

DNP Final Report: Formative Evaluation of an Opioid Overdose Prevention Program at a Center

for Integrative Health

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### Abstract

This paper describes the formative evaluation of a naloxone program at a center for integrative health. The aim of this project was a small part of a larger, nationwide effort to mitigate opioid overdose death fatalities. The scope of the opioid epidemic is growing and current literature supporting the efficacy of naloxone and opioid overdose prevention programs highlights the need for widespread collaboration in addressing this problem. The clinical project involved initiating an opioid overdose prevention program to train staff in the outpatient clinic setting who work with high-risk populations. A repeated measures design was used to evaluate changes in staff self-efficacy, willingness to assist, and general knowledge and comprehension prior to and 30 days after undergoing opioid overdose management and naloxone training. Participants were found to have higher than expected levels of pre-existing knowledge and comprehension and showed post-training improvement in both self-efficacy and willingness to respond in an opioid overdose situation. Ultimately, the clinic established an opioid overdose prevention protocol by utilizing the guidance of the Oregon Health Authority, 35 staff members were successfully trained in opioid overdose recognition and treatment, and the clinic obtained multiple rescue doses of the opioid overdose reversal medication, naloxone, for on-site emergency utilization. This project successfully initiated training for clinic staff and helped to acquire access to naloxone; in this way, the clinic is now better able to safely serve its high-risk population. There are ongoing barriers with regards to widespread naloxone distribution and access. Moving forward, the national movement to mitigate opioid abuse/misuse and opioid-related deaths will require the support of public policies that support and implement widespread opioid overdose prevention and treatment education, increased access to and distribution of naloxone, and increased access to addiction treatment and medication-assisted treatment programs.

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**The Clinical Problem**

In 2015, opioid overdoses resulted in 33,091 fatalities in the United States, a number that has quadrupled since 1999 (CDC, 2016). According to the Oregon Health Authority, an average of 3 Oregonians die each week from prescription opioid overdose and many more develop an opioid use disorder (OHA, 2016). As these numbers rise, more families are affected. Between 2013 and 2014, the rate of opioid overdose fatalities increased 14 percent from 7.9 per 100,000 to 9.0 per 100,000 (Rudd, Aleshire, Zibbell, & Gladden, 2016).

Opioids include drugs such as morphine, oxycodone, hydrocodone, methadone, fentanyl, tramadol, and heroin. According to McAuley, Aucott, and Matheson (2015), the most notable risk factors for opioid overdose include: loss of tolerance (e.g. following release from prison or recent detoxification treatment), poly-drug consumption, use via injection, male gender, and history of non-fatal overdose. However, opioid abuse and mortality affects a wide spectrum of victims; 2014 opioid overdose death rates increased significantly in people of both genders, persons aged 25–44 years and  $\geq 55$  years, non-Hispanic whites and non-Hispanic blacks, and in the Northeastern, Midwestern, and Southern regions of the United States (Rudd et al., 2016). In Oregon, there were an estimated 12.8 deaths from overdose per 100,000 inhabitants in 2014 (CDC, 2016).

Opioid overdose can be reversed given timely administration of naloxone, an opioid antagonist, and subsequent emergency medical treatment. Recent evidence indicates that communities with better access to naloxone and opioid overdose training had significantly lower opioid overdose death rates than those that did not (Walley et al., 2013). Widespread distribution

of naloxone and training of the general public in its use will help to mitigate the rising number of opioid overdose fatalities.

The Quest Center for Integrative Health (Quest) is a community-based health center in Portland, Oregon. Quest provides physical and mental healthcare and drug and alcohol addiction treatment to insured, underinsured and uninsured clients, most with Medicaid and Medicare (Quest, 2016b). Of approximately 20,000 patient encounters in 2015, 6,380 were for patients undergoing drug and alcohol addiction treatment (Quest, 2016a).

During the past year, a patient overdosed on opioids while at Quest for treatment. After the event, the management team noted the absence of a standardized procedure for response to overdose in the clinic and recognized the need for a staff-oriented opioid overdose prevention program (OOPP) with on-site access to naloxone. Almost 32% of patient encounters at Quest in 2015 were for patients seeking addiction treatment services, a population that has been identified as high-risk for opioid overdose (Rudd et al., 2016). In addition, Quest also provides care to patients with conditions such as chronic pain and cancer who often use opioids prescribed elsewhere.

The purpose of this project was to fulfill the request of Quest management to establish an opioid overdose treatment protocol, to initiate an OOPP, and to obtain access to on-site naloxone kits. This effort was an essential part of Quest's overall goal to protect patients and prevent opioid overdose fatality. These goals fall in line with current literature highlighting the alarming rise in opioid overdose fatalities (Rudd et al., 2016) and evidence supporting the efficacy of OOPPs to train laypersons to administer naloxone and assist in an opioid overdose scenario (Giglio et al., 2015). My aim, through this project, was to contribute to the nationwide effort to reduce preventable death from opioid overdose.

## **Literature Review**

A review of current literature was conducted utilizing online databases PubMed/Medline, Cochrane Library and Google Scholar. Searches were performed using different combinations of search/MeSH terms including ‘naloxone’, ‘opioid overdose’, ‘naloxone overdose prevention’, ‘naloxone program’, ‘naloxone training’, ‘naloxone distribution’, ‘outpatient naloxone’, ‘‘naloxone rescue kits’, ‘provider training’, ‘OOPPs’, and ‘OEND.’ Filters included ‘meta-analysis’, ‘randomized controlled trial’, ‘clinical trial’, ‘review’, ‘systematic review’, ‘government publications’, ‘English language’, and ‘human subjects.’ Year of publication was filtered from 2006 to 2017. These searches yielded over one hundred recent publications. In addition, primary source citations were examined from systematic reviews and from references of governmental and institutional agency statements and publications from the U.S Department of Health & Human Services, Centers for Disease Control & Prevention, The Harm Reduction Coalition, and OHA. Literature was reviewed and selected based upon a specific focus on overdose prevention in the community, use of naloxone for opioid overdose in the outpatient setting, implementation of naloxone training programs, and training both laypersons and healthcare providers to manage opioid overdose and administer naloxone.

### **Naloxone for Opioid Overdose Reversal**

Naloxone was approved by the United States Food and Drug Administration (FDA) for opioid overdose in 1971 and is stocked on ambulances and medical facilities that administer opioids (Davis & Carr, 2015). It was added to the list of essential medicines by the World Health Organization (WHO) in 2013 and is now routinely dispensed to opioid users and their families and friends in countries across the world. Naloxone produces no euphoria or analgesia, and, thus,

has no potential for abuse (McAuley et al., 2015). Naloxone plays a significant role in reducing opioid overdose fatalities; between 1996 and 2014, community organizations provided naloxone rescue kits to 152,283 laypersons and recorded 26,463 overdose reversals (Wheeler et al., 2015).

### **Implementation of OOPPs for Bystanders/Laypeople**

Since their development in 1996, OOPPs have equipped opioid users and communities through training and access to the antidote to reverse opioid overdose and accidental deaths (Clark, Wilder, & Winstanley, 2014). The efficacy of naloxone is fundamentally time dependent; death from overdose typically occurs within 1 to 3 hours. Peers or family members of overdose victims are often the ‘first responders’ in an overdose scenario and are often best positioned to intervene immediately (Kim, Irwin, & Khoshnood, 2009).

A meta-analysis by Giglio, Li, and DiMaggio (2015) evaluated the efficacy of overdose education programs and bystander naloxone administration and favored bystander treatment. Findings indicated that laypersons who were dispensed naloxone were effective in treating overdose and that overdose prevention training improved participant knowledge of overdose recognition and management (Giglio et al., 2015).

In a systematic review by Clark et al. (2014), researchers determined that bystanders can and will use naloxone to reverse opioid overdoses when properly trained, and that this training can occur successfully through OOPPs. Although confidence was somewhat limited by methodological rigor, findings also suggested that OOPPs may increase knowledge of overdose prevention and risk factors. A lack of randomized controlled trials (RCTs) of OOPPs limits evaluation of their overall effectiveness, but will likely remain given the ethical challenge of conducting RCTs with naloxone, which has well-established efficacy in reversing opioid overdose (Boyer, 2012).

Community distribution of naloxone kits and provision of supportive training decreased opioid overdose deaths between 27% and 46%, with more deaths prevented as the percentage of kits per capita increase (Lim, et al., 2016; Walley et al., 2013).

### **Training Healthcare Providers**

In a repeated-measures study, evaluators found that training physicians in opioid overdose awareness and naloxone administration resulted in a significant change in their willingness to utilize naloxone (77% pre-training to 99% post-training) (Mayet, Manning, William, Loaring, & Strang, 2011). Evaluators also reported an increase in clinician knowledge. It is important to consider that not all healthcare professionals are familiar with opioid overdose and/or naloxone administration. Therefore, it is essential to assess existing knowledge and post-training knowledge to evaluate efficacy of training in any individual, even healthcare professionals.

Quest staff were trained with materials designed for lay bystanders so that those with the lowest levels of medical training could understand them. Current literature does not specifically address the mixed training of laypersons and health care professionals in the outpatient clinic or community center setting.

### **Current Laws/Legal Issues/National Policy**

In March 2015, the United States Department of Health and Human Services identified three priority areas to reduce opioid use disorders and overdose nationally: Opioid-prescribing practices, expanded use and distribution of naloxone, and expansion of medication-assisted treatment (Lim, Bratberg, Davis, Green, & Walley, 2016).

Community access to naloxone was limited by laws and regulations that pre-dated the current overdose epidemic including the requirement of a prescription for naloxone (Kim, et al.,

2009). However, due to the alarming increase in preventable deaths from opioid overdose, many historical legal barriers are now being removed and/or amended in order to improve access to emergency treatment for those experiencing opioid overdose. In 2015 and 2016, the majority of states passed legislation designed to: (1) Improve layperson naloxone access, (2) Encourage Good Samaritans to summon aid in an overdose situation, and (3) Simplify the prescription and distribution of naloxone and use naloxone by laypersons without fear of legal repercussions (The Network for Public Health Law, 2016).

Oregon law now permits laypersons to carry and administer naloxone to another individual during an opioid overdose after completion of approved training and protects bystanders from arrest or prosecution for drug-related charges or parole/probations violation based on information provided to EMS (OHA, n.d.).

Because regulations for prescribing naloxone vary by state, OOPP curriculum and the qualifications of individuals who conduct training sessions is variable. According to Scott Burris, JD, of Temple University Beasley School of Law, “In the US, naloxone programs fall within the scope of normal medical practice and no specialized legislation is required for them to operate” (Wheeler, Burk, McQuie, & Stancliff, 2012). In the future, creating a standardized OOPP curriculum as well as a standardized assessment tool to assess for changes in knowledge of participants after training may help to develop more universally effective OOPPs (Clark et al., 2014).

### **Gaps in the Literature**

There is currently a lack of research regarding the efficacy of opioid overdose management and naloxone training programs for multidisciplinary medical and nonmedical staff members at outpatient clinics such as Quest where staff members are in routine contact with



patients at high risk of opioid overdose (McAuley et al., 2015). Most previous studies of OOPPs have analyzed evidence related to community OOPPs that provide “take-home” naloxone, specifically training opioid users and nonmedical bystanders or medical professionals. Future research should investigate the efficacy of initiating clinic-based OOPPs, establishing naloxone access, and training non-medical staff in outpatient treatment settings where there is frequent exposure to high-risk populations. This project’s formative program evaluation allowed for identification of facilitators and barriers to the implementation of an OOPP and aided in assessing the efficacy of training non-medical employees in opioid overdose management in the outpatient clinic setting.

### **Approach to the Conduct of the Project**

#### **Project Setting**

Participant training and evaluation took place at The Quest Center for Integrative Health. Barriers to the project included difficulties in scheduling and participant drop-out in completing the 30-day post-intervention questionnaire. Facilitators included management buy-in and staff support, pre-approved funding for naloxone and supplies, and pre-existing medical knowledge of some staff members.

#### **Methods**

**Participants:** 35 staff members at Quest. Participants included front desk staff, drug treatment counselors, mental health therapists, recovery mentors, acupuncturists, and medical/mental health clinicians and were selected based upon management’s determination of participant’s level of patient contact. All participants underwent the same training program and received the same pre/post questionnaires. Participants were trained in their workplace setting in order to establish familiarity with procedures and locations of treatment supplies.

Protection of participants: All pre-and post-training questionnaire results remained anonymous. Data obtained from questionnaires was utilized only for formative project evaluation.

**Materials:** A questionnaire was constructed with seven questions including two Likert scale questions and five true/false and multiple-choice questions. Likert scale questions evaluated changes in participant self-efficacy and willingness to assist in an overdose situation. True/false and multiple-choice questions assessed pre/post training general knowledge regarding opioid overdose recognition, response, and naloxone administration. The questionnaire was carefully constructed and reviewed in such a way that quantitative analysis of results could accurately identify statistical changes in participant responses. Physical materials included pens, written questionnaire forms, naloxone training statement of completion forms, and practice materials including a naloxone rescue kit and naloxone. The group training session utilized a Quest computer and monitor for viewing a brief OHA naloxone training video.

**Procedures/Design:** A repeated-measures design was utilized to assess changes in participant self-efficacy, willingness to assist, and overall knowledge prior to and after undergoing training. Participants were evaluated on two occasions: pre-training and 30 days post-training.

Participants underwent a 20-minute training session outlining OHA opioid overdose treatment protocol, recognition and response to an opioid overdose, initiation of EMS, the essentials of administering naloxone, rescue breathing, and follow-up care. Locations of clinic naloxone kits were reviewed. Questionnaires took less than 10 minutes to complete and were used to assess changes in (1) Participant perception of self-efficacy in opioid overdose awareness and self-reported willingness to assist in an overdose scenario; (2) Participant knowledge regarding (a) Recognition of opioid overdose (b) Appropriate opioid overdose treatment measures, and (c) Naloxone administration.

## **Outcome Evaluation**

### **Measures/Outcomes**

The most significant outcome measure of the establishment of a staff-oriented OOPP at Quest is the prevention/reduction of fatal opioid overdose in the clinic setting. Given that the incidence of opioid overdose in the Quest Center clinic setting is quite rare, rather than relying on this outcome measure for project evaluation, several process measures were also utilized to assess program development. Process measures included:

(1) Adoption of a standardized protocol for opioid overdose treatment (measured by established protocol at end of project); (2) Change in participant perceived self-efficacy in recognizing and responding to opioid overdose in the clinic setting (measured by analysis of pre/post questionnaire); (3) Change in participant knowledge regarding recognition and treatment of opioid overdose and administration of naloxone (measured by analysis of pre/post questionnaire); (4) Number of clinic staff trained in recognition of opioid overdose treatment (measured by naloxone training completion forms) and (5) On-site access to naloxone and naloxone supplies with standardized plan for replacing/reordering medication and supplies (measured by presence of naloxone rescue kits/medication in clinic and established standardized procedure for continued access).

Statistical analysis of data obtained from participant questionnaires was performed with Microsoft Excel software.

## **Implementation of Project**

### **Evolution of the Project Over Time**

Frequent email correspondence and intermittent face-to-face meetings with stakeholders at Quest and the Multnomah County Health Department (MCHD) evolved over many months.

Significant planning and organization was involved prior to conducting training in order to ensure that Quest employees would receive training that met the guidelines of current state policy. Once the guidelines for training were established and trainers were designated and underwent “train-the-trainer” sessions, staff training was scheduled and finally carried out during a clinic-wide staff meeting. Prior to training, significant barriers surfaced with regards to obtaining naloxone due to current prescriptive and dispensing laws. These barriers specifically pertained to obstacles obtaining a small bulk supply of naloxone emergency doses that were not prescribed to a specific individual, but rather, to an organization as a whole. Through ongoing collaboration with MCHD, The Oregon Board of Pharmacy, and local retail pharmacies, eight two-dose packs of naloxone were eventually obtained for clinic emergency use through a new dispensing program initiated by the MCHD and their pharmacy. Naloxone was obtained for Quest after verification of approved opioid overdose and naloxone training of staff members and Quest’s ongoing commitment to complete refresher training as directed by Oregon laws.

**Unintended Consequences:** There was significant delay in obtaining naloxone due to the previously discussed barriers; however, this delay allowed adequate time to carefully prepare for staff training and to determine which method of naloxone administration was preferred by the clinic. Originally, nasal Narcan (a nasal spray unit) was selected, although, due to cost, this was later changed to nasally administered naloxone using a syringe and atomizer device.

**Details of Missing Data or Information:** There are ongoing barriers to obtaining naloxone for use by those who are not individually prescribed the medication by a provider or do not obtain it through a naloxone program for individual use. Dispensing doses to clinics and groups for public health benefit is an ongoing hurdle that is likely to gradually evolve into a simpler process as the safety profile and benefit of naloxone becomes more and more obvious and is recognized and

endorsed by local and national governments.

### **Key Findings**

Qualitative analysis of pre/post questionnaires was conducted to determine statistical significance and effect size. The first two Likert-style questions measured participant self-efficacy and willingness to assist in an overdose situation. The data from these questions was analyzed separately using independent samples t-tests. For the remaining knowledge and comprehension style-questions, a single knowledge score was created to represent the number of overall correct answers for each participant. These summary scores were then analyzed using an independent samples t-test again. Cohen's *d* was utilized to emphasize changes in pre/post questionnaire results in order to avoid confounding these results with small sample size.

Independent samples t-tests did not show statistically significant changes in participant knowledge and comprehension after undergoing training ( $p = 0.18$ ), however, participants notably scored an average of 4.6 out of 5 correct answers in knowledge and comprehension prior to receiving training. These results indicate that non-medical persons may have a strong base knowledge of the recognition and prevention of opioid overdose and the administration of naloxone. Data analysis from the two Likert scale questions suggested a positive influence of training on participant self-efficacy and willingness to assist. Independent samples t-tests did not indicate statistical significance, however, results indicated a medium positive effect size ( $d=0.6$ ) with results nearing statistical significance ( $p = .06$ ) between pre/post responses to the question "I know what to do if someone overdoses at the clinic." There was a small positive effect ( $d=0.2$ ) for the statement "I would be willing to help if someone overdosed while I was working;" these results were not statistically significant ( $p = 0.60$ ).

This data suggests that training can be an effective method to increase confidence and

willingness to respond to opioid overdose in addition to, and perhaps in response to, reinforcing participant overall knowledge and comprehension. Ongoing barriers exist in making naloxone readily available to organizations that wish to have it available for emergency use. However, as evidenced by this project, it is possible to provide access to naloxone in high-risk environments and to adequately prepare those who may find themselves in a position to respond to opioid overdose and administer naloxone to another individual.

### **Outcomes**

#### **Comparison of Findings to Literature and Expected Results**

Evaluation of the data obtained from this project and from the literature indicate that OOPPs are, indeed, effective methods to increase the likelihood of naloxone utilization in an opioid overdose (Clark et al., 2014).

**Differences Between Expected and Observed Results:** Much of the base knowledge regarding opioid overdose and naloxone administration may already exist in those who work in healthcare and/or addiction care settings. As indicated by the data from this project, as well as the literature, responder confidence and willingness may be positively influenced by training that reinforces and solidifies pre-existing and new knowledge (Mayet et al., 2011). This increased self-efficacy may lead to increased responsiveness to opioid overdose and increased naloxone utilization, thereby helping to reducing the amount of deaths caused by opioid overdose.

**Impact of the Project on the System:** The cost of naloxone is still quite prohibitive. Unless it is purchased with insurance coverage as an individual, it must be purchased at cost, which resulted in a cost of \$82 per 2-dose unit for Quest. For eight two-unit packs of naloxone, the total cost to The Quest center was \$656. The cost of training employees was negligible, as it was incorporated into a pre-scheduled staff meeting. The cost of naloxone is not at a sustainable

price-point for many small clinics and public health agencies that operate on limited budgets.

In terms of the project's impact, several process measures were met, impacting Quest's broader ability to respond to opioid overdose effectively. Quest does not have its own opioid treatment policy, rather, it will follow the guidelines of the OHA protocol for opioid overdose treatment. 35 staff members completed training, each of these staff members completed the official statement of completion and are now qualified to administer naloxone in an opioid overdose situation. The clinic now has access to on-site naloxone with eight emergency kits stocked in its various clinic buildings and community outreach vehicles. In addition to current naloxone accessibility, the clinic has also completed all required paperwork for ongoing access to naloxone replacement as needed through partnership with the MCHD pharmacy. These successfully achieved process measures significantly impact the staff's ability to effectively respond to opioid overdose, administer naloxone, and, ultimately, prevent death from opioid overdose in the clinic setting; this was the most important goal of the entire project.

**Practice-Related Implications/Recommendations/Limitations:** Widespread education in opioid overdose prevention, recognition, and response plays a pivotal role in decreasing the number of people who die from opioid overdose each year (Giglio et al., 2015). Naloxone is an integral part of this effort and must be made more accessible by decreasing the existing legal and cost-prohibitive barriers. This study was an extremely small, regional assessment of a national and global situation. Outcomes may vary widely depending on local population and regional laws and regulations. However, the fact remains that deaths due to opioid use are on the rise and widespread OOPPs and naloxone accessibility are paramount in addressing the problem (Clark et al., 2014).

**Conclusions**

This project may provide guidance and/or reference for other outpatient clinics or public health agencies who are seeking to implement opioid overdose training and naloxone access to staff who come in frequent contact with high-risk populations. Findings from this data may provide insights for navigating the complicated legal pathways to naloxone access and helpful ideas for effectively training both medical and lay persons.

**Summary and Next Steps**

Moving forward, the national movement to mitigate opioid abuse/misuse and opioid-related deaths will require the support of public policies that support and implement widespread opioid overdose prevention and treatment education, increased access to and distribution of naloxone, and increased access to addiction treatment and medication-assisted treatment programs. Ideally, the implementation of these harm reduction measures will provide hope and assistance to the estimated 2.1 million people in the US suffering from substance use disorders related to prescription opioid pain relievers and the estimated 467,000 who are addicted to heroin (SAMHSA, 2013). The health and well-being of each of these individuals depends on a collaborative and focused commitment to this cause.



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