Naloxone Distribution Program: Program Summary

Background -

- 2017:
  - US drug overdose deaths rose from 16,894 in 1999 to 70,237 in 2017 with the majority of overdoses due to opioids[1]
  - For the first time on record, the National Safety Council finds the odds of dying from an accidental opioid overdose to surpass the odds of dying in a motor-vehicle crash[2]
  - The opioid crisis is declared a national Public Health Emergency under federal law, effective immediately.[3]

Prior processes -

1. Clinician identifies a patient at risk for opioid overdose
2. Clinician writes a prescription
3. Patient fills prescription in pharmacy
4. Alternative- Providing naloxone in hand in the ED
   a. Clinician identifies a patient at risk for opioid overdose
   b. Clinician writes a prescription
   c. Prescription is sent to the pharmacy (often via hand delivery by ED pharmacist)
   d. Prescription is filled and sent back to the Emergency Department (often via hand delivery by ED pharmacist)
   e. ED Pharmacist trains patient in naloxone use and gives kit to patient

Problems with prior process:

- Most potential recipients are never identified
- Prescription writing and filling rates are very low[4].
- Providing naloxone kits in hand in the ED is cumbersome, inefficient, and underutilized
- After hours, ED pharmacist is not present and in hand naloxone is unavailable
- Minimal impact on community health
- Low potential to save a significant number of lives
- Ineffective response to the opioid crisis and national Public Health Emergency

[1] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

[2] https://www.nsc.org/in-the-newsroom/for-the-first-time-were-more-likely-to-die-from-accidental-opioid-overdose-than-motor-vehicle-crash

[3] https://www.whitehouse.gov/opioids/

[4] One prior study investigating naloxone prescription and filling rates found that only 11% of ED patients at risk for opioid overdose were prescribed naloxone, and only 1.6% of ED patients actually filled those prescriptions (Lebin 2017). Highland ED has an estimated 7150 annual visits by people who inject drugs, however in 2018 only 320 total ED prescriptions were written for naloxone and 88 prescriptions were filled by the outpatient pharmacy,

New process background -

- 2013:

  In response to the opioid crisis California Assembly Bill 635 (AB-365) passed and amends *Section 1714.22 of the CA Civil Code* to allow a licensed health care provider authorized to prescribe an opioid antagonist to issue a standing order for the distribution and administration of naloxone.[5]

- 2018:

  Naloxone Distribution Project (NDP) funded by SAMHSA and administered by the California Department of Health Care Services (DHCS) to combat opioid overdose-related deaths throughout California. Starting in October 2018, qualified organizations and entities (schools, libraries, emergency medical services, etc.) are able to submit applications to receive free naloxone from DHCS for dispensing at these locations.[6]

- 2019:
  - [HOSPITAL NAME] Standing Order and [HOSPITAL NAME] Standard Operating Protocol and NDP Application created in partnership with Pharmacy department
  - NDP Application, [HOSPITAL NAME] Standing Order, [HOSPITAL NAME] Standard Operating Protocol reviewed by DHCS
  - DHCS approves application and awards free naloxone for distribution at [HOSPITAL NAME]

Program Goals

- Reduce opioid overdose deaths through the efficient provision of free naloxone.

- Take action in the manner promoted by the Surgeon General in his **Surgeon General's Advisory on Naloxone and Opioid Overdose**:

  I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone. For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, knowing how to use naloxone and keeping it within reach can save a life.

  "increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic"[7]

[5] http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140AB635

[6] https://www.dhcs.ca.gov/individuals/Pages/Naloxone_Distribution_Project.aspx

[7] https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html

New process:

1. Any [HOSPITAL NAME] staff member can identify a [HOSPITAL NAME] patient or visitor at risk of an opioid-related overdose, or a patient or visitor who is a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose
2. Any [HOSPITAL NAME] staff member (examples include MD, PA, NP, Pharmacist, RN, LVN, Health Coach, Substance Use Navigator, Clinical Social Worker, Research Staff, Emergency Department Technician, Clerk, Medical Assistant, Security Guard) may act as an Overdose Prevention Educator provided they complete the standardized training video and abide by the Standard Operating Procedure
3. An Overdose Kit containing a minimum of 2 naloxone nasal spray devices and an instructional brochure (located on box flap) is obtained by accessing a storage area at [HOSPITAL NAME]
4. Overdose Prevention Educator provides education while reviewing instructional brochure with patient
    a. The instructional brochure is produced by the manufacturer Emergent Biosolutions (formerly Adapt Pharma) and is provided with every kit in the form of a box flap brochure
5. The Overdose Kit is directly dispensed
6. Dispensing is documented in log sheet. For patients, dispensing also documented in EMR.

Improvements with new process

- Streamlined process using **distribution by standing order** rather than traditional prescription
- Many [HOSPITAL NAME] staff engaged in identifying eligible recipients and helping distribute and educate
- Increased identification of the large target population already visiting [HOSPITAL NAME]
- Low threshold for target population to receive naloxone
- Simplified workflow for staff to deliver naloxone
- Visitors included
- Available 24/7
- Naloxone provided free without copay or self pay
- Increased awareness among staff, patients and visitors
- Easier compliance with AB-2760 (see below)
- Much bigger impact on community health
- Far greater potential to save lives
- More appropriate response to the opioid crisis and national Public Health Emergency

Timeline:

- Program start [date]
- [#] Naloxone Kits estimated arrival [date]

Training:

- Standardized training via California Department of Public Health (CDPH) produced 11 minute training video[8] [9]

[8] https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/SACB/pages/naloxonegrantprogram.aspx#

[9] https://www.youtube.com/watch?v=nurz9qPGKws&feature=youtu.be

Storage:

- DHCS NDP requires "Separate storage of naloxone received through the program from other medications that may be billed to patient insurance"[10]
    - Kits are stored in a cabinet in the ED charting room that is accessible by Overdose Prevention Educators. The charting room is secured by a digital commercial keypad lock. A reserve supply of kits is secured in the program director's office, where access is limited to the program director.
    - These storage areas are separate from other medications that may be billed to patient insurance and are similar to naloxone storage areas used at other NDP grant entities such as libraries, schools, and community organizations
- Training completion and kit dispensing documented via standardized process in log sheets located at storage areas.

Expected impact

[HOSPITAL NAME] is a busy urban trauma center with an annual patient census of [census] visits located in a community highly impacted by the opioid crisis.

- In 2018, using a closed response survey to assess the prevalence of patients who use injection drugs, we found an 11% prevalence of people who inject drugs among our patient population.[11] (approximately [#] ED visits in 2018)
- In addition we have a large population of people who ingest, smoke and snort opioids and stimulants that are now being unexpectedly exposed to fentanyl, often with catastrophic results.
- We also have other large patient populations at risk for overdose for which prescribers are now required by California state law (*Business and Professions Code Article 10.7 of Division 2 of Chapter 1*[12]) to provide naloxone and overdose education:

    > (A) The prescription dosage for the patient is 90 or more morphine milligram equivalents of an opioid medication per day.
    >
    > (B) An opioid medication is prescribed concurrently with a prescription for benzodiazepine.
    >
    > (C) The patient presents with an increased risk for overdose, including a patient with a history of overdose, a patient with a history of substance use disorder, or a patient at risk for returning to a high dose of opioid medication to which the patient is no longer tolerant.

Given the high number of patients and visitors to [HOSPITAL NAME] ***at risk for overdose; as well as family, friends, and community members in contact with individuals at risk for overdose; we anticipate direct distribution of [#] free naloxone kits to these target populations to save lives and to have a significant impact on the health and safety of our patients and the community at large.***

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[10] https://www.dhcs.ca.gov/individuals/Documents/Naloxone_Distribution_Project_FAQ_03.01.19.pdf

[11] White et al. "The Prevalence of Injection Drug Users and Blood-Borne Viral Infections among Emergency Department Patients." Abstract submitted to Society for Academic Emergency Medicine (SAEM), 2019.

[12] https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB2760