OneUp: A Lifesaving Wearable Device

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ABSTRACT
Opiate overdose is a significant and growing cause of death in the United States. The current standard practice for intervention in an active opiate overdose is administration of naloxone hydrochloride (AKA: naloxone, or Narcan), a potent opioid antagonist that can be safely and effectively administered by intranasal, intramuscular or intravenous mechanisms. Existing means for delivery of naloxone require the presence of a respondent who is aware of the overdose, willing to respond, and able to do so. This report proposes the design of a wearable naloxone autoinjector that uses photoplethysmography to identify overdose and trigger a sequence of response elicitations leading to intramuscular injection of naloxone.

Author Keywords
Overdose; opiate; wearable; autoinjector; photoplethysmography; naloxone, Narcan.

PROBLEM
In 2010 opiate overdose killed 19,687 Americans, representing a fourfold increase since 2000 and making it the single leading cause of fatal overdoses.[1,2] The current standard practice for intervention in an active opiate overdose is administration of naloxone hydrochloride (AKA: naloxone, or Narcan), a potent opioid antagonist that can be safely and effectively administered by laypersons and emergency services responders via intranasal, intramuscular or intravenous mechanisms.[3,4] Existing means for delivery of naloxone require the presence of a respondent who is aware of the overdose, willing to respond, and able to do so. Reliance upon the presence, awareness, willingness and ability of a bystander/responder poses a significant limitation to the delivery of naloxone. The primary strategy to address this limitation has been the recommendation that users not consume opiates without potential respondents present. This approach is potentially effective if followed, but presents a challenging behavioral adaptation and continues to rely upon a second party to accurately detect overdose and intervene appropriately. The recently-released EVZIO autoinjector simplifies the administration of naloxone, but retains the reliance upon respondents who are present, aware and willing to intervene in the overdose. [5] The design described in this proposal seeks to reduce reliance upon second parties to recognize overdose and to effectively administer naloxone. The aim of the design is to provide opiate users with a tool to reduce risk of fatal opiate overdose while simultaneously acknowledging awareness of that risk and increasing autonomy and self-efficacy surrounding efforts to address it.

PROPOSAL
The proposed design is for a sensor-enabled naloxone autoinjector to be worn around the users' upper calf. This positioning allows for placement of the autoinjector component over a suitable site for intramuscular injection, as well as placement of the sensor array over a major artery. The autoinjector component is comprised of two ampules of .4mg naloxone in .4ml of carrier solution, arranged in a pair of automatic, machine-activated syringes oriented towards the user's calf muscle. The autoinjector component also contains the batteries, MicroUSB charging poort, control circuitry, a vibration motor and speaker, as well as an external button used to register user input. The sensor array consists of three sets of LED lights and photodiodes, used to conduct photoplethysmography on the anterior tibial artery.[6] In this application photoplethysmography is used as a mechanism to monitor respiratory rate, which is a primary indicator of opiate overdose.[7]

Precedents for automated, wearable medical intervention devices can be found among modern insulin pumps and implantable cardioverter-defibrillators. Both classes of device use continuous physiological monitoring to trigger therapeutic interventions that previously required user or second-party actions. Those precedents also employ interventions with significantly greater consequences for false-positive activation or adverse reactions. In the case of naloxone, no adverse events are associated with administration when an overdose is not occurring. From an innovation perspective, this proposal represents the first documented application of automatic, device-based monitoring and intervention to the problem of opiate overdose.

USAGE SCENARIO

The use of the device begins when the user straps the device to their upper calf. The inside face of the autoinjector component includes a capacitive sensor mounted on a physical detent, used to determine that the device is being worn firmly against the skin. Simultaneous activation of the capacitive sensor and detent will activate all three units of the photoplethysmography array, which will begin measurement of respiratory rate. If the device detects respiratory depression, it will deliver an audible cue to the user to confirm activation, and will disable any photoplethysmography components that are not generating a significant signal. While being worn, the device monitors respiratory rate for 15 seconds each minute. If breathing drops below a safe threshold, a sequence of response elicitations is initiated. The use of response elicitations is based upon current standard practice for identifying potential opiate overdose.[7] The first elicitation will be tactile, using vibration to prompt users to press the heart-shaped button placed on the outside of the device. If no response is given after one minute, an audible prompt is delivered. If not response is given to the audio prompt after one minute, the autoinjector is activated and the first dose of naloxone is administered, followed by audio instructions to press the device's response button and seek emergency care. If no response is given after one minute, a second dose of naloxone is administered, followed by continued instructions to seek emergency care. If the patient activates the response button at any point in this sequence, the device resets to the monitoring phase and continues to operate as described above.

Renderings of the proposed design can be found as Figures 1 and 2 below, with the photoplethysmography sensors and response button identified as items A and B respectively on Figure 1, and the detent and capacitive sensor identified as item C in Figure 2.

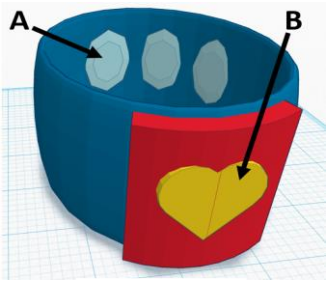

Figure 1.

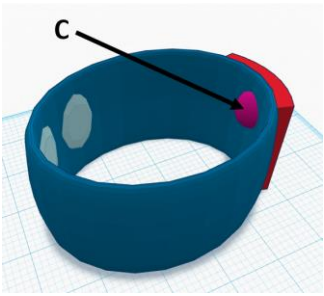

Figure 2.

EVALUATION

Evaluation of this proposal was conducted via anonymous, one-on-one key informant interviews in current opiate users and staff members from Harm Reduction programs in California and Massachusetts. The autoinjector portion of the rendering depicted in Figures 1 and 2 was printed in red ABS plastic and used as a prop to facilitate discussion. That model was was paired with a store-bought 'knee band' that allowed users to experience the sensation of putting on and wearing the device. Interviews followed a semi-structured format, with elicitations of feedback on potential device features and interviewees' feelings about them. Feedback was recorded as text by the interviewer after each session. Future evaluations would include asking users to wear a test version of the device containing sensor components, but without naloxone or syringes, as a means for identifying the risks or patterns of false positive activation.

DESIGN DECISIONS

The original concept for this proposal included a number of features that were removed per user feedback. The original concept called for a remote respiration sensor, modelled after the Spire device [8], that would pair with the autoinjector and a user's mobile phone via low-power Bluetooth connections. Early key informant interviews indicated that any wireless connectivity would undermine the perceived security and autonomy of the device, and would associate it too closely with products used to enforce legal house arrest mandates. That input led to the removal of all connectivity functions, and to the integration of sensors into the device itself.

While the original design included a single dose of naloxone, conversations with Harm Reduction and overdose prevention experts led to the inclusion of a second dose in the final design. This is consistent with best practices for naloxone distribution, and is based on the shorter metabolic half-life of naloxone as compared to common opiates. That difference in half-life can lead to relapse into overdose once naloxone is metabolized, necessitating administration of a second dose. In the interest of keeping users alive long enough to seek emergency care, a second ampule of naloxone, along with a second autoinjector syringe mechanism, has been included in the final design.

Another design decision influenced by key informant interviews is the inclusion of a mechanism for manual emergency administration of naloxone. An informant posed a hypothetical scenario in which a user was in a position to intervene in a witnessed overdose, but unable to attach and activate the device in time to intervene effectively. This led to the inclusion of an 'Emergency Mode' that allows users to activate the autoinjector with a specific sequence of button pushes. Design of that Emergency Mode also identified the utility of a backup battery that could be used to activate the controller if the primary battery were

depleted, ensuring that emergency use would be possible between charges.

LESSONS

Several important lessons arose in the course of designing this device. The first related to the ease and power of prototyping as a means to facilitate key informant interviews. The first several interviews employed diagrams and verbal descriptions, and were less productive of feature critique and emotional response. A quick and low-cost model changed the nature of subsequent interviews, leading to more clear and concrete feedback

A second lesson regarded the liabilities involved in making presumptions about attitudes and intentions about technology adoption. Key informants with otherwise skeptical views of digital and medical technology were eager to share feedback on the design, and expressed interest in testing future iterations. Early evidence of that eagerness influenced the interviewer to reach out to a more diverse group of key informants.

A third lesson regarded the importance of maintaining fidelity to the concept's inspirations and motivations. Designing products and services for stigmatized populations can pose temptations to pivot towards more socially accepted target audiences. Initial proposals for this device shied away from injection drug users in favor of a focus on pain management patients and others with medically-sanctioned opiate use. That pivot strayed from the project's original inspiration, and refocused design considerations on a population already served by the biomedical services industry. Returning to a focus on injection drug users reinstilled a sense of innovation and purpose in the project, while reemphasizing the core motivation towards serving the underserved.

FUTURE WORK

This concept is central to a workshop proposal submitted for the Harm Reduction Coalition's 2014 National Harm Reduction Conference. That workshop will focus on design thinking and human-factors research to inform development of novel naloxone products. Designs will also be shared and discussed with organizations currently developing and distributing naloxone products, with the aim of providing insights into consumer attitudes, belief and intentions regarding next-generation naloxone delivery devices.

ACKNOWLEDGMENTS

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