overdose mortality, without increases in non-medical opioid use

Universal adoption of naloxone access and Good Samaritan laws could save an additional 981 and 1,896 lives, respectively

Impact of Legislation[84]

McClellan C, et al.



Impact of Legislation[85]

Erfanian E, et al.

Purpose	To investigate the effect of naloxone access laws on opioid overdose death rates
Methods	Reviewed mortality data from CDC Wonder and legislative data from Prescription Drug Abuse Policy System, 1999-2014
Result	Three legal provisions decreased overdose death rates Three legal provisions increased overdose death rates
Conclusion	Overall, no statistical evidence that naloxone access laws reduce opioid death rates

Impact of Legislation[86]

Rees DI, et al.

Purpose	To examine the effect of naloxone access and Good Samaritan laws on opioid-related deaths
Methods	Reviewed data from National Vital Statistics System mortality files, Policy Surveillance Program, and Network for Public Health Law from 1999-2014
Result	Adoption of a naloxone access law was associated with 9-11% reduction in opioid-related deaths
Comments	Effect was stronger ≥2 years after law adoption and for non-heroin-related deaths; Removing criminal liability for naloxone possession was associated with 13% reduction in deaths; Laws did not increase recreational use of prescription opioids

Summary

- Legal Concerns
  - Prescriber/Dispenser/Patient/Bystander/Administrator
- Statewide Legislation
  - Not comprehensive in every state
  - Very nuanced
  - Unique/creative provisions
- Impact of Legislation
  - Increase pharmacy dispensing of naloxone
  - Increase distribution to Medicaid-eligible patients
  - Facilitate OEND implementation
  - Improve layperson activation of emergency response
  - **?? Reduce opioid-related mortality ??**

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