



Northwest (HHS Region 10)

ATTC

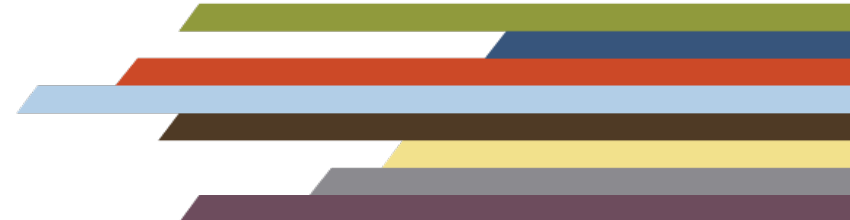
Addiction Technology Transfer Center Network
Funded by Substance Abuse and Mental Health Services Administration



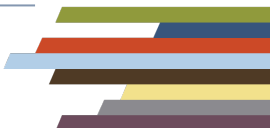
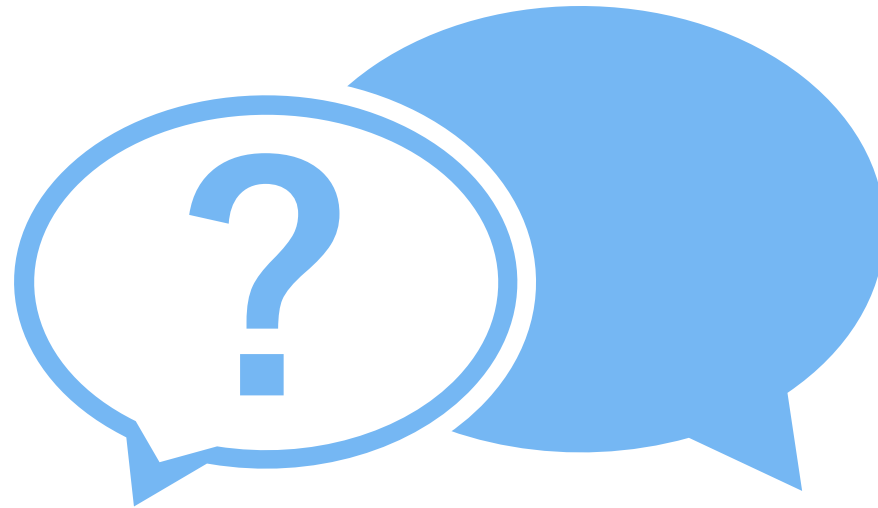
Northwest ATTC presents:
Crisis and Hope: Trends, Risk Assessment, and Innovation in Overcoming Overdose

**Thank you for joining us!
The webinar will begin shortly.**

- **Participants are automatically muted during this presentation**
- **Got questions?** Type them into the chat box at any time and they will be answered at the end of the presentation.
- An ADA-compliant recording of this presentation will be made available on our website at:
<http://attcnetwork.org/northwest>



Questions? Please type them in the chat box!



Surveys

Look for our surveys in your inbox!

We greatly appreciate your feedback! Every survey we receive helps us improve and continue offering our programs.

It only takes **1 minute** to complete!



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Viewing Groups:

Please send each individual's name
and email address to
northwest@attcnetwork.org
within 1 business day.

Your certificate will be emailed within a week to the address you registered with.

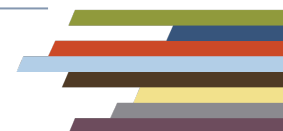




Northwest ATTC presents: Crisis and Hope: Trends, Risk Assessment, and Innovation in Overcoming Overdose



Dr. Desislava (Desi) Hite & Michael Hite, MBA



Tribal Land Acknowledgement

I'd like to offer a specific acknowledgement for the land from which I'm joining you today, Seattle in King County WA.

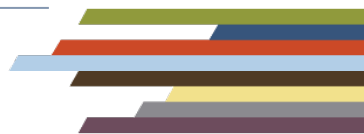
We at Ayuda Medical acknowledge this as the traditional home of the Snoqualmie Tribe and Muckleshoot Tribe. I take this opportunity to thank the original caretakers of this land who are still here.



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Addiction Technology Transfer Center Network
Funded by Substance Abuse and Mental Health Services Administration



Disclosure

Desi Hite, MD, ABEM

13yrs Emergency Physician

Michael Hite, MBA

20yrs device design and development

Ayuda Medical

Diagnosing medical emergencies in the home setting

Recipients of Phase I, Phase II, TABA, and I-Corp awards

Active Phase II with NIDA: The ARMBand

On-body diagnostic device for opioid overdose



American Board of
Emergency Medicine



Learning Objectives

Part I

1. Intro to Opioids and Overdose (OD)
2. Evolving trends in last 5yrs
3. Factors that increase risk of fatal OD

Part 2

4. OD Education and Intervention
5. New Naloxone, Devices and Mobile Apps
6. Challenges in adopting new tools
7. Our story: Ayuda Medical



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Opiate vs Opioid



Unsplash.com

Opiate: derived from opium poppy plant (e.g. morphine)



Unsplash.com

Opioid: any natural or synthetic substance that acts on opiate receptors

Opioids: How they work

Mu (μ) receptors mediate:

- ▶ Euphoria
- ▶ Physical dependence
- ▶ **Centrally mediated apnea**
- ▶ Gastrointestinal dysmotility

All opioid receptors mediate analgesia.

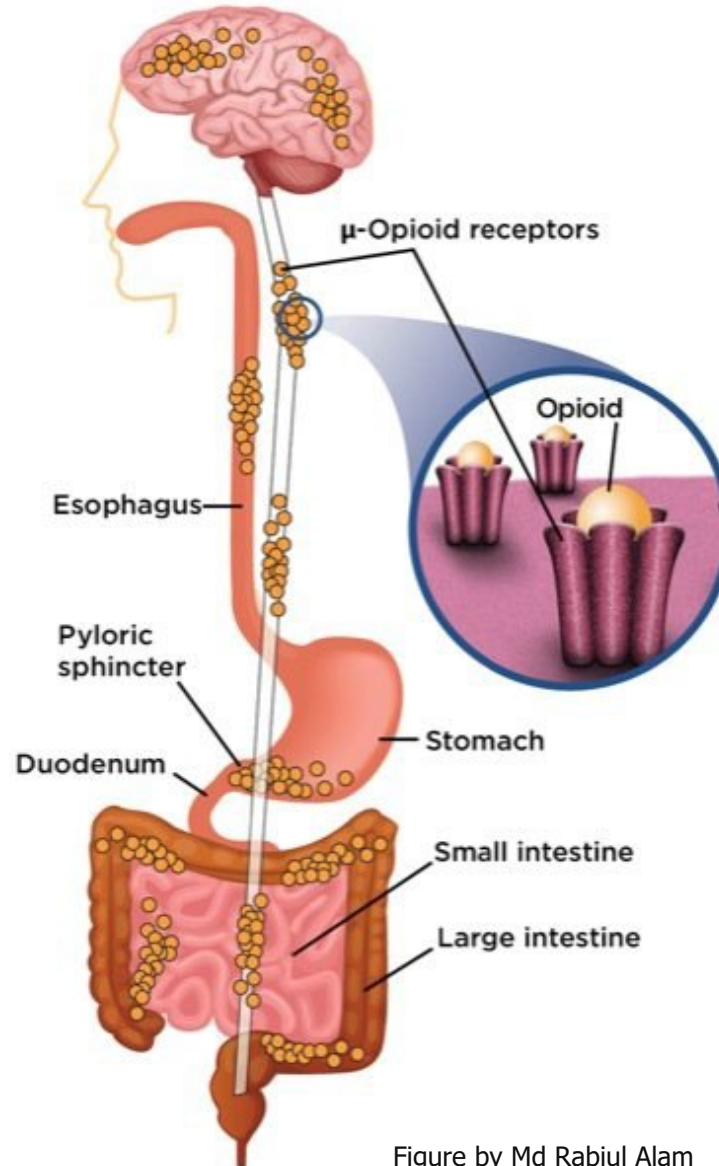
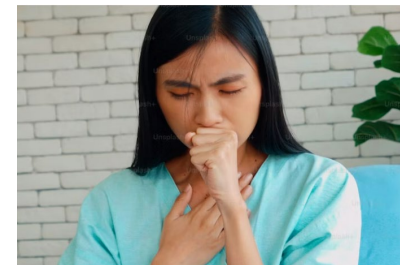


Figure by Md Rabiul Alam



Kappa (κ) mediate miosis.



Delta (δ) mediate cough suppression.

Opioid Subcategories

Natural



Morphine



Codeine

Semi-Synthetic



Oxycodone, Hydrocodone



Oxymorphone,
Hydromorphone

Heroin

Synthetic



Tramadol



Methadone

Fentanyl!

Opioid Subcategories

Natural

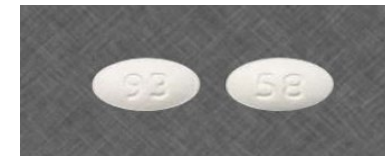


Semi-Synthetic



Heroin

Synthetic



Fentanyl!

Fentanyl



100x potency of Morphine



2mg can be lethal



0.02mg to 5.1mg found in individual tablets

Fentanyl



100x potency of Morphine



2mg can be lethal



0.02mg to 5.1mg found in individual tablets

The #1 driver of OD deaths!

Opioid OD Deaths, King County, WA



Figure 1: Rolling 4-week average number of overdose deaths in King County, January 2019-September 2022, stratified by fentanyl involvement

Civic Alert, Eugene, OR

Posted on: August 6, 2023

[ARCHIVED] Eugene Police Respond to Multiple Overdose Deaths



UPDATE ON AUGUST 6, 2023:

EPD is continuing to respond to overdose calls. Since yesterday's report, there have been two more deaths.

"We have seen fentanyl contamination in cheap, counterfeit pills sold as common medications such as oxycodone, Adderall, or Xanax. It should be assumed that any illicit drug could contain fentanyl."

New Player: Carfentanil

DEA Issues Carfentanil Warning To Police And Public

Dangerous opioid 10,000 times more potent than morphine and 100 times more potent than fentanyl



**Drug Enforcement
Administration**



New Player: Xylazine



PUBLIC SAFETY ALERT

DEA Reports Widespread Threat of Fentanyl Mixed with Xylazine

- Non-opioid tranquilizer
- Not approved for human use
- Mixed with fentanyl
- Found in 48/50 states

<https://nida.nih.gov/research-topics/xylazine>

<https://www.dea.gov/alert/dea-reports-widespread-threat-fentanyl-mixed-xylazine>

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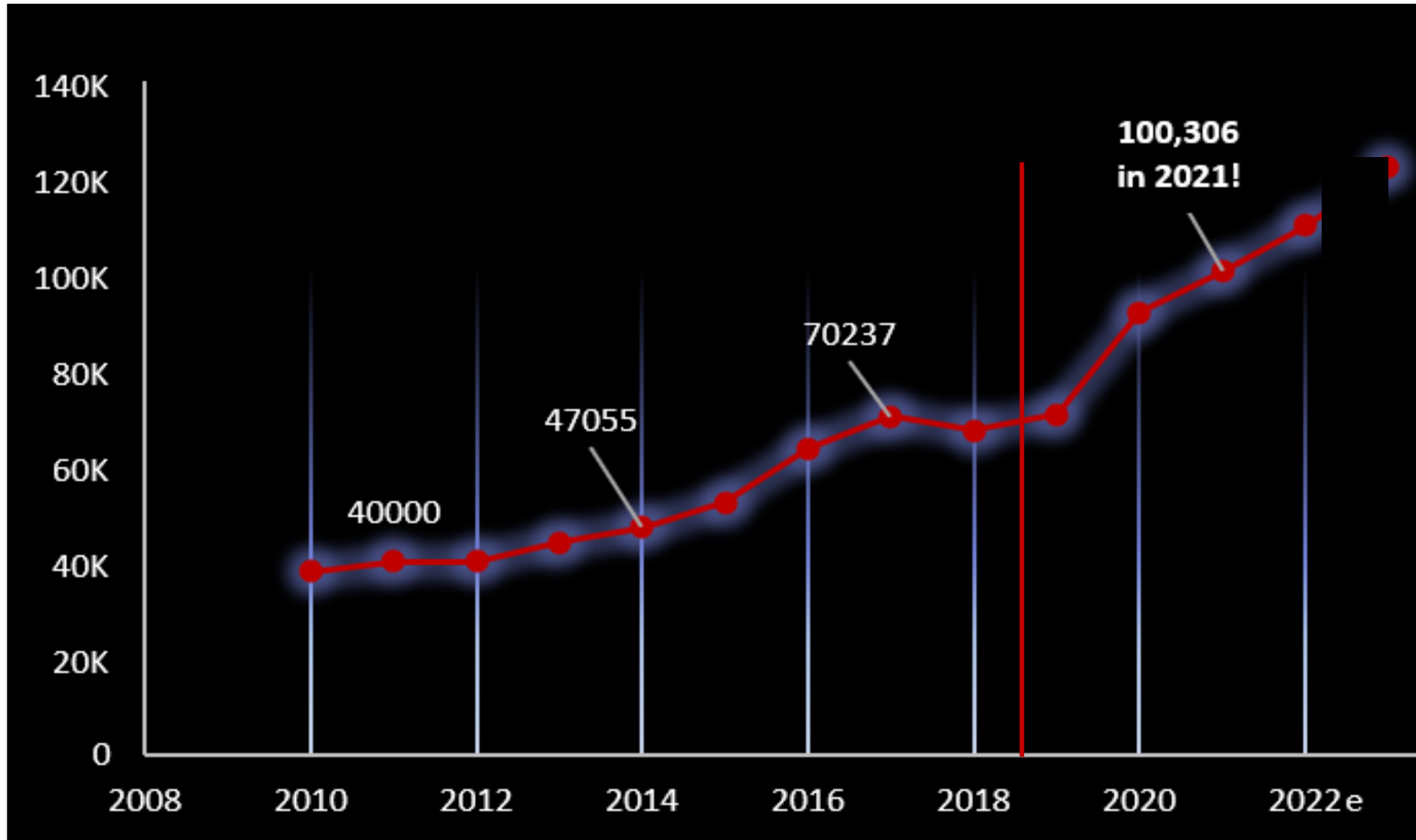
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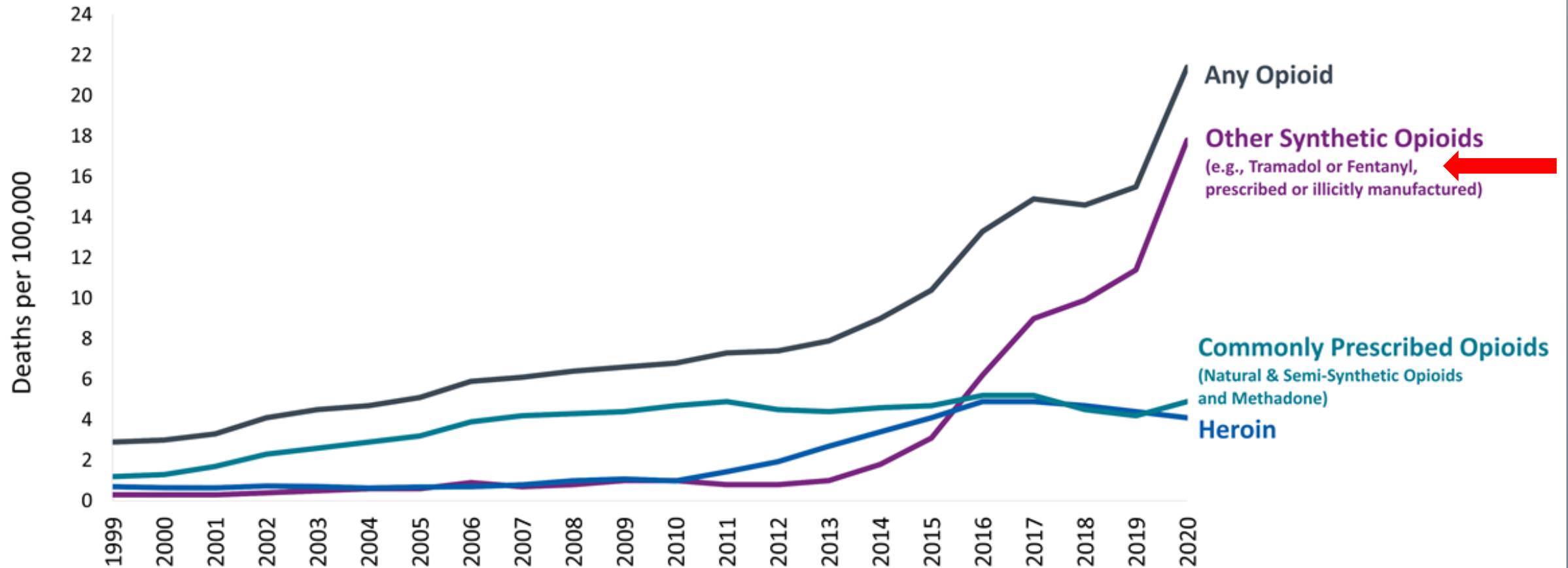


Fatal Drug Overdoses in USA

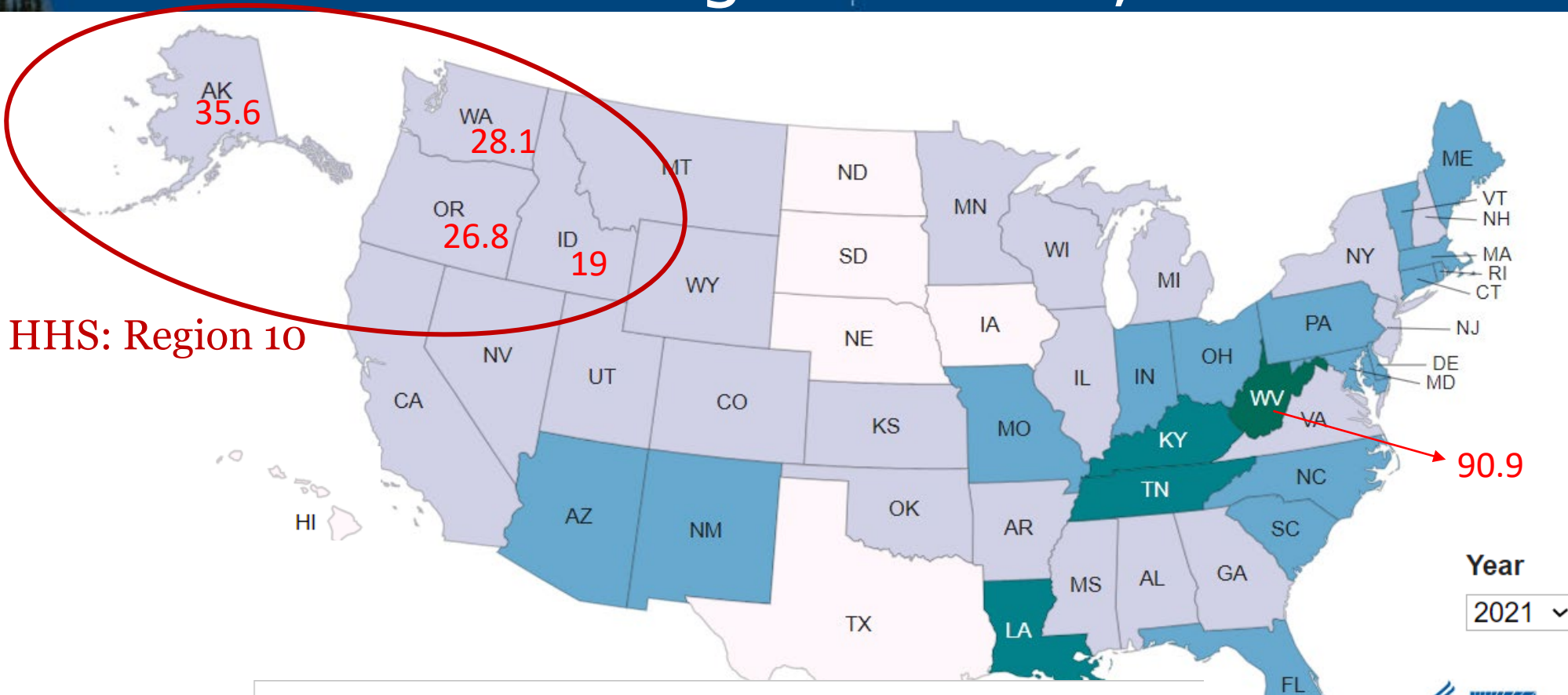


11.5 people
died of OD
each hour
in 2021!

Fatal Opioid Overdoses in USA



Fatal Drug Overdoses, 2021

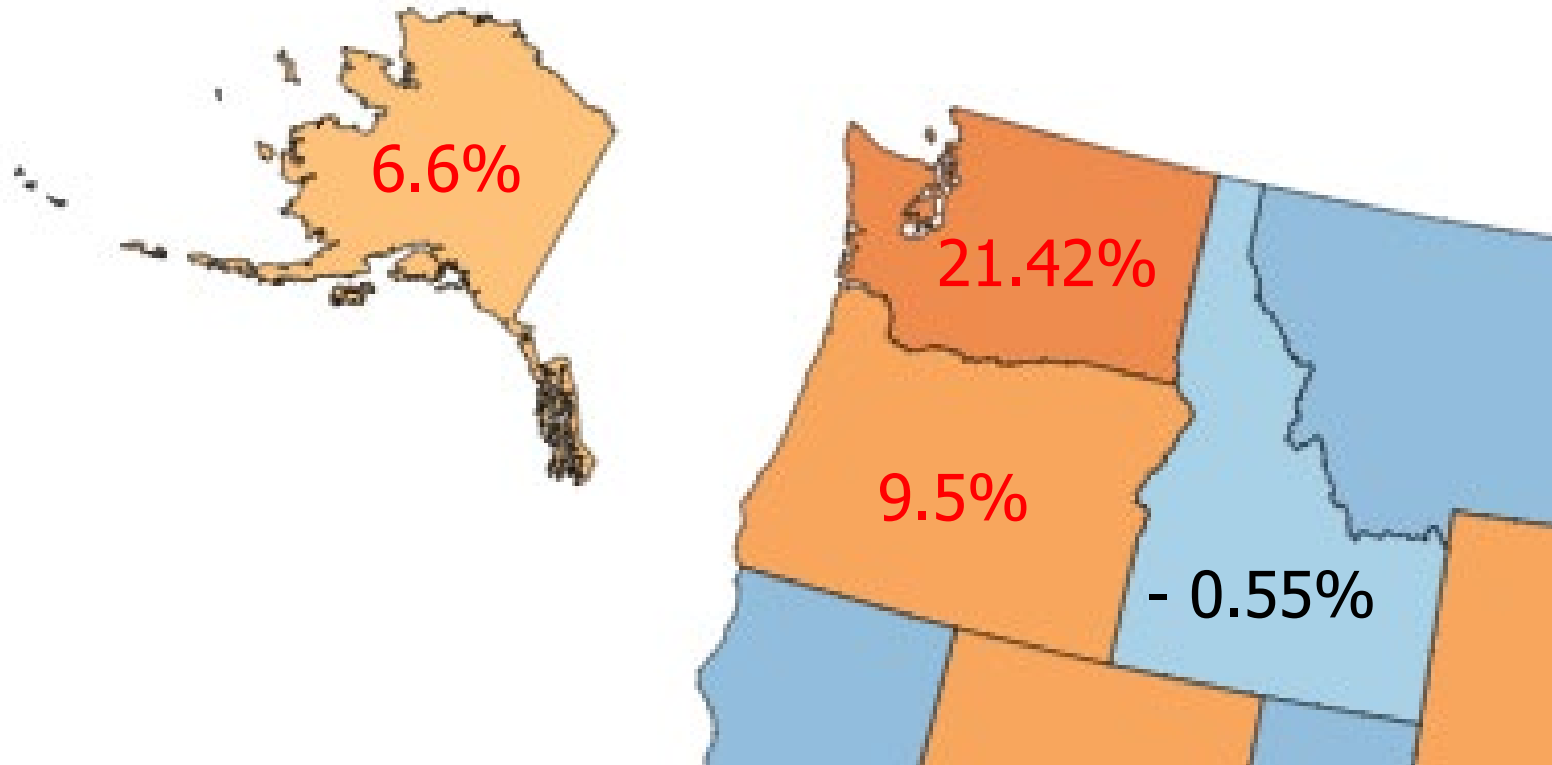


Age-Adjusted Death Rates¹ per 100,000 total population.

- 0 - < 18.18
- 18.18 - < 36.36
- 36.36 - < 54.54
- 54.54 - < 72.72
- 72.72 - 90.9



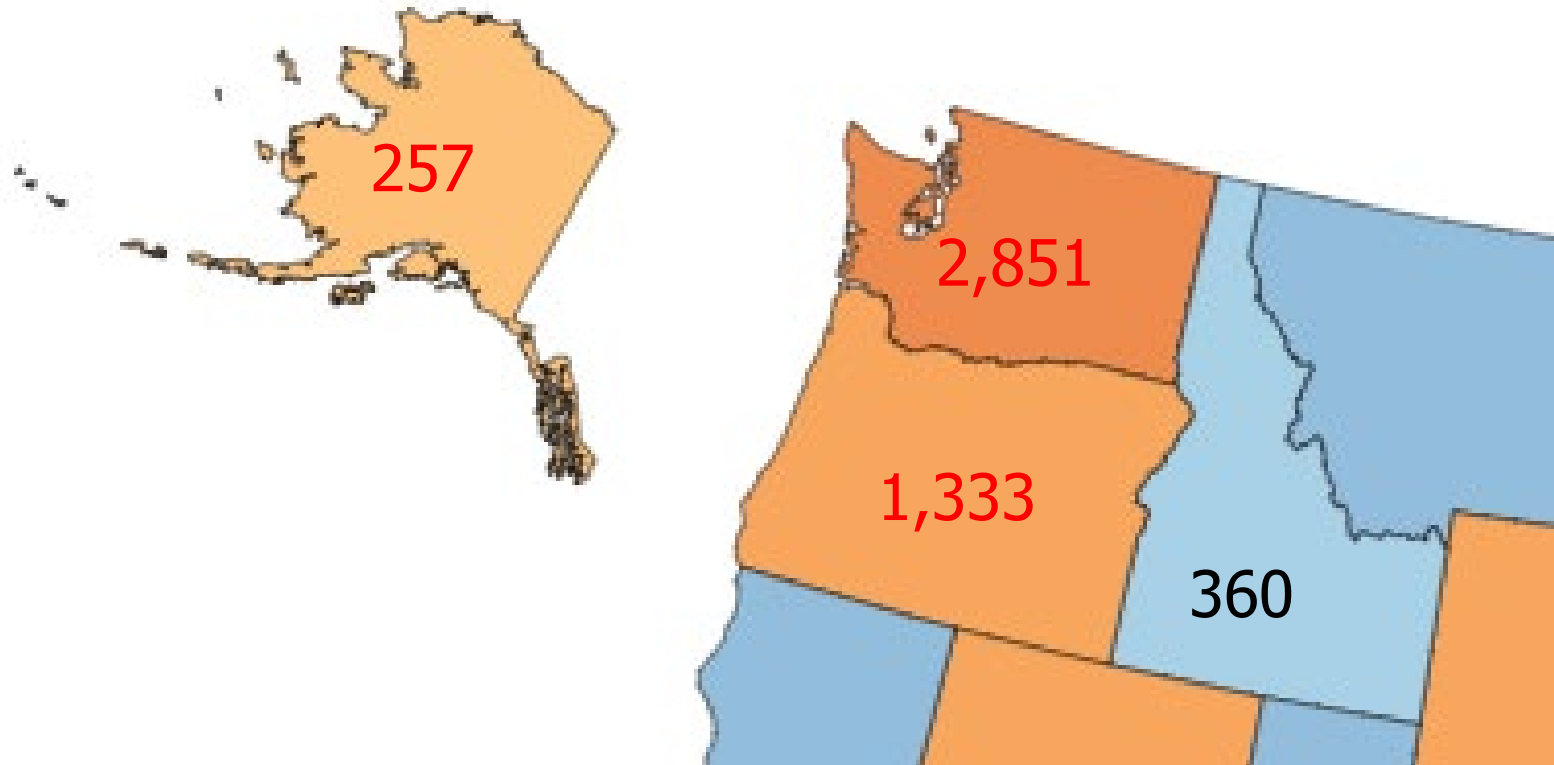
% Change of OD Deaths, 2022 vs 2023



Legend for Percent Change in Drug Overdose Deaths Between 12-Month Ending Periods



OD Deaths, Feb. 2022 until Feb. 2023

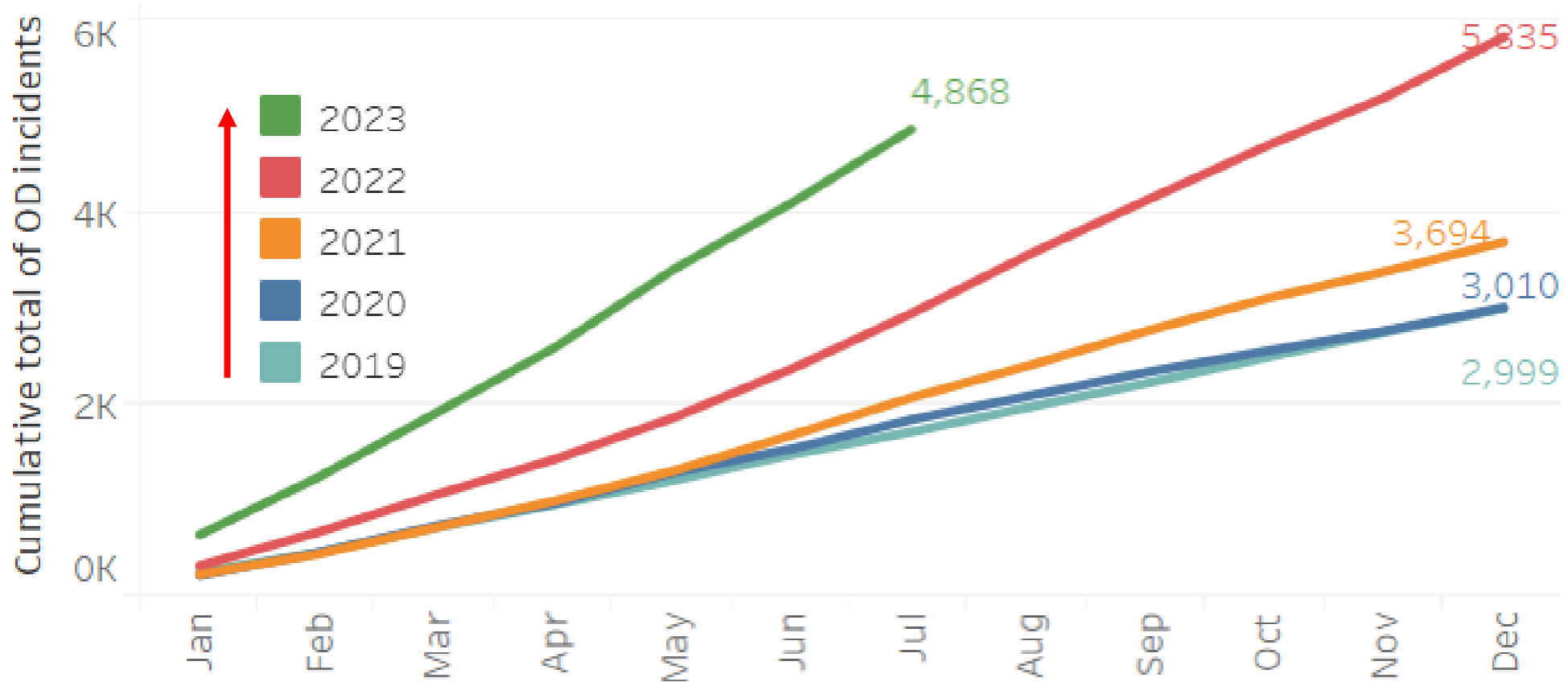


Legend for Percent Change in Drug Overdose Deaths Between 12-Month Ending Periods



Opioid OD treated by EMS, King County, WA, 2023

Cumulative total # of Opioid Overdoses treated by KC EMS





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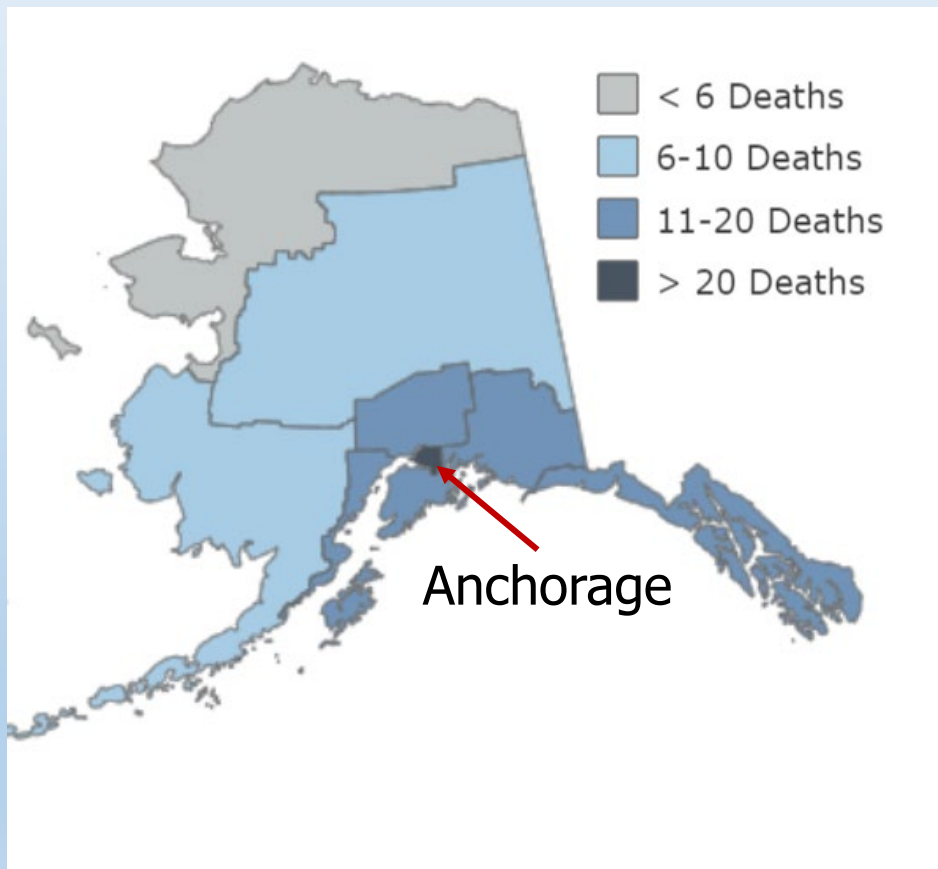
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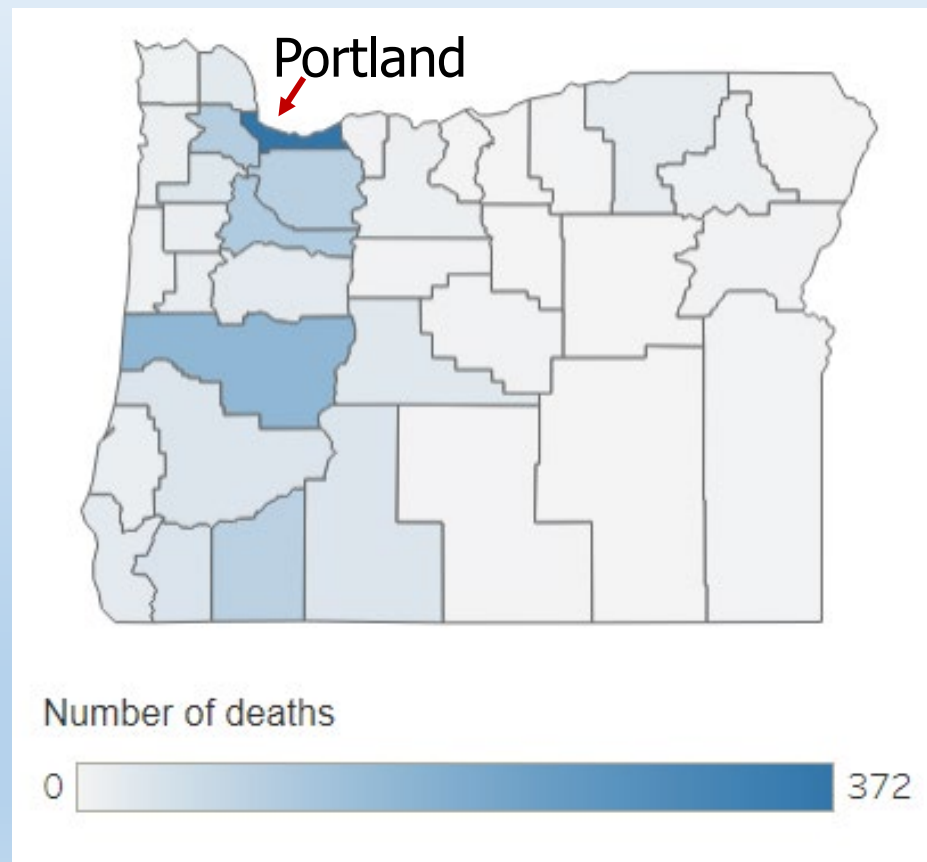
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Rural vs Urban

Opioid OD deaths, 9/21-8/22, AK

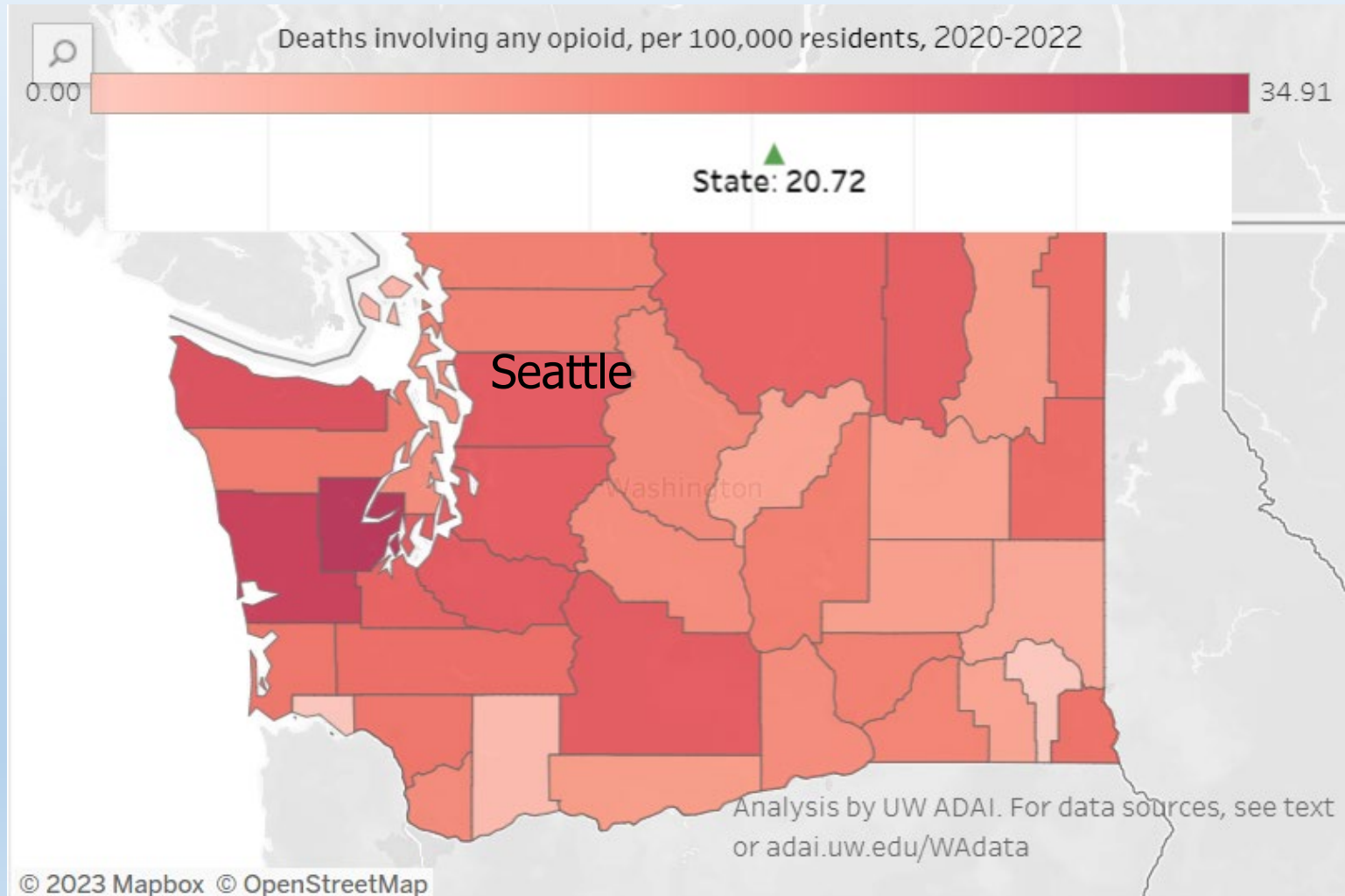


Poisoning & OD deaths, 9/21-8/22, OR



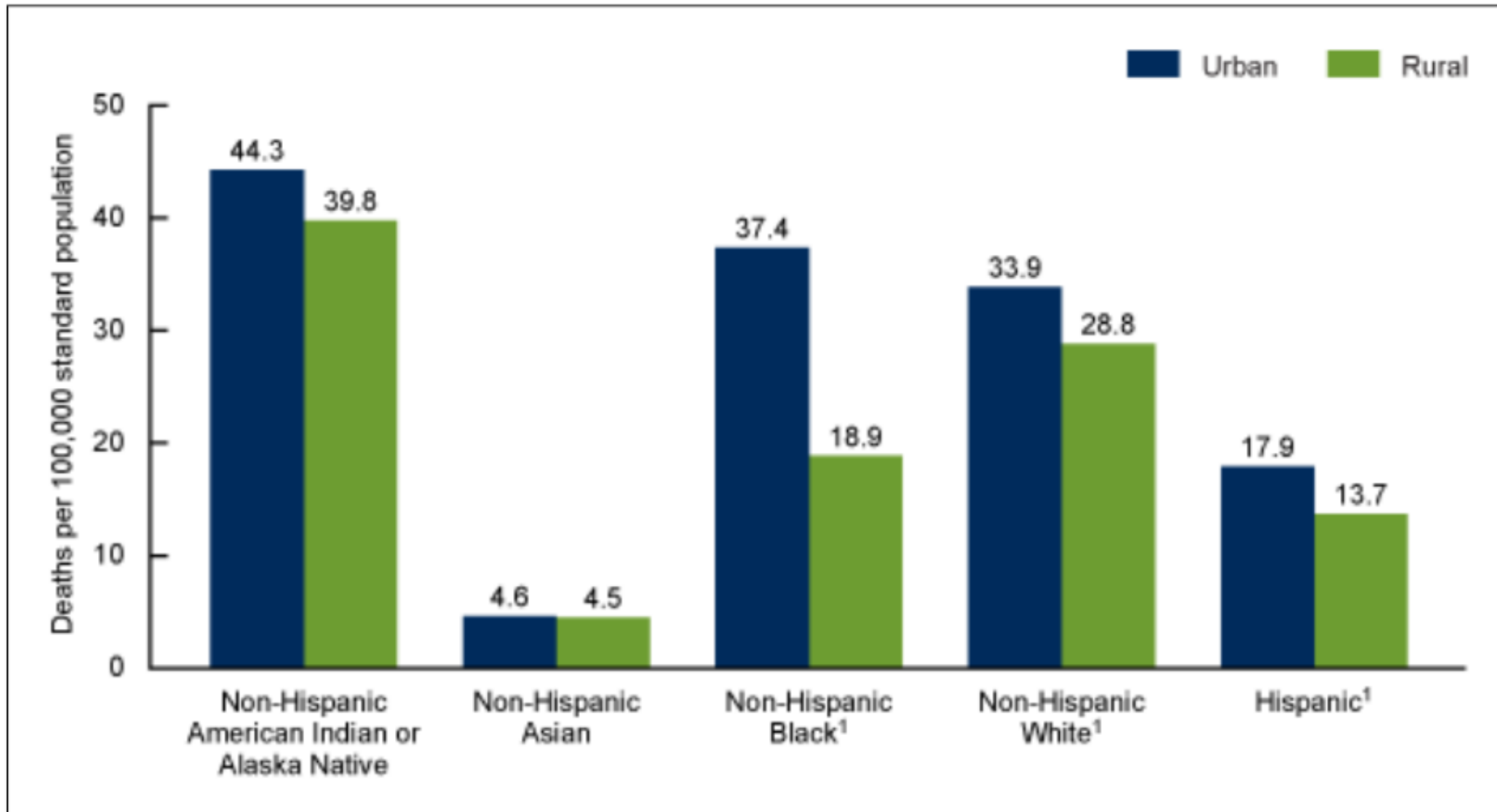
Rural vs Urban

OD Deaths, Any Opioid, WA, 2020-22



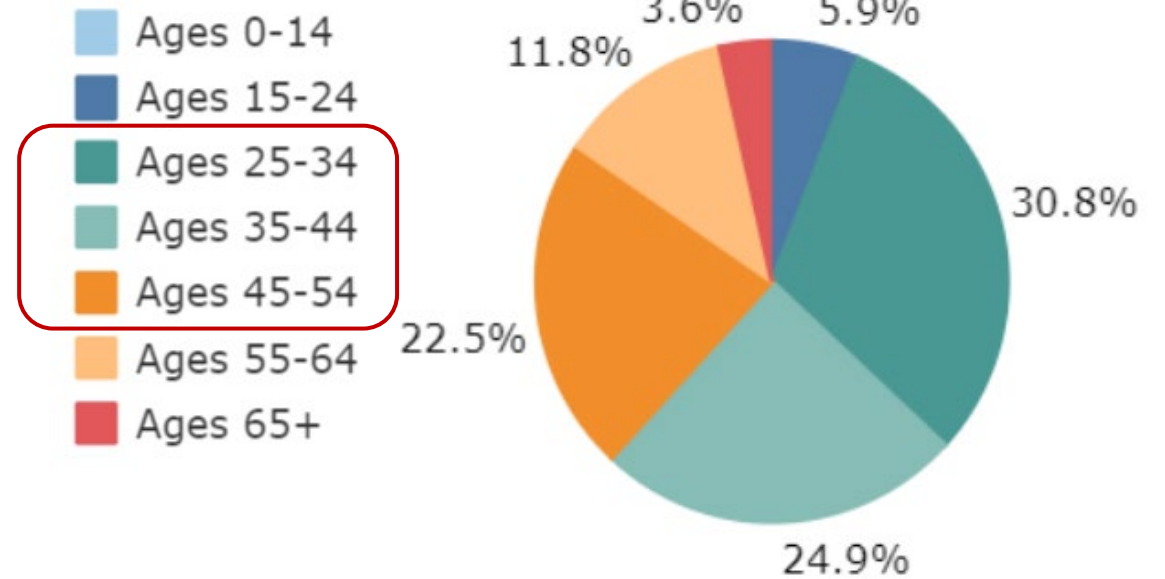
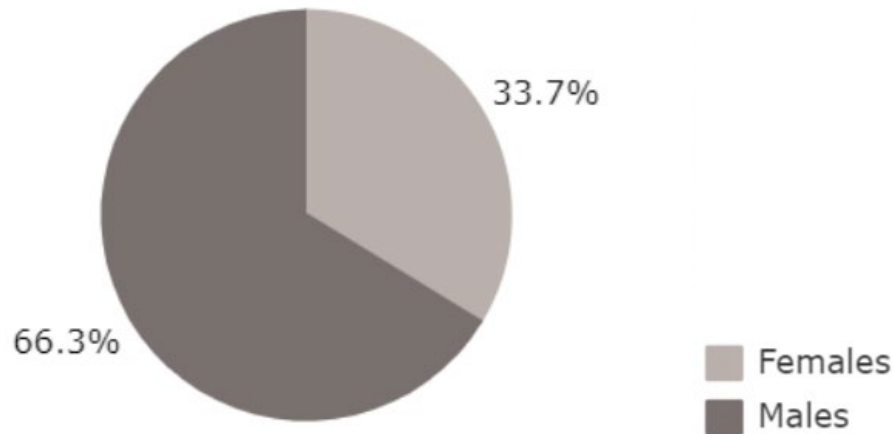
Race and Ethnicity

Age-adjusted rates of drug overdose deaths, by race and Hispanic origin and urban-rural status: United States, 2020



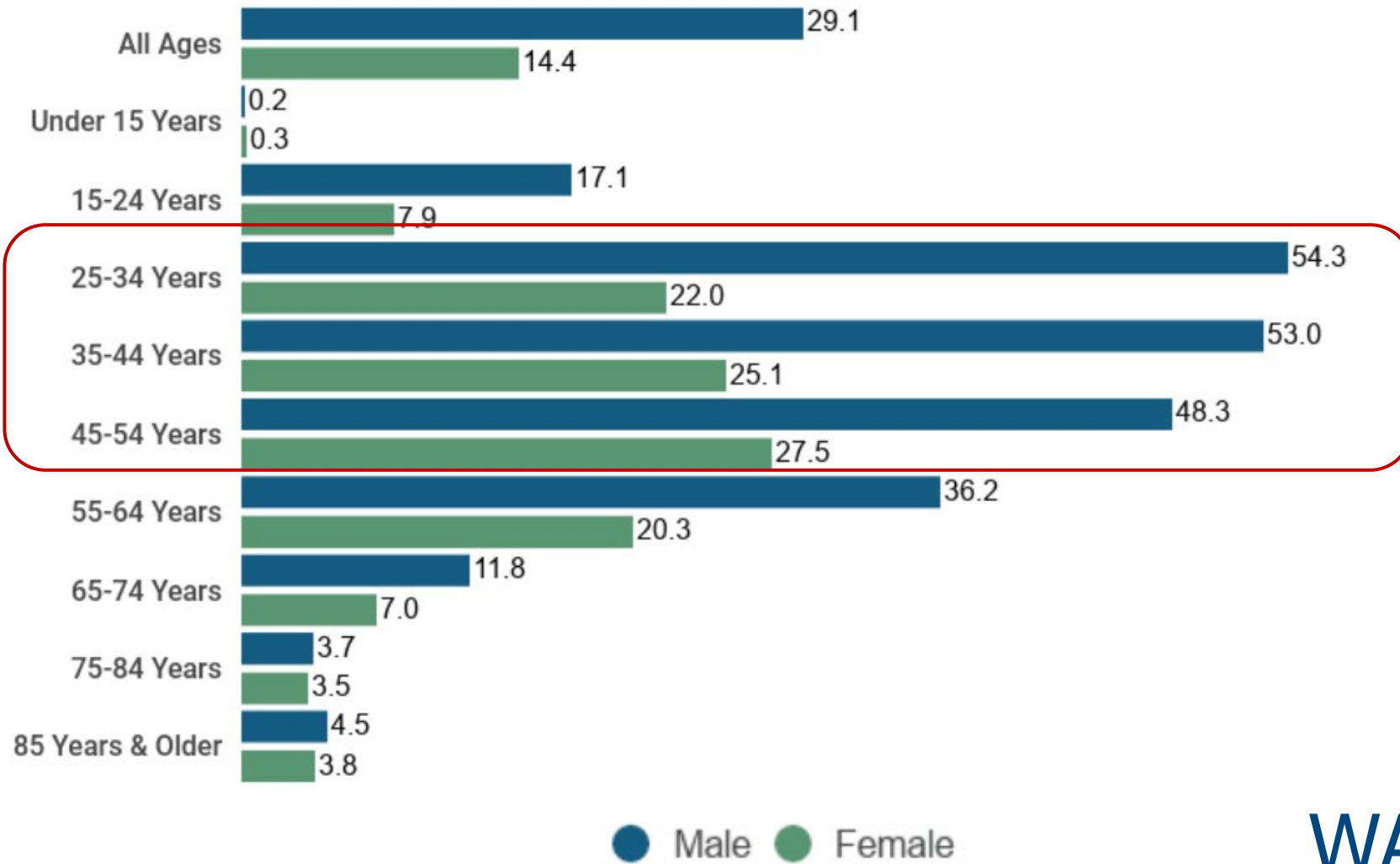
Age and Gender

Fatal Opioid OD; AK, 2022



Age and Gender

Drug Overdose Deaths Among Age Groups per 100,000 Residents



WA, 2021

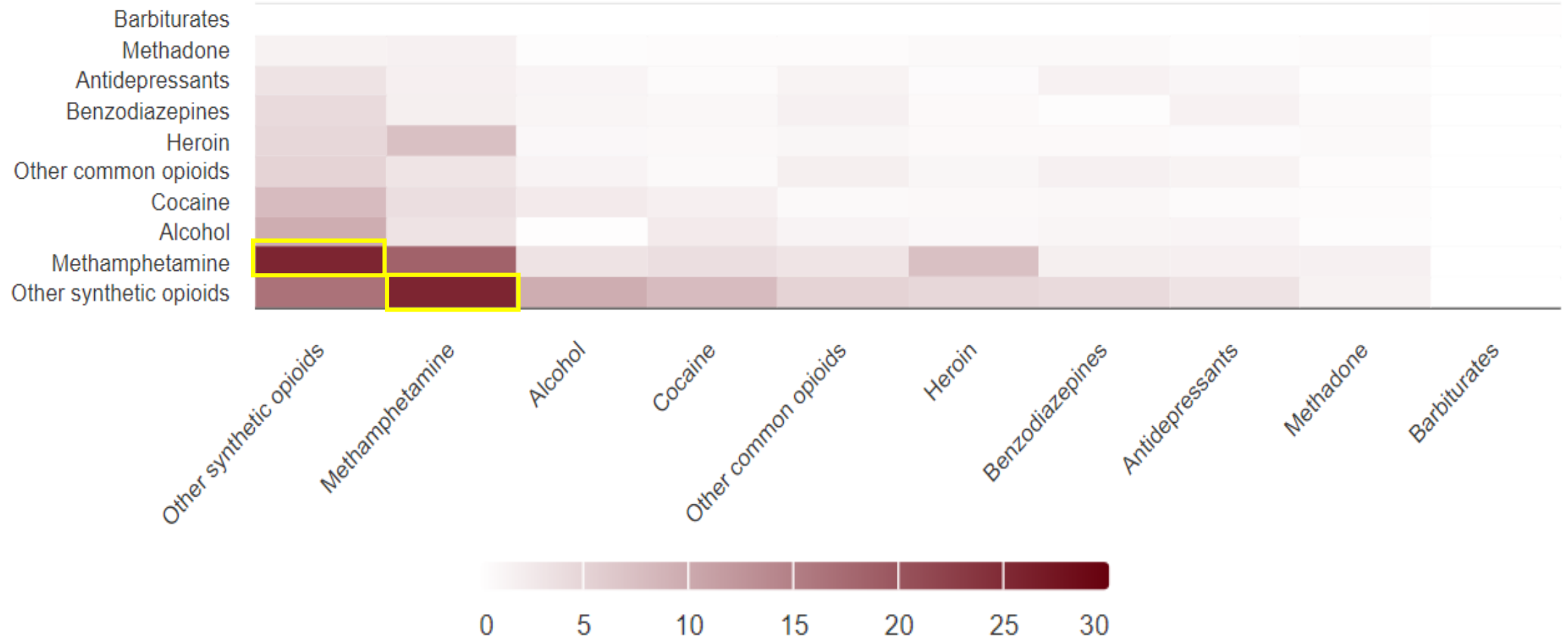


Who is at highest risk of fatal OD?

1. Prior Overdose – ask!
2. High dose opioids
 - >100 MME/day or
 - >50 MME/day + BZD or antidepressant
3. Experimenting with counterfeit medications
 - Poisoned drug supply
4. A change in opioid tolerance in chronic use
 - Recovery and Relapse
 - Incarceration and release
5. Mixing with respiratory depressants: Alcohol, BZD
6. Mixing with stimulants: methamphetamine

% OD Poisonings involving Drug Pairs, WA

2021-2022



Poisonings involving Drug Pairs, ID



2022 Update & Final Report

Idaho Opioid Misuse and Overdose
Strategic Plan 2017-2022

“of the 287 drug overdose deaths in 2020, 96 were reported to specifically involve **methamphetamine** - making it the second most frequently involved substance in drug overdose deaths in Idaho.”

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OD Prevention Education

OD Recognition and Response

Can you find them?



Locate

- Bathroom
- Bedroom
- Public space

Are you sure it's OD?



Recognize

- Unresponsive
- Difficult breathing
- Hypoxic (blue)

Can you help?



Decide

- Knowledge
- Confidence
- Willingness

Respond

- Call EMS/911
- Rescue breath
- Give Naloxone

OD Prevention Education

Opioid Overdose



If someone you know is using opioid pills, fentanyl, or heroin...

...would you know what to do if they overdosed?

1 Check: could this be an opioid overdose?

Look and listen for:

- Slow or no breathing
- Gurgling, gasping, or snoring
- Clammy, cool skin
- Blue or gray lips or nails
- Pill bottles, needles, or alcohol

Try to wake them up:



- Shake them and call their name.
- Rub your knuckles hard over their chest bone.

If they don't wake up, you need to act fast!

2 Call 911.



- Say where you are and that the person isn't breathing.
- You don't need to say anything about drugs or medications.

3 Give naloxone and start rescue breathing.

- Give the naloxone.
- Follow the instructions on the package
- Start rescue breathing.
- If they don't respond in 3-5 minutes,



give a **second dose of naloxone**. Keep rescue breathing.

Do rescue breathing even if you don't have naloxone. Oxygen is critical!

4 Stay with them.



StopOverdose.org

ADAI
ADDICTIONS, DRUG &
ALCOHOL INSTITUTE

OD Prevention Education

EMS-based Crisis Teams

2 Firefighters + 1 Social Worker

OD Response and stay on scene

Follow-up & services navigation

"Crisis Now" model

Pre/Post-OD intervention

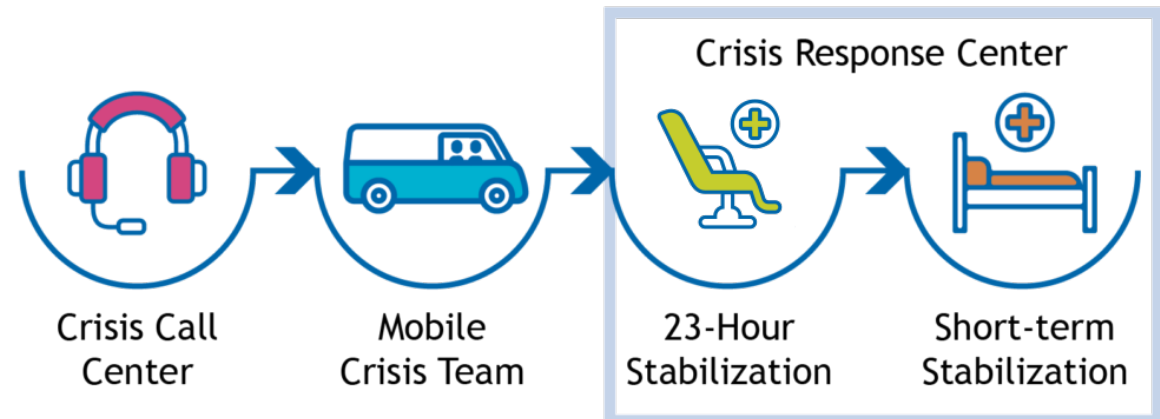
Mobile Team helps navigate services



Trust
Alaska Mental Health
Trust Authority

What is the Crisis Now Framework?

Someone to Talk to, Someone to Respond and a Place to Go



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New Products: Naloxone options

Naloxone available in multiple forms

- IM 2mg (Pfizer)
- IM/SC 5mg (ZIMHI®)
- Nasal 4mg (Narcan®) – now available Rx and OTC
- Nasal 4mg (Teva) – generic Rx naloxone
- Nasal 3mg (RiVive®) – generic OTC naloxone; 40% cheaper
- Nasal 8mg (Kloxxado®) – intended for fentanyl OD



Naloxone considerations

...but Naloxone isn't a panacea

- Multiple doses may be required for fentanyl
- Xylazine extends opioid effect
- Can be false-sense of security
- Cost & availability

*Challenge to balance "just-enough" naloxone dose to rescue
without inducing side-effect of withdrawal*

New Products to Prevent Fatal OD

Wearable devices

- Masimo *OpioidHalo*TM

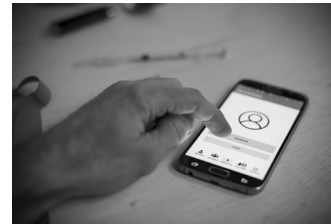


- Ayuda *ARMBand**



Mobile apps

- Verily SecondChanceTM



- BTCO *Brave*TM *



* *not FDA approved*

Detects opioid-induced impairment of oxygenation

Fingertip pulse-oximeter

- + Wrist-worn transmitter
- + Tabletop monitor
- + Mobile app



Approved by FDA April 2023

Masimo *OpioidHalo*™

Tabletop monitor audibly alarms

Mobile app visually alarms and texts User contacts for help

Call-center contacts User – can alert 911 if no response



Audible Alarm

Text Contacts

Call EMS

Available as Rx and OTC

Advantages

- First FDA-approved device for opioid-impaired oxygenation
- Traditional fingertip sensor can be removed easily
- Effective in range of skin tones

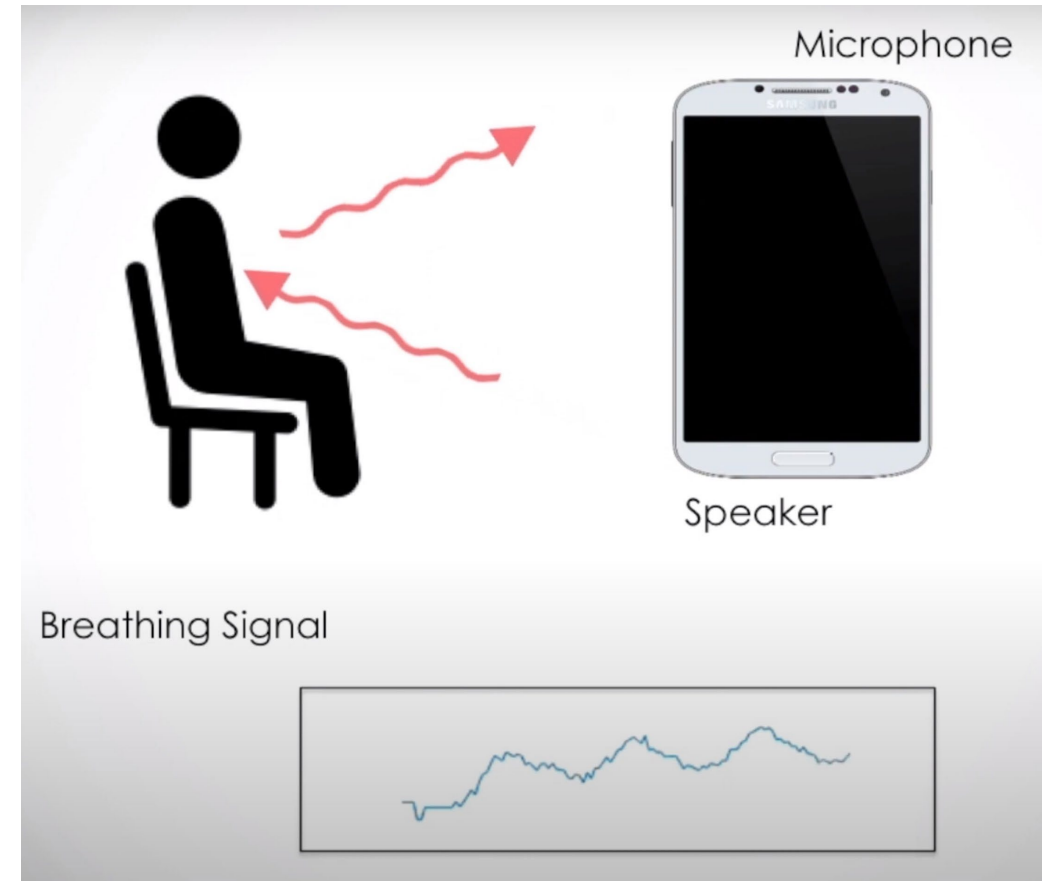
Limitations

- Fingertip sensor may interfere with daily activities
- In-home use only
- Continuous monitoring
- \$250 per unit

Designed for Hospital-at-Home setting

**Uses smartphone speaker
+ microphone as sonar**

Detects respiration rate changes
indicative of overdose



Cleared by FDA 510(k) Nov 2021

Verily *SecondChance*™

Developed at Univ. of Washington &
Sound Life Sciences

Clinical study in opioid (heroin) users
at InSite in Vancouver, BC

Successfully detected opioid-induced
respiratory depression & apnea



Opioid overdose detection using smartphones,
Nandakumar et al., Sci. Transl. Med. 11, eau8914 (2019)

Advantages

- First acoustic respiration rate Dx
- Evaluation in opioid users
- Non-invasive RR & apnea measurement
- Very low-cost to deploy

Limitations

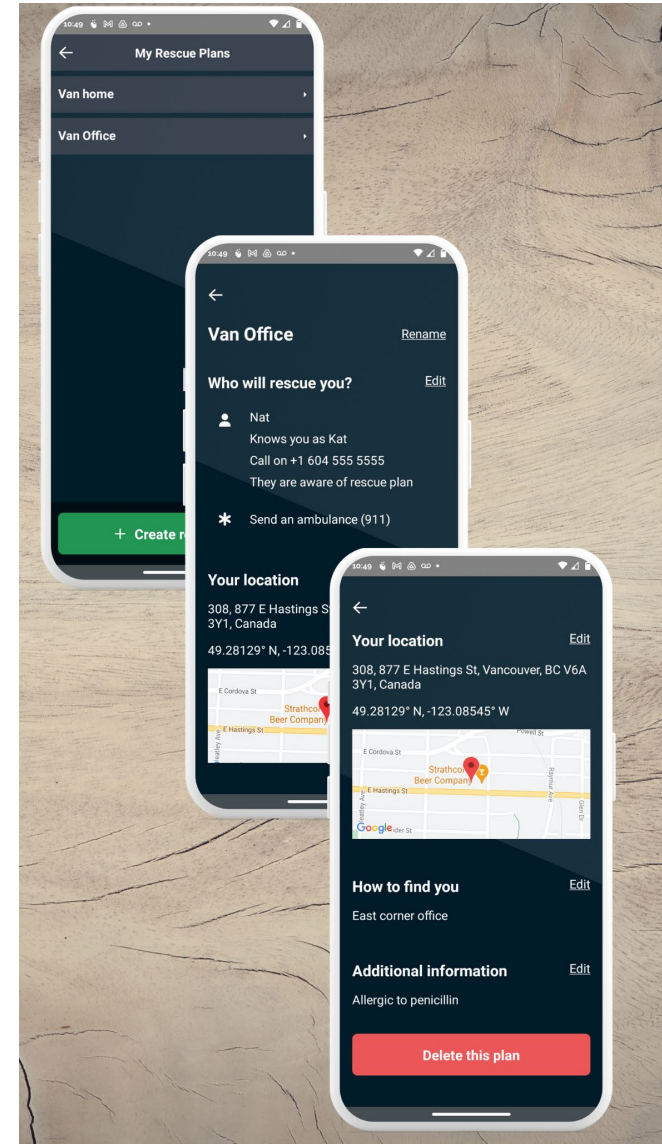
- Microphone must be within 3ft, and in quiet environment
- Does not work if phone is in pocket; App must be activated
- Verily acquired in 2022, but not yet actively marketed

May help protect from overdose when alone

Engages live monitoring prior to opioid use

Call center monitors user until they
confirm they are "OK"

Novel approach to Safe Consumption



Developed at Univ. of British Columbia

Users establish their own rescue plan

Call center can notify contacts,
and EMS (if desired)



***Brave* partnered with *RapidSOS Ready* to enable
direct connection to 911/EMS**

Advantages

- First live OD-monitoring service
- Evaluation by trained staff
- Relies upon active confirmation of status (“I’m ok”)
- Accessible without data/wi-fi

Limitations

- Intrusive, requires 1:1 interaction
- Difficult to differentiate between heavy sedation and OD
- Not FDA cleared
- Small co, uncertain support level

Safe (remotely monitored) Consumption

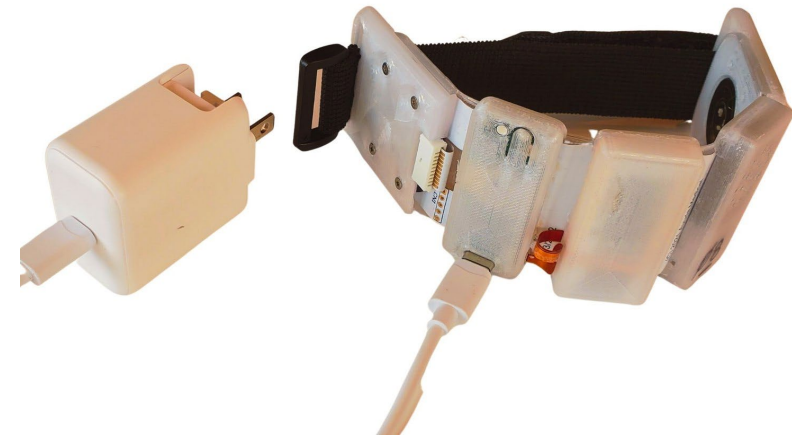
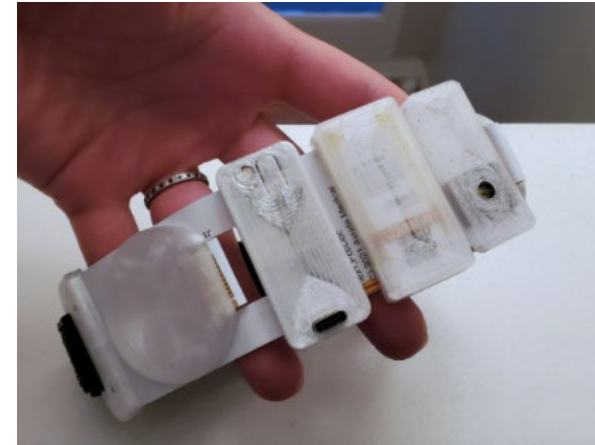
Ayuda ARMBand™

Wearable monitor for opioid & drug overdose

Discreet device alarms if OD detected

Functions independent of phone

Mobile app can call contacts or EMS for help



NIH/NIDA supported Phase I-II SBIR

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People want choices of:

Who is called to help

People trust friends and family – they know who can be relied upon to help

People want choices of:

Who is called to help

People trust friends and family – they know who can be relied upon to help

What data is being recorded

People care about privacy – they don't want their data used against them

People want choices of:

Who is called to help

People trust friends and family – they know who can be relied upon to help

What data is being recorded

People care about privacy – they don't want their data used against them

Where they can be seen

People don't want to be tracked – they want to be protected, not surveilled

People want choices of:

Who is called to help

People trust friends and family – they know who can be relied upon to help

What data is being recorded

People care about privacy – they don't want their data used against them

Where they can be seen

People don't want to be tracked – they want to be protected, not surveilled

When to use tools

People know when they are at-risk – they know when to protect themselves

People want choices of:

Who is called to help

People trust friends and family – they know who can be relied upon to help

What data is being recorded

People care about privacy – they don't want their data used against them

Where they can be seen

People don't want to be tracked – they want to be protected, not surveilled

When to use tools

People know when they are at-risk – they know when to protect themselves

How we support choices of People at-risk significantly impacts adoption



Device Adoption Challenges

Multiple barriers to adoption for People at-risk:

User Experience

Privacy Protection

Social & Legal Concerns

Cost & Access Issues

**Addressing concerns of highest-risk populations
can have greatest impact**

Device Adoption: User Experience

**“Meeting people where they’re at” means
OD prevention tools must fit into their life**

“How will I look?”

No-one wants to be labelled

“Will it alarm by mistake?”

No false alarms

“Is it easy to use?”

Simple interface required

“Do I have to wear/use it all the time?”

Protect when most at-risk

OD prevention tools can’t add to stigma

Device Adoption: Privacy Protection

People at-risk have real Privacy Concerns:

- Additional stigma – “Not another ankle monitor / breathalyzer”
- Drug-use monitoring – “Just looking for an excuse to bust me”
- Location tracking – want to avoid putting others in legal jeopardy
- Biometric data sharing – “feel like lab rats”
- 911 interaction – concern about police response, separate from EMS
- Medical/Legal records – concern about OD event remaining confidential

Reframing “watching you” to “watching out for you”



Device Adoption: Social & Legal Issues

People are concerned about impact of “sharing” OD events:

Justice-involved

Many people at-risk can have legal consequences due to OD event

Housing-related

Many people at-risk can lose housing & other resources due to OD event

Good Samaritan laws vary

Many people at-risk concerned about legal risks to potential OD rescuers

**OD Prevention Tools will only be used by people at-risk
if they trust them**



Device Adoption: Cost & Access Issues

OD Prevention is Public Health:

Rx, OTC and Harm Reduction

Multiple channels to reach People at-risk

State (Settlement) and Federal (SOR) Support for New Approaches

Pilot programs at Opioid Treatment Program sites and FQHCs

Contingency Management

Significant potential to improve device adoption

**OD Prevention must be covered by Payors to have an
significant Impact on the opioid epidemic**

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Problem to Solve

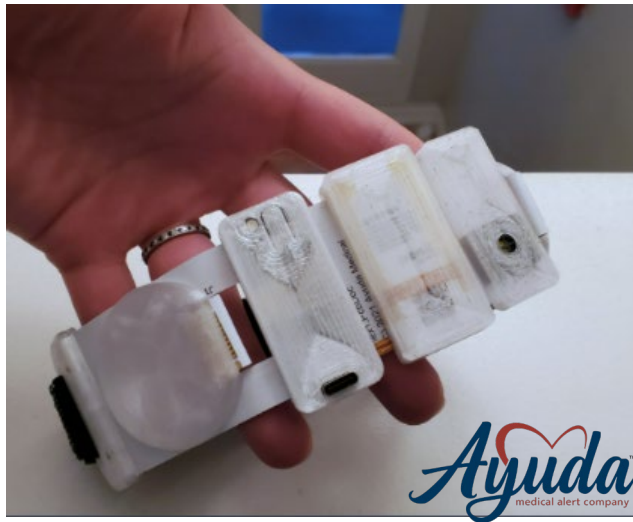
80% of Fatal ODs happen at-home,
half had family or friends nearby who
simply were not aware



Imagine the
thousands of lives saved
if they were notified in time

Our Solution

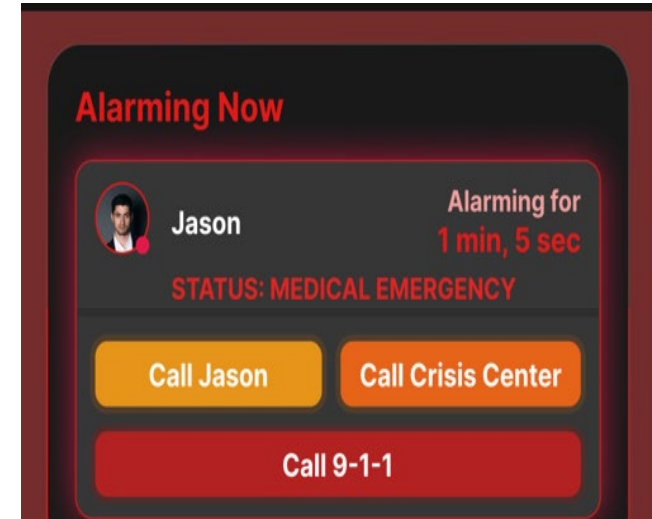
Our ARMBand aims to Detect OD and alarm for help



Small
Comfortable
Discreet

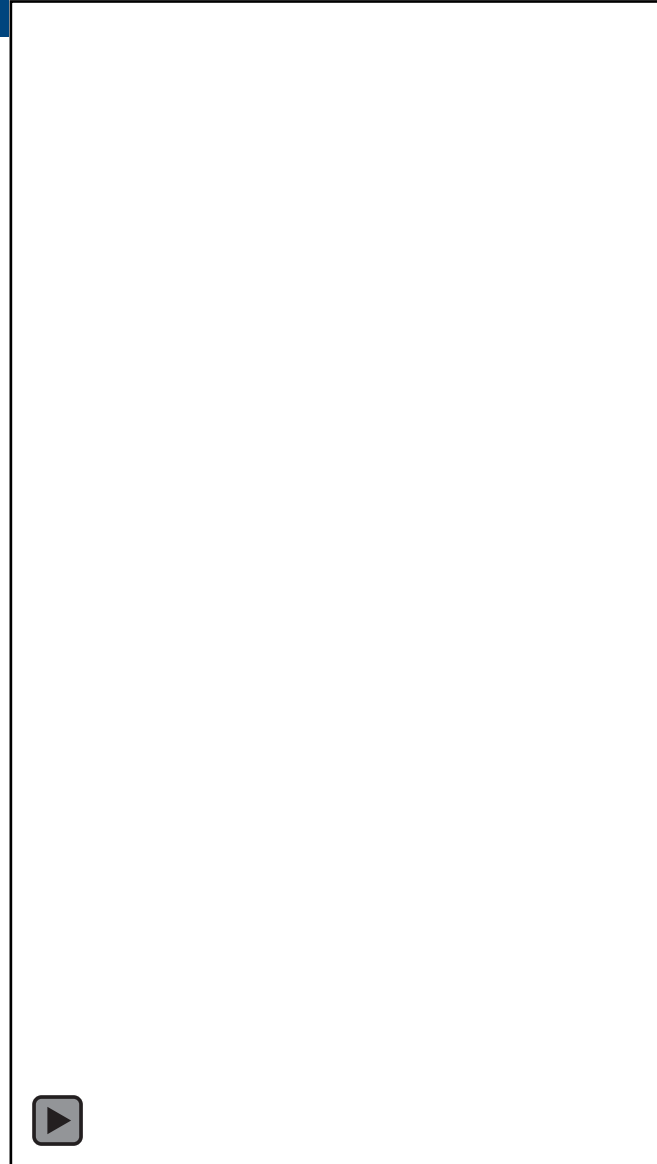


When worn, Device will identify OD and audibly alarm to attract help



Associated Mobile App will notify Patient-chosen contacts and give options to act

Ayuda Medical: Our Solution



Ayuda's *ARMBand*

For at-home and ambulatory settings

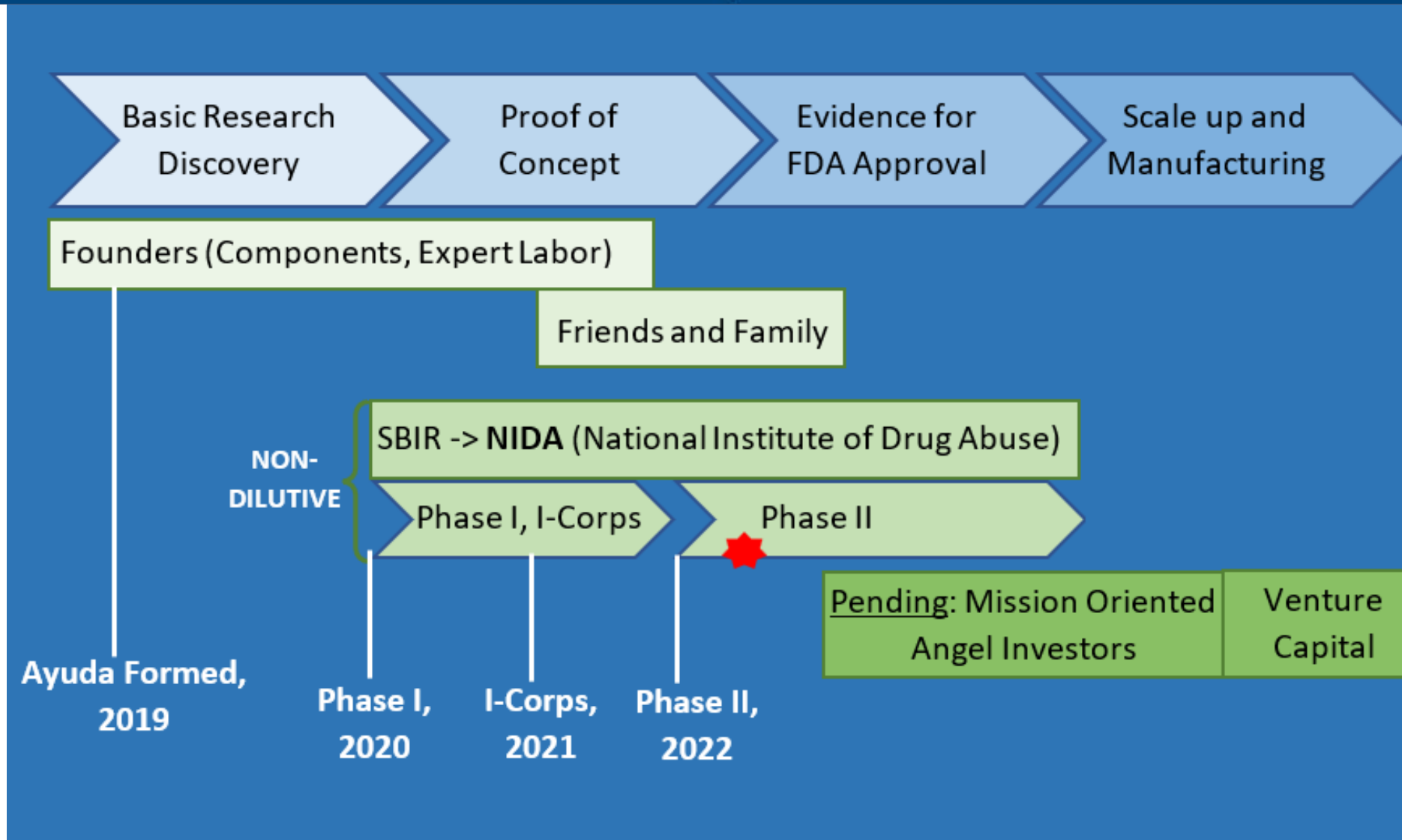
Advantages

- OD-specific algorithm
- Adjusts for skin tone variation
- Has acoustic and haptic alarms
- Gives voice instructions

Limitations

- Not for 24/7 wear
- 3-7d battery charge
- Not yet FDA approved
- Target launch 2025-26

Our Experience



Key Part: Patient Interviews

Ayuda Medical gave options to Patients, Before MVP



1. Alarm



2. Speaker



3. Notification to Patient- designated contacts



4. Automatic call to 911



5. Automatic injection of Naloxone

Interviews Provide Objective Evidence

Yes, Designated Contacts [6/6]

- “I love patient chosen contacts” (HR)
- “It’s often not immediate family” (SW)
- “I’m excited to know if they’re in trouble someone will find them” (PRS)
- “Choice of DC is essential to autonomy”
- “I can be a DC” (PRS)

No, 9-1-1 [7/9]

- “I’ve heard horror stories”
- “the police lights are a trigger”
- “75% naloxone rescue refuse transport” (EMS)
- “90% don’t call 9-1-1” (Harm Reduction)

DC: Designated Contact
HR: Harm Reduction
SW: Social Worker
PRS: Peer Support Specialist
EMS: Emergency Medical Services



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Interviews Provide Direction and Save Money

Ayuda Medical gave options to Patients, Before MVP



1. Alarm



2. Speaker



3. Notification to Patient- designated contacts **Yes! 100%**



4. Automatic call to 911 ~~No, >75%~~



5. Automatic injection of Naloxone ~~No, >65%~~



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Relevant Resources

Thank you!

NIH Reporter: Active awards by Institute: see what's being funded

[ProjectReporter.nih.gov](https://projectreporter.nih.gov)

FDA Guidance: Demonstrating endpoints for OUD:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/opioid-use-disorder-endpoints-demonstrating-effectiveness-drugs-treatment-guidance-industry>

FDA Guidance: Patient Engagement:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies>

FDA Guidance: Early Payor Feedback Program:

<https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force>

Surveys

Look for our surveys in your inbox!

We greatly appreciate your feedback! Every survey we receive helps us improve and continue offering our programs.

It only takes **1 minute** to complete!

