



Compassionate Overdose Response: A Structural Perspective

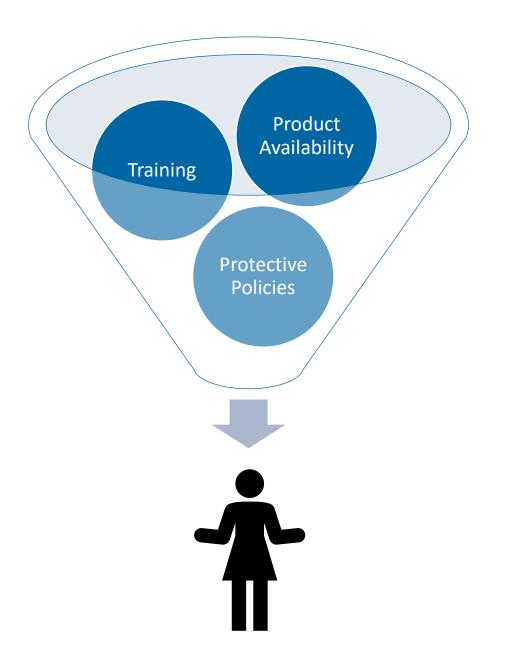
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AGENDA

- 1. A structural perspective
- 2. Areas for Action
- 3. Compassionate Response
- 4. Q&A

What influences bystander overdose response?



KEY INFLUENCES

- 1. Product availability = the dose, route of administration, the accessibility of no-cost naloxone, and saturation level of the community.
- 2. Training = the education provided to the person or that they seek out online or through their social network, training quality and whether it is up to date with best practices.
- 3. Protective Policies = laws that protect a responder from civil and criminal liabilities, the strength of the law, and the implementation of the law, drug criminalization.

IF YOU TAKE NOTHING ELSE AWAY...

- » Overdose response is structurally determined by policy, resource allocation, and product selection.
- >> All decision points can be influenced by fear or compassion.
- >> While there is ultimate personal choice in overdose response, government agencies, policy makers, and programs can set someone up for success reducing the harm for everyone involved.

"The great, gaping hole of the response to the opioid epidemic is that withdrawal is the most important aspect, and it's barely given lip service."

Elizabeth Grey, a person with lived experience of heroin use, quoted by the Washington Post in 2022

WITHDRAWAL IS A RISK AND A CONCERN

- Strong relationship between withdrawal and a person's riskinvolved behavior
 - More frequent withdrawal associated with syringe sharing vulnerability to costly infectious disease
 - >> Weekly or more withdrawal associated with increased odds of nonfatal overdose
- >> We underestimate the dysphoria and pain associated with withdrawal – profound anxiety
- >> It may be perceived as punitive and stigmatizing, because the choice was made to use a higher dose of naloxone than was necessary resulting in fewer 911 calls
- >> Will ensure that someone does not want post-overdose intervention

PRODUCT AVAILABILITY

CROWDED MARKETPLACE

Standard Dose Products – Essential

4 mg IN Spray – Default Standard

High Dose Products – No Evidence of Need



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Scienture Launches REZENOPY, Most Potent Naloxone Nasal Spray for Opioid Overdose Treatment

5 months ago 3 min read



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Key Insights

- Scienture Holdings has secured exclusive U.S. rights to launch REZENOPY, a 10mg naloxone HCl nasal spray, marking the higheststrength opioid overdose treatment available in the market.
- Through collaboration with Kindeva Drug Delivery, REZENOPY will be manufactured and distributed, addressing the growing opioid crisis with annual naloxone market sales reaching \$189 million.
- The FDA-approved treatment offers enhanced effectiveness against potent opioids, featuring a quick-acting nasal delivery system designed for emergency overdose situations.





CRITICAL FDA ROLE

- October 2016: FDA convened a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management to discuss naloxone appropriate dose or doses of naloxone and the role of having multiple doses available in this setting.
 - >> Committee determined the risk of withdrawal was acceptable given the comparable risk of under-dosing naloxone in a community setting
 - >> Minority recommendation for higher initial doses of naloxone
- >> Supported the OTC application with labeling suggestions, etc.
- >> Held other community meetings in 2015 at which harm reduction advocates called for OTC designation

NALOXONE PURCHASING DIAGRAM



TRAINING



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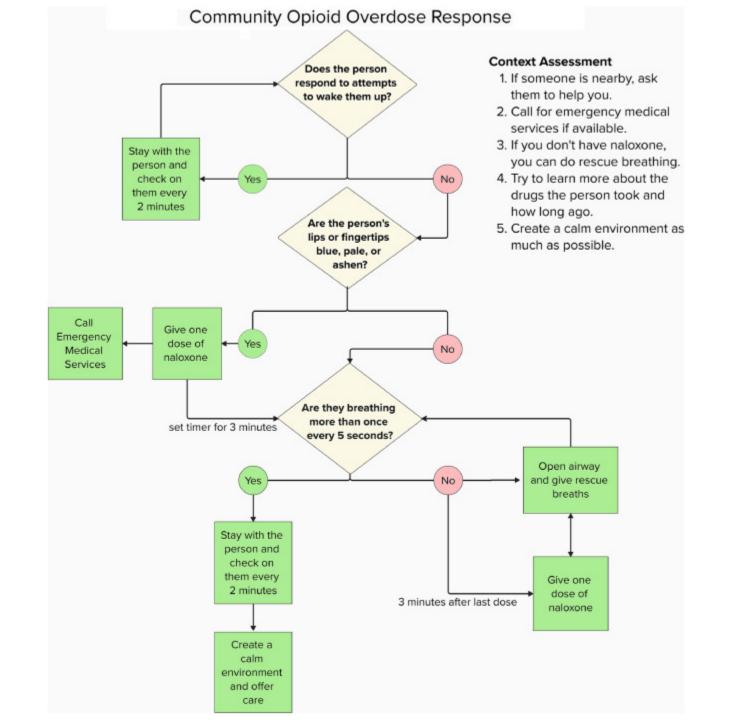
DRUG POLICY

Volume 133, November 2024, 104587

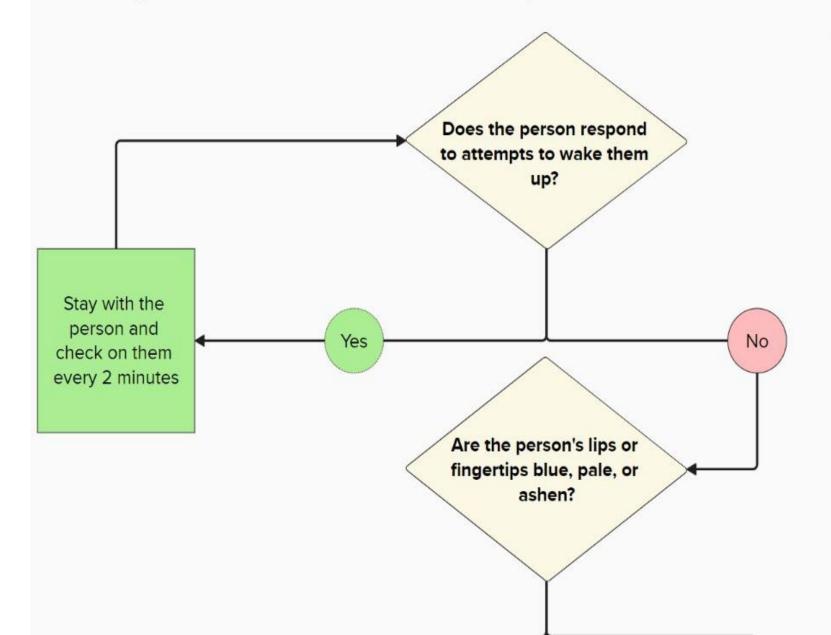
Essay

A call for compassionate opioid overdose response

Erin Russell $^a \ \stackrel{\triangle}{\boxtimes}$, Mary Hawk $^b \boxtimes$, Joanne Neale $^c \boxtimes$, Alex S. Bennett $^d \boxtimes$, Corey Davis $^e \boxtimes$, Lucas G. Hill $^f \boxtimes$, Rachel Winograd $^g \boxtimes$, Lauren Kestner $^h \boxtimes$, Amy Lieberman $^e \boxtimes$, Alice Bell $^i \boxtimes$, Tim Santamour $^j \boxtimes$, Stephen Murray $^k \boxtimes$, Kristin E. Schneider $^l \boxtimes$, Alexander Y. Walley $^m \boxtimes$, T. Stephen Jones $^n \boxtimes$

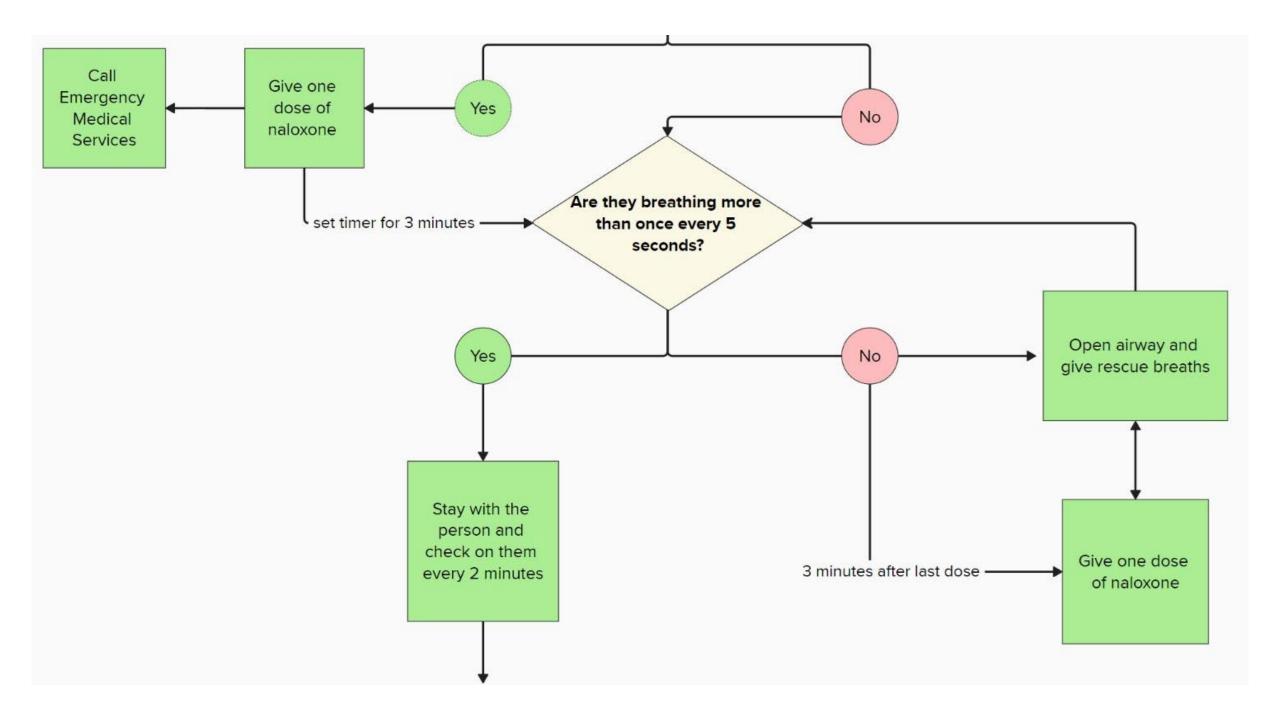


Opioid Overdose Response Standard of Care



Context Assessment

- 1. If someone is nearby, ask them to help you.
- Call for emergency medical services if available.
- If you don't have naloxone, you can do rescue breathing.
- Try to learn more about the drugs the person took and how long ago.
- 5. Create a calm environment as much as possible.



POST-OVERDOSE CARE

- Speak in a quiet tone
- Explain what happened as calmly as possible
- Get on their level by crouching down or kneeling
- Offer water and/or a blanket
- Provide a take-home naloxone kit
- Offer to connect the person to further care



SUPPORTIVE POLICIES

POLICIES THAT SUPPORT ACCESS AND RESPONSE

- 1. Good Samaritan Laws
- 2. Naloxone access laws
- 3. Program requirements
- 4. Cost funds for naloxone to make it no-cost for individuals
- 5. Support for distribution of education and supplies
- 6. Post Overdose Support

POLICY RISK ENVIRONMENT

- Drugs are more available and potent than ever
- >>> The drug supply is unpredictable, contributing to increased overdoses
- >> Treatment is not adapting to changing drug market
- Overdose response looks different now than 5 years ago



COMPASSIONATE RESPONSE

COMPASSIONATE OVERDOSE RESPONSE SUMMIT MARCH 18, 2024





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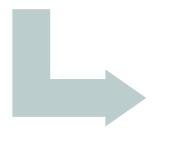
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- 1. People who use drugs should be involved in decisions regarding the research, development, selection, and distribution of opioid overdose reversal products.
- 2. Regulatory agencies and pharmaceutical manufacturers should carefully consider and communicate the risk and duration of withdrawal associated with higher dose and longacting opioid antagonists.
- 3.Take-home naloxone kits should include at least two doses of an IM product containing 0.4 mg or an IN product containing ≤4 mg.
- 4. At this time, high dose and long-acting opioid antagonists have no use in acute opioid overdose response.
- 5. Overdose response educational materials, instructions on overdose response, and training should emphasize the restoration of breathing, avoiding withdrawal, and compassionate post-overdose support and care.

STRUCTURAL COMPASSION - SUMMARY

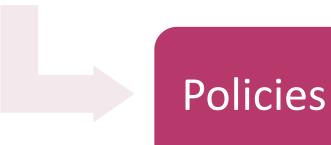
Product

- Select or request compassionately dose products
- Create feedback loops with people who overdose and programs to inform product purchasing



Training

- Fund training and QI of harm reduction programs
- Ensure standards without requiring training



- Evaluate policies and propose changes
- Reduce policy barriers to naloxone access
- Advance facilitating policy for harm reduction programs



THANK YOU