

Expert discusses FDA approval of OTC naloxone

March 30 2023, by Laura Bailey



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The Food and Drug Administration has approved a recommendation that naloxone, the opioid overdose reversal drug commonly known as Narcan, be made available over the counter without a prescription.



Since 2013, Chin Hwa (Gina) Dahlem, a <u>nurse practitioner</u> and clinical associate professor of nursing, has developed and delivered naloxone training to thousands of first responders and laypeople. She discusses what OTC naloxone would mean in Michigan and beyond.

Is OTC naloxone a good idea?

Yes, this is generally a great idea to increase access to a lifesaving medication. We know that naloxone distribution is a cost-effective strategy to prevent overdose deaths and empowers people to save lives. Making it available over the counter removes barriers to access for average Michigan citizens and removes the possible stigma of needing to request it at the <u>pharmacy</u> counter.

Under this approval, how would one get naloxone?

It would be like any OTC medication. Anyone could simply walk into a pharmacy and buy it, like Tylenol. A person's insurance will not be billed.

How do people in Michigan get naloxone now?

Most Michiganders get naloxone either through a pharmacy or through free distribution programs. The Michigan Pharmacy Standing Order allows anyone to go to a pharmacy that is registered under the standing order to obtain naloxone without a prescription. The pharmacist would then bill the naloxone through the person's insurance and the person pays a copay to obtain the naloxone. This copay is sometimes so high that it's a barrier to obtaining naloxone.

There are also free means of accessing naloxone. The state of Michigan has a portal where individuals and <u>community organizations</u> can access



Narcan for free. Some pharmacies also use the portal to distribute naloxone for free. In addition, Narcan vending machines and dispensing boxes are being placed in key hot spots to increase <u>public access</u> to naloxone such as public libraries, health departments and jails. There are multiple initiatives through syringe service programs, emergency departments and other community agencies that distribute naloxone for free using federal or <u>state funding</u>.

All of these programs have increased access to naloxone to people who need it the most and their social networks, and hopefully will continue to receive funding. Addressing our state's opioid crisis requires all of the current programs and more.

What are some barriers to implementation of OTC naloxone?

Cost is a barrier. We need to ensure the cost of OTC naloxone is not a barrier to access, particularly for people who will need it the most. For instance, in <u>our study</u>, the average cost of intranasal naloxone in Michigan through the pharmacy standing order was \$127. Depending on the insurance copay, Narcan can be as much as \$149. Full coverage of nonprescription naloxone without a copay would facilitate this process.

There are two notable organizations that have worked hard to reduce the cost of naloxone. Remedy Alliance, a nonprofit, works with other programs to distribute intramuscular naloxone at a fraction of the cost compared to intranasal naloxone. In addition, Harm Reduction Therapeutics has developed a 3 mg intranasal naloxone that will be offered OTC. However, any generic intranasal naloxone will be more expensive than intramuscular naloxone.

We should also ensure that increasing access to naloxone via OTC does



not result in drug supply shortages. So it would be important to have an adequate supply to meet the demands.

Given that the standing order has not been as effective as it could be, will stores be willing to stock it OTC?

I would hope so. Naloxone is a widely accepted practice and it has been shown to save lives. Naloxone should be part of everyone's emergency kit, and hopefully with increased education and distribution it will be. In spite of the standing order, not all pharmacies in the state have chosen to stock and make naloxone available. It's hard to say what all of their reasons are, but making naloxone available OTC removes the stigma of needing to speak to someone at the pharmacy counter, frees up pharmacist resources for other tasks and creates a barrier-free process for anyone who wants to procure naloxone. I am hopeful that stores will choose to participate and stock OTC <u>naloxone</u>.

What is the current state of Michigan's opioid crisis?

The number of overdose deaths appears to be trending downward in 2022, as compared to 2021 when we experienced more than 3,000 overdose deaths. This shows the impact of statewide efforts to address the opioid crisis, but also highlights the need to continue to fund substance use disorder programs that increase access to harm reduction supplies, recovery supports and treatment services.

Provided by University of Michigan

Citation: Expert discusses FDA approval of OTC naloxone (2023, March 30) retrieved 27 April 2024 from <u>https://medicalxpress.com/news/2023-03-expert-discusses-fda-otc-naloxone.html</u>



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