

Attorney argues against SAMHSA overdose toolkit

In the February 26 issue, *ADAW* wrote about the “toolkit” on overdose prevention and rescue from the Substance Abuse and Mental Health Services Administration (SAMHSA) that calls for giving one dose (4 mg) of naloxone initially followed by a second dose two or three minutes later. The toolkit references studies that show increased doses of naloxone are not necessary in the fentanyl era. This is despite a study published in January from the U.S. Food and Drug Administration which found that 35% of overdose victims would die from that two-to-three-minute wait for the second dose.

The toolkit focused on “precipitated withdrawal,” and warned that overdose victims could experience this if given too much (or any) naloxone. It did not discuss the risks, i.e., death, of not giving enough.

For example, in a list of rescue medications, the toolkit notes the following about Kloxxado, which is an 8 mg intramuscular dose of naloxone: “High dose compared to other products; may cause severe withdrawal symptoms in people with opioids in their body.”

We asked Robert Kent, president of Kent Strategic Advisors and former general counsel for the federal Office of National Drug Control Policy, and before that general counsel for the New York State Office of Addiction Services and Supports, to comment on this. Below is what he said.

“As an attorney, I would have advised against including that information. The government should strenuously avoid doing or saying anything that could be perceived as supporting or questioning any product, especially one that has been approved by the FDA [as] safe and effective.”

“Beyond that, their ‘panel of experts’ appears to represent only one segment of folks who use naloxone, those who work with folks who knowingly use fentanyl. There are many others who are unknowingly exposed to fentanyl where the use of any of the products is unlikely to produce significant withdrawal symptoms.”

“I wish SAMHSA would use their time to force states to maximize the use of [state opioid response] SOR, and other SAMHSA grant funds to purchase as much naloxone as possible. Every state should issue competitive procurements to purchase naloxone to ensure that they are purchasing as much as possible. Every state should end these exclusive arrangements with one particular company.”

Below is the chart of rescue medications from SAMHSA’s toolkit. •

OORMS AVAILABLE TO THE PUBLIC*

OORM	Brand	Formulation	Dosage	Availability	Considerations
Naloxone	N/A	Adaptable Nasal Spray	2 mg/ml	Rx, community naloxone distribution, harm reduction organizations	Assembly required to attach nasal spray adapter to needle-less syringe. Not approved by FDA. Possible to titrate to meet the needs of the patient and facilitate a gentler overdose reversal with potential for less severe withdrawal in people with opioids in their body.
Naloxone	RiVive™	Single-use Nasal Spray	3 mg	Rx, OTC, community naloxone distribution, harm reduction organizations	Lower dose can facilitate a gentler overdose reversal with less severe withdrawal in people with opioids in their body.
Naloxone	Narcan, generic	Single-use Nasal Spray	4 mg/ 0.1 ml	Rx, OTC, community naloxone distribution, harm reduction organizations	May cause withdrawal symptoms in people who have opioids in their body.
Naloxone	N/A	Single-dose Vial Intramuscular Injection; can also be given intravenously or subcutaneously	0.4 mg/ml	Rx, community naloxone distribution, harm reduction organizations	Has been studied and used in the real world to reverse overdoses for decades; cheapest naloxone available; easy to use.
Naloxone	Zimhi®	Intramuscular or subcutaneous Auto-Injection	5 mg/ml	Rx, community naloxone distribution, harm reduction organizations	Accessible product format that auto-injects the medication; high dose compared to other products; may cause severe withdrawal symptoms in people with opioids in their body.
Naloxone	Kloxxado®	Single-use Nasal Spray	8mg/0.1 ml	Rx, community naloxone distribution, harm reduction organizations	High dose compared to other products; may cause severe withdrawal symptoms in people with opioids in their body.
Naloxone	Opvee	Single-use Nasal Spray	2.7 mg/0.1 ml	Rx, community naloxone distribution, harm reduction organizations	Longer lasting than naloxone but may cause severe extended withdrawal in people with opioids in their body.

Source: SAMHSA

*Editor’s note: This “Considerations” column of this chart has many incorrect assumptions, including that there having a “gentler reversal” is better than death or brain damage. See FDA study: <https://onlinelibrary.wiley.com/doi/10.1002/adaw.34010>