

Introduction

Opioid related deaths in the US are increasing at a staggering rate. The CDC estimates that the number of deaths related to opioid overdose has tripled over the last 15 years.¹ In 2014 there were 28,647 opioid overdose deaths – more than any other year on record.¹ This number is even more devastating given the propensity of opioid overdose to strike at such a young age. This is quite a contrast from other substances such as alcohol and tobacco where users often fail to achieve sobriety early in life, but may live long enough to do so in later decades. Thus, an aggressive approach to prevent overdose is critical in order to give opioid users the best chance of achieving recovery and chance at a fulfilling life.

The overdose reversal drug naloxone has achieved dramatic results in combatting the opioid epidemic, yet given the record numbers, additional approaches must be considered. The efficacy of this medication is limited by having the medication on site as well as the presence of a caring bystander. The importance of this limitation cannot be understated, because overdoses are unpredictable and opioid users are not always nearby other capable individuals.

Given that so many people use opioids alone, and naloxone is incredibly effective when administered early on during the course of overdose, it would follow that a device capable of delivering naloxone automatically could have a dramatic impact. It can take over 10 minutes for EMT personnel to arrive once alerted to an overdose, and often there is a delay in calling them, both of which can dramatically raise the risk of death following accidental overdose. By addressing these issues and improving the way in which naloxone is administered, thousands of lives could be saved every year.

Proposed Solution

The Opioid Recovery Bracelet (ORB) is a novel design that can detect signs of overdose and automatically administer life-saving naloxone without the participation of bystanders or first responders. The ORB combines wearable technology that can detect physiological changes of overdose, and activate the device to inject naloxone into the patient's tissues. This device obviates the need for bystander administration, which is a major disadvantage of existing solutions.

¹ National Center for Health Statistics, CDC Wonder

Physiologic parameters including pulse oximetry and heart rate could serve as inputs into an algorithm that determines necessity for medication administration. A pressurized injector, electrically activated, will eject a needle through which a dose of naloxone will be infused.

Background

Often innovation is a product of desperation. I have seen too many of my patients die from opioid overdoses, and I've decided to create something that can stop this. As an addiction psychiatrist, I have borne witness to the pain and struggle my patients and their families go through after an overdose. This has given me a much greater understanding and appreciation of the disease of opioid addiction. While patients may have chosen to take that first opioid, they certainly did not choose to become addicted.

My experience in the outpatient treatment setting has permitted me to see the course of treatment. I know that people get better, but that it is rarely on the first attempt. I know that patients do not want to go to jail, lose their jobs, homes, and families. They most certainly don't want to die from an accidental overdose. I know that some want to achieve sobriety, while others simply want to avoid the consequences of their use. It is this expertise that allowed me to create an idea such as the Opioid ORB – one which could save lives, and yet still be accepted by patients since it would not prevent users from getting high or managing withdrawal symptoms.

Prototype

The ORB would be a bracelet worn on the wrist. It would be discrete, light in weight, and appear similar in design to other watches or fitbits to reduce the chance that it could be used to easily identify opioid users. It would measure physiological data in real-time and trigger a response once an algorithm detected an overdose had occurred. Early research supports the use of pulse oximetry as the best tool for determining overdose given the ease of recording this data with established technology, and its utility at recognizing overdose. Still, other data such as respiratory rate using photoplethysmography could be used to increase the accuracy and efficacy of the device, though this will have to be evaluated further.

The device will recognize changes in pulse oximetry that occur during overdose, yet not react to changes that occur simply during typical opioid use. To alleviate concerns that patients may have about inadvertent naloxone injections, there will be an abort or “snooze” button that may be pressed in the unlikely event of a false positive.

To ensure the device is worn during opioid use, and not easily misplaced, the device will lock onto the wrist and not be easily removed. Battery life should be expected to last about a month which will enable patients enough time to get replacement batteries without being vulnerable to overdose. Each ORB will contain 2 vials of naloxone 1.2 mg. This dose permits the reversal of overdose even due to large doses of synthetic opioids like fentanyl and carfentanil. Having 2 vials will permit a second dose to be administered should the first not be sufficient, but also to provide a safety net until the device can be serviced after an overdose reversal.

Naloxone loses efficacy when sustained at hot temperatures, therefore the medication will be kept separate from the patient’s skin, and the device will be designed such that it is cooled through mechanical vents with natural arm swing. It is unclear at this time exactly how quickly it will lose its efficacy in hot temperatures, so perhaps more frequent refills may be required in hot locations during peak temperatures.

Table 1 Device Process

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| <ol style="list-style-type: none">1) Device identifies change in physiological data consistent with overdose2) Algorithm initiates activation3) Audible alert for patient of impending injection4) If patient does not execute override, device will deliver injection5) Device may notify first responders or significant others via wireless communication6) Device continues to monitor physiologic parameters, determines if 2nd dose required7) After activation, naloxone cartridge must be returned for refill |
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Target Population

Because every opioid user is at risk for overdose, this device could reasonably be offered to anyone prescribed an opioid. Patients in recovery from opioid addiction are at increased risk of overdose after a period of sobriety because of decreased opioid tolerance. Thus, our device is an excellent adjunct to standard addiction therapies as it can keep a patient alive throughout treatment. This would include active intravenous opioid users, with particular

concern for those with a history of overdose. The opioid recovery bracelet is the only solution that can save the lives of patients who use alone. Risk stratification would likely be required so the device may first be offered to those patients with the highest risk of opioid overdose.

Cost and Reimbursement

A device with the level of sophistication to automatically detect and treat an opioid overdose will likely cost more than other existing solutions of overdose reversal. Nevertheless, establishing a cost for this device could be equated with establishing the cost of a life given its proposed use. We believe that health insurers will recognize the additive value of this device over current solutions and provide coverage in select patients, as they ultimately have done with the naloxone kits.