Identifying barriers in the implementation of a harm reduction program for opiate overdose.

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Intro

Prescription opiate overdose is a leading cause of death among adults in the United States (CDC, 2011). Deaths by prescription opiates far outweigh those by street-level opiates (CDC, 2011). Interventions for opiate overdose are increasing across the US, and often include multipronged community interventions to decrease the burden of fatal opiate toxicity. Primary care providers are being educated regarding the risks of chronic opiate therapy for non-cancer pain as well as the addictive potential of opiate medication. Pain management centers are promoting pain treatment that avoids the use of chronic opiate therapy. All of these interventions, and more, seek to decrease the public health burden of dangerous opiate medications. And yet, individuals do (and will) continue to engage in risky behavior with opiate medications (SAMHSA, 2013).

Naloxone is a safe and effective opiate-overdose antidote (Coffin, Sherman, & Curtis, 2010).

In the spring of 2015, Old Town Clinic, a homeless health clinic in downtown Portland, Oregon, implemented the Comprehensive Opiate Safety Program (COSP). COSP builds on a larger program that monitors opiate prescriptions and provides integrative and holistic pain treatment, but also specifically seeks to distribute take-home naloxone to those patients at high risk for opiate overdose. The purpose of this project is to understand the barriers that created difficulty in implementing this clinically necessary program.

Clinical Problem: Prescription Opiate Overdose

Prescription opiate overdose was responsible for 14,800 deaths in 2009 (CDC, 2011), exceeding the number of deaths during the year caused by heroin and cocaine overdose combined. Many of these deaths involve individuals who do not have prescriptions for opiate painkillers and obtain them illegally. However, there are a staggering number of individuals who have legitimate prescriptions for the medications that ultimately cause their death, often caused

by drug-drug interactions and drug combining, such as concurrent benzodiazapine-opioid use (CDC, 2011). In Oregon, nearly 300 people died of opiate overdose in 2011; more than half of those deaths were caused by prescription opioids.

Overdose is defined as the ingestion of more substance than a body can handle, resulting in the central nervous system's inability to perform basic life functions. Fatal overdose occurs when these basic life functions, specifically respiratory function, slow to the point of death (Coffin, Sherman, & Curtis, 2010).

One reason for this dramatic increase in opiate-related deaths is directly related to provider attitudes related to pain treatment. Attitudes among medical personnel have shifted drastically regarding pain management. In the 1980s and 1990s, it became more likely for medical personnel to respond to any reported pain, viewing one aspect of their job as providing immediate pain relief (Paulozzi & Xi, 2011). Because of this shift in attitudes and knowledge, prescription pain medication use has risen dramatically. National prescription-tracking data show that more than 40% of opiate prescriptions are written by general or family practitioners, osteopaths, or internists, most commonly for diseases of the musculoskeletal system and connective tissues (CDC, 2011).

Naloxone is the most commonly used, safest opioid overdose antidote. While it has traditionally been used by health care providers to reverse the effects of an opioid overdose, there is growing research that suggests that it should be in the hands of all opioid users (illicit and non-illicit users) and not solely in the hands of medical personnel. Take home naloxone (THN) programs have proven to be cost effective, and newer forms of naloxone, such as intranasal naloxone, are now available, making it an even more client-centered intervention (Coffin, Sherman, & Curtis, 2010).

To date, program implementation and research has focused primarily on the interventions focused on intravenous drug users (IVDUs), with little to no focus on those individuals who are *not* IVDUs but for whom there is a high risk for overdose—those taking prescription opioids, specifically those with comorbidities of mental illness and/or concurrent lower socioeconomic status. Recent epidemiological reviews of overdose deaths clearly indicate that fatal prescription drug overdose is a public health epidemic, causing more fatalities than even heroin overdose (CDC, 2011).

Population and Epidemiology

Interest in opioid overdose epidemiology has grown in recent years in an effort to understand the root cause of the drastic rise in opiate-related fatal overdoses. Like most public health crises, it is clear that marginalized populations are more at risk. A 2004–2007 study in Washington State (where prescription opioid death is known to be high) sought to understand who was most affected by the overdose epidemic. Patients on Medicare were significantly more likely to die of prescription opioid overdose than those with private insurance (CDC, 2011), suggesting that the patients most affected are of lower socioeconomic status. Likewise, a 2006 study in New York City demonstrated that even outside of individual-level factors, patients living in lower socioeconomic neighborhoods were more likely to die of narcotic overdose. In other words, despite controlling for individual-level factors, those living in the top decile of poverty-stricken neighbors were more likely to experience fatal overdose (Nandi et al., 2006). Anecdotal evidence agrees and suggests that, even when knowledgeable about how to intervene on overdoses, bystanders are less likely to respond to potentially fatal overdoses when the external environment is chaotic and/or there is fear of police involvement (Lankenau et al., 2013).

Those with a comorbid mental health diagnosis have the highest incidence of opiate overdose, though is it currently unknown which psychiatric diagnoses were the most prevalent for the decedents. It is more generally known, however, that diagnoses of schizophrenia and bipolar disorder often accompany opiate abuse (Bohnert et al., 2011). Amongst veterans who died of opioid overdose, the primary psychiatric diagnosis was posttraumatic stress disorder (PTSD); within the veteran population, those with a PTSD diagnosis were twice as likely to die of narcotic overdose (Seal et al., 2012).

Regardless of race, gender, or social class, the following components increased risk of prescription opiate overdose: high relative dose (more than 100mg/morphine equivalent), recent release from jail or prison, past history of opioid abuse, concurrent benzodiazepine use, concurrent antidepressant use, respiratory system disease such as COPD, renal disease, alcohol abuse, and any methadone prescription for an opioid naïve patient (Green et al., 2013).

Purpose of this Project

If prescription opiates are the causative factor for multiple drug overdoses each year, then it would follow that naloxone needs to be distributed to both IV drug users and to prescription opiate users. However, while multiple organizations, including SAMHSA (2014), now promote co-prescribing models (wherein naloxone is consistently prescribed with all opiates), and consider it to be best practice, there are often significant barriers to implementing this practice.

Old Town Clinic, implemented the Comprehensive Opiate Safety Program (COSP) in 2015. This program, in conjunction with the chronic pain management programs, seeks to decrease the burden of opiate-related deaths on the community by distributing naloxone in the primary care setting. It is distinct from most take-home naloxone programs in that it provides naloxone to both illicit drug users and patients utilizing chronic pain management. The program

has been in existence since May 2015 and has successfully co-prescribed and/or distributed naloxone to more than 200 patients. However, there were multiple barriers to the implementation of this program, specifically within the context of being one of the first national programs of its kind.

Literature Review

The literature addressing implementation barriers, regardless of intervention, setting or population, is abundant. For the sake of this investigation, we will be utilizing the framework developed by Glasgow and Emmons (2007). This framework emphasizes whole-systems while addressing barriers across four categories: characteristics of the intervention, situation of intended target settings, program design, and most importantly, the interactions of the former three categories. The framework by Glasgow and Emmons is particularly useful given it's grounding in public health/population-based interventions and it's understanding of the political and social contexts in which implementation exists.

The literatures outlining the usefulness of THN and opioid-overdose prevention programs is currently growing, and is already substantial. It has been clearly demonstrated that introducing THN into a community significantly affects the rate of fatal overdose (Albert et al., 2011; Evans et al., 2012; Maxwell, Bigg, Stanczykiewicz, & Carlberg-Racich, 2006; Walley et al., 2013), with relatively small take-home naloxone programs (THN) decreasing the rate of fatal overdose for entire populations. It has also been demonstrated that drug users who are trained, even briefly, in opiate-overdose prevention are able to retain a significant amount of knowledge regarding opiate-overdose recognition and response (Bennett & Holloway, 2012). It was originally believed that opiate users needed hands-on training in overdose response to be effective, but new research suggests that education is efficacious with as little as 10 minutes of

education and no additional hands on component (Behar, Santos, Wheeler, Rowe, & Coffin, 2015). Moreover, there has been significant hesitancy to promote take-home naloxone interventions in the past because there is a long-held belief that drug users will use more opiates and seek out a more intense high if they feel they have a "safety net". According to Seal et al. (2005), drug users actually decrease their use in the twelve months after naloxone training and are more likely to engage in recovery services. In this same study, when drug users were asked if they would use more opiates when carrying naloxone, respondents reported that they were afraid of the withdrawal effects of naloxone. This combined with the loss of money/drugs associated with a reserved "high" was a deterrent for drug users to overuse opiates and rely on naloxone for revival.

THN interventions, as currently conceptualized within non-intravenous drug user programs are generally part of larger community interventions. These interventions are often with programs aimed at decreasing opiate abuse and addiction in primary care. According to Bowman et al. (2013) programs that seek to address opiate overdose and opiate addiction in primary care include the following components: screening for opiate addiction or misuse, brief intervention for addiction or misuse, clean syringe distribution, controlled substance review committees to monitor narcotic prescription safety, and use of narcotic databases.

Green et al. (2013) sought to understand the barriers to medical providers in prescribing take-home naloxone to lay responders. Twenty-four various types of medical providers were questioned regarding their hesitation in prescribing take-home naloxone to substance abusers. Their attitudes were reduced to two essential concerns. The first, as mentioned previously, is the "safety net effect" in which there was a belief that patients would use more narcotics if they had

a "safety net". The second barrier-promoting belief was that education needed to be substantial in order for patients to retain and utilize the opiate overdose prevention knowledge.

One of the most notable (and well-studied) primary-care-inclusive opiate overdose interventions is that of Project Lazarus in Wilkes County, North Carolina (Albert et al., 2011). Wilkes County had one of the nations highest overdose rates and sought to reverse that statistic with a four-pronged, community-based intervention. The intervention consists of consistent elements: education and coalition building of primary care providers and stake holders, data tracking and monitoring, program evaluation, and direct overdose prevention with naloxone distribution. It is important to note that while this intervention is county wide, all elements were considered essential for the success of the program. After just one year of existence, the fatal overdose rate in Wilkes County was cut by almost 50% (Albert et al., 2011).

While the Project Lazarus literature looks at community-wide interventions there is some limited work addressing implementation barriers of take-home naloxone within a smaller substance abuse treatment program (Wilder et al., 2014). This setting is, in some ways, similar to the target setting because the larger organization is grounded in the world of the abstinence-based, twelve-step addictions model. The primary barrier noted was lack of buy in from staff. There was large belief among staff that naloxone distribution would increase risky substance use and trigger those clients in early recovery. There was specific concern regarding the needles included in the naloxone kits; any and all needles were seen as potential triggers to those working diligently to avoid intravenous drug use.

While the literature cited above is meaningful, there is no literature addressing take-home naloxone program implementation specifically within a primary care clinic setting. Moreover, while many pieces or iterations of a primary-care, naloxone co-prescribing model have existed,

there is no literature reviewing and examining the barriers that have prohibited this desperately needed intervention from existing widely within the primary care setting.

Context of the Investigation

Old Town Clinic is a primary care clinic that is under the umbrella of a larger social services agency. The larger organization's mission is to create sustainable housing solutions for homeless and addicted persons and to offer recovery services for addiction and mental health. The organization, including the primary care clinic, has existed for roughly 30 years and was built during a time and place committed to abstinence-based, twelve-step recovery. More recently, however, the primary care clinic has integrated with a large teaching university, with new administration committed to evidence based care. As a federally qualified health care center, funding is garnered via federal funds and via direct patient billing of both Medicaid and Medicare.

The primary care clinic, by nature of its location within the larger organization, serves as primary care, but carries within it many specialty services. Level-one addiction services, as well as mental health services, are integrated into the primary care setting – including services such as bupenorpherine treatment. Most importantly, however, chronic pain services are included. The chronic pain program includes psychotherapy and psychiatric care as needed, yoga, acupuncture, a controlled substance oversight committee and monitoring task force, and, of course, medication management. A large portion of the population are considered to be high risk for opiate overdose. A significant number of the patients are included in the clinic's chronic pain program (roughly 1000 out of a population of roughly 3500), have a high incidence of mental health and comorbid substance abuse, and are frequently in and out of institutions that mandate abstinence

(e.g., jails and substance abuse treatment facilities) – all elements that increase the likelihood of death by opiate overdose (CDC, 2011; Nandi et al., 2006; SAMHSA, 2014).

The culture of change within the primary care clinic is generally one of warm embrace.

There is an organizational commitment to trying new and creative ideas. However, the culture of change that exists within the primary care clinic is not always reflected in the larger organization.

There is, at times, conflict between the change-promoting culture of the primary care clinic and the change-averse culture of the umbrella system.

The Project

The purpose of this project is better understand barriers to the implementation of The Comprehensive Opiate Safety Program at Old Town Clinic. The scope of this project is to understand all potential barriers, while simultaneously understanding the key barriers more fully within the context of the Glasgow and Emmons barriers scale (2007).

Ten key informants were interviewed to gather information about barriers to implementation of this program. Key informants are determined by and located according to their knowledge of the non-profit's culture, history and current day program development. Initial interviews were in writing, with data gathered remotely via survey monkey and were open ended and narrative style.

Five face-to-face interviews were conducted to follow up on key themes identified by the initial interviews. The participants of these five interviews were selected based on their position in the agency and their responses to the initial questions. Content analysis was performed on these final interviews. Protection of participants was provided by Oregon Health and Science Universities integrity office.

Outcomes

As reviewed above, Glasgow and Emmons propose that barriers fall into one of four main categories: characteristics of the intervention, situation of intended target settings, program design, and most importantly, the interactions of the former three categories (2007). Content analysis demonstrated that barriers to implementation of the COSP program at Old Town Clinic existed in each of the four areas listed above, and yet two areas from above stood out as worthy for review.

The first notable area that respondents sighted as being a barrier to implementation was the characteristics of the intervention itself. The intervention depends on primary care providers to identify high risk patients in their office visit. If a primary care provider does not identify and refer a patient within an office visit, it is likely that said patient will not be referred to the COSP class. This concern was noted primarily by administrators who were also clinicians, and by respondents who were solely clinicians. These respondents noted that they would have liked more support in identifying panel members who were high risk, such as receiving reports of all patients on a certain dose of opiates, or all patients receiving care for opiate use disorder.

The second barrier and the more complex barrier noted across the board and by almost every interviewee was the situation of the intended target. In this case, what was highlighted by respondents was a deep incongruence in the cultural values of twelve-step, abstinence based recovery work and the cultural values that were believed to be attached to THN programs. Seven out of ten respondents had always been in favor of THN programs at Old Town Clinic, though noted that there was tension in brining naloxone into the "12 step world". Three out of ten respondents, all of whom are in long term recovery themselves and work addictions programs felt that THN was an inappropriate intervention for the organization to offer and had actively campaigned against all naloxone distribution programs within the organization. They sighted two

reasons quite easily. The first was that they believed that giving naloxone to people in early recovery sent mixed messages. One respondent noted, "you can't just say to people saying 'we believe you can stay clean. You need to stay clean to stay alive. Oh, but just in case, here's naloxone". The mixed message concern was particularly notable in the context of providing alcohol and drug free housing, wherein clients are evicted immediately upon relapse.

Respondents who had been actively against THN interventions also believed that giving naloxone to be administered intramuscularly, and giving out needles in the naloxone kits created a potential to trigger people. Despite reviewing that naloxone is given intramuscularly, and not intravenously, and has a very different look to the needle, one respondent said "any needle is a trigger, which can cause a craving and ultimately lead to relapse".

Interestingly, woven throughout the concerns noted above by those against THN, was a larger and more nebulous concern. Those who were in active recovery and had come to be employed in the world of addictions recovery by way of their own journey in addiction held a deep feeling that the medical model of addiction treatment was "taking over". Naloxone, it was noted, was seen as part of a larger shift in the organization towards the medicalization of substance use treatment. Administrative staff in the world of alcohol and drugs felt that more money was being funneled to addiction programs that relied on medications to treat addiction, rather than the 12 steps. They did not feel that there was a way for 12 step programs and medication assisted treated to work together. All three of the respondents who had been primarily against THN in the organization used language that questioned, or even mocked, evidence based treatment. And most concerning, a few of the respondents held a deep fear that their work and their way of life, would soon be eroded by "the medicalization" of the addiction treatment wherein doctors, and others with money and funding, would begin to control all things

addiction related. One respondent noted that he felt that alcohol and drug treatment had become "the dirty step child" within the organization and received less resources, less funding, and significantly less communication and collaboration with the rest of the organization. THN, though not actually a medical treatment for addiction, became a symbol of the medicalization of addictions treatment, and was seen as a move away from traditional abstinence based treatment.

Conversely, those in the medical clinic and those who had been historically in support of THN at the organizational level felt that many in the alcohol and drug and housing arms of the organization were afraid of change, and were in denial about the deadly nature opiate epidemic. There was certainly a sense within the medical arm of the organization that those committed to a 12 step method of recovery from addiction were, as one respondent noted, "behind the times and not paying attention".

Recommendations & Future Steps

In reviewing the outcomes and experiences of both sides of the above debate, the tension is notable. And yet, the outstanding sentiment is a lack of organization wide education and collaboration. Prior to initiation of the Old Town Clinic COSP program, there needed to be significant efforts made to increase staff buy in. The first step in increasing staff buy in, specifically in the realm of the alcohol and drug treatment center staff, is to provide education about naloxone and take home naloxone programs. Multi-day staff in-services on naloxone are recommended, as well as in-service days on medication-assisted treatment, specifically for those located primarily in alcohol and drug. Likewise, multi-day staff in-services for those in the medical setting are needed to boost knowledge and understanding of 12 step and abstinence based treatment modalities. The second step in staff buy in is building collaboration between the medical clinic, alcohol and drug treatment and housing. Suggestions for collaboration building

are having behavioral health clinicians from the medical lead groups within alcohol and drug and weekly educational staffings on addictions with staff from across practice settings, including housing.

To address the request on the part of clinicians to remove some burden from their office, there are multiple interventions to offer. However, with new laws passed in Oregon in 2016 allowing pharmacists to prescribe/distribute naloxone, we will propose moving naloxone prescribing to the pharmacists at the medical clinic and outside of the realm of the primary care office visit.

Summary

We are currently in the midst of an opiate overdose epidemic. This epidemic is largely due to prescription opiate medication use and iatrogenic addiction (CDC, 2011). This is particularly true in vulnerable populations with co morbid psychiatric diagnoses and lower socioeconomic status; however, the opiate epidemic is far reaching and affects people from all socioeconomic backgrounds (CDC, 2011). There are many avenues being explored and utilized to address the opiate epidemic. One notable avenue is an attempt to increase public access to take home naloxone, the opiate overdose antidote. In this paper we reviewed the implementation of a harm reduction, THN program in a primary care clinic with a high-risk population and the subsequent barriers to implementation of that program. The primary finding of a survey of 10 key informants was that there was a cultural barrier wherein people who has historically worked in the 12-step addictions field were overwhelmingly against THN programs. Moreover, many people in the 12-step addictions field felt that naloxone was a symbol of their lack of voice in the rapidly shifting field of addictions treatment in which medication assisted treatment is becoming more common. Suggestions for reparation and to decrease the future incidence of this cultural barrier in the

practice setting are varied. First and foremost, 12-step addictions treatment team members need more education in THN programs and the offerings of the evidence. Moreover, there is a necessity to promote more collaboration and team building across specialties, and to integrate traditional twelve step addictions treatment modalities into medication assisted treatment. THN programs are desperately needed in multiple and varied practice settings including needle exchange programs, pharmacies, primary care clinics and addictions treatment center and detox centers. The cultural barrier addressing lack of openness to harm reduction interventions in 12-step treatment must be addressed.

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