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Qualitative study of opioid overdose
education and naloxone access
strategies in community health center
primary care settings: opportunities for
expanding access and saving lives

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BOSTON UNIVERSITY
SCHOOL OF PUBLIC HEALTH

Dissertation

**QUALITATIVE STUDY OF OPIOID OVERDOSE
EDUCATION AND NALOXONE ACCESS STRATEGIES IN
COMMUNITY HEALTH CENTER PRIMARY CARE SETTINGS:
OPPORTUNITIES FOR EXPANDING ACCESS AND SAVING LIVES**

by

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Submitted in partial fulfillment of the
requirements for the degree of
Doctor of Public Health

2017

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DEDICATION

To my husband and daughters who made this possible

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ABSTRACT

Background: Naloxone, an opioid antagonist, offers a powerful tool for preventing opioid overdose deaths. Because studies have shown opioid overdose education and naloxone distribution (OEND) programs to be a safe, feasible, and effective intervention, several policymakers and public health agencies have advocated for broader access to this life-saving medication. Community health centers (CHCs) are a promising location for expanding naloxone access. This investigation examined the experience of CHC-based HIV primary care teams with a variety of overdose education and naloxone access (OENA) strategies in order to inform future dissemination efforts.

Methods: A mixed methods study was conducted with eight CHCs located in Massachusetts communities experiencing high opioid overdose fatality rates. Individual and group interviews with 29 clinic staff members; clinic and participant surveys; and document review were used to elucidate the OENA strategies. The Consolidated Framework for Implementation Research guided the data collection process and subsequent analysis, which revealed several factors supporting or hindering

implementation of OENA activities in CHC primary care settings.

Results: Operating in a facilitative state policy environment, the CHCs utilized a mix of approaches to OENA: providing clinic-based services, issuing prescriptions, utilizing pharmacy standing orders, and making referrals to existing community-based OEND programs. With prescribers having limited time and competing priorities, nurses, health educators, and other staff played a prominent role in OENA. Pharmacies also served as important access points for patients and community residents. Several strategies were used to engage patients, including active outreach, partnerships with external organizations, and efforts to destigmatize substance use disorders. Clinic staff participation was enhanced through leadership support for harm reduction approaches, ongoing training, peer modeling, and information sharing.

Conclusions: This study demonstrated that OENA can be integrated into CHC primary care services, adapted to the clinic context, and modified as needed. Successful implementation required a systems-level response, grounded in a team-based care model and a consideration of patient needs. The process for naloxone reimbursement needs to be determined to minimize CHC or patient barriers and ensure sustainability. Clinic training and technical assistance plans should be customized according to the staff members' potential roles and their stage of readiness.

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LIST OF ABBREVIATIONS

AIDS:	Acquired Immunodeficiency Syndrome
ASAM:	American Society of Addiction Medicine
BUMC:	Boston University Medical Campus
CAB:	Consumer Advisory Board
CDC:	Centers for Disease Control and Prevention
CFIR:	Consolidated Framework for Implementation Research
CHC:	Community Health Center
CPA:	Collaborative Practice Agreement
DPH:	Department of Public Health
EMR:	Electronic Medical Record
EMS:	Emergency Medical Services
EMT:	Emergency Medical Technician
FDA:	Federal Drug Administration
FQHC:	Federally Qualified Community Health Center
FTE:	Full-time Equivalent
HIV:	Human Immunodeficiency Virus
HRSA:	Health Resources and Services Administration
IDU:	Injection Drug Use
IRB:	Institutional Review Board
MAT:	Medication-assisted Treatment
OBOT:	Office-based Opioid Treatment

OENA:	Overdose Education and Naloxone Access
OEND:	Overdose Education and Naloxone Distribution
PLWH:	Persons Living with HIV
PMP:	Prescription Monitoring Program
PWID:	Persons Who Inject Drugs
SAMHSA:	Substance Abuse and Mental Health Services Administration
SBIRT:	Screening, Brief Intervention, and Referral to Treatment

CHAPTER 1: INTRODUCTION

The purpose of this study is to identify strategies that support the implementation of opioid overdose education and naloxone access (OENA) in community health center (CHC) primary care settings in order to help stem the escalation in opioid overdose fatalities. Qualitative methods were employed to understand the implementation experience, based on individual and group interviews with staff at eight CHC HIV primary care programs in the Commonwealth of Massachusetts. The research findings will contribute to models for expanding access to this urgently needed, effective, and life-saving intervention in these settings.

This chapter provides a brief overview of the background for this study and the research methods, which are presented in greater depth in Chapter 2 (Literature Review) and Chapter 3 (Research Design and Methods). The chapter starts with an overview of recent data on opioid overdose fatalities, followed by a problem statement and the research aims. Next, a description of the study rationale and the potential role of this research in informing public health practice are described, followed by a summary of the dissertation chapters.

Background and Context

Deaths from drug overdoses in the United States (U.S.) have more than doubled since the 1990s.¹ Drug overdoses are now the leading cause of accidental death, and have surpassed deaths from motor vehicular injuries among adults aged 25–64 nationally in 2009² and in 35 states and the District of Columbia as of 2013.³ Opioids, including both prescription opioids and heroin, are responsible for the steep increase, with prescription

opioids causing nearly twice as many deaths as heroin, even though heroin-related overdose deaths have more than tripled since 2010.⁴ Nearly 80% of people who recently started using heroin previously used prescription opioids—prescribed or not⁵— and switched to or also use heroin which is a cheaper and more accessible drug.⁶⁻⁹

The increase in opioid overdose fatalities has led to national recognition of opioid overdose as a major public health issue.¹⁰⁻¹² Notably, both U.S. presidential candidates put the opioid crisis at the top of their 2016 campaign agendas, though they proposed vastly different policies.¹³ Furthermore, several state health officials have called for an emergency response due to the surge in opioid overdoses.¹⁴⁻¹⁷ Public health and political leaders have recognized that comprehensive, long-term change is needed to address the complexities of addiction, but that in the short-term, proven strategies to prevent harm and death from opioid overdoses are needed.^{18,19} The expansion of one such strategy in CHC primary care settings, called overdose education and naloxone distribution (OEND) in community settings, is the focus of this research.

Naloxone—commonly referred to by its brand name, Narcan™—is an opioid antagonist that immediately reverses an overdose upon administration.²⁰ It has been the standard of care for reversing opioid overdoses by emergency department (ED) and emergency medical services (EMS) personnel since 1971.²¹ Numerous studies have shown OEND to be a safe, feasible, and effective intervention in community (non-clinical) settings where persons who inject drugs (PWID) are assisted through harm reduction and substance use treatment programs.^{22,22-25} Over 15 years of OEND program experience demonstrates that following a brief education session, laypersons who witness

an opioid overdose can effectively identify overdose signs and administer intranasal naloxone.^{26,27} National public health agencies^{28–32} and professional associations^{33–36} also endorse broad access to naloxone in an effort to curb overdose fatalities.

Building on the success of community-based OEND programs, there is a need to broaden the provision of naloxone to persons who use opioids but do not inject them, access harm reduction services, or perceive themselves to be at risk of an opioid overdose, including those prescribed chronic opioid therapy for pain management and their household members. The latter group is especially significant, as more than half of overdose deaths in the U.S. involve a prescription opioid.⁴ Clearly, with the feasibility and effectiveness of OEND having been established, there is an urgent need to expand access to life-saving naloxone for these individuals as well.

OEND is an effective intervention that is ripe for widespread dissemination in routine primary care clinical care settings.³⁷ There has been a recent call to expand access to naloxone through clinical care settings, including primary care and pain management centers where patients receive long-term care and opioid prescriptions.^{38,33,37,39–44}

Recognizing the need for opioid safety initiatives in clinical care settings, the Substance Abuse and Mental Health Services Administration (SAMHSA)³⁰ and the Centers for Disease Control and Prevention (CDC)⁴⁵ recommend co-prescribing naloxone for patients receiving chronic opioid therapy for non-cancer pain management. Furthermore, the expanded use of medication-assisted treatment (MAT) programs in primary care settings⁴⁶ points to the need for OEND for patients receiving treatment for substance use disorder, in accordance with SAMHSA and American Society of Addiction Medicine

(ASAM) guidelines.^{47,48} Online training programs, such as *Prescribe to Prevent*, offer prescriber education on OEND.^{49,50} SAMHSA has also created a toolkit for prescribers and pharmacists with important information to support implementation.³⁰

Primary care-based OENA interventions can build on lessons learned from community-based OEND programs. Some studies have documented barriers to overdose education and naloxone prescribing in clinical care settings, including low provider awareness of the benefits; discomfort discussing overdose because of the stigma surrounding addiction; concern about layperson use of naloxone; complications involved in payment, reimbursement, and stocking of naloxone; and competing clinical priorities.^{39,40,51–55} While there are some documented clinic-based OENA initiatives in the U.S.,^{25,41,56} there is minimal information available about actual implementation experience.³⁷

To understand the implementation experience among community health center (CHC) primary care programs, this study examined the perspective of CHC HIV primary care teams. A meta-analysis found that people living with HIV (PLWH), specifically those who inject drugs, are 1.7 times more likely to die from an opioid overdose compared to those without HIV.⁵⁷ The specific overdose risk factors for PLWH are not clear, though the literature has suggested several explanations for this increased risk, including biological mechanisms as a result of a compromised immune system, increased risk-taking behaviors, psychiatric comorbidities, structural factors such as lack of access to substance use treatment, homelessness, and incarceration,⁵⁷ plus opioid prescribing practices for pain management.^{58,59}

Because of the HIV transmission risk of injection drug use, HIV primary care providers have been on the front lines of addressing HIV and substance use comorbidities. These providers are ideally placed to screen for opioid overdose risk, conduct overdose education, prescribe or distribute naloxone, and link or offer persons in need of opioid treatment services. CHCs have long focused on addressing HIV and substance use comorbidities and implementing innovations in care delivery. Many are located within communities affected by the opioid crisis. Given this background, these sites can serve as implementation models for other CHC primary care settings. Furthermore, the prevention and treatment response to HIV can serve as a model for how to respond to the opioid overdose crisis, including the use of harm reduction approaches, clinic-based treatment interventions,⁶⁰ interdisciplinary team models,⁶¹ and the involvement of persons infected and affected by HIV in program decision-making.⁶²

This study focused on clinical care teams that provide routine primary care to PLWH at community health centers (CHCs) that were implementing various OENA strategies. Massachusetts CHCs were selected as the study setting type for three reasons. First, CHCs are located within many of the communities hardest hit by the opioid epidemic, and have been at the forefront of addressing public health challenges faced by their communities. In Massachusetts, these seemed to be the settings spearheading OEND activities. Second, CHCs have received additional state and federal funding to expand clinic-based opioid treatment services to patients, thus offering opportunities for both current and future OEND implementation.^{63,64} Finally, given the reach of CHC primary care settings to persons with and without HIV, findings from these sites are likely to have

broader applicability and transferability.

The Commonwealth of Massachusetts has a policy environment that would likely support CHC OENA efforts. Unintentional opioid overdose death rates in the state have been rising and stood at 25.8 deaths per 100,000 residents in 2015, a 32% increase from the rate of 19.5 deaths per 100,000 in 2014. The 1,574 opioid-related overdose deaths in Massachusetts were the highest ever and 2016 data indicate that the numbers deaths are continuing to climb.⁶⁵ Both the current and prior Governors have prioritized an urgent response, culminating in an action plan by Governor Baker with more than 65 recommendations proposed by an appointed task force.^{15,66}

One of these recommendations was to build on Massachusetts' pioneering community-based OEND work⁶⁷ by increasing access to naloxone,⁶⁸ including use of pharmacy standing orders for naloxone distribution.⁶⁹ Other facilitating policies were issued, including guidelines to integrate naloxone provision into state buprenorphine treatment programs⁷⁰ and co-prescribing with chronic opioid therapy.⁷¹ In addition, the Commonwealth has several laws in place to support the prescribing and use of naloxone by third parties. State-negotiated purchasing agreement resulted in low naloxone cost, allowing municipalities increased access to naloxone. Innovative initiatives, including several with city police departments, also began in 2015.⁷² New state legislation related to first-time opioid prescribing, use of the prescription monitoring program (PMP), and treatment referral for persons who overdose was put into place in 2016.⁷³ This supportive policy context set the stage for this study.

Problem Statement

Both at the national and state levels, policymakers and healthcare professionals are seeking to identify promising strategies to reduce the growing number of opioid overdoses.^{66,74} Multi-sector, comprehensive strategies are needed to prevent and address the complexities of opioid addiction, but in the short term, naloxone offers a safe, effective means to reduce deaths from opioid overdose.⁴⁹ Among persons at high risk of opioid overdose are PLWH,⁵⁷ both those with an opioid use disorder and those prescribed chronic opioid therapy for pain management. CHC primary care settings are opportune places for expanding access to this life-saving intervention. Despite the promise, primary care settings are underutilized venues for overdose education and naloxone prescribing.³⁷ A better understanding of the strategies and factors that support CHC primary care OENA implementation is urgently needed.

Study Purpose and Research Aims

The scope of this study was limited to understanding the implementation of OENA at CHCs, examined through the lens of clinical care teams providing primary care to PLWH at different CHCs in Massachusetts, and with a specific focus on contextual factors that affect implementation. The study did not pilot or evaluate an intervention; rather, it explored the implementation process, successes, and challenges experienced through individual and group interviews with HIV primary care team members. In short, the study involved a retrospective and current assessment of “real-world” implementation of this relatively new clinic-based innovation.³⁷ It is important to emphasize that while the study was initiated with the HIV care team members, findings often represented

activities conducted across the broader CHC or focused on other populations and not just PLWH because of the way in which primary care was integrated at the study sites.

This study was guided by the following three aims:

1. To document how opioid OENA strategies are delivered within community health center primary care settings;
2. To identify factors that influence implementation of OENA in this setting, examining the intervention, individual, outer setting, inner setting, and process domains; and
3. To determine which strategies are likely to enhance the implementation of OENA in community health center primary care settings.

Research Approach

Given the nascent stage of OEND in primary care clinical settings, qualitative methods were well-suited to address the research aims, as these methods made it possible to identify contextual factors that facilitate or hinder such initiatives within CHC settings. Surveys were completed by clinic staff to characterize the study participants and clinical settings. Observation and review of relevant documents (i.e., posters, EMR templates) provided further context to the study findings. All study activities were approved by the Boston University Medical Center (BUMC) Institutional Review Board (IRB).

The study began with three interviews and one focus group with physicians at a large, urban HIV clinic in Massachusetts to pilot test the tools and identify barriers and facilitators to overdose education and naloxone prescribing in this setting. The Consolidated Framework for Implementation Research (CFIR) was selected to guide

development of the data collection tools and data analysis. The CFIR is comprised of multiple constructs from other health services implementation models, plus factors that influence the adoption, implementation, and spread of healthcare delivery practices.^{75,76}

A purposive sampling of eight CHCs in Massachusetts involved in overdose prevention and naloxone access activities made it possible to explore different strategies and the variety of contextual factors that influenced their implementation. A total of 17 individual or group interview sessions were conducted with 29 CHC staff members, beginning with the HIV medical director or program manager, and then moving to the nurses, pharmacists, case managers, and/or health educators identified by the clinical team leader or program manager. Relevant documents and observational data were collected in conjunction with the interviews. Clinic and participant surveys were completed for each study site to describe the study context and the participants. Multiple perspectives from different HIV clinics, coupled with the use of different data sources, made it possible to triangulate and cross-validate the data.⁷⁷

Constructs from the CFIR were used to code the data using NVivo 11.0 software⁷⁷ with certain constructs emerging as predominant from the analysis across the framework's intervention, outer setting, individual, inner setting, and process domains.⁷⁵ Throughout the study, content experts and practitioners were consulted to ensure the relevance and transferability of the findings.⁷⁸

Rationale and Significance

This study seeks to identify strategies for providing opioid overdose education and naloxone to patients, and to examine the factors that facilitate or impede their

implementation in primary care CHC settings that serve PLWH. Getting naloxone into the hands of persons at risk of experiencing or witnessing an opioid overdose offers a low-cost, effective way to prevent death. CHC primary care settings have the potential to reach persons who may not have access to community-based OEND services, including those receiving opioid treatment or prescription opioids. OENA interventions in CHCs are essential given increasing use of office-based opioid treatment.⁶³ In addition, prescription opioids account for the majority of opioid-related deaths.²⁹ Primary care providers prescribe the most opioids,⁷⁹ and up to one in four patients prescribed chronic opioids for non-cancer pain management in primary care settings have experienced an opioid use disorder.⁸⁰ At this time, the implementation experience of OENA in CHC primary care settings remains unexplored.

Several studies have identified barriers and facilitators to opioid overdose education and naloxone prescribing in various clinical settings, and many of these articles revealed provider-level barriers that impede implementation.^{37,44,39,25,40,53,55,54} In contrast, this study, for the first time for this topic, examines the full range of critical factors known to influence innovation implementation in healthcare settings through a comprehensive implementation science framework.⁷⁵ Additionally, the study highlights actual implementation experience within CHCs rather than anticipated barriers and facilitators. This practice-based experience can support effective replication in other primary care clinical settings.

The timing of this project is also significant, given the attention to the opioid epidemic from national and state policymakers, and the recommendation to offer

naloxone to patients receiving substance use disorder treatment (i.e., buprenorphine) and chronic opioid therapy.^{45,81} Expanding naloxone access is one part of the comprehensive, state-based initiatives aimed at decreasing opioid overdose deaths, and this study can facilitate an understanding of how to best implement and scale-up this priority activity in CHCs reaching PLWH and other individuals at risk of an opioid overdose.

Summary of Chapters

This dissertation is comprised of five chapters. Chapter 2 provides a review of the literature that describes the opioid epidemic and opioid overdose risk, both in general and among PLWH in particular. A summary of OENA programs in community and clinical settings is presented, including identified models and barriers to implementation. The political and programmatic context of OEND activities in Massachusetts is described next to set the stage for the study setting. Chapter 3 outlines the research methodology that was employed. The chapter includes a description of the study sample, the recruitment process, data collection tools, and data analysis methods. The study setting is also described, including survey data summarizing clinic and participant characteristics.

Chapter 4 describes the qualitative analysis findings along with relevant descriptive data from the clinic and participant surveys, organized according to constructs from the implementation science framework (CFIR) that emerged from the analysis. This chapter addresses the three research aims. Finally, Chapter 5 discusses the findings in light of the literature and recommends strategies for future practice and research. To conclude, limitations to the study design are assessed.

CHAPTER 2: BACKGROUND AND LITERATURE REVIEW

This chapter summarizes the need for a public health response to prevent opioid overdose deaths in the U.S. A brief overview of the rising trends in opioid overdose fatalities in both the U.S. and the Commonwealth of Massachusetts, the study setting, is provided. Opioid overdose causes and risk factors, both in general and for PLWH, are then presented. Both national and Massachusetts' policy and programmatic responses to avert opioid overdose deaths are summarized.

A review of the literature assessing community-based OEND activities offers valuable guidance to help shape future initiatives in CHC primary care settings. Clinic-based models for OENA, in general, as well as available resources, are then described. Barriers to implementation in various clinical settings identified in the literature are highlighted, followed by program findings from community-based OEND programs related to these barriers.

Opioid Overdose Explained

Deaths from drug poisonings (also referred to as drug overdoses) have more than doubled in the U.S. since the 1990s.¹ This increase in overdose deaths, primarily caused by opioids, has led to national recognition of opioid overdose as a major public health issue.^{10,29} Most overdoses are not fatal, but unfortunately are not rare among people who use drugs.⁸² Two different studies reported that 25% and 28% of study participants respectively reported a past overdose.^{83,84} Another study reported that 57% of people who use drugs in an urban area had witnessed at least one overdose among a peer who used drugs.⁸⁵ Knowledge of what constitutes an opioid and leads to opioid overdose is

necessary background for addressing this issue.

Both opiates and opioids are referred to as “opioids.” Opiates are drugs naturally derived from the poppy plant (i.e., morphine and heroin), and opioids are synthetic or semisynthetic formulations (i.e., prescription painkillers such as hydrocodone, oxycodone, fentanyl, and methadone). All opioids bind to receptors in the brain that alleviate pain and produce feelings of euphoria.⁸⁶ For that reason, prescription opioids play a vital role in the clinical management of pain following surgery, illness, or injury.

Prescription opioids used in ways other than as prescribed lead to similar effects as heroin.⁸⁷ While many people believe prescription opioids to be safe because they are prescribed by a medical provider, the physiologic effects and highly addictive properties of these medications can lead to misuse, abuse, and dependence.⁸⁸⁻⁹⁰ When taken over time, opioids create— that is, a need for more or stronger opioids in order to achieve the initial effect and eventually to prevent painful symptoms of withdrawal.⁹¹

The brain receptors that opioids bind to, resulting in pain relief or a sense of euphoria, also control breathing. An overdose occurs when high concentrations of opioids bombard these receptors or when opioids are combined with other drugs or alcohol, leading to depressed respiratory function.⁹² An overdose is rarely instantaneous, and typically happens over a few minutes to hours. During an overdose, a person’s respiratory rate decreases, blood pressure drops, and the heart rate decreases. This leads to unconsciousness; the victim cannot be awakened, and a blue tone to the skin, lips, and fingernail beds develops. Oxygen deprivation can result in cardiac arrest and anoxic brain injury, eventually leading to death.⁹³ Non-fatal overdoses can lead to long-term

morbidities included renal failure, pneumonia, and cognitive impairment.^{92,94}

The mechanisms of opioid overdose are also well understood. As noted earlier, opioid abuse can lead to tolerance. Periods of abstinence, such as following drug treatment or incarceration, result in decreased tolerance, and therefore use of the same dosage of opioids taken previously can lead to overdose. The combination of opioids with other medications or alcohol can also depress respiratory rate.⁹⁵ In fact, the majority of people who die of a prescription opioid overdose had ingested another drug as well, most often a benzodiazepine.^{3,95,96} The increase in heroin adulteration with the synthetic opioid fentanyl, led to a surges in opioid overdose deaths beginning in 2013.⁹⁷

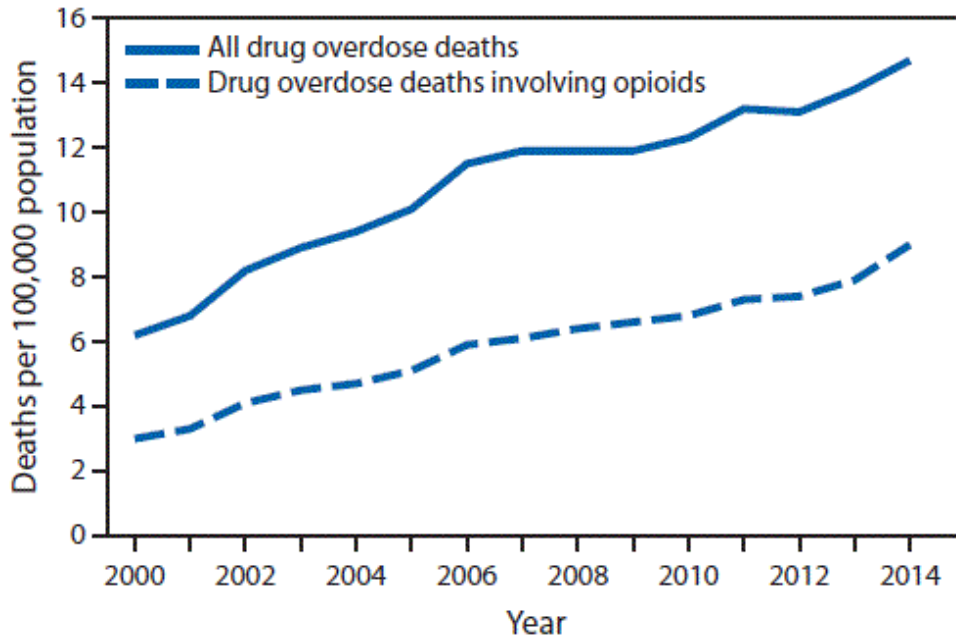
Trends in Opioid Misuse, Abuse, and Overdose

Drug overdose fatalities surpassed deaths from motor vehicular injuries as the leading cause of injury death among adults aged 25–64, both nationally beginning in 2009² and in 35 states and the District of Columbia as of 2013.³ In 2014, 47,055 drug overdose deaths occurred in the U.S.— a record high. From 2000 to 2014, the age-adjusted drug overdose death rate increased from 6.2 per 100,000 persons to 14.7 per 100,000.⁹⁷ The majority (61% or 28,647) of these deaths were opioid-related, and about half (more than 14,000) involved prescription opioids.⁴

Figure 1 below shows that the age-adjusted rate of opioid-related overdose deaths tripled from 2000 to 2014, with a sharp 14% increase from 2013 to 2014, from 7.9 to 9.0 deaths per 100,000 persons.⁹⁷ This contributed to a drastic increase between 2013 and 2014 in the number (N=3,073 more deaths) and rate (6.5% higher) of overall drug overdose deaths. Massachusetts, the setting of the current study, was one of 14 states that

experienced a statistically significant increase in the rate of drug overdose deaths during this time period.⁹⁷

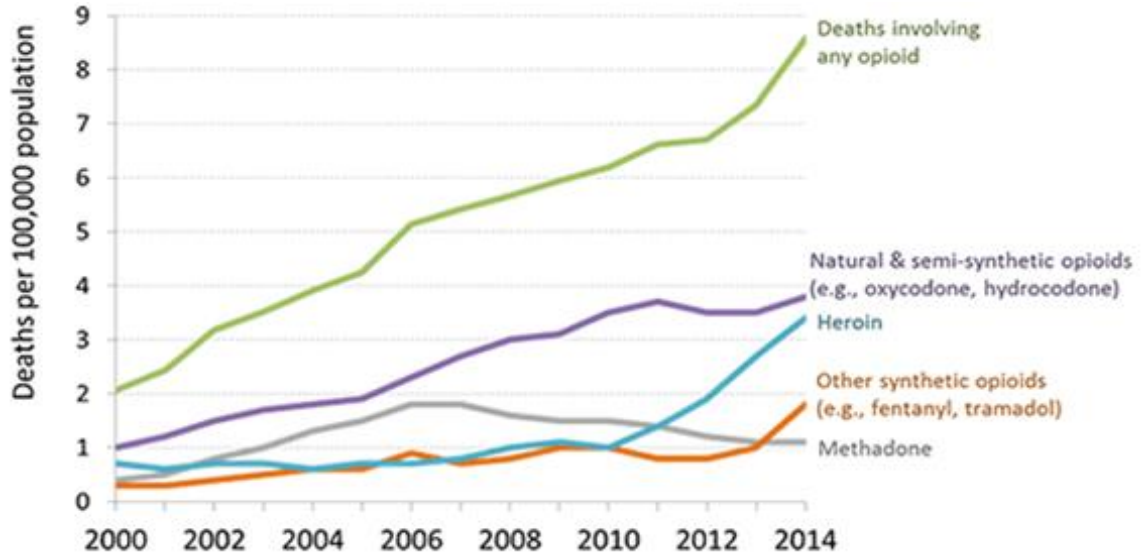
Figure 1. Age-adjusted Rate of Drug Overdose Deaths and Drug Overdose Deaths Involving Opioids— U.S., 2000–2014



Source: Centers for Disease Control and Prevention. MMWR, 2016.

Figure 2 depicts the rising national trend in drug overdose fatalities caused by prescription opioids and heroin.⁹⁷ A dramatic increase in overdose deaths from 2013 to 2014 (1.0 to 1.8 per 100,000) due to synthetic opioids such as fentanyl, but not including methadone, contributed to this spike. Overdose death rates due to natural and semisynthetic opioids such as morphine and oxycodone also increased from 2013 to 2014; they were the greatest contributor to opioid overdose deaths at 3.8 per 100,000 persons in 2014, up from 3.5 per 100,000 in 2013. Heroin overdose death rates climbed by 26% from 2.7 deaths per 100,000 in 2013 to 3.4 deaths per 100,000 in 2014.⁹⁷

Figure 2. Drug Overdose Death Rates Involving Opioids, by Type of Opioid—U.S., 2000–2014



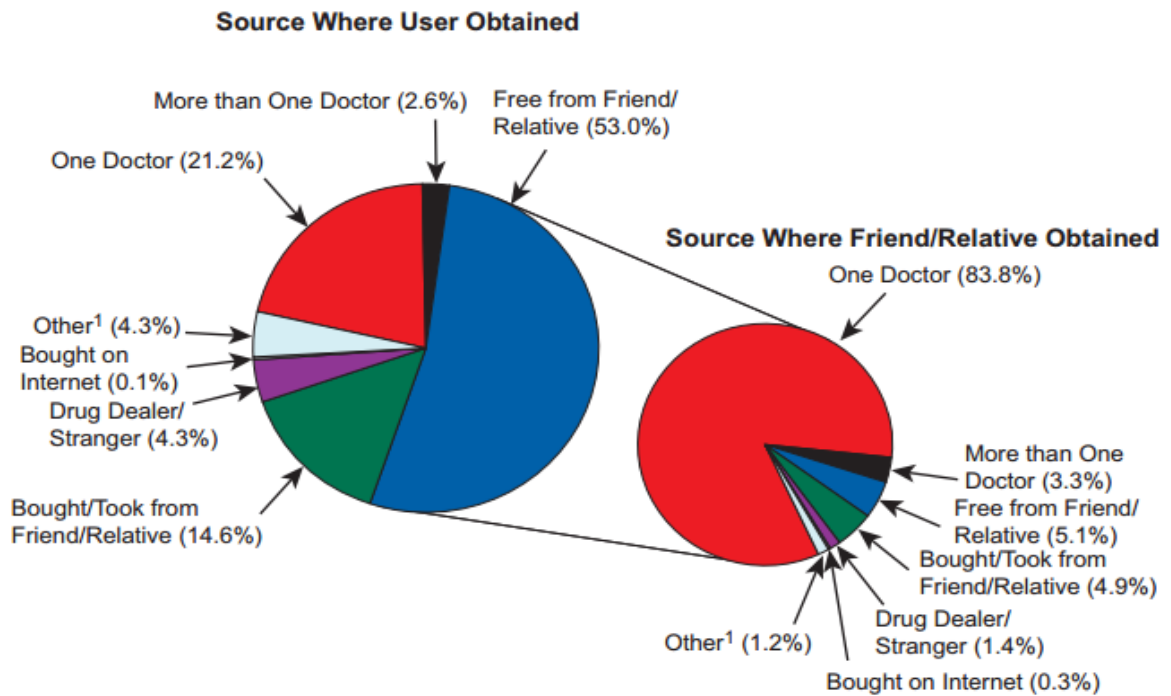
Source: Centers for Disease Control and Prevention. MMWR, 2016.

From 1999 to 2014, the highest prescription opioid death rates were among males, people aged 25 to 54 years, and non-Hispanic whites and American Indian/Alaskan Natives.⁴ While more men die from prescription opioid overdoses, the percentage increase in women’s deaths from 1999 to 2012 was more than 400% compared to a 265% increase in men’s deaths. This rise in prescription opioid deaths among women has been associated with increased prescribing to women.⁹⁸ For heroin-related overdose deaths, non-Hispanic whites aged 18 to 44 years experienced the highest overdose death rates.⁹⁹

The number of prescriptions for opioids in the U.S. has increased over the past ten years,⁵ correlating with the surge in fatal overdoses.^{100,101} Non-medical use of prescription opioids plays a major role in the overdose death epidemic.¹⁰² Prescription opioids are among the most commonly abused substances in the U.S.⁵ In 2015, more than 12 million people in the U.S. reported misusing prescription opioids, and over 2 million

people reported a prescription opioid use disorder.¹⁰³ Around one in four people who receive long-term prescription opioids for non-cancer pain in primary care settings experience an opioid use disorder.⁸⁰ Nearly seven out of ten people who reported using opioids for non-medical purposes in the prior year obtained the painkillers from a friend or relative, 80% of whom got their prescription opioids from just one doctor (Figure 3).⁵ So while the majority of prescription opioids were in fact prescribed, they often ended up being used by people and in ways other than what was prescribed.

Figure 3. Source of Prescription Opioids, Most Recent Non-medical Use in Past Year, Users 12 Years and Older— U.S., 2012–2013



¹The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Note: The percentages do not add to 100 percent due to rounding.

Source: SAMHSA. Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, 2015.

While previously thought to be separate epidemics, a tight link between prescription opioid use and initiation of heroin use has been demonstrated.^{88,101,104} An

analysis of the SAMHSA 2011 National Survey on Drug Use and Health data showed that among persons 19–49 years of age, nearly 80% who used heroin in the past year used prescription opioids non-medically before starting heroin.¹⁰⁵ This connection is unidirectional; only one percent of people recently misusing prescription opioids had previously used heroin.⁷ Even though only a small percentage (3.6%) of first-time prescription opioid users subsequently started using heroin within five years,⁷ these findings do help explain the increase in heroin overdose deaths seen since 2010.¹⁰⁶

Several studies help explain the “twin epidemics”¹⁰⁷ of prescription opioid and heroin addiction. In one study, 39% of heroin injectors reported prior addiction to prescription opioids.¹⁰⁸ In three studies, nearly half of the young adults who injected heroin reported abusing prescription opioids before turning to heroin. Their reported reasons for switching to heroin included ease of access and affordability compared to prescription opioids.^{109,110,8,111} Creation of an abuse-deterrent formulation of the prescription painkiller OxyContin has also been associated with switching to heroin.¹¹⁰ Some researchers have hypothesized that increased legislative scrutiny of opioid prescribing practices has led to increased uptake in heroin use,^{112,113} though a review of deaths from 28 states found that decreases in prescription opioid overdose deaths did not correspond with increases in heroin overdose deaths.¹¹⁴

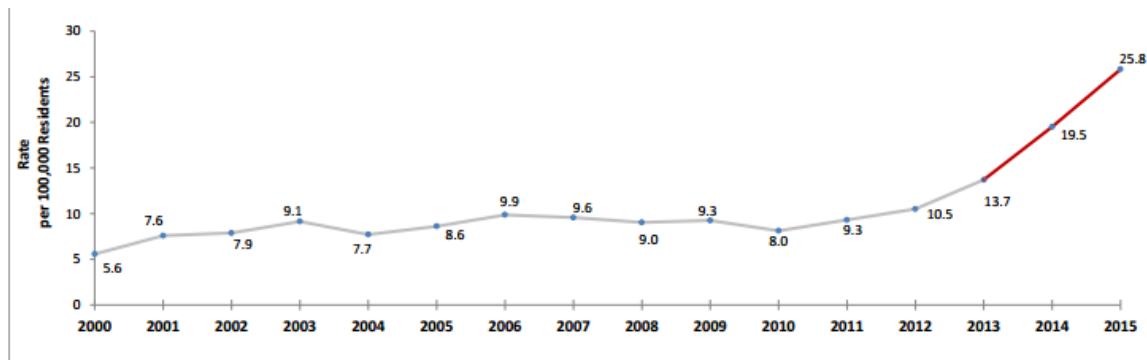
A 2016 CDC analysis revealed the role of polysubstance among people who use heroin, with prescription opioid abuse or dependence being the most common. In fact, the percentage of people who use heroin with prescription opioid abuse or dependence increased from 20.7% in 2002–2004 to 45.2% in 2011–2013.⁹ It is paramount that

overdose prevention strategies take into account the complex interplay between prescription opioids and heroin.

The Study Context: Opioid Overdose Trends in Massachusetts

Similar to the national trend, the Commonwealth of Massachusetts has experienced a continued and sharp increase in opioid overdose mortality (Figure 4).⁶⁵ In fact, in 2015 Massachusetts faced a record high number of deaths from unintentional opioid overdoses, with 1,574 confirmed cases—a dramatic 43% increase from 2013 (918 deaths) and a 20% increase from 2014 (1,316 deaths). Every county in the state has experienced opioid overdose deaths. Unfortunately, the uptick in deaths does not appear to be abating; the number of unintentional opioid-related deaths during the first 9 months of 2016 (n=1,005) was higher than what was seen during the same time period in 2015.⁶⁵

Figure 4: Rate of Unintentional/Undetermined¹ Opioid²-Related Deaths— Massachusetts Residents, 2000–2015



¹Unintentional poisoning/overdose deaths combine unintentional and undetermined intents to account for a change in death coding that occurred in 2005. Suicides are excluded from this analysis.

²Opioids include heroin, opioid-based prescription painkillers, and other unspecified opioids. This report tracks opioid-related overdoses due to difficulties in identifying heroin and prescription opioids separately.

Source: Massachusetts Department of Public Health. Data Brief: Opioid-related Overdose Deaths Among Massachusetts Residents, November 2016.

In 2014, the Massachusetts opioid overdose death rate of 19.5 deaths per 100,000 residents exceeded the national rate of 9.0 deaths per 100,000 persons.⁹⁷ In 2015, the state's death rate rose to 25.8 per 100,000, the highest rate that the Commonwealth has

ever experienced, and an increase of 32% from 2014.⁶⁵ Similarly, EMS responses to opioid-related transports almost doubled between 2013 and 2015.¹¹⁵

Similar to the national trend, the state's dramatic increases in Schedule II opioid prescribing from 2001 to 2011 (88% increase) correlates with increasing opioid-related fatalities during that same period.¹¹⁶ Toxicology tests have revealed the frequency of polysubstance use among people who succumb to an opioid overdose, and the increase in fentanyl-related deaths. Among the toxicology screens available from opioid-related deaths in 2016, nearly three-quarters (74%) revealed the presence of fentanyl. Heroin was present in over half (53%) of the opioid-related deaths. Benzodiazepines and cocaine were present in about half and 30% respectively.⁶⁵

Similar to the national trend, the majority (75%) of unintentional opioid deaths were among males and white non-Hispanic (82%) and Hispanic (12%) persons. The toll of this epidemic on young adults has been enormous: 58% of opioid deaths in the state were among persons aged 25 to 44 years of age compared to only 5% of all deaths in the state in 2016.¹¹⁷ Opioid-related EMS transports in the state also increased by 18% in the first two quarters of 2016 compared to that time period in 2015. Incidents where EMS personnel administered naloxone also increased, as did the frequency at which naloxone had to be administered more than once, indicating the potency of opioids used.¹¹⁸

Risk Factors for Opioid Overdose

There are several factors that increase a person's overdose risk as summarized in Table 1.^{21,37,41,49,119,120} As noted above, a person who has used opioids is at risk of an overdose following drug treatment or incarceration because of decreased tolerance.

Persons with a history of substance abuse, past overdose history, and mental illness are also at increased risk of overdose. Patients seeking prescription opioids from multiple providers contribute to a significant percentage of overdoses, as many of these patients are using opioids for non-medical purposes.^{29,121,122} Use of opioids along with sedatives, such as benzodiazepines, antidepressants, and alcohol, greatly increases opioid overdose risk.^{123,124} Along with mental health disorders, diseases of the respiratory, circulatory, and hepatic systems present additional risks for overdose due to pulmonary and liver dysfunction.^{94,125}

The risk of overdose is not limited to those who use heroin or misuse or abuse prescription opioids. Complex medication regimens, often managed by different providers, can put patients on long-term opioid medication at risk. Higher opioid dosages have been associated with higher opioid overdose death rates.^{126,127} This finding is particularly concerning given that a report identified an increase of 20% from the period of 1999–2002 and 2002–2012 in the percentage of people who were prescribed an opioid more potent than morphine.¹²⁸ For this reason, clinic-based OENA programs recommend targeting both patients who use opioids as prescribed and those who may be using opioids for non-medical reasons.²⁵

Table 1. Patient Risk Factors for Opioid Overdose

a)	History of non-medical use of prescription opioids or heroin
b)	Previous overdose history
c)	Prescribed high-dose opioid prescriptions (>50 mg morphine equivalent/day)
d)	Rotated from one opioid to another
e)	Use of opioids with antidepressants, benzodiazepines, or alcohol
f)	Starting methadone or buprenorphine for addiction treatment
g)	Use of opioids in patients with a respiratory illness or who smoke
h)	Use of opioids in patients with chronic renal, hepatic, or pulmonary disease
i)	Release from a drug detox program or prison following opioid use abstinence

Increased Overdose Risk for PLWH

In 2014, injection drug use was the risk group for an estimated 6% of incident HIV infections in the U.S.¹²⁹ Similarly, in Massachusetts, injection drug use was the risk group for 7% of persons with incident HIV infections from 2011–2013. In Massachusetts, as of January 2015, 18% of the state’s approximately 23,000 PLWH identified injection drug use as a risk factor, but about half of all deaths among PLWH were among that group.¹³⁰

While HIV infection is not listed as a specific risk factor in Table 1, opioid overdose is a major cause of non-HIV related death among PLWH.^{57,131,132} A brief overview of some of these risk factors appears in Table 2.^{49,57,131} Compared to persons who use drugs without HIV, those with HIV infection are 1.7 times more likely to die from an opioid overdose.⁵⁷ A national study examining causes of death among U.S. HIV-seropositive women from 1995 to 2004 found that mortality from non-AIDS causes increased over the ten years, with deaths from trauma and intentional or unintentional self-harm causing the greatest non-AIDS related mortality, most frequently due to overdose.¹³³

Given the connection between injection drug use and overdose, OEND programs have prioritized working with HIV-prevention programs designed to reach PWID, including syringe access programs,¹³⁴ as PWID are at risk for both HIV transmission and overdose. The Massachusetts Overdose Prevention Pilot started as a joint initiative between the Massachusetts Department of Public Health (DPH) Bureau of Substance Abuse Services and the Office of HIV/AIDS. In the program guide, the DPH specifically

identified HIV as a risk factor for opioid overdose among those using opioids, both non-medically and as prescribed.¹³⁵ The International Eurasian Harm Reduction Network and Open Society Foundations implore programs reaching PLWH to integrate opioid overdose prevention and naloxone prescribing into their services.¹³⁶

HIV providers, nurses, and other clinical care team members have been on the frontlines of addressing HIV and its comorbidities, including substance use disorder, mental health disorder, hepatitis C virus, and other chronic diseases. Along with this comes the need to address the risk of a potential overdose, particularly for patients who were diagnosed with an opioid use disorder and/or prescribed long-term opioid therapy for chronic pain management.

Table 2: Opioid Overdose Risk Factors for PLWH

-
- Past or current use of heroin
 - Non-medical use of prescription opioids
 - Prescribed long-acting opioids for chronic pain management
 - Diagnosed with conditions or comorbidities known to increase risk of overdose
 - Use of opioids with other prescription medications associated with increased risk of overdose
-

It is important to note that there are several explanations for PLWH increased risk of overdose, as described in a systematic review and met-analysis of 27 studies, including biological, behavioral, and structural mechanisms. Several co-infections, including hepatitis C virus, occur frequently among PWID.¹³⁷ As PLWH are living longer due to anti-retroviral therapy (ART), the combination of HIV and other chronic conditions are likely to compromise long-term health. For example, persons with both HIV and diabetes are at significantly increased risk of progressive chronic kidney diseases compared to those with only HIV or only diabetes.¹³⁸ Many of these comorbidities can compromise

the metabolic and respiratory systems⁵⁷ and can increase the likelihood of an overdose as well as lessen the chances of survival from an overdose.¹³⁵

Immune system functioning among PLWH has also been thought to affect overdose risk. One study among a cohort of women with HIV in the U.S. reported an association between the level of HIV and overdose/traumatic death.¹³³ Another study found that the risk of overdose is reduced by 5.7% if ART is initiated early rather than deferred.¹³⁹

A meta-analysis of studies revealed several other causal factors thought to be associated with increased risk. These included structural factors such as poor access to medication-assisted therapy, homelessness, and poverty. Incarceration release has also been found to increase the risk of overdose among persons who contracted HIV through injection drug use because they have not taken opioids for a period of time and so are more severely affected by a dosage level they may have taken in the past.³⁹

Opioid prescribing patterns for PLWH with mental health disorders may exacerbate overdose risk. Mental health disorders— which can occur frequently among PLWH.^{140,141}— have also been linked with opioid misuse and overdose.¹²⁶ Co-prescribing of sedating medications, such as benzodiazepines for anxiety, exacerbate overdose risk.¹⁴² In one study, chronic co-prescribing of sedating medications occurred in 6% of PLWH prescribed opioids. Of greatest concern, patients at the highest risk of overdose were the ones who received an opioid prescription with a sedating medication co-prescription: those over 50 years of age, receiving public insurance, and experiencing depression and anxiety.¹⁴³

Pain commonly occurs among PLWH¹⁴⁰ with prevalence ranging from 25% to 80%.¹⁴¹ Even with the use of ART to restore immunologic function, PLWH are at increased risk of age-related morbidities and mortality compared to HIV-seronegative persons.^{144,145} As more and more people are living longer with HIV, chronic pain management is a key component to clinical care management.¹⁴⁶ Pain related to HIV comorbidities, such as peripheral neuropathy,¹⁴⁶ is a commonly reported condition among PLWH.¹⁴⁷ A few studies in clinical care settings found that PLWH were more likely to be prescribed opioids at a higher dose,⁵⁸ over a longer period of time,⁵⁹ and into older age¹⁴⁸ compared to non-HIV infected patients. Studies have shown chronic opioid prescribing rates among PLWH to be 8%,⁵⁹ 10%,⁵⁸ and 17%.¹⁴³

Opioid prescribing among PLWH with a history of substance use disorder introduces additional complications. Among PLWH, pain is reported more frequently by persons with a history of substance use,¹⁴⁹ but a review of the literature found that HIV providers offered lower rates of pain treatment for PLWH with substance use histories. This could lead to opioid misuse through self-medication.¹⁴¹ Alternatively, persons with a history of or current substance use disorder may have decreased tolerance for pain, thus leading to earlier initiation and potentially more potent opioid use. A study examining pain and prescription opioid use among 2,267 HIV-infected persons from 1996 to 1997 reported heightened risk of pain and misuse of opioids among those with a history of substance use disorder.¹⁵⁰

To put these data in context, for PLWH with an opioid use disorder, provision of buprenorphine treatment has been shown to improve quality of life and mental health.¹⁵¹

Both buprenorphine and methadone treatment have resulted in improved HIV treatment adherence and improved health outcomes.^{152–155} Thus, MAT plays an important role in decreasing opioid overdose risk.

These findings point to the need for strategies in healthcare settings to prevent opioid overdose and overdose deaths among PLWH.^{57,131} While multiple strategies are needed, clinical care settings providing routine care to PLWH have an opportunity to integrate opioid overdose education and naloxone provision into routine care and thereby minimize the risks of a potential overdose.

Cost of Opioid Overdose

In addition to the soaring number of preventable deaths, fatal and non-fatal opioid overdoses take a toll on the healthcare system and ultimately create both direct and indirect societal costs. In 2010, there were nearly 136,000 ED visits in the U.S. due to opioid overdoses. Unfortunately, this number does not represent the full extent of overdose cases: for some non-fatal overdoses, emergency medical help is never called and in other cases, an overdose is fatal before emergency help arrives. An analysis of relevant ED visits found that 68% of the overdoses involved prescription opioids, while heroin accounted for 16%. About half of the opioid overdose patients evaluated in an ED were then admitted for inpatient hospital care.¹²⁵

In Massachusetts, the opioid epidemic is taking a toll on the state's substance use treatment and healthcare systems. Nearly half of those who sought publicly-funded substance use treatment in the state in 2013 listed opioids as their primary or secondary drug of choice; 40% of these people were between the ages of 13–29 years.¹⁵⁶ That year,

opioid overdoses also contributed to more than 2,000 hospital stays and 4,570 ED visits.¹⁵⁷

The burden of overdose among patients insured by the Medicaid system has also been documented.¹⁵⁸ A CDC study of Washington state's prescription opioid overdose deaths from 2004–2007 found that 45.4% of the victims were Medicaid enrollees.¹⁵⁹ Given the costs of opioid overdose, Project Lazarus in North Carolina expanded its opioid overdose prevention program to include the state's regional Medicaid program, thus integrating opioid safety into the clinical program's broader pain management initiative.^{25,160} Advocacy with state Medicaid programs has been recommended to enhance clinic-based overdose education and naloxone prescribing.¹⁶¹

A cost analysis from 2009 estimated the economic toll of opioid overdose in the U.S. at \$20.4 billion a year— with \$2.2 billion attributed to emergency department and inpatient medical costs and the remaining to absenteeism and lost productivity. The researchers concluded that a single opioid overdose costs society \$37,274, with the majority of the estimated total cost being associated with deaths from overdose. Therefore, interventions that prevent and reverse opioid overdoses should have the greatest immediate impact on reducing these societal costs.¹⁶²

Policy Recommendations to Prevent Opioid Overdose

In response to the rise in opioid overdose deaths, several federal government agencies, including the U.S. Office of National Drug Control Policy,¹⁶³ U.S. Department of Health and Human Services,¹⁸ and the CDC¹⁹ have recommended several strategies to reduce the number of opioid overdose deaths. In 2016, the U.S. Surgeon General

implored physicians to sign a pledge to enhance pain management education, promote screening for substance use disorder and referral to treatment, and recognize that addiction is a chronic disease.¹⁶⁴

While the national policy agenda drives funding, states play a critical role in the opioid epidemic response. States enforce their laws and regulations regarding controlled substances, licensure, opioid prescribing, and naloxone access; oversee state programs such as Medicaid; and fund substance use treatment programs. These policies influence the level of access to prescription opioids, substance use treatment services, and naloxone.^{165–167} Importantly, the focus on state-level initiatives allows for data-driven, community-based responses to the opioid epidemic, as demonstrated by Project Lazarus.¹⁶⁰

In recognition of the state role, SAMHSA and the CDC have set out to support state-based policy initiatives focused on decreasing opioid overdose fatalities through targeted funding and policy guidance.^{168,169} An overview of the national policy recommendations, many of which are focused on state action, frames the broader context of this research.

1. **Training on safe opioid prescribing practices.** Federal agencies recommend enhanced education for prescribers on opioid prescribing and safety. For example, states could stipulate that prescribers are required to complete training about the risks of opioid prescribing before getting their controlled substance registration and prescribing authority from the U.S. Drug Enforcement Agency. Providing education for medical professionals is a first step in increasing awareness about

the risks of opioid overdose and strategies to prevent overdose deaths.

Some states have developed training resources for primary care providers^{170,171} and prescribers. Several states have legislation requiring such training prior to opioid prescribing certification.⁴⁹ Massachusetts, for example, passed a law requiring prescribers to complete continuing education related to opioid prescribing and associated risks of abuse.⁷³

2. **Enforcement of safe prescribing practices.** Several state governmental agencies and other entities developed clinical practice guidelines.^{71,172–174} Then, in March 2016, the CDC published *Guidelines for Prescribing Opioids for Chronic Pain*. These evidence-based guidelines detailed: 1) when to initiate or continue opioids for chronic pain; 2) opioid selection, dosage, duration, follow-up, and discontinuation; and 3) assessing risk and addressing harms of opioid use.”⁴⁵ Alongside these, some states enacted opioid prescribing legislation, such as in Massachusetts which was the first state in the U.S. to limit first-time opioid adult prescriptions to a 7-day supply, and all minor prescriptions to a 7-day supply.⁷³ Increased regulatory action against medical providers who do not follow evidence-based opioid prescribing guidelines aim to minimize the availability of for-profit pain management clinics (i.e., “pill mills”).¹⁶³ Several states have laws to monitor the establishment and operation of pain clinics, legislation which has been shown to reduce prescription opioid overdose deaths in Florida.¹⁷⁵
3. **Use of Prescription Monitoring Programs (PMP).** PMPs store and share information about controlled medication prescriptions for authorized prescribers

and pharmacists. Use is intended to help prevent patients from obtaining opioid prescriptions from multiple prescribers, though the impact of PMP on lowering overdose rates has not yet been determined.¹⁷⁶ As of September 2016, all 50 U.S. states, the District of Columbia, and one U.S. Territory have operational PMPs in place.¹⁷⁷ In Massachusetts, a law was passed that requires prescribers to check the PMP before prescribing a Schedule 2 or 3 narcotic and then to update the PMP within 24 hours.⁷³

4. **Proper prescription opioid storage and disposal.** Efforts to promote proper storage and disposal of prescription opioids minimize the likelihood of unintentional poisoning and non-medical use. Approaches to minimize diversion of prescription opioids are essential given that nearly 70% of people who used prescription opioids for non-medical reasons in the past year got them from a friend or relative.⁵ In a survey, 30% of Massachusetts and 17% of national respondents reported saving their prescription opioids for future use, raising safety concerns about drug diversion and accidental ingestion.¹⁷⁸ Most community police stations offer safe prescription drug disposal.¹⁷⁹ Such initiatives, still to be evaluated, aim to protect friends, family, and others sharing a household with someone who has a current or past opioid prescription.
5. **Access to opioid MAT services.** Research has shown that patients in opioid treatment programs have improved health outcomes including reduced opioid use and decreased overdose deaths.^{180,181} For this reason, it is important to increase the availability of accessible MAT. Recognition of the role of opioid treatment,

specifically methadone and buprenorphine therapies, has led to a call for expanded services;¹⁸² primary care settings are a targeted venue for expanded buprenorphine treatment.¹⁸³

6. **Expanded access to overdose education and naloxone.** Provision of effective, proven harm reduction strategies is needed to prevent overdose and reduce overdose fatalities. OEND programs, described in detail below, have played an important role in reducing the number of opioid overdose deaths. SAMHSA released the *Opioid Overdose Prevention Toolkit*, which provides guidance to local governments, communities, and prescribers for implementing opioid overdose prevention and response policies and programs.³⁰

Summary of Massachusetts Policy and Program Context

Along with the national context, it is important to understand the Massachusetts policy and program context for this study. Since 2014 the Commonwealth's leadership has prioritized a broad-spectrum response to the rising and record high number of opioid overdose fatalities in the state.^{15,66} The dramatic increase in opioid overdose deaths in 2013 led former Governor Deval Patrick to declare a public health emergency in March 2014,¹⁵ precipitating release of "Opioid Overdose Response Strategies in Massachusetts" in that April.¹⁸⁴ Current Governor Charlie Baker also placed opioid addiction on his political agenda before he entered office in January 2015.¹⁷ An overview of the program and policy response to opioid overdose provides useful context for this dissertation research. Several significant activities in the Commonwealth's response to the opioid crisis are presented in Table 3.^{41,67,185-187}

Table 3: Summary of Massachusetts Opioid Overdose Response Milestones

Year	Activity
2005	Boston EMT use of intranasal naloxone
2006	Two city health department OEND pilot programs operate through syringe access programs
2007	Standing order to distribute naloxone through community public health programs; Expansion of office-based opioid treatment program to 14 CHCs through DPH
2010	State police and fire department staff equipped with intranasal naloxone
2011	Involvement of opioid addicted caregiver support group with OEND
2012	Passage of Good Samaritan and patient and prescriber protection laws (Chapter 192 of the Act of 2012)
2014	Governor Patrick declares Public Health Emergency
2014	Standing order for OEND at authorized pharmacy retailers
2015	Governor Baker creates Opioid Addiction Working Group
2015	Expansion of OEND pilot program to first responders and bystanders throughout state Creation of police department initiatives (i.e., Police Assistance in Addiction and Recovery Initiative; The Angel Program in Gloucester; and Arlington Outreach Initiative)
2016	Passage of opioid bill An Act relative to substance use, treatment, education, and prevention inclusive of screening, prescribing, education, referral to treatment, and civil liability protections for persons who use naloxone

Massachusetts' pioneering OEND activities have been shown to reduce opioid overdose deaths²⁷ and serve as a national model.^{41,67} In 2005, Boston EMS responded to the high number of overdoses by equipping Boston EMTs with intranasal naloxone.⁶⁷ The following year, two OEND pilot programs operating out of the Boston and Cambridge health departments distributed naloxone through syringe access programs. In 2007, the Massachusetts DPH expanded OEND activities to four community organizations through a DPH-issued standing order, which authorized persons who met certain criteria to distribute naloxone. From 2007 to the present, the OEND program has operated under existing Commonwealth law (Massachusetts General Law-MGL c. 94C and DPH/Drug Control Program regulations at 105 CMR 700.000) through the Massachusetts DPH's Commissioner's Office and the DPH's Bureau of Substance Abuse

Services and the Office of HIV/AIDS.¹³⁵ This set the stage for the program's expansion.⁴¹

Over time, OEND program activities expanded from HIV prevention program sites (e.g., syringe access programs) to homeless shelters, EDs, methadone clinics, and residential drug treatment programs, resulting in 21 agencies conducting OEND in 2015. The DPH also funds the purchase of naloxone rescue kits for first responders in 23 municipalities and for 16 chapters of the Learn to Cope caregiver support network.¹⁸⁸ As of 2015, statewide OEND activities resulted in the training of 32,000 bystanders and first responders and over 5,000 reported opioid overdose reversals.⁶⁷ A state policy allows adults to purchase naloxone at retail pharmacies with a standing order; currently, there are approximately 1,200 pharmacies with standing orders across the state.¹⁸⁹ Also of note, local police departments have played a role in distributing naloxone as part of their innovative opioid addiction treatment and recovery initiative, such as the Gloucester Police Department's Angel Initiative which has served as a model for police departments across the U.S.¹⁸⁷ Clearly, coordination of efforts between policymakers, public health departments, law enforcement agencies, medical providers, and pharmacies is necessary.¹⁹⁰

Upon taking office, current Governor Baker built on former Governor Patrick's efforts¹⁹¹ and convened a 16-person Opioid Addiction Working Group. In a recommendations report released in July 2015,^{68,157} the Working Group proposed more than 65 recommendations that resulted in Governor Baker creating an Action Plan⁶⁶ with activities focused on the following four areas:

- **Prevention:** education for the general public, parents, students, and prescribers about the risks of opioid use;
- **Targeted interventions:** activities including mandatory PMP use by prescribers; analysis of data to target overdose death “hot spots” across the state; increased co-prescribing of naloxone with prescription opioids; lowered prices for naloxone through bulk purchasing; and promotion of the Good Samaritan law;
- **Treatment:** expanded substance use treatment services through partnerships with several state agencies (e.g., Department of Corrections and Division of Insurance) and their federal counterparts to enhance treatment access; and
- **Recovery:** strengthened recovery support services after treatment.

As part of this plan, on March 14, 2016, Governor Baker signed an opioid bill with legislation⁷³ that included limiting first-time opioid prescriptions for seven days and all prescriptions for those under the age of 18 to seven days; use of PMP before prescribing, prescriber continuing education on opioid prescribing and addiction; and increased referral to treatment for persons who experience an overdose.⁷³

Perhaps due to a combination of the widespread opioid crisis and the media attention, public concern about the opioid crisis is high in Massachusetts. In April 2015, a poll found that 71% of Massachusetts residents, compared to 45% of residents nationally, reported that heroin use is an extreme or very serious problem. Sixty percent of residents thought prescription painkiller abuse is an extremely or very serious problem, compared to about half of all Americans surveyed. Almost one-half of Massachusetts residents surveyed thought prescription painkiller abuse is getting worse, compared to 39%

nationally.¹⁷⁸

Community and Clinic-based Overdose Education and Naloxone Programs

As described above, addressing the complexities of the opioid overdose crisis requires a comprehensive response. Use of the opioid antagonist naloxone hydrochloride, commonly known as naloxone or by its brand name, Narcan®, has been shown to be a feasible, effective, and inexpensive tool for reducing opioid overdose fatalities.

Clinical practice experience related to opioid OENA is limited, focusing primarily on prescribing, but community-based OEND programs have built a strong foundation for future interventions in healthcare settings. The next section describes OEND programs, lessons learned from past experience in community settings, models for clinic-based activities, and barriers to implementation in clinical care settings.

Naloxone: The Opioid Overdose Antagonist

Several U.S. public health agencies, including the Office of National Drug Control Policy, CDC, SAMHSA, National Institutes of Health, and the U.S. Food and Drug Administration (FDA)²⁸⁻³² encourage the adoption of overdose prevention interventions and naloxone distribution. In addition, several professional associations, such as the American Medical Association, American Public Health Association, American Pharmacists Association, and American Academy of Clinical Toxicology³³⁻³⁶ advocate widespread distribution of naloxone, as does the World Health Organization and the Global Fund to Fight AIDS, Tuberculosis, and Malaria.^{192,193}

For over 45 years, naloxone has been the standard of care for reversing potentially fatal opioid overdoses in EDs and by EMS personnel. Administered intramuscularly,

intravenously, subcutaneously, or nasally, naloxone quickly binds to opioid receptors and blocks the effects of the opioid. Typically, naloxone reverses an opioid overdose in less than two minutes and restores normal respiratory function. It only works if an opioid is present, and has no effect on non-opioid overdoses (e.g., from cocaine or alcohol).²¹

Naloxone is non-addictive. It causes few adverse reactions, other than withdrawal symptoms immediately after administration. A review of Massachusetts OEND program data found that 49% of persons experienced withdrawal symptoms following naloxone use.¹⁸⁵ Furthermore, because naloxone is a short-acting drug, a secondary overdose due to a long-acting prescription opioid may quickly occur after the naloxone's effect subsides. Thus, it is important that emergency medical services (EMS) are called at the first signs of an overdose and that the victim be monitored until help arrives.^{32,194,195}

In most U.S. states and cities, naloxone is administered by EMS personnel and hospital-based providers.¹⁹⁶ Administration of naloxone with a syringe and needle carries a risk of blood-borne disease transmission and therefore can be a barrier for use by non-medical bystanders. To increase ease of use and safety, a nasal spray atomizer was introduced in 1999 for “off-label” naloxone use, particularly by EMS personnel.¹⁹⁷ The FDA approved an auto-injector device for naloxone administration in April 2014,¹⁹⁸ and approved a single-step intranasal naloxone device in November 2015.¹⁹⁹

Several studies conducted in emergency medical settings have demonstrated the safety and effectiveness of nasal administration. Given this, intranasal naloxone has been the standard of care for use in pre-hospital and community settings.^{21,200,201} National and state policymakers have called on all first responders, including law enforcement and

firefighters, to use naloxone to reverse opioid overdoses whenever they are the first ones to arrive after a 911 call.^{202,203} As of April 2016, 971 law enforcement departments in 38 states and the District of Columbia carry naloxone.²⁰⁴

Naloxone has been shown to be a cost-effective intervention. A 2013 study of a U.S.-based naloxone distribution program for PWID found that naloxone prevented about 6% of overdose deaths, with one death prevented for every 227 kits distributed. OEND produced a savings ranging from \$438 to \$14,000 per Quality Adjusted Life Year gained.

Image 1. Naloxone Rescue Kit



Source: Harm Reduction Coalition, 2015.

These findings prove that OEND is a cost-effective intervention, even with conservative assumptions applied to the cost model.²⁰⁵

The present study is focused on the provision of overdose education and naloxone rescue kits, pictured in Image 1.²⁰⁶ Typically, in community distribution

programs, a naloxone rescue kit includes two vials of naloxone, mucosal atomizer devices, an educational insert, and optional supplies such as rubber gloves and a mask for rescue breathing.²⁰⁶ With the FDA's approval of the single-step naloxone spray device in 2015, prior acquisition of a mucosal atomizer device and pre-assembly of the intranasal

spray device by a bystander is no longer necessary with this formulation.¹⁹⁹ The single-step spray device has a stronger dosage and comes at a higher price, so the feasibility and acceptability of its use is currently being explored for community distribution programs.

Naloxone requires a prescription. However, several city and state health departments have created physician-signed standing orders to facilitate broader distribution. Through a standing order, a designated physician authorizes distribution of naloxone by select programs or personnel meeting specified criteria.²⁰⁷ Such standing orders have facilitated naloxone distribution by first responders, pharmacists, registered nurses, and harm reduction program staff,^{41,135,208} though have been shown to be difficult to implement in an ED setting.²⁰⁹

Community-based OEND Programs

Recognizing that drug overdose fatalities are preventable and typically occur in the presence of another person, several community-based organizations and health departments began implementing OEND programs in 1996. Different studies have reported the percentage of PWID who have witnessed a drug overdose (between 24% and 94%), noting that it is those at highest risk of overdose who are most likely to witness another person's overdose.⁸² Therefore, OEND programs have targeted PWID and their friends, peers, and family members.

In an effort to scale-up naloxone use, 644 sites from 140 organizations in 30 states and the District of Columbia collectively distributed 152,283 naloxone rescue kits from 1996–2014. Programs targeting those who use heroin and opioids non-medically— such as drug treatment, methadone, and syringe access programs— were early adopters of

OEND programs. Through these programs, emergency responders, but also opioid-using individuals and their family members and support network, were equipped to administer naloxone. Expansion of OEND programs has grown rapidly in recent years: from 2010 to 2014, there was a 243% increase in the number of sites providing naloxone across the U.S.,¹³⁴ resulting in nearly 26,500 overdose reversals.²⁶

Overdose education messages focus on the signs of opioid overdose and how to respond, including how to administer naloxone. Table 4 outlines the specific content for an overdose prevention and response training program, based on the experience of community programs.^{49,210,211} Trainings for peers or non-medical staff educators, ranging from 15 to 60 minutes in duration,^{41,212} prepare them to dispense a naloxone rescue kit to a friend, family member, or peer who may be likely to witness an overdose. SAMHSA's *Opioid Overdose Toolkit* provides further support to community OEND program development and implementation.³⁰

Table 4: Key Components of Opioid Overdose Education

-
1. Risk factors for overdose
 2. Preventing overdose
 3. Signs of an opioid overdose
 4. When to call 911 for help
 5. How to rescue breathe
 6. How to administer naloxone
 7. Importance of staying with victim until emergency medical help arrives
-

Several studies of programs have found OEND to be a feasible intervention targeted to potential bystanders,²² PWID,^{23,56,213,214} people on methadone treatment,²¹⁵ ED patients,²¹⁶ and formerly incarcerated individuals who inject drugs.²¹⁷ OEND has also demonstrated effectiveness in reducing overdose fatalities, primarily in community settings with harm reduction programs. An observational study of a seven-year OEND

program in Massachusetts measured changes in opioid overdose death rates across communities that had no, low, and high naloxone rescue kit distribution rates. Compared to communities with no naloxone distribution, there was a 27% and 46% decrease in death rates among low- and high-level communities, respectively.

OEND program experience in Chicago,²¹⁸ Baltimore, San Francisco, North Carolina, New York, and New Mexico also suggest that OEND programs will decrease opioid overdose deaths.²¹⁹ Preliminary findings from Project Lazarus have shown promise in reducing opioid overdose rates from prescription opioid misuse and abuse.²⁵ From 2009–2010, overdose fatality rates in that program’s catchment area decreased from 46.6 per 100,000 to 29.0 per 100,000.²⁵

Interestingly, a national spatial analysis of naloxone distribution sites found that they were located in areas with higher drug arrest and overdose deaths rates, and therefore noted that “alternative delivery methods...to reach individuals in other areas with less concentrated risk”²²⁰ are needed. In another study, interviews with primary care patients on chronic opioid therapy who were prescribed naloxone found that most patients had neither received nor heard about naloxone before getting a prescription, even in a city with a high concentration of OEND sites.²²¹ Given these issues, CHCs are emerging as an important venue for expanding awareness of and access to naloxone in a greater number and wider range of communities.

The number and type of OEND programs has increased dramatically since their inception in 1996. From 2010 to 2014, the number of organizations reporting OEND activities to the Harm Reduction Coalition increased by 183%, from 48 to 136.

Community-based programs have used different distribution models. Of the 136 organizations that participated in a Coalition survey on OEND activities, 44.1% of the programs utilized non-medical staff via standing orders. Others utilized medical staff (36.0%) to distribute naloxone or had medical providers write prescriptions to be filled at a pharmacy (28.7%) or arranged for pharmacists to distribute the medication directly through a standing order or collaborative practice agreement (8.8%). Many of these programs (n=33) utilized more than one delivery model.²⁶ New naloxone distribution models continue to emerge, including the innovative Gloucester, Massachusetts Police Department's Angel Initiative that includes naloxone distribution as one element of its treatment access program.²²²

Expanding OENA in Clinical Settings

With the feasibility and effectiveness of OEND having been established, there is an urgent need to expand access to naloxone in order to curb the rise in opioid deaths. OEND programs have reached PWID and members of their social network largely through harm reduction programs. Alongside these community interventions, there is also a need for interventions that can reach people at risk of opioid overdose who may not inject drugs, access harm reduction services, or perceive themselves to be at risk of overdose. Furthermore, clinic-based naloxone access initiatives have the potential to expand the geographic reach of OEND programming— which is a pressing need for addressing the current scale of the opioid overdose death crisis.²²³

To date, primary care settings have been underutilized for naloxone access, despite the major role that prescription opioids play in overdose fatalities.²¹⁰ There has

been a call to expand access to naloxone through clinical care settings, including primary care and pain management centers where patients receive routine care and may be prescribed opioids.^{33,37,39-44} While EDs have been identified as an important venue for naloxone provision,^{119,135} they provide episodic and urgent care, not the longer-term care offered in primary care clinical care settings.

There are a few clinic-based opioid overdose and naloxone prescribing programs that offer instructive programmatic experience, such as Project Lazarus aimed at reaching both medical and non-medical prescription opioid users; the Prevention Point Project in Pittsburgh, Pennsylvania using a pharmacy collaboration; and co-prescribing initiatives in San Francisco and New Mexico for patients receiving chronic opioid therapy in ambulatory care settings.^{25,41,224,225} Primary care clinics in other states, including Massachusetts, New York, and Washington, plus large federal healthcare systems such as the Veteran's Administration, have also implemented opioid naloxone prescribing initiatives.^{41,226,227}

The traditional model of naloxone access in a clinical setting involves a prescriber writing a prescription for the patient to fill at a pharmacy. Naloxone is not a controlled substance, so the prescription can be written by any licensed prescriber (i.e., physician, physician assistant, nurse practitioner). The patient pays out-of-pocket or a co-payment determined by the health insurance company.¹⁷¹ To address pharmacy access and cost issues for patients, naloxone rescue kit distribution through clinical settings has been supported by state grants in some states.^{186,228} Recommended educational messaging is summarized in Table 5,⁴⁹ which can be delivered in-person or through web-based videos

along with brochures.^{229,230}

Table 5: Opioid Overdose Prevention Education Messages Clinicians Can Convey to Patients

-
- Only take prescription opioids prescribed to you and as directed
 - If you have an opioid problem, there are treatment options
 - Make sure your medical providers and pharmacists know your different medications
 - Do not mix opioids with other drugs or alcohol
 - Store medications in a safe, secure place; dispose of unused medication
 - Breaks in opioid use can affect tolerance, necessitating a lower dose if restarting
 - Teach friends and family how to respond to an overdose and use naloxone
-

It is important to note the increasing role that pharmacists have played in expanding naloxone access in outpatient settings. Over an 18-month period spanning 2013 to 2015, there was an increase of 1,170% in naloxone dispensing through retail pharmacies across the U.S. Interestingly, primary care physicians prescribed 35% of these prescriptions.²²³ Table 6 outlines the roles that a pharmacist can play in assessing a patient's risk of opioid overdose.⁴⁹ In addition, pharmacists can directly distribute naloxone and offer overdose education to persons prescribed opioids or at risk of an overdose through collaborative practice agreements (CPAs), standing orders,²³¹ and prescriptive authority.²³²

Table 6: Pharmacist Role in Assessing Patient Opioid Overdose Risk

-
- Review list of current prescriptions in the PMP
 - Check to see if patient takes concomitant psychoactive or sedating medications
 - Alert prescribers of multiple prescriptions
 - Ask patient about knowledge of overdose risks
-

The CPA defines the prescriber and pharmacist roles in naloxone distribution.^{41,161} For example, pharmacists at the Prevention Point Project alert a prescriber that a patient needs a naloxone prescription, after which they receive a faxed prescription to fill.^{41,233} New Mexico passed legislation that grants pharmacists naloxone

prescribing authority if they deem patients to be in need.²³² Other states, such as Rhode Island and Washington, have CPAs by which approved pharmacists can dispense naloxone to pharmacy clients without a prescription.^{161,234} As explained above, standing orders between an authorized prescriber and designated pharmacies or pharmacists allow people to access naloxone directly from the pharmacy without a prescription.^{49,207,231} As of July 2016, 40 jurisdictions in the U.S., including Massachusetts,²³¹ have authorized naloxone prescription by standing order.²³⁵

While pharmacies have been utilized to expand access to naloxone, barriers to implementation have been documented. These include limited pharmacist time, the need for pharmacist training, negative attitudes toward PWID, lack of a private space to conduct naloxone education, concerns about legal issues, and cost and reimbursement issues.^{236,237}

Table 7. Opioid Overdose Risk Assessment Steps for Clinicians

-
- Review medications
 - Assess substance use history
 - Check PMP
 - Take an overdose history (experienced and witnessed)
 - Enquire about past overdose education and naloxone receipt/use
-

Training tools for clinical providers have been developed over the past few years through national,^{30,49} state, and city initiatives. To begin with, providers are encouraged to conduct an opioid overdose risk assessment (Table 7),^{30,49} taking into account the multiple factors that increase patients' risks of overdose. A list of these available opioid safety resources is summarized in Table 8 below. For example, the SAMHSA *Opioid Overdose Toolkit*, the online training module *Prescribe to Prevent*, and mytopcare.org

provide guidance on the steps prescribers can take to reduce opioid overdoses and fatalities among their patients.^{30,49,238}

Table 8. Opioid Overdose Training Resources for Clinical Settings

Online Training Videos and Webcasts for Providers and Staff

- Prescribe to Prevent. *Overdose Prevention and Naloxone Rescue Kits for Prescribers and Pharmacists* (prescribetoprevent.org)
- California Society for Addiction Medicine. *Talking About Naloxone in a Primary Care of Pain Management Setting* (www.csam-asm.org/naloxone-resources)
- California Society of Addiction Medicine. *Opioid Safety with Naloxone: A Life-saving Tool for California Physicians* (www.csam-asm.org/naloxone-resources)
- Prevention Point Pittsburgh. *Overdose Prevention and Response Training* (wpic.pitt.edu)
- Harm Reduction Coalition. Training Curricula for Providers (<http://harmreduction.org/issues/overdose-prevention/tools-best-practices/training-materials/curricula-for-providers/>)
- Reach For Me. Video and individual interviews with OEND program leaders (reach4me.org)
- Portsmouth Department of Health, Ohio. Project DAWN. Training Video-Part 1 (<http://www.ncbi.nlm.nih.gov/pubmed/26507172>)
- My Top Care. Prescriber, pharmacist, and patient education on chronic opioid therapy (www.mytopcare.org)

Toolkits

- SAMSHA. *Opioid Overdose Toolkit: Part IV. Information for Prescribers* (samhsa.gov)
- Project Lazarus, North Carolina. *Community Toolkit* (projectlazarus.org)
- San Francisco Department of Public Health. *Naloxone for Opioid Safety* (prescribetoprevent.org)
- Harm Reduction Coalition. *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*. Includes case studies and worksheets for training activities (harmreduction.org)
- University of Washington Drug and Alcohol Abuse Institute. *Guidance on Setting up Prescriber and Pharmacy Agreements* (stopoverdose.org/pharmacy.htm)

Job Aids

- Prescribe to Prevent. Various job aids to guide risk assessment prescribing, coding, and reimbursement of opioid safety and naloxone prescribing (prescribetoprevent.org)

Patient Education Materials

- University of Washington Drug and Alcohol Abuse Institute. Patient videos and brochures (stopoverdose.org)
- Boston Public Health Commission. Patient video (<http://www.bphc.org/whatwedo/Addiction-Services/prevention/Pages/Narcan-Program.aspx>)
- Prescribe to Prevent. Multiple patient videos about naloxone and overdose response (prescribetoprevent.org/videos)
- Harm Reduction Coalition. Patient videos about naloxone and overdose response and patient education brochure (harmreductioncoalition.org)
- San Francisco Department of Public Health. Patient education brochure

-
- (http://www.csam-asam.org/sites/default/files/pdf/detailing_patient_final.pdf)
- Stop Overdose.org. Patient education brochure (<http://stopoverdose.org/docs/OpioidOverdose.pdf>)
 - Massachusetts public awareness campaign posters and brochures (<http://massclearinghouse.ehs.state.ma.us/category/ALCH.html>)
 - Allegheny County Health Department, Pennsylvania (<http://www.achd.net/overdoseprevention/#access>)

Naloxone Access Laws

- The Network for Public Health Law. Naloxone access and Good Samaritan laws in the U.S. (lawatlas.org)
-

Lessons Learned from Community-based OEND Programs Extrapolated to Clinical Settings

Several studies highlighted below have identified barriers to overdose education and naloxone prescribing in clinical settings, categorized into provider, clinic or administrative, and system barriers (Table 9). A 2015 literature review summarized what has been learned from the operation of community-based OEND programs, with the goal of offering guidance to opioid safety initiatives in clinical settings.³⁷ It is important to note that the community-based OEND programs that were studied have primarily targeted PWID. More recent studies have assessed naloxone access initiatives for patients who have been prescribed opioids for pain management. This section summarizes OEND program experience to date in addressing identified barriers to clinical implementation.

Table 9: Potential Barriers to Opioid to Naloxone Prescribing in Clinical Settings

Provider Level Barriers

- Lack of provider knowledge about naloxone
- Low provider confidence in discussing overdose risk and naloxone with patients
- Negative attitudes and stigma towards PWID
- Concern about offending patients
- Belief that naloxone sanctions drug use and enables high-risk opioid use
- Belief that naloxone does not address patient treatment needs
- Belief that laypersons cannot identify and respond correctly to an overdose

Clinic or Administrative Level Barriers

-
- Lack of consensus regarding who should receive overdose education and naloxone
 - Minimal provider training in chronic opioid therapy prescribing
 - Appropriate family member or peer unavailable to receive overdose education
 - Limited provider time with patient and high patient caseloads

System or Policy Level Barriers

- Fear that naloxone prescribing could result in criminal or civil liability
 - Challenges related to naloxone stocking, price, and insurance reimbursement
-

Lack of provider knowledge about naloxone. A 2004 national survey assessed 563 physicians' willingness to consider prescribing naloxone and talking to patients who inject drugs about its use. Only 23% "had heard" of naloxone as a tool for preventing overdose among their patients who inject drugs. Over half (54%) indicated that they would never "consider prescribing naloxone and explaining its use to an IDU [injection drug user] patient."⁵¹ A 2003 survey of New York City healthcare providers found that only 33% were willing to prescribe naloxone to their patients, while 29% were unsure what they would do.⁵² Two more recent qualitative studies, one among primary care providers in a Colorado healthcare system (2015) and one among academic physicians and medical students at a large urban hospital (2016), also found a low level of provider knowledge about bystander administration of naloxone.^{40,54}

Studies have suggested that medical providers who are knowledgeable about the benefits of naloxone are more likely to support its use among PWID.^{51,52,239,240} The two early studies described above were conducted prior to heightened national policy and media attention focused on opioid addiction, which most likely increased clinical providers' awareness of naloxone and its effectiveness. A qualitative study conducted in Rhode Island and Connecticut in 2011— with a sample of 24 of general medical providers and specialists in emergency medicine, addiction, and pain management—

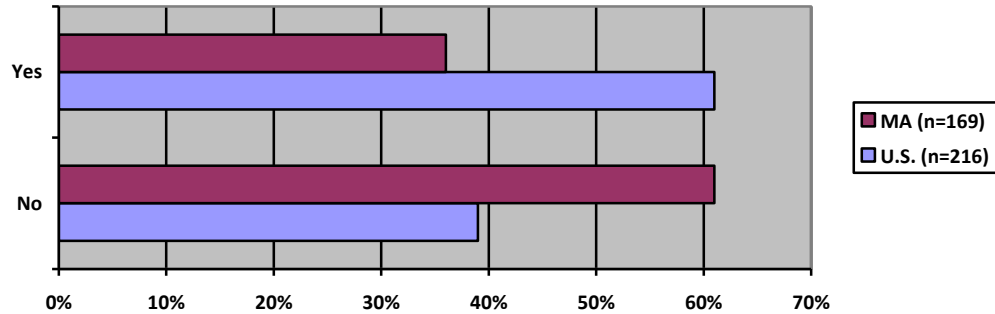
found overall support for prescribing naloxone to patients who use drugs and pain patients.³⁹

Still, implementation of clinic-based overdose education and naloxone prescribing remains a challenge. A study of an ED naloxone prescribing initiative found that barriers to education and prescribing were posed by a lack of staff knowledge about the policy and their role in prescribing.²⁰⁹ Two recent studies (2016), one with internal medicine residents and another with ED physicians, found that knowledge about naloxone and its benefits was high, but that having that knowledge did not correlate with actual prescribing practices.^{53,55}

Low provider confidence in discussing opioid overdose risk and naloxone with patients. Medical providers may not feel comfortable or prepared to talk with their patients about overdose.²⁴⁰ A study of Scottish general practitioners found low self-confidence in their ability to educate patients about overdose and naloxone, and a lack of clarity in what their role should be related to overdose education and naloxone prescribing.²⁴¹ Other recent U.S.-based studies identified low provider self-efficacy in performing overdose education and prescribing naloxone among internal medicine residents⁵³ and ED physicians.⁵⁵ In Massachusetts, a survey found that only 36% of respondents who were prescribed opioids in the prior two years had a discussion with their provider about any associated risks, compared to 61% nationally (see Figure 5).¹⁷⁸ In this context, it can be noted that there is a more general lack of provider self-confidence in recognizing and responding to substance use disorders.²⁴² In a national

survey of PLWH, of the 71% who reported substance use, only 24% received treatment and less than half discussed substance use with their HIV providers.²⁴³

Figure 5. Percentage of Adults Prescribed Strong Opioids Who Had a Conversation with Their Doctor about the Risks of Addiction— Massachusetts and U.S., 2015



Source: Boston Globe and T.H. Chan Harvard School of Public Health. Survey: Prescription Painkiller Abuse: Attitudes Among Adults in Massachusetts and the United States, 2015.

Negative attitudes and stigma toward PWID. Three studies assessing perceptions of naloxone use among medical providers and EMS personnel found negative attitudes toward PWID.^{51,239,241} Negative attitudes of physicians toward PWID have been shown to impede provision of other harm reduction interventions in clinical settings.^{51,244,245} Similarly, pharmacists' negative attitudes toward PWID has been found to impede their participation in a non-prescription syringe pharmacy access program for PWID in San Francisco.²³⁶ Given the stigma around substance use, patients may also be concerned about having naloxone listed on their medication list or in health insurance records.²⁴⁶ A meta-analysis of studies about healthcare professionals' attitudes toward persons with substance use disorder found that negative attitudes perpetuated stigma and negatively impacted healthcare professional and patient engagement in care. Furthermore, negative attitudes resulted in lower treatment outcomes.²⁴⁷ In an effort to stem

stigma in clinical settings, the ASAM and federal agencies have advocated for changing the language used to describe substance use.²⁴⁸

Concern about offending patients. A survey of academic physicians and medical school students at a large U.S. urban hospital identified fear of offending patients as a barrier to overdose and naloxone discussions.⁵⁴ Care providers' unease about insulting patients may be particularly heightened when patients are using prescription opioids. One qualitative study noted that providers especially expressed concern about notifying their pain patients without any overdose history.³⁹ Providers may also be concerned that patients will think they are being accused of drug abuse.^{40,249} All of this points to providers having differing perceptions of overdose risk when patients use illicit opioids as opposed to prescription opioids.³⁹

To combat stigma, primary care providers in a qualitative study suggested creating clinic-wide protocols that would call for offering overdose education and naloxone prescribing to all patients being given an opioid prescription.²⁰⁹ Clinical programs implementing opioid safety initiatives have presented similar recommendations.¹⁰⁷ Importantly, interviews conducted with patients and providers at safety net clinics in San Francisco following a co-prescribing initiative for patients on chronic opioid therapy, found that opioid safety discussions enhanced open communication and trust between providers and patients.^{221,226} This was substantiated by another study in which patients receiving substance use disorder treatment reported that a naloxone prescription from their hospital-based provider would strengthen their patient-provider relationship.²⁵⁰

Belief that naloxone sanctions drug use and enables high-risk opioid use.

Studies have documented that some medical providers and EMS responders expressed concern that naloxone could potentially increase risky opioid use by offering a “safety net.”^{25,39,40,54,209,239,250,251} Fear of being perceived as enabling drug use also emerged in a survey of academic physicians and medical school students at a large urban hospital.⁵⁴ Research has not substantiated this concern. A study of a pilot OEND intervention among PWID in San Francisco found that the provision of naloxone did not increase drug use or heroin overdose.²⁵² A review of the Massachusetts OEND program found similar results.²⁵³ These findings were substantiated by a systematic literature review of 18 additional studies of community-based OEND programs.²¹⁰

In contrast to this concern, two observational studies of OEND programs found that PWID who received OEND were more likely to enroll in substance use treatment programs compared to those who did not receive OEND.^{24,253} Another study evaluating an OEND program in Los Angeles, California found a reported decrease in drug use and an increase in treatment enrollment among PWID.²¹⁴ In addition, a recent qualitative study assessing the experience of patients on chronic opioid therapy found that several patients reported beneficial therapeutic behaviors, such as taking their prescribed dose at the right time, after having received a naloxone prescription.²²¹ Furthermore, because of the uncomfortable withdrawal-like symptoms that can occur after naloxone is administered, it is likely to be used only for necessary, life-saving measures.²⁵⁴

Belief that naloxone does not address patient treatment needs. Some medical providers have stated that naloxone prescribing by itself does not properly address

addiction.^{39,54,239} Rather, these providers state that overdose education and naloxone prescribing should instead focus on patients needing comprehensive pain management services (e.g., risk assessment, prescription monitoring program, pain treatment contracts, and dosage monitoring). This point of view is not uncommon. A U.S. study of medical doctors' attitudes about naloxone use among PWID, plus a qualitative study assessing naloxone prescribing by primary care staff, reported that many providers are concerned about peer or patient disapproval.^{40,51} In contrast, advocates of naloxone distribution recognize that addiction is a powerful, complex disease that can take multiple recovery attempts, and that providing access to naloxone enhances the likelihood that a person will live to seek drug treatment and recovery.^{39,255}

Belief that laypersons cannot identify and respond correctly to an overdose.

Healthcare providers and emergency medical personnel have expressed concerns about a layperson's ability to properly identify an overdose, remember to have naloxone on-hand and administer it, perform rescue breathing, and monitor a victim for possible adverse reactions to naloxone or repeat overdose.^{39,40,239}

Countering these concerns, studies of OEND programs have consistently found that equipping non-medical health care providers and family, friends, and neighbors of persons at risk with the knowledge and skills needed to recognize and respond to an overdose is a feasible, life-saving harm reduction strategy.^{252,256,257,27} Several studies of OEND training for PWID and their peers and family members reported improved knowledge about overdose and naloxone use after the training,^{213,219,252,258,259} Laypersons were able to understand the signs of an overdose and to feel confident in administering

naloxone during an overdose,^{213,260} even up to a year later in one study.²⁶¹ In turn, administration of naloxone by laypersons has been shown to be an effective means of reversing opioid overdoses,^{20,262} with few adverse effects.^{218,263}

An important step in addressing the overdose crisis is activation of the local EMS. Recognizing the importance of clinical monitoring following an overdose, many providers have expressed concern about bystanders not calling 911.^{39,40} This concern is



grounded in research findings; studies have shown that deaths from overdose occurred when witnesses did not call for medical help for fear of arrest and prosecution

for drug use or possession.^{23,56,85,252,264} Studies assessing 911 calls following naloxone administration by PWID found a wide range of contact rates across cities, with calls made 74%,²¹³ 40%,⁸⁵ 23%,²⁶⁴ and 10%⁵⁶ of the time. These findings heighten the importance of OEND programs emphasizing the message to call 911.

To alleviate bystanders’ concerns about criminal repercussions, as of July 2016, nearly all jurisdictions in the U.S. have passed Good Samaritan laws that protect laypersons who use naloxone and call 911 from criminal (n=32) and/or civil (n= 40) liability.²³⁵ Despite the presence of these laws, there is still a need to educate providers, bystanders, and law enforcement about the protections that this law offers. A

Massachusetts campaign in 2016 illustrates the importance of conveying this information in simple, understandable terms (see Image 2).²⁶⁵ As of yet, the impact of the Good Samaritan law on the opioid overdose response has not been evaluated, but is identified as an important step for addressing the crisis.

Lack of consensus regarding who should receive overdose education and naloxone. Absent a clear protocol, providers' beliefs about which patients should receive overdose education and naloxone prescribing may vary, as demonstrated in an assessment of a naloxone rescue kit dissemination project in an urban ED²⁶⁶ and a qualitative study among primary care providers.⁴⁰ In the context of these differing opinions, another study found that internal medicine residents had low levels of confidence in their ability to assess overdose risk and identify patients in need of naloxone.⁵³

Risk-based approaches for identifying patients in need of naloxone may miss patients whom providers or patients do not perceive to be “at-risk.”^{120,249} Furthermore, given the proportion of prescription opioids used for non-medical purposes that are obtained from friends or family members,⁵ prescribing naloxone alongside an opioid prescription could be a lifesaver for non-medical users or for children who inadvertently ingest them.^{39,40,120,226} In order to reach everyone at potential opioid overdose risk, SAMHSA has recommended co-prescribing naloxone with opioids.³⁰ Dr. Phillip Coffin, Director of Substance Use Research at the San Francisco DPH, urges clinicians to adopt an “opioid safety” or “medication safety” plan for all patients prescribed opioids for pain management.⁵⁰ With this arrangement, naloxone is explained to be an antidote to opioids, equivalent to an epinephrine pen for reversing a potentially fatal allergic response.⁵⁰

Another concern expressed by primary care and ED providers is that a patient at-risk of an overdose is unable to self-administer naloxone during an overdose, and providing education to that patient's family member or friend is often not feasible in a clinical context.^{40,209} Therefore, the effectiveness of the intervention relies on the patient training others on how to respond or the patient using naloxone as a bystander.

Minimal provider training in chronic opioid therapy prescribing. Overall, primary care providers receive minimal training on opioid prescribing, pain management, and addiction screening and treatment,²⁶⁷⁻²⁶⁹ and therefore they do not feel confident prescribing opioids to their patients.^{270,271} A study of a national sample of HIV care providers revealed that most do not feel prepared to manage chronic pain.²⁴² CDC's recently released chronic opioid therapy prescribing guidelines recommend screening for overdose risk and co-prescribing of naloxone. Online training programs have been made to provide training to prescribers.⁴⁹

Fear that naloxone prescribing could result in criminal or civil liability. Fear of liability resulting from naloxone prescribing can also impede wider prescribing and distribution. Even though there are minimal legal risks to a medical provider for prescribing naloxone, as of July 2016, 33 states have acted to grant immunity from criminal prosecution (n=33) and civil liability (n=37) for prescribing, dispensing, or distributing naloxone to laypersons.²³⁵ Of course, when prescribers offer patient education on overdose prevention, this further minimizes their risk.⁴⁹

Third-party prescribing laws further protect prescribers. Given that naloxone is administered by a bystander, the person at risk of overdose may not be the best person to

receive the prescription, but instead a family member, friend, or peer. As of July 2016, 41 states have laws that authorize third-party naloxone prescribing.²³⁵ These laws are seen as a low-cost strategy for creating a supportive regulatory environment in response to the opioid overdose crisis.²⁷²

Challenges related to naloxone stocking, insurance reimbursement, and price. Prescription-based naloxone is a relatively recent initiative, and with increased demand, pharmacies do not always have sufficient stock of naloxone or the mucosal atomizer device used for intranasal administration. Research has documented that naloxone's limited availability at pharmacies is a barrier to prescribing by primary care providers.⁴⁰ Because of this, providers must take the time needed to verify the availability at each patient's pharmacy.⁴⁹ The single-step intranasal device approved by the FDA in 2015¹⁹⁹ should eliminate the additional barrier due to having to order mucosal atomizer devices and then assembling the kits prior to dispensing.

The cost of naloxone has also posed a barrier to the implementation and expansion of community programs.¹⁶⁰ Increased demand has led to increased prices for naloxone, which particularly affects budgets for state and local health departments and first responders.^{273,274} One survey found that nearly 30% of 136 OEND programs in the U.S. reported limits on their program activities resulting from increased cost of maintaining a naloxone supply.²⁶ Amphastar, the only pharmaceutical company manufacturing naloxone for nasal administration before 2016, increased the price of the medication in Massachusetts from \$42 per kit in late 2014 to approximately \$75 per kit in early 2015.¹⁸⁶ Of course, such sudden and drastic price increases limit the purchasing

power of grant-funded state and municipal programs. The Massachusetts Attorney General led an investigation into the state's soaring naloxone prices,²⁷⁴ which resulted in discounted bulk purchased naloxone pricing for municipalities and towns.²⁷⁵

In some states, restrictions on Medicaid reimbursement for naloxone also impede OEND programs' ability to distribute the medication.^{161,229} Increasingly, private and public insurers are covering naloxone prescriptions, though billing and reimbursement policies do vary by payer and state. For example, there are variations in insurance policy coverage of the mucosal atomizer device for intranasal naloxone, the number of vials included in the kit, the number of refills, and the co-payment amount for the different naloxone formulations.¹⁶¹ Providers' uncertainty regarding how to bill for the education session and naloxone rescue kit is also a concern.⁴⁰ SAMHSA recommends billing opioid safety activities under the Screening, Brief Intervention, and Referral to Treatment (SBIRT) code.³⁰ Likewise, pharmacists' lack of certainty regarding insurance coverage for naloxone if the medication is for someone other than the insured individual can also impede access.²⁴⁶

Limited provider time and high patient caseloads. Five studies assessing naloxone prescribing by medical providers working in various settings in the U.S., Scotland, and the United Kingdom (U.K.), found that limited provider time, competing priorities, and high patient caseloads were barriers to providing overdose education and prescribing naloxone.^{40,54,55,240,241} The U.K. study found that these barriers persisted despite provider training.²⁴⁰ Time concerns are very real, particularly given the potential need to coordinate pain medication management across multiple clinical providers³⁹ for

patients with comorbidities.⁴⁰ ED providers have recommended integrating overdose education and naloxone prescribing into the hospital electronic medical record (EMR) as one strategy for prompting busy clinicians.²⁶⁶

Summary of OEND Program Lessons for Clinic Implementation

Despite the many identified barriers to OENA through clinical care, several lessons from community-based OEND programs can be applied in those settings (Table 10). In summary, naloxone is safe, does not increase risky opioid use, and is cost-effective. Effective partnerships among multiple OEND stakeholders serve to support broader dissemination. Staff other than prescribers can provide overdose and naloxone education. Therefore, in routine clinical care settings where clinicians have multiple priorities, staff including nurses, in-house pharmacists, case managers, and health educators can conduct overdose education. OEND programs have shown that laypersons can identify an opioid overdose and respond using naloxone, pointing to the additional need to equip patients who may be in a position to help others by using naloxone. Finally, a facilitating policy environment can support engagement of both prescribers and bystanders in implementing the intervention.

Table 10. Summary Lessons Learned from Community-based OEND Programs

-
- OEND programs have reduced community opioid overdose death rates
 - OEND programs are cost-effective
 - Multiple stakeholders can be engaged in naloxone access initiatives (e.g., community-based organizations, medical providers, pharmacists, law enforcement leadership)
 - OEND training can be conducted by non-medical staff and peers
 - Overdose education can be conducted in a brief amount of time
 - Provision of naloxone does not increase risky drug use behavior
 - Laypersons can be trained to identify and respond to an overdose, including administration of intranasal naloxone
 - Good Samaritan laws, and increased awareness of those laws, may decrease overdose witnesses' fear of calling 911
-

-
- Third-party naloxone laws offer civil and criminal liability protection to prescribers and bystanders, and can support clinic and pharmacy staff participation in prescribing and dispensing
-

There are multiple opportunities for expanding naloxone program beyond community settings to reach people through primary care settings. In Massachusetts, a standing order to allow pharmacists to dispense naloxone without a prescription expands naloxone access for both patients and other community members. There are several additional issues to be addressed when seeking to increase naloxone access through community-based clinical care settings.

First, there is a need to determine who will be responsible for conducting overdose education and prescribing or distributing naloxone in the context of a busy primary care clinic. Second, it is important to identify and communicate which patients should receive overdose education and naloxone and in what healthcare delivery context. Third, networks within the CHC and partnerships with pharmacy(ies) are needed to sustain the clinic's OENA-related activities. Fourth, training and skill development for staff assigned to conduct overdose education and naloxone prescribing will be important, alongside leadership and organizational supports. Finally, determining the role of external partnerships in bolstering CHC overdose response is also important.

Chapter Summary

Drug overdose deaths, having risen at alarming rates over the past decade, are now responsible for the highest number of unintentional injury fatalities in the U.S., with opioids, primarily prescription opioids, being responsible for the majority of those deaths. PLWH are a group at significant risk of death from an opioid overdose. Naloxone, an

opioid antagonist, can quickly reverse an opioid overdose with minimal adverse reactions. Past community OEND programs have demonstrated their feasibility and effectiveness in reversing overdoses, primarily among PWID.

Because naloxone has emerged to be the standard of care for opioid overdose treatment, national health organizations strongly endorse its expanded use. Extending opioid safety activities into primary care offers an opportunity to broaden naloxone access to patients who may be at risk of overdose due to either medical or non-medical opioid use. Such programs can build upon lessons learned from extensive community-based OEND program experience and emerging clinical experience to develop effective interventions.

An assessment of implementation strategies applied by CHC teams that provide primary care is needed to guide future program development. In meeting this need, this research study will help unravel the complex factors challenging CHC primary care OENA for patients, many of whom may never otherwise know about or access naloxone for themselves or people in their lives who may be at risk of an overdose. While this study was conducted through the lens of HIV care teams due to their past efforts to address the needs of PWID and their documented increased risk of opioid overdose fatalities, what is learned from this study will be transferable to other primary care teams and patient groups. The primary care setting is particularly important given the disproportionate role that prescription opioids play in overdose fatalities, and the enhanced opioid treatment services available in CHCs.

This dissertation is intended to fill the current research gap by assessing real-world clinic implementation experiences in Massachusetts, from which useful guidance to the development and implementation of future programs within and outside the Commonwealth can be developed. The state is a prime location for this research given its new policies to address the opioid crisis, including expansion of naloxone access. OENA in primary care settings is not the sole solution, but it is an essential component of a comprehensive response to address the opioid crisis, and an urgent need to curb the rising overdose fatalities.

CHAPTER 3: RESEARCH DESIGN AND METHODS

This chapter begins with an overview of the study and a description of the conceptual framework selected to guide the research design and analysis. This is followed by an explanation of the rationale for the selected methods, the study site and participant sampling plan, the data collection tools, and methods used for analyzing and interpreting the data. With the protection of study participants being the highest priority, the chapter also outlines the steps taken to ensure the ethical conduct of this research.

Summary of Main Study and Methods

This section documents the research aims and provides an overview of the methods used and types of data collected for the study, followed by the rationale for the selected research methods.

Three research aims guided this study:

1. To document how opioid OENA strategies are delivered within community health center primary care settings;
2. To identify factors that influence implementation of OENA in this setting, examining the intervention, individual, outer setting, inner setting, and process domains; and
3. To determine which strategies are likely to enhance the implementation of OENA in community health center primary care settings.

The six major research activities and related methods conducted during this study are described below.

I. Preliminary research

- a. An initial review of the literature was conducted to provide an overview of the programmatic issues related to OENA programs, with a focus on their relevance to clinic-based settings.
- b. Based on key concepts from the literature, qualitative and survey data collection instruments were developed for the preliminary pilot study.
- c. An application to BUMC's IRB for the preliminary study to obtain feedback from physicians at one of the study sites was submitted in November 2014. The IRB designated the research as exempt.
- d. A pilot study was conducted through interviews and a focus group with physicians at a large, urban HIV clinic in Massachusetts to test the data collection tools and explore implementation barriers and facilitators to overdose education and naloxone prescribing among HIV providers.

II. Literature review

- a. A comprehensive review of the literature was undertaken to understand the background, context, and past research related to OENA initiatives. Existing training materials and educational resources used for community and prescriber trainings were identified. A review of opioid overdose prevention activities in Massachusetts set the policy and programmatic context. An implementation science framework was selected to guide the research process. Updates were made to the literature review during the study.

III. Research protocol development

- a. Data collection tools were developed based on the literature review, the research questions, and the implementation science framework.
- b. After the pilot, an amended IRB application was submitted in December 2015 to BUMC's IRB for approval to conduct the main study. After expedited review, the study was deemed exempt.

IV. Site selection

- a. Selection criteria for site selection were developed.
- b. A structured matrix was used to describe potential CHC study sites in order to identify a diverse set of CHCs.
- c. Experts were consulted to gather background information on the study sites and to obtain recommendations for site selection.
- d. Eight Massachusetts CHCs that provide primary care to PLWH and had OENA efforts in place were selected to participate in the study.

V. Data collection

- a. Interviews and/or focus groups were conducted with at least two providers and/or staff at each of the eight participating CHCs. Surveys were completed to characterize the clinics and participants.
- b. Interview and focus group recordings were transcribed. Clinic and participant survey data were entered into an online survey software program.

VI. Data analysis, synthesis, and interpretation

- a. A qualitative, content analysis of the data was conducted in NVivo 11.0 using

codes from an implementation science framework.

- b. Descriptive clinic and participant data from the surveys were aggregated.
- c. Key findings were described using constructs from the framework.

Implications of the findings and their relevance to the research literature were discussed.

Summary and Rationale for the Selected Methods

A study of CHC-based OENA implementation was performed employing primarily qualitative research methods to document the factors that facilitate or hinder overdose education and naloxone prescribing initiatives in primary care CHC settings which provide routine care to PLWH. Table 11 below summarizes the data collection methods for each study aim. Several types of data were needed for the study:

- Contextual information required to understand each clinic's organizational structure and opioid OENA activities were obtained through a clinic characteristics survey, collection of relevant clinic documents, and observations at a subset of the clinics.
- Descriptive information to characterize the interview and focus group participants was gathered through participant surveys.
- Implementation experience related to each clinic OENA program was gathered through individual and group interviews with clinic staff.

These methods and related data sources are described in more detail later in the chapter.

Table 11. Overview of Research Aims by Purpose and Data Collection Method

Aim	Purpose	Method
<i>1: To document how opioid OENA is delivered within community health center primary care settings</i>	Understand commonalities and variation in implementation approaches	<ul style="list-style-type: none"> • Interviews and focus groups • Clinic surveys • Observation • Document review
<i>2: To identify factors that influence implementation of OENA in this setting, examining the intervention, individual, outer setting, inner setting, and process domains</i>	Assess factors that impede or support implementation from the perspective of clinic staff members	<ul style="list-style-type: none"> • Interviews and focus groups • Provider questionnaires • Clinic surveys • Document review
<i>3: To determine which strategies are likely to enhance the implementation of OENA in community health center primary care settings</i>	Identify promising practices that could be adopted by other primary care CHC settings	<ul style="list-style-type: none"> • Document review • Interviews with key stakeholders

Because this study did not rely on a single method, the findings developed through any particular method could be corroborated, thereby building confidence in the study's conclusions.²⁷⁶ Because qualitative individual and group interviews served as the study's primary data source—with the other methods providing additional context—the rationale for the selection of this methodology warrants discussion.

Individual interviews made it possible to learn each individual's perspective regarding OENA at their CHC. Issues could be explored in-depth with multiple clinic staff members, each playing a different role in the clinic's opioid safety activities, such as a clinic manager, a physician who champions naloxone prescribing, a nurse providing buprenorphine treatment services, or a pharmacist who dispenses naloxone through a standing order at the CHC's in-house pharmacy. Across the CHCs, these interviews resulted in a respectable sample size adequate for generating key themes and achieving data saturation.²⁷⁷

Focus group and small group interviews were used to elicit a range of opinions and perspectives. This format made it possible to hear from clinical teams that work together and learn about their varying roles, perspectives, and experiences. This format also generated new ideas to explore in later individual interviews.²⁷⁶ As an example, one group consisted of a physician, nurse, and health educator, all of whom play different roles related to OENA. In another clinic, a nurse and pharmacist who serve complementary roles in their clinic's naloxone access model were interviewed together.

The semi-structured nature of the interview guide meant that the interviews could easily include themes and specific issues that emerged from one session to the next and to ask clarifying questions to develop the richest data possible.²⁷⁶ Probes were added across the interviews and focus groups within and across clinics based on reviews of the data during the collection process.⁷⁷ This proved to be a critical requirement for understanding the implementation process across multiple sites. For example, after participants at one site mentioned a specific patient-level barrier to naloxone acquisition, later interviews included questions to determine if this was a barrier in other CHCs.

Several measures were taken to help ensure the credibility, relevance, and transferability of the qualitative research findings. First, the study's credibility was enhanced by using multiple sources of data to validate the findings.⁷⁸ Second, a codebook of constructs from the CFIR implementation science framework was used to organize the analysis. An external reviewer coded three transcripts to validate the use and interpretation of the analysis coding schemes. Third, summary memos after each interview provided background information about the session, including notes regarding

interpersonal dynamics during group interviews that may have affected the findings. Finally, the data collection, coding, analysis, and synthesis process was documented along the way, including the rationale for mid-course decisions made during the study.²⁷⁶

The methods chosen also helped ensure the relevance and transferability— as opposed to the generalizability— of the research findings to other settings.^{77,78} The data collection methods took into account the context of the clinic and the study participants. Descriptive information presented with the findings can help guide other practitioners' understanding of how the findings might apply to their setting.⁷⁷ A review of clinic documents helped identify relevant examples for other settings. Finally, ongoing informal consultations with state overdose education and naloxone experts during the data synthesis and interpretation phase helped evaluate the relevance of the study findings to other clinical settings. A presentation of findings to a group of clinical providers in another state was an opportunity to determine the degree to which the study findings resonated with their practice settings.

Research Conceptual Framework

Implementation science has established that effective innovations, combined with high-fidelity implementation and an enabling context, results in successful change.²⁷⁸ This study sought to learn how the innovation of overdose education and naloxone distribution— shown to be effective in community-based settings— has been translated into primary care settings. It set out to understand what implementation looks like in these settings— the what, how, and who— and the context that supported or hampered OENA. To understand that context, the study design and analysis was guided by the

Consolidated Framework for Implementation Research (CFIR).

Since its development in 2009,⁷⁵ CFIR has been used to assess several clinic-based interventions, including weight management,²⁷⁹ opioid treatment,²⁸⁰ mental health services,²⁸¹ and blood pressure control.²⁸² CFIR has been especially useful in understanding barriers and facilitators that affect intervention implementation and the mechanisms that support or inhibit success in differing health service delivery settings.^{76,283} CFIR was selected because of its comprehensive and flexible design. Another strength is that it takes into account the multiple levels and complex factors that influence the implementation and maintenance of evidence-based healthcare delivery practices.⁷⁵ CFIR consolidates 18 theory-driven health services implementation models plus theoretical concepts from the fields of organizational behavior, sociology, and psychology, such as Diffusion of Innovation theory.^{75,284,285}

The framework translates these into 41 constructs across five domains.⁷⁵ Table 12 depicts the CFIR framework and briefly defines each construct.²⁸⁶ The CFIR constructs served as an analytical lens for designing the data collection tools and then coding, organizing, and comparing the data.²⁸³ The nimble nature of the CFIR framework allowed for the addition and removal of constructs as needed during the data collection and analysis process.²⁸⁶

Table 12: Conceptual Framework (CFIR) Construct Definitions by Domain

Domain and Constructs	Brief Definition
I. Innovation Characteristics	
A. Innovation Source	Understanding of innovation source (internally or externally)
B. Evidence Strength and Quality	Perceptions regarding the evidence, benefits, and quality of research related to the innovation
C. Relative Advantage	Beliefs about the advantage of implementing the innovation
D. Adaptability	Adaptability of the innovation
E. Trialability	Ability to pilot the innovation and alter its implementation
F. Complexity	Perceived difficulty of implementing the innovation
G. Design Quality and Packaging	Perceived quality of innovation materials and their assembly
H. Cost	Costs of developing and implementing the innovation
II. Outer Setting	
A. Needs and Resources of Patients	Degree to which the organization understands and prioritizes patient needs
B. Cosmopolitanism	Extent to which organization is connected to other agencies
C. Peer Pressure	Pressure to adopt the innovation from other organizations
D. External Policies and Incentives	Policies and guidelines to support dissemination of the innovation
III. Inner Setting	
A. Structural Characteristics	Characteristics of the organization (i.e., type, size)
B. Networks and Communications	Communication networks within the organization
C. Culture	Shared values and norms related to the innovation
D. Implementation Climate	Expected practice and support of innovation
E. Tension for Change	Stakeholders' perception that a response is needed
1. Compatibility	Innovation's fit with individual values and clinic systems
2. Relative Priority	Beliefs about the importance of implementing the innovation
3. Organization Incentives & Rewards	Existence of awards for staff engaging in the intervention
4. Goals and Feedback	Mechanisms for sharing innovation goals with staff
5. Learning Climate	Strategies that support leadership and staff implementation
F. Readiness for Implementation	Visible indicators of organization's commitment to change
1. Leadership Engagement	Degree of leadership engagement with the innovation
2. Available Resources	Resources that support implementation (i.e., time, space)
G. Access to Knowledge and Information	Ease of getting information about the innovation to support integration into clinic activities
IV. Characteristics of Individuals	
A. Knowledge and Beliefs	Implementers' awareness and attitudes about the innovation
B. Self-efficacy	Implementers' belief that they can implement the innovation
C. Individual Stage of Change	Clinic staff members' stages in implementing the innovation
D. Individual Identification with Organization	Individuals' commitment to the organization
E. Other Personal Attributes	Individual personal attributes that influence implementation
V. Process	
A. Planning	Extent to which innovation process is determined in advance
B. Engaging	Strategies for reaching implementers and patients

1. Opinion Leaders	Individuals in organization who influence implementation
2. Formally Appointed Internal Leaders	Individuals designated with innovation oversight
3. Champions	Individuals dedicated to promoting implementation
4. External Change Agents	Individuals with influence external to the organization
5. Key Stakeholders	Individuals in organization impacted by the innovation
6. Innovation Participants	Individuals prioritized to receive the innovation
C. Executing	Conducting implementation activities as planned
D. Reflecting and Evaluating	Ongoing team sharing of data, staff experience. and feedback

Study Sample

This section describes the study site sampling plan, including study site and participant selection criteria and areas of expected variation across the clinic sites. It then describes the characteristics of the study sites and the participants who took part in the interviews.

Sampling Plan

The unit of analysis for this study is the CHC. This term is used to include both neighborhood/community-based health centers affiliated with larger medical institutions and federally qualified community health centers (FQHCs). CHCs have created systems of care to respond to the clinical and social needs of some of the most vulnerable residents in the local community. Furthermore, they have and will continue to play a major role in the response to the opioid crisis through increased provision of primary care-based opioid treatment.⁶³

HIV care teams were the focus of the research because they have been on the forefront of responding to the multiple needs of PLWH, including the integration of harm reduction services for PWID. Persons with HIV who inject drugs have been shown to be at increased risk of opioid overdose mortality.⁵⁷ In addition, several CHCs received

overdose education and naloxone training sponsored by the New England AIDS Education and Training Center²⁸⁷ in the year prior to the study, and some CHCs were selected as an OEND pilot grant site through HIV, hepatitis, and STD testing programs.²⁸⁸ These settings should be able to provide detailed implementation experience in patient populations at high risk of an opioid overdose.

Sampling criteria. The goal of the study site selection process was not to obtain a representative sample that can then provide generalizable findings, but instead to identify sites that offer information into the range of clinic implementation experience with overdose education and naloxone prescribing.^{77,276} With that in mind, the following criteria guided the selection of study sites:

1. **CHC located in a Massachusetts county or town with an overdose fatality rate higher than the state rate.** CHCs located in counties that had experienced overdose rates close to or higher than the state rate of 17.7 deaths/100,000 (January 2013–December 2015)²⁸⁹ were selected to ensure the need and urgency for a response.
2. **CHC that initiated opioid OENA activities at least three months before the start of the data collection phase.** The study sites represent early adopters as clinic-based OENA activities were not yet widespread. “Initiation” was defined as implementation of clinic-based OENA for patients, so that healthcare prescribers and other clinic staff could speak to the actual implementation experience. Level of implementation (measured through naloxone prescription, dispensing, or distribution data) was not considered in the selection process.

3. **CHCs providing routine primary care to PLWH.** Clinic teams providing primary care to PLWH, along with patients without HIV, were the focus and entry point for the study given their past role in harm reduction services. In the interest of assessing clinic practice and policy, the selected clinics needed to have two or more prescribers on the HIV clinic team in order to assess implementation beyond a single prescriber.

Variation was expected and sought in several areas including clinic size, patient population, means of naloxone access [i.e., in-house, on-site pharmacy (with and without standing order), and external referral], geographic location in the state, and implementation duration.

Sample size. Eight CHCs were selected in order to produce findings both unique and shared across the study sites.²⁷⁶ It should be noted that this sample size did result in data saturation, where additional data gathering and analysis did not offer additional concepts or other information related to the research aims.⁷⁷

Study Site Recruitment

With the three selection criteria in view, a purposive, criterion sampling approach²⁷⁶ was employed to select eight CHCs in Massachusetts. The following key stakeholders in the Commonwealth were consulted to understand the state context and identify an initial list of potential sites:

- Sarah Ruiz, Massachusetts DPH, Bureau of Substance Abuse Services
- Dr. Alexander Walley, Massachusetts Opioid Overdose Prevention Program
Medical Director, Massachusetts DPH

- Dawn Fakuda, ScM, Director, Office of HIV/AIDS, Massachusetts DPH
- Barry Callis, Director of Behavioral Health and Infectious Disease Prevention, Office of HIV/AIDS, Massachusetts DPH
- Brianne Fitzgerald, RN, New England AIDS Education Training Center

To prioritize sites, a Study Site Selection Matrix was created to describe the clinics in terms of the factors anticipated to affect implementation, including clinic size (staff and patients), patient characteristics, naloxone access model, geographic location, implementation duration, and other relevant information such as presence of an on-site champion or completed staff naloxone training. Working from a draft list of sites, a letter (Appendix A) was emailed to the HIV medical director or clinic director at each site to invite the clinic's participation in the study and explain the study protocol. If there was no response, three additional emails were sent before a site was removed from the list.

In several cases, follow-up emails and/or telephone calls with the medical director helped to clarify the purpose of the study and review the staff proposed to participate in interviews. Twelve sites were initially contacted; of these, eight agreed to participate in the study, two did not respond, and two did not meet eligibility criteria (one site explained that they were not implementing OENA, and one was a provider practice and not a CHC).

Study site sample. The study site characteristics are described in Tables 13 and 14. A snapshot of each study site is presented in Table 15 to illustrate the degree of variation across the sites. All of the study sites were CHCs, located in cities or towns in five Massachusetts counties with high opioid overdose fatality rates. Each site had a

different catchment area. Six were FQHCs; the other two health centers were affiliated with different hospital healthcare systems. All of the sites offered routine care to PLWH in the context of a primary care clinic that also provided care to persons without HIV. Nearly all of the CHCs received Ryan White HIV/AIDS Program funding. The number of PLWH seen for primary care ranged from 40 to 1,300 (average 374; median 282).

Table 13. Study Site Characteristics (N=8)

Characteristic	Average (Range)	Number (%)
Clinic Type		
FQHC	--	6 (75)
CHC	--	2 (25)
Affiliated pharmacy		
Yes	--	6 (75)
No	--	2 (25)
HIV Clinic Size		
Small (< 500 patients)	241 (40–380)	7 (88)
Medium (501 – 1,500 patients)	1,300	1 (12)
Funding for HIV services		
Ryan White (state or federal)	--	7 (88)
Other state, non-Ryan White	--	4 (50)
Other federal, non-Ryan White	--	2 (25)
No external funding	--	1 (12)
HIV Staffing: Full-time Equivalent		
Physician	1.3 (.10–6)	8 (100)
Nurse	3.0 (2–5)	8 (100)
Case manager	3.8 (2–6.3)	8 (100)
Nurse practitioner	1.8 (.2 – 3)	4 (50)
Social worker	2.2 (.8 – 6)	4 (50)
Patient/peer educator	.94 (.75–1)	4 (50)
Community education /outreach worker	2.6 (.5 – 5)	4 (50)
Physician assistant	.45 (.15–1)	3(38)
Pharmacist	.47 (.16–1)	3(38)
Patient navigator	1 (.2–2)	2 (25)
County		
Bristol	--	1 (12.5)
Essex	--	2 (25)
Hampden	--	2 (25)
Middlesex	--	1 (12.5)
Suffolk	--	2 (25)
Number of towns primarily served		
One	--	4 (50)
Two	--	1 (12)

Three	--	3 (38)
Began offering naloxone		
Past 13–18 months	--	2 (25)
Past 19–24 months	--	2 (25)
More than 24 months	--	4 (50)
State-funded OEND pilot program		
Yes	--	3 (38)
No	--	5 (62)

Half of the CHCs had “in-house” pharmacies, and two utilized a nearby pharmacy that served the CHC patients. All but one of the pharmacies had a pharmacy standing order, signed by the CHC’s medical director, for pharmacy dispensing without a prescription, though one of the CHCs had not yet begun referring patients to the pharmacy for naloxone. Three of the CHC-based HIV programs had a DPH-funded OEND pilot grant to distribute naloxone rescue kits to clients seen for HIV, hepatitis, and STD testing and through community outreach efforts.

Staffing models for the HIV clinics varied, based on clinic size and available funding for staffing (e.g., grants to support case managers). HIV clinical teams were comprised of a physician, nurse, and case manager. Physician assistants, pharmacists, social workers, health educators, and outreach workers were part of the HIV care teams at about half of the sites. Compared to physicians, nurses, case managers, social workers, health educators/outreach workers, and nurse practitioners had more full-time equivalent (FTE) time dedicated to HIV patient care.

The characteristics of patients living with HIV also varied across the sites. At the time of the study, more than half of the patients were male, had MassHealth (i.e., Medicaid) insurance coverage, and were 45–64 years of age. Slightly over half of the

patients living with HIV were Hispanic/Latino. The percentage of white (7 % to 68%) and African American (7% to 36%) patients also varied greatly across the study sites.

The average estimated percentage of patients living with HIV with injection drug use as a risk factor for HIV infection was 32%, though the range across the sites was extremely wide: one CHC estimated 9% and another 80%. It is important to note that in one of the CHCs with a small number of patients living with HIV, there was still a high number of patients at risk of overdose, and many living with chronic hepatitis C virus. An average of 10% of PLWH were estimated to be receiving prescription opioids for chronic pain management, and 20% of PLWH were estimated to be misusing or abusing opioids.

Table 14: Percentage Estimates of HIV Patient Characteristics at Study Sites

Patient Characteristics	Average Estimated Percentage of HIV Patients (Percentage Range)
Insurance coverage	
MassHealth	66% (40–80%)
Medicare	14% (10–23%)
Dually eligible Medicare/MassHealth	14% (9–20%)
Commercial insured	10% (1–30%)
None/uninsured	3% (3–7%)
Age (years)	
18–24	3% (2–7%)
25–44	28% (10–50%)
45–64	62% (33–85%)
65 and older	9% (3–19%)
Race/Ethnicity	
Hispanic/Latino	53% (10–85%)
White (not Hispanic or Latino)	34% (7–68%)
Black/African American (not Hispanic or Latino)	17% (7–36%)
Multi-racial (not Hispanic or Latino)	12% (1–28%)
Asian (not Hispanic or Latino)	5% (1–10%)
Gender	
Male	61% (48–68%)
Female	38% (30–52%)
Transgender	4% (2–10%)
Injection Drug Use HIV Risk Factor	32% (9–80%)
Currently Prescribed Opioids for Pain Management (N=6)	10% (1–25%)
Currently Misusing or Abusing Opioids (N=5)	20% (10–50%)

Table 15. Clinic Characteristics by Study Site

Site	Location in state	Type	PLWH seen (#)	OENA start	Affiliated pharmacy	Pilot OEND grant	Percentage of patients with IDU risk factor
1	Eastern	Hospital-affiliated CHC	40	+ 2 years ago	No	No	20%
2	Western	FQHC	160	Past 13 to 18 months	Yes	Yes	9%
3	Western	Hospital affiliated CHC	1,300	+ 2 years ago	Yes	No	80%
4	Northeastern	FQHC	325	Past 19 to 24 months	Yes	Yes	25%
5	Northeastern	FQHC	279	+ 2 years ago	Yes	No	19%
6	Eastern	FQHC	285	+ 2 years ago	Yes	No	40%
7	Northeastern	FQHC	380	Past 13 to 18 months	Yes	Yes	32%
8	Southeastern	FQHC	220	Past 19 to 24 months	No	No	34%

Research Design: Data Collection Tools and Protocol

Table 16 below lists the data collection methods and tools used during the study for both the pilot study and the main study. The IRB granted a waiver for both studies. Interview participants reviewed a written one-page summary (Appendix B) of the study and verbally consented to participate.

Table 16. Data Collection Methods and Tools by Study Type

Study Phase	Methods	Tools
Pilot study	<ul style="list-style-type: none"> • Focus group • Interviews • Questionnaire 	<ul style="list-style-type: none"> • Interview and Focus Group Guide • Participant Characteristics Survey • Interview Summary Memo
Study of Implementation Experience	<ul style="list-style-type: none"> • Interviews • Focus groups • Questionnaire • Document review • Observation 	<ul style="list-style-type: none"> • Interview Guide • Clinic Characteristics Survey • Participant Information Questionnaire • Document Summary Form • Interview Summary Memo

Pilot Study Data Collection Process

To inform the main study methods and tools, preliminary interviews and a focus group were conducted at a large, urban HIV clinic (estimated 1,653 patients seen in 2015 by 13 physicians) in Boston, Massachusetts. This work was completed over a 3-month period (November 2014 – January 2015) when the clinic was planning a clinic-wide opioid overdose education and naloxone prescribing initiative to begin in January 2015. The intent of the sessions was to learn about anticipated barriers and facilitators to naloxone prescribing from the perspective of the clinic’s physicians.

Data collection tools for the pilot study included a participant characteristics questionnaire and an interview/focus group guide (Appendix C). Three interviews (30 to 60-minutes each) were conducted with the following medical providers, each of whom provided a unique perspective as a result of their clinic role: 1) HIV medical director; 2) a physician currently prescribing naloxone to patients; and 3) a physician prescribing buprenorphine treatment to patients. One 50-minute focus group, scheduled in consultation with the medical director and held during the monthly clinic physician meeting, was conducted with 10 physicians practicing at the clinic.

The interviews and focus group were digitally audio-recorded with the participants’ verbal informed consent at the start of each session. All data recording and storage procedures outlined in the IRB application were followed to ensure participant confidentiality. Participants were not compensated for their participation.

The initial physician interviews and focus group served two purposes. First, they provided the opportunity to pilot test the data collection instruments. Second, the findings

provided a snapshot of provider perceptions about opioid overdose education and naloxone prescribing prior to clinic-wide implementation. These findings informed the development of the final interview guide. A summary of the pilot study participants' characteristics and the findings is included in Appendix D.

Main Study Data Collection Protocol

For the main study, focus groups and interviews were conducted with various clinic providers and staff members from the eight participating clinic study sites over a three-month period (January – March 2016). Table 17 below offers a summary of the number and type of sessions held across the eight study sites.

Table 17. Summary of Study Data Collection Sessions across Eight CHCs

	Number (Percentage or Range)
Total Number of Study Participants	29 (1–7 per session)
Interview Type (N=17)	
Individual	12 (70.5)
2–3 participants	4 (23.5)
Focus group	1 (6.0)
Average Number of Interview Sessions/CHC	2.1 (1–3)
Interview Format (N=17)	
In-person	10 (59)
Telephone	7 (41)
Average Duration	38.3 minutes (10–55 minutes)

A total of seventeen interview sessions, composed of twelve individual interviews, four discussions with two or three participants, and one focus group, made it possible to collect data from twenty-nine clinic staff across the eight sites. Scheduling was done through a clinic point-of-contact or with the study participants directly. Clinic size, number of relevant staff, availability of staff, and the preference of clinic director/manager determined whether it was more appropriate to conduct an individual or

group interview.

Clinic staff to be interviewed were selected in consultation with the clinic director/manager, while ensuring that at least one clinic manager was included from each site. A description of the study sent by email to the clinic medical director or HIV manager was emailed to all interviewees. Participants were sent a confirmation email two days before the interview. Stipends were not provided for participation. There was a 100% participation rate for the scheduled interviews.

More than half of the sessions were conducted in-person. In some cases, snowball recruitment methods resulted in the identification of additional persons to be interviewed either through impromptu in-person interviews or through telephone follow-up. There was an average of 2.1 interview sessions per site. As can be seen in Table 13, the roles of the participants varied across sites, in part due to the particular implementation strategy being employed.

Interview sessions lasted an average of 38.3 minutes (range 10 – 55 minutes), a length feasible for busy clinic providers and staff. All interviews and focus groups were digitally audio-recorded. Telephone-administered interviews were audio-recorded using an application on a password-protected iPhone. Participant consent to audio-record the interviews was obtained verbally prior to recording.

Data Collection Tools

The following four data collection tools were used:

- 1) Clinic Characteristics Survey.** This tool captured key descriptive characteristics about the clinic. This 17 item close-ended survey (Appendix E) included several

descriptive items, some of which were linked with specific CFIR constructs, including:

- *Structural Characteristics*: Organization type, affiliation, services provided, funding, staffing, patient load
- *Cosmopolitanism*: Degree of external organizational networks to support OENA and related services
- *Readiness to Implement*: Training, policies, pharmacy partnership
- *Implementation Climate*: Policies and EMR supports
- *Patient Needs and Resources*: Patient demographic data
- *Reflecting and Evaluating*: Collection and review of naloxone data

The survey was completed by the clinic director or manager prior to, during, or after the interview. Most of the study sites completed a hard copy survey in-person, through the mail, or at the end of the interview. For others, the same survey in online format was sent to participants.

- 2) **Participant Survey.** This tool gathered descriptive information about the study participants. This 14-item close-ended survey queried about demographics, role, duration of time practicing at the clinic, perceived overdose risk of patients with HIV, and stage of readiness for overdose education and/or naloxone prescribing. Participants completed the questionnaire (Appendix F) in about three minutes prior to their interview or focus group.
- 3) **Interview and Focus Group Guide.** A semi-structured interview and focus group discussion guide created for the pilot study was modified for the main study

to reflect a) barriers and facilitators identified from the literature; b) findings from the pilot interviews and focus group; and c) conceptual framework constructs of interest. The same guide was used for both individual and group interviews. The interview/focus group guide (Appendix G) covered the following areas related to CFIR constructs:²⁸⁶

- *Available Resources*: Funding, staff time, physical space, and training to implement the intervention
- *Champions*: Presence and identification of a champion in the clinic
- *Complexity*: The steps and time involved in conducting overdose education and naloxone prescribing
- *Cosmopolitanism*: External organizations involved in the intervention
- *Cost*: Supplies and costs associated with the intervention
- *Key Stakeholders*: Which staff in the organization are directly impacted by delivery of the intervention
- *Intervention Participants*: Who is prioritized for intervention; strategies used to engage patients in the intervention and inclusion of patient feedback in the design and ongoing implementation
- *External Policies and Incentives*: The role of policies external to the agency in supporting the intervention
- *Leadership Engagement*: Degree of support from clinic leadership in support of the intervention

- *Patient Needs and Resources*: Extent to which patient needs and preferences are known and considered
- *Readiness for Implementation*: Tangible steps the clinic has taken to commit and prepare for implementation
- *Reflecting and Evaluating*: Mechanisms in place to discuss implementation experiences; use of data to assess progress and inform future implementation

4) Document Summary Form. Copies of documents referenced by participants that were related to their OENA activities were requested. In other cases, photos were taken (with permission). Each document was summarized using a form (Appendix H) to record its context or use.²⁹⁰ These documents included the following:

- Patient education materials
- Signs in the clinic or pharmacy
- EMR templates
- Written policies

Clinic documents, obtained from six of the study sites, provided additional insights into clinic processes and offered information about the decisions and steps taken during planning and implementation stages.²⁷⁶ Finally, in many cases, these documents provided important background information that was useful during the provider and patient discussions.

5) Interview and Focus Group Summary Memo. Immediately after each interview and focus group, a summary memo was written using a standardized format

(Appendix I),²⁹⁰ to immediately capture key findings by CFIR constructs which emerged from the interviews as well as areas for future inquiry. Additionally, the memo documented contextual information specific to the setting or group dynamics that would not be apparent from the transcript.²⁷⁶ This memo was reviewed during the data coding and analysis process to lend additional context to the data.

Study Participant Characteristics

As can be seen from Table 18, over half of the study participants were female, and most were between 36 and 45 years of age. Half of the participants had worked at their clinic for more than fifteen years. The participants' role at the clinics varied, with program directors or managers represented at each site, followed by a mix of physicians, nurses, nurse practitioners, physician assistants, case managers, health educators, and pharmacists. Across the participants, the average caseload of HIV patients was fourteen patients per week, but most of the prescribers, representing about one-third of the participants, were seeing about 50 patients a week.

Table 18. Study Participant Characteristics (N=29)

Study Participant Characteristic	Number (Percentage)
Gender	
Male	11 (37.9)
Female	18 (62.1)
Age (years)	
26–35	5 (17.2)
36–45	11 (37.9)
46–55	8 (27.6)
56–64	4 (13.8)
More than 65	1 (3.5)
Role	
Physician	7 (24.1)
Physician Assistant	1 (3.5)
Nurse Practitioner	1 (3.5)

Registered Nurse	5 (17.2)
Case Manager	3 (10.3)
Program Director or Manager	9 (31.0)
Pharmacist	2 (7.0)
Health Educator	1 (3.4)
Prescriber	
Yes	9 (31.0)
Years worked at clinic	
Less than 2	6 (20.7)
3–5	7 (24.1)
6–10	1 (3.5)
More than 10	15 (51.7)
Average weekly caseload of patients living with HIV*	14.6 (range: 1–50)

*Includes both clinical and non-clinical staff.

Data Analysis and Synthesis

This section describes the process undertaken for organizing, managing, categorizing, analyzing, and synthesizing the data. As previously explained, the CFIR served as the conceptual lens for the study, leading to a comprehensive set of codes applied to the data. An iterative, continuous review of the study data yielded a final set of constructs that frequently occurred within and across the transcripts. Patterns and themes emerged from the data through this coding process. Comparisons across the sites, plus other program experience described in the literature, supported the interpretation and transferability of the findings.

Data management. All surveys were entered into Survey Monkey online survey software to house the data. All audio recordings were transcribed verbatim into a Microsoft Word file using an online transcription application on a password protected computer, and then reviewed for completeness. Each interview and focus group transcript was classified with a de-identified code, tracked in a separate, secure file in order to protect the confidentiality of the study site and the participants. Descriptive information

about the clinic site from the clinic survey and the clinic summary memo was linked with the transcript.

For the pilot study, a rapid analysis of the transcripts was performed to identify key themes and issues to help inform the main study design. For the main study, the Microsoft Word files of the transcripts, interview summary memos, and copies of documents obtained from the sites were uploaded into QSR International's NVivo 11.0 qualitative data analysis software. This software was selected for its ease of access, training resources, and key features, including the ability to cross-code and visualize patterns that emerge from the coded data. Furthermore, NVivo was able to connect coded text to participants' demographic information, clinic characteristics, and the memo insights documented after each interview or focus group.²⁹¹ Table 19 summarizes the steps taken to work with the data.²⁹¹

Table 19. Process of Data Coding, Analysis, Synthesis, and Interpretation

- | |
|---|
| <ol style="list-style-type: none"> 1. Identify "nodes" (e.g., codes) to extract from the data sources (e.g., transcripts, documents) 2. Interact with the data through coding and memo writing 3. Explore and query the data and examine data visualizations 4. Organize results by research aim and significant conceptual constructs 5. Determine the implications of the findings |
|---|

Data coding. An existing CFIR codebook, populated with definitions and coding criteria,²⁸⁶ was used to ensure a clear understanding of each construct (Appendix J) and served as the coding legend.^{77,276} The post-interview summary memos highlighted prominent CFIR constructs that emerged from the interviews. The transcribing process resulted in still other constructs being identified, which were documented in an additional memo.

All of the CFIR constructs were drawn upon during the data collection process and initial round coding in order to be as comprehensive as possible in the identification of key themes that emerged from the data. While some constructs emerged as more significant than others during the data interpretation phase, and some were not used at all, this open approach facilitated a thoughtful coding process that resulted in the identification of several constructs not hypothesized to be relevant.

To support the validity of the coding process, two coders each coded a small sample of transcripts and met after each one to discuss the codes. This process stopped after three transcripts when agreement was reached on the coding rubric to be used. Any revised understanding of the constructs was then applied to remaining transcripts.⁷⁷

All of the transcripts and documents were coded within NVivo 11.0 over a five-week period to help ensure continuity of the coding process across the transcripts. In many cases, multiple codes were applied to the same text, thereby recognizing the complex interplay between the constructs. Meetings with content experts prior to and after the coding process allowed for discussion of the process and the resolution of any questions. Given the data-driven nature of qualitative analysis, the codes selected were sometimes revised.

The flexible nature of the CFIR framework allowed for codes to be collapsed, removed, or added as needed throughout the data collection and analysis process.²⁸⁶ When a new code was identified in a transcript, past transcripts were then reviewed again to see if that code applied. Coded data were housed within NVivo's "nodes." As needed, sub-codes ("child nodes" in NVivo parlance) were created to further classify the data

within the “parent nodes.”

Data analysis. Key themes were identified by reviewing the data within each node. NVivo was also used to create visualizations of the patterns that emerged from the coded data, including word clouds and inter-code relationships. Such visualizations were especially useful when thinking through the data at the earlier stages of the analysis.²⁹¹

Data from the online survey program were downloaded into Excel files for ease of analysis. Basic descriptive analyses were performed (e.g., sums, percentages, averages, ranges). Descriptive information related to the participants and clinic sites were also linked to the qualitative data, which allowed for the contextualization and comparison of the findings. The post-interview and focus group summary memo was also useful in providing context to the data.

In addition to using NVivo software, the data were organized through the use of flipcharts, index cards, matrices, and tables to facilitate interpretation of the data. This was particularly helpful in documenting the clinical pathways for patient access to overdose education and naloxone. Through an iterative data review process, the observed codes, themes, and relationships were continually validated against the incoming data and modified throughout the analysis process.⁷⁷ Overlap across the CFIR constructs was continually examined to determine which construct was the best fit for categorizing each key finding. Frequent references to the coded data and transcripts occurred during the analysis process to cross-check findings and to incorporate important information related to the clinic and participant context. Select quotes were identified to illuminate key findings.

Data synthesis and interpretation. Findings from the analysis were written with the three research aims in mind, and structured by domains and relevant constructs from the CFIR conceptual model. As noted above, illustrative quotes and examples from the coded transcripts bolstered the findings. Variations related to particular clinic characteristics were explained.

Frequency tables were created during the data analysis to describe particular clinic characteristics, such as the number of sites which utilized particular clinic staff to conduct overdose education or that disseminated naloxone through a particular channel. Because quantifying frequency of responses is not the goal of qualitative research,²⁷⁶ these tables are not presented in the findings. Instead, the analysis focused on finding meaning in the data. While the number of study sites with a particular characteristic was referenced, this is not meant to signify increased strength to the findings, but to contextualize them.

Conclusions from the findings were identified, along with similarities to and differences from what was expected and what was found in the literature. Suggestions for future CHC-based OENA activities were based on specific strategies identified at the different study sites. Broader recommendations for future practice and research were also articulated (see Chapter 5, Discussion).

Human Subjects Research Considerations

All study participants were aged 18 and older. Recruitment methods were based on participant selection criteria outlined in the sampling plan, which included women and minorities. Participation in the study was completely voluntary.

An application to conduct this research was submitted to BUMC's IRB in November 2014 (Reference Number 491076), and the study was determined to be exempt in accordance with 45 CFR 46.101. This study was also deemed exempt from authorization under provisions of the Health Insurance Portability and Accountability Act (HIPAA). An amendment was submitted in December and was also deemed exempt (Reference Number H-33572). This research qualified as exempt because information obtained from participants was collected, recorded, and managed in a manner that did not allow for the identification of individuals participating in the study, thus preventing any risks related to confidentiality.

The IRB determined that written consent was not needed, and a waiver of documentation was granted. All participants provided verbal consent at the start of the study after reviewing a one-page consent form describing the study's purpose, the types of questions to be asked, the length of interview, data confidentiality, the voluntary nature of their participation, and contact information if participants had questions (Appendix B).

For two of the CHC study sites, additional documentation was prepared to support internal clinic research ethics review protocols; both CHCs approved the study.

Chapter Summary

This research, organized through the lens of the CFIR, identified strategies for expanding naloxone access in CHC primary care settings for patients who may be at risk of experiencing or witnessing an overdose. This chapter described the study's methodology, which relies upon interview methods to identify factors that influenced OENA activities in CHC primary care clinics. Additional data collection methods,

including clinic and participant surveys and document review, helped contextualize that qualitative data. Review of the literature and pilot study data collection guided the selection of constructs from the CFIR, which was used to develop the data collection instruments and structure the analysis.

The study sample is comprised of eight CHCs providing routine care to PLWH in Massachusetts, purposefully selected using predetermined eligibility criteria. In an effort to focus this study, clinic teams providing primary care to persons living with HIV were targeted for interviews, though the activities that were reported reflected OENA activities occurring within the primary care clinic. Within each clinic, interviews were conducted with clinic staff involved in the delivery of OENA activities.

A continuous, iterative review of the transcripts, initiated at the start of the data collection process, supported the coding process. CFIR constructs were used as the primary codes. Chapter 4 presents a comprehensive overview of the study findings based on the research aims— starting with a summary of which patients are reached, by whom, and with what means of naloxone access, and followed by a description of CFIR constructs found to influence implementation. This is followed by Chapter 5 which highlights conclusions from the study and discusses implications for practice, future research ideas, and limitations to the study design.

CHAPTER 4: FINDINGS

This chapter reports the study findings in two sections, each focused on one of the primary research aims. Based on these findings, the chapter also lists strategies that could be considered and ultimately transferred to other primary care settings interested in implementing or scaling up OENA. Findings from the pilot study can be found in Appendix D.

The first section documents different opioid OENA activities implemented by the CHCs. Implementation science emphasizes the importance of describing the intervention and implementation process,²⁷⁸ in this case who receives overdose education and naloxone, who implements it, and how naloxone is accessed. Variation and commonalities across the study sites are explained.

The second section identifies the CFIR constructs that facilitated implementation of opioid OENA at the intervention, individual, organizational, external, and process domains. These findings are described by the constructs that emerged from the qualitative data analysis. Strategies employed by the CHCs related to CFIR domains are included, as well. These findings can help explain what will support the adoption and implementation of OENA activities in other settings.²⁷⁸

Steps and Strategies for OENA

The goal of this first section is to describe variation and commonalities in OENA activities across the eight CHCs that participated in this study. An understanding of what activities took place is an important starting point for investigating the contextual factors

that influence program implementation. The following four questions related to the first research aim are examined below:

- A. Which patients were identified for overdose education and naloxone receipt?
- B. What were the components of the provided overdose education?
- C. Who conducted the overdose education session?
- D. How was naloxone provided to the patients?

While the study's focus was on the HIV team's activities, the findings apply to the broader primary care clinic. All of the CHCs in this study provide both HIV and primary care to patients and are set up to provide integrated primary care. There are no physically separate or distinct HIV clinics.

Within four of the CHCs, the naloxone access program was managed out of the clinic's HIV program. Staff overseeing the naloxone access programs at two of the CHCs also managed the clinic's buprenorphine program. One CHC with a broadly disseminated overdose education and naloxone program noted that while it originated in the HIV program because of the high number of HIV patients with injection drug use as a risk factor, *"Now we have made such a big emphasis about this in the clinic. All of the teams are really focused on it and all of the case managers and nurses in the entire clinic are really up to speed."*

In sum, the approaches reported below reflect activities throughout the primary care clinic and therefore have relevance beyond patients with HIV who are seen at the CHC. The extent to which these activities apply to the patients with HIV depends in large part on the number of patients with HIV who have an opioid use disorder or are on

chronic pain medication— risks that can be found with patients seen in the primary care clinic for other reasons.

A. Which patients were identified for overdose education and naloxone receipt?

The following three groups of patients were prioritized to receive overdose education and naloxone: 1) patients with an opioid use disorder, with a focus on those accessing medication-assisted treatment; 2) family members and friends of those with an opioid use disorder; and 3) patients prescribed chronic opioid therapy. Each of these groups is described below. A summary of risk factors used to identify patients in need of overdose education and naloxone is included in Table 20.

Patients with an opioid use disorder. All of the study participants identified patients with an opioid use disorder to be in need of overdose education and naloxone. In fact, patients receiving MAT— meaning methadone, buprenorphine, or naltrexone— are at risk of overdose or relapse while in a treatment program. One pharmacist stated, “*I think that anybody who is using opioids, who are on either Suboxone or methadone, or...if somebody is friends or family of someone also using opioids or methadone, they should be trained.*” One nurse practitioner actively involved in OENA activities in her clinic explained:

It’s part of my repertoire when I speak to any patient. They say, ‘I’ve been clean for three weeks.’ I’m like, ‘Do you need assistance, methadone, Suboxone, have you been on Vivitrol? ...Do you have a Narcan kit?’ ...It’s just part of what I say.

Another participant explained how overdose education and naloxone is incorporated into the buprenorphine program assessment and induction process at her CHC, “*Any patient that comes in that’s requesting addiction medicine treatment is*

automatically referred over to our addictions nurse or myself and is screened as appropriate for our program. Part of that initial screening is their risk for overdose and naloxone.”

Specifically, patients transitioning in or out of medication-assisted treatment were considered at risk, as explained by one physician: *“I will prescribe naloxone to my patients that I think are at risk because they are transitioning from one stage to another whether that’s going into or coming out of maintenance therapy.”* History of overdose was also listed as a risk factor necessitating OENA activities, though past overdose assessment was performed inconsistently across the study sites, and CHC physicians rarely received reports about patient overdoses from EDs unless the physician was affiliated with the hospital.

Table 20. Patient Factors Prioritized for OENA

- 1) Opioid use disorder
 - Receipt of medication-assisted treatment, including buprenorphine, methadone, and naltrexone
 - Transitioning in or out of medication-assisted treatment program
 - History of overdose
- 2) Family member or friend of person with opioid use disorder
- 3) Receipt of chronic opioid therapy

Family members and friends of those with an opioid use disorder. Study participants were keenly aware that patients who receive naloxone cannot administer it to themselves. One CHC clinic manager voiced this as a barrier: *“Yeah, but then if you give it to the patient and the patient gets trained but the patient is who it would actually get used on, then you have a disconnect as well.”* However, there was widespread recognition that patients with an opioid use disorder are likely to witness an overdose and

therefore have high priority for naloxone receipt. One participant explained, *“Anybody who has a history of addiction or has been struggling with it in the past, we know that they are still associated with persons and places that could put them in a situation where they might be rescuing somebody else.”*

With this in mind, participants expressed the idea of “blanketing” communities at high risk by reaching patients likely to witness an overdose. One physician at a CHC with a high percentage of patients with opioid use disorder reflected on this approach:

Initially, we were thinking what the criteria are for this and we basically said everyone should be prescribed naloxone. So everyone over 18 should be prescribed naloxone here. Anyone who is coming to this practice has the chance of encountering someone who is overdosing and could administer it. So it is really much more universal precautions. Everyone should have this. We are now following it as a performance measure for the program.

This community health focus was also voiced by a nurse program manager at another CHC who said, *“Everyone who was already enrolled in the [Suboxone] program got Narcan also. So for us, it is getting more of it out there in the community, even if the patients are not actively using, often times they know someone who is.”*

Study participants acknowledged that it is not often feasible or realistic to educate a family member or friend of an at-risk patient about overdose prevention and response. One participant explained,

It’s not as easy. What we do encourage when a patient is treated in the clinic...I make sure they know that when they go home, to share the information packet and the naloxone with the family members because they are not going to be able to help themselves. We emphasize that as part of the teaching-- is this is for you to help others or to teach your family members to help you? If we aren't teaching them that, then we aren't doing our job.

The majority of study participants spoke about the toll of opioid addiction in their communities, and often saw patients who are not personally at risk of an overdose, but had a family member or friend struggling with opioid addiction. Two participants spoke about the role naloxone plays in reassuring family members— by equipping them with a tool to prevent an overdose death. One physician shared an experience with one of his patients who had a family member struggling with addiction, and how his clinic team was able to respond and provide naloxone to the patient:

One of my patients saw the naloxone sign [hanging in the clinic], and so asked our nurse and said, 'It's been really sad, one of my grandchildren is into this [heroin].' And so the nurse knew how to educate about Narcan. She took the patient to the room, educated her about Narcan. And she walked out of here with two doses of Narcan, an atomizer, and training on how to use it.

Patients prescribed chronic opioid therapy. Only half of the eight CHCs assigned priority to patients being prescribed chronic opioid therapy for pain management as candidates for overdose education and naloxone. Two other CHCs identified these patients as a future priority. Two of the CHCs addressing this group reported that it was more feasible to start with this group because, as one CHC's nurse practitioner explained, it was easier to engage providers by appealing to prescriber concern about overdose risk for their patients on prescription opioids.

This CHC implemented a pilot in the primary care clinic by targeting patients on chronic opioid therapy, as explained by the nurse practitioner championing the initiative:

I think a lot of the docs who had patients on chronic pain meds or who were worried completely jumped right on.... We tried to lessen the stigma by saying, "Let's just start with all of the chronic pain patients because this is a life-saving medicine for them."

A physician at another CHC explained how her CHC co-prescribes naloxone for every patient on chronic opioid therapy. She talked about framing the conversation with patients in terms of opioid safety, making it is a non-judgmental and therefore easier conversation to have:

For me it's like I offer this to every patient who is prescribed opioids. So for my chronic pain patients, in some ways it's an easier sell because it's "I'm not worried about you necessarily but what if this gets in the hands of somebody else? A child for example. You want to be able to reverse an accidental overdose." So it's not threatening. I'm not saying, "I think you are overusing your medicine or you are abusing it." It's like, "If there was an accident, wouldn't you want to have a tool in your hand to reverse an overdose? And that is an opportunity to talk about locking up medications. It's also a no-brainer."

Staff at the CHCs not yet addressing this group identified several barriers. One participant explained that patients and providers thinking there was a little if any risk of overdose posed a barrier to discussing the need for naloxone:

It isn't an easy conversation to have because the folks who have been on the chronic opioids for pain don't really see themselves at high risk. And, compared to many folks, and heroin use, they aren't, of course. I can't say that many of the folks actually particularly wanted to have naloxone at home available for themselves, those who are on chronic opioids, if they didn't have some other reason with kids in the house, or a child, typically a grown child who has an addiction problem.

Two physicians from separate CHCs reflected on how rarely they discuss overdose education or offer naloxone to patients being prescribed chronic opioid therapy for pain management. One of the physicians explained, *"If I have a 20- to 30-year history of them*

taking their medicine responsibly and not overdosing I probably don't think about it. I haven't even done it.” The other physician noted, *“I've never actually prescribed naloxone for patients on chronic opioids. I do have a number of them on chronic opioids for pain management.”* A clinic manager at another CHC explained one prescriber’s reaction to co-prescribing naloxone with chronic opioid therapy— realizing the potential risk to an opioid prescription, *“They thought it was interesting that they are prescribing something and then saying ‘But if you overdose on something I prescribe you, here is something that might help.’ They were struggling with that concept.”*

Table 21. Content of Opioid Overdose Education Session

- Overdose risk factors
- Overdose signs
- Overdose response, including calling 911
- Naloxone rescue kit assembly and use demonstration

B. What were the components of the provided overdose education?

Overdose education included overdose risk factors and signs and how to respond to an overdose, including the mechanics of using a

naloxone rescue kit (Table 21). Participants described overdose education sessions lasting between five and 20 minutes, depending on the degree of “buy in” from the patient and the number of questions asked. Most participants highlighted the importance of having patients handle and practice using a naloxone rescue kit during the education session.

One nurse explained her CHC’s process:

So we give it [naloxone] to the patients or family member right on site, and do training and open up a demonstration kit and actually show step-by-step how to use it and educate the patient or family member when to use it, what are the signs and symptoms of someone who is overdosing, when they should give it, the importance of calling 911 and all of the instructions that go along with it.

Most CHCs provided written education materials to patients receiving naloxone education. As required, pharmacies dispensing naloxone through a standing order also provided educational materials, such as the Massachusetts DPH-provided “Naloxone Pamphlet” for pharmacy use (Image 3).²³⁰ One nurse commented on the need for patient education materials:

We have them coupled with the prescription. I think the written materials are important. My impression is that folks do not remember months later. I don't expect people to remember how to do things. So having the written information with the naloxone makes sense. From the folks who I've talked to who have used it, they did not feel confident putting it together at the time.

Important elements of patient education materials included use of pictures for low-literacy audiences and availability in Spanish.

Image 3. Naloxone Education Pamphlet

Naloxone Pamphlet

What is naloxone?
Naloxone is an antidote for opioid overdose. In an overdose, opioids can cause difficulty breathing, sedation, and death. Naloxone is a medication that reverses these effects.
Naloxone only works if opioids are present in the body, and has no effect if they are not. It does not work on other drugs or alcohol. Naloxone usually takes effect in 3 to 5 minutes and lasts 60 to 90 minutes.

Who should take naloxone?
Naloxone should be given to someone experiencing an opioid overdose. Overdose death can occur over one to three hours. This gives time to take life saving actions.
Overdose most often occurs when people take a large or increased amount of opioids, mix opioids with alcohol or other drugs, or have had recent changes in tolerance levels.
If a person is not responding, not breathing, or is struggling to breathe, they may be experiencing an overdose and it is time to begin the steps of naloxone administration.

How to Respond in an Overdose:

Step 1: IDENTIFY OVERDOSE

Opioids can be dangerous because they suppress the body's urge to breathe, which can possibly lead to death. If someone is not breathing or is struggling to breathe, try calling the victim's name and rubbing your knuckles on their chest. If he/she is still unresponsive, he/she may be experiencing an overdose.
Other signs that may help you identify an overdose are:
blue or pale skin color, small pupils, low blood pressure, slow heart beat, slow or shallow breathing, snoring sound, gasping for breath.

Step 2: CALL 9-1-1

After identifying an overdose, get help as quickly as possible. Send someone to
Call 9-1-1. Make sure to say the person is unresponsive and not breathing or struggling to breathe. Give a clear address and location. Also send for Automated Electronic Defibrillator (AED) and naloxone.

Examples of Opioids:
MORPHINE (MS Contin[®])
COCAINE
HYDROCODONE (Vicodin[®], Norco[®])
HYDROMORPHONE (Dilaudid[®])
OXYCODONE (Percocet[®], OxyContin[®])
OXYMORPHONE (Opana[®])
FENTANYL (Duragesic[®])
BUPRENORPHINE (Suboxone[®])
METHADONE
HEROIN

The Massachusetts Good Samaritan Overdose Prevention Law protects people who overdose or seek help for someone overdosing from being charged or prosecuted for drug possession. Protection does not extend to drug trafficking or distribution charges.

Step 3: BEGIN CPR

If victim is unresponsive with no breathing or only gasping, begin CPR. CPR technique should be based on the rescuer's level of training.


RESCUE BREATHING:

- Make sure nothing is in the person's mouth blocking their breathing.
- Place one hand on the chin and tilt the head back. With the other hand pinch the nose closed.
- Administer two slow breaths and look for the chest to rise.
- Continue administering 1 breath every 5 seconds until the person starts breathing on his or her own.

If alone, perform CPR for about 2 minutes before leaving to get naloxone and Automatic Electronic Defibrillator (AED).

Prevent Overdose:

- Only take medication prescribed to you, and take it as directed.
- Don't mix opioids with drugs or alcohol.
- Store your medication in a safe and secure place and dispose of any unused medication.
- Not taking opioids for a while changes tolerance levels, which means if you restart you need to start at a lower dose.
- Teach your family and friends how to respond to an overdose.



Source: Massachusetts DPH, 2015.

Follow-up with patients who received overdose education and naloxone was reported to occur regularly. This follow-up step provided the opportunity for prescribers and nurses to assess naloxone use, provide refills, and answer questions. One nurse practitioner spoke about her clinic’s approach: *“Every visit we ask if they have naloxone, do you need it, and I always educate them to watch expiration dates— how long have you had it for— it is time to get you a new kit.”* Another CHC conducted follow-up every six months with patients in the Suboxone program to ensure they had naloxone on-hand.

C. Who conducted the overdose education session?

Overdose education and naloxone provision were often done by the same individual, but they are described in separate sections since that is not always the case. Overdose education was performed by various clinic staff members or pharmacists, depending upon the study site. As can be seen in Table 22, the actual clinic staff involved in the provision of overdose education varied.

Nurses. Across the study sites, nurses were the staff most frequently responsible for providing overdose education. Education often occurred in the context of an HIV case management session or buprenorphine assessment.

Table 22. Clinic Team Members Conducting Overdose Education

- Nurses
- Prescribers (physicians, nurse practitioners, physician assistants)
- HIV counselors
- HIV case managers
- Health educators
- Pharmacists
- Behavioral health providers

Prescribers. While they supported the intervention, prescribers played a less direct role due to barriers explained later. Mostly, prescribers referred a patient to other staff for overdose education or wrote a prescription when requested by another clinic team member who was seeing a patient. Some prescribers did have discussions about

overdose and naloxone during patient visits.

Pharmacists. Pharmacists played a key part in providing overdose education, especially when their role in dispensing naloxone was formalized through an agreement or standing order with the CHC. One nurse explained the primary role that pharmacists play in overdose education: *“I’m not a certified [overdose education and naloxone] trainer. But I can certainly go through the steps for them of how to use it, and I have a kit at my desk, but the pharmacy does most of the training at this point.”* A couple of CHCs called upon the pharmacists to identify and educate patients in need of naloxone, as explained by one study participant:

Anybody who is receiving a chronic opioid prescription is also offered Narcan through the pharmacy. The pharmacy knows who they are and that’s also a part of the agreement or discussed in the nurse and physician agreement, and patients are encouraged to ask the pharmacist and the pharmacist is also offering them Narcan when they pick up the script.

Case managers and health educators. Case managers and health educators provided naloxone education in some of the CHCs. Typically this was conducted during a “warm hand-off” from the prescriber to the case manager or health educator.

Behavioral health providers. In some CHCs, the behavioral health providers identified the need for and provided overdose education, but several study participants spoke about the expanded role that behavioral health team members could play. One nurse practitioner explained:

“They [behavioral health providers] have 45 minutes with a patient. A lot of them are dealing with family issues, and a lot more of them would [be able to say] more about it than a 15-minute visit with a primary care provider... It is everyone’s duty or responsibility to bring this up. Because as a therapist if you are sitting in and discussing that a client’s loved one is using then you can do a reverse warm-hand off to the nurses and say

this person needs a kit.

Team-wide responsibility. While particular team members were identified as playing a greater role than others in OENA activities, many participants believed that OENA should be provided by anyone who interacts with clients at risk of overdose. One nurse shared his perspective:

I think everybody should be doing it. Any of those people, wherever the patient is at. If they are just coming to their case manager and they are actively using, then that is the person that, if they have the Narcan and can do the training, then that is where the patient is going to get it. That person might not go to the pharmacy if you tell them to. So I think as many people that are trained and able to provide it, the better.

A pharmacist participating in the interview added, *“It doesn't make one person more qualified than someone else to be involved in this. It is a simple process to explain— just [need] everyone being on board.”* A physician at another site agreed:

I would say anyone who is seeing patients, just ask the question. It's a lot of just asking, are you using substances, does your family member-- it is asking the question and giving them the referral and places they can get help or Narcan kits. Everyone is touched by it at some point.

D. How was naloxone provided to the patients?

CHCs have implemented a variety of strategies to provide patients with naloxone, as they recognized that expanded access would require additional avenues beyond prescribing. While the initial research questions focused on naloxone prescribing, the focus of inquiry quickly turned to naloxone access more

Table 23. Points of Naloxone Access

- Internal clinic distribution
- Pharmacy partnership via prescription or standing order- patient request or pharmacist initiated
- External referral to community OEND

generally, as prescribing was rarely utilized by the CHCs in this study sample.

Points of naloxone access varied across the CHCs (see Table 23), including 1) internal clinic distribution, 2) pharmacy dispensing, and 3) external referral to an OEND program. The avenue that is utilized also determines how naloxone is paid for or reimbursed. Each of these options is described below.

Internal clinic distribution. Two of the CHCs stocked naloxone for direct distribution to patients, typically in an exam or counseling room, during the patient visit. (This is to be distinguished from naloxone stocked as part of clinic emergency response kits.) With this in-house distribution model, both prescribers and nurses identified patients who needed a naloxone rescue kit and made a “warm hand-off” to a trained clinic nurse, health educator, or case manager, who in turn provided OEND. One nurse explained her CHC’s rationale for choosing this avenue:

You hand a patient a prescription and it’s like with anything— do they choose to pick it up? The thing I love about having naloxone here, you actually hand it to the patient. There’s not going to be any question if they went and got it or not.

One hospital-affiliated CHC received funding for naloxone as part of the hospital’s substance use response initiative. Another center purchased naloxone rescue kits as part of a clinic pilot program with the expectation of future pharmacy reimbursement, which turned out not to be feasible. As a result, the clinic eventually maintained a small number of naloxone rescue kits for direct distribution to patients deemed to be unlikely to access kits under the established standing order at the pharmacy across the street.

Three of the CHCs received Massachusetts DPH-funded OEND pilot grant funding which paid for naloxone rescue kits, though the kits were earmarked for non-patient populations. Nonetheless, some of these OEND programs were utilized as an in-house source for patients in immediate need of a naloxone rescue kit. Recognizing the merit in this approach, one physician working at a CHC with a different model reflected,

It would be easier and more effective if we could give it out in-clinic. Not everybody goes down and picks up that prescription. And people who get their medicines normally at other pharmacies don't want to wait here because there is a wait time. That is a barrier for patients. So that would definitely improve things if there was a way to dispense it out of the clinic.

Pharmacy dispensing.ⁱ Six of the CHCs used a pharmacy, either co-located within the CHC or a nearby CHC-affiliated pharmacy vendor, to provide naloxone, with patients using their health insurance or paying out-of-pocket. There was variation across the study sites in how this method was implemented.

The most common method, used by five of the study sites, was having a standing order with the CHC-affiliated pharmacy, by which the CHC's medical director authorized naloxone dispensing for patients or community members who request naloxone without a prescription. As part of the standing order, pharmacists are required to provide overdose education. A CHC pharmacist outlined this approach:

We have a standing order where anyone can come off the street and buy naloxone. Because of the standing order you can actually use your insurance. So we have the kits already set up. We have all the pharmacists trained. We met with DPH to get approval for this. The prescription is "pre-filled" out. We do our best to get the patient in and out.

ⁱ While naloxone rescue kits were available through a DPH standing order with select commercial pharmacies in the state without a prescription (i.e., Walgreens), partnerships with or referrals to commercial pharmacies were not in place among the eight study sites.

Existence of a standing order did not preclude prescription writing. In fact, one CHC continued to write prescriptions to ensure that patients would receive naloxone at the pharmacy and to support documentation in the EMR. Naloxone prescribing was reported to be relatively infrequent, however, in part due to time barriers and competing priorities faced by prescribers, and possibly because of the standing order itself being in place.

One CHC used a pharmacy to dispense naloxone without a standing order by establishing an agreement with the pharmacy. Patients received overdose education from the nurse at the CHC, a prescriber wrote the naloxone prescription, and the patient picked up the prescription at the pharmacy after confirming that education had occurred.

External referral to community-based OEND program. One of the CHCs referred patients to a Massachusetts DPH-funded OEND pilot grant program operated by a nearby behavioral health agency. Staff from the agency also came to the CHC agency's opioid treatment program once a month to offer OEND directly to patients. "*[Overdose and naloxone] is more of an everyday conversation and referral,*" stated the clinic manager. "*We have [an organization] a couple of miles down the road that is funded to distribute naloxone.*" Reflecting on this, he said, "*Of course, once someone leaves the clinic, the likelihood that they will go to another place goes down.*"

Summary of naloxone access approaches. These naloxone distribution methods were not mutually exclusive; three of the CHCs implemented two or more approaches at the same time. One nurse program manager explained her CHC's rationale for having multiple pathways for naloxone access:

For our clinic, you need to have it in both places [pharmacy and clinic] because there are people who won't walk into the pharmacy and wait. So if you have someone who is agitated and not willing to wait in the pharmacy, you know, stand in the line, wait for the pharmacist, they have to fill it, and then you have to get educated. People aren't going to be willing to sit there and do that; you have to meet them where they are at. And that is why being able to provide it in our model works really well. But also giving people the freedom to walk into the pharmacy and request it works really well. So you have to have both. [I] think that what makes our program so great [is] that we are all integrated and working together and have these different options.

The advantages and disadvantages of the different means of accessing naloxone should be considered to determine which approach— or approaches— might work better in a given organizational context at a particular point in time based on patient needs. The benefits and challenges of the different approaches identified in the study are summarized in Table 24.

Naloxone Access Point	Advantages	Disadvantages
Internal clinic distribution (by clinic staff during patient visit)	<ul style="list-style-type: none"> • Integrated into patient visit • Provides patient with naloxone directly to ensure access • Offers private space to conduct training. • Minimizes pharmacy access barriers that may occur outside the clinic (i.e., travel, long wait, lack of privacy) • No patient cost for naloxone 	<ul style="list-style-type: none"> • Obtaining funding for clinic-purchased naloxone kits • Sustaining funding for kits • Need to ensure providers and clinic staff are trained • Need to ensure naloxone distribution is built into clinic flow and appropriate staff are available • Need system to track naloxone distribution
Pharmacy dispensing (by CHC-affiliated pharmacy through prescriptions or a standing order)	<ul style="list-style-type: none"> • Naloxone cost covered by patient health insurance • Naloxone prescribing or referral integrated into clinical care (i.e., Suboxone induction or chronic opioid therapy) • Pharmacist can support protocols to offer naloxone as part of co-prescribing initiatives for buprenorphine and chronic opioid therapy • <u>Prescription access</u>: Ensures 	<ul style="list-style-type: none"> • Cost of naloxone if insurance does not fully cover the prescription • Need to ensure pharmacists are trained and comfortable providing overdose education • Stigma can impede patient request for naloxone • Lines, waiting time, and space constraints in the pharmacy limit the opportunity for private overdose education sessions • Concern that patient will have naloxone

	<p>prescription will be prepared for patient pick-up at pharmacy</p> <ul style="list-style-type: none"> • <u>Standing order</u>: Allows patients and other persons to request naloxone without prescription 	<p>on health insurance record</p> <ul style="list-style-type: none"> • Naloxone receipt tracking hindered by different CHC and pharmacy systems • <u>Prescription access</u>: Getting a prescription from prescribers with competing priorities and limited time can be a barrier • <u>Standing order</u>: Unless a prescription or other supportive measure is in place, the onus of requesting naloxone is placed on patients
External referral (to a community organization funded to provide OEND)	<ul style="list-style-type: none"> • Collaboration with a local organization providing OEND services • Links patient to an organization that could offer other supportive services • No patient cost for naloxone 	<ul style="list-style-type: none"> • Requires patient to access another service in a different location, with a risk of referral drop-off • OENA is not built into CHC clinical care systems • No follow-up information on referral uptake

CFIR Constructs Influencing Implementation

This section describes the 20 constructs from the five CFIR domains that were found to support or inhibit implementation success (Table 25). The constructs are stated in positive terms as facilitators, but their absence could pose a serious barrier and be just a neutral factor. For example, the presence of a champion at the CHC who drives implementation forward would facilitate implementation. The reverse, however, is also true—the absence of a champion would impede implementation. Each of the constructs is described by domain. Table 12 in the Methods chapter provides a brief glossary of construct definitions for reference.

Table 25. CFIR Constructs Identified During Analysis by Domain

Domain	Constructs Found to Facilitate OENA Activities
Innovation Characteristics	<p>Adaptability: OENA can be tailored to the needs and resource of the CHC and revised in an ongoing manner as program needs evolve.</p> <p>Trialability: OENA activities can start as a pilot initiative with a particular group of patients or clinic and then be changed or expanded based on experience.</p> <p>Complexity: Integrating OENA activities into clinical care provision by clinic team members who are non-prescribers (i.e., nurses) supports implementation.</p> <p>Cost: OENA activities involve minimal costs, depending on the means of naloxone access by the CHC.</p>
Outer Setting	<p>Needs & Resource of Patients: Clinic staff's understanding of addiction theory, a harm reduction approach, and non-judgmental communication supports patient engagement.</p> <p>Cosmopolitanism: Partnerships can be put in place to help initiate and expand the clinic's naloxone access activities.</p> <p>External Policies: Governmental policies offer opportunities for enhancing naloxone access in clinic settings.</p>
Inner Setting	<p>Networks & Communications: Partnerships with pharmacies support the provision of naloxone to patients and the community.</p> <p>Culture: The CHC culture and mission supports patient-centered health services and is open to innovations that could better meet patients' needs</p> <p>Implementation Climate: Team-based provision of OENA supports clinic staff participation and implementation of OENA.</p> <p>Tension for Change: An expressed sense of urgency to address the local opioid epidemic serves as a catalyst for CHC response.</p> <p>Readiness for Implementation: Clinic-wide training on a clinic's overdose response and leadership support are among two key initial steps for OENA adoption.</p> <p>Leadership Engagement: Ongoing clinic and pharmacy leadership supports program initiation, adaptation, and long-term maintenance of OENA activities.</p> <p>Available Resources: ongoing training, educational materials, physical space in the pharmacy and clinic, and identified staff roles are important components to OENA implementation.</p>
Characteristics of Individuals	<p>Knowledge & Beliefs about the Intervention: Clinic staff understanding of how naloxone benefits different patient groups at risk of experiencing or witnessing an overdose supports engagement.</p> <p>Individual Stage of Change: Implementers with differing levels of comfort and skill development need different supports depending on their stage.</p>
Process	<p>Engaging: Training, peer guidance, inclusion of OENA in regular meetings, and decision tools help engage clinic staff. Outreach efforts, signage, and models of delivery that address patient barriers support patient engagement.</p> <p>Champions: The presence of a passionate champion who leads the clinic team's implementation effort can keep the OENA intervention on track.</p> <p>External Change Agents: Reputable experts and advocates help get CHC staff on board during the initial OENA implementation phase.</p> <p>Reflecting & Evaluating: Staff sharing of implementation experience and ongoing data reviews provide feedback to staff and guide quality improvement efforts related to CHC-based OENA activities.</p>

Domain 1: Intervention Characteristics

Four characteristics of the intervention were found to affect the adoption and implementation of OENA activities: adaptability, trialability, complexity, and cost.

Findings related to each construct are described below.

Adaptability

The first finding from this study was that CHCs have implemented a variety of strategies in addition to traditional prescribing to equip patients with naloxone. The study therefore focused on implementation of naloxone access activities, as opposed to naloxone prescribing alone. The variety of strategies used at each of the sites, combined with differences in who conducts the activities, demonstrate that **OENA activities can easily be adapted to meet the needs of** a specific CHC. Where policies were in place, they were developed after implementation started and offered guidance rather than a rigid protocol. The flexible nature of the **intervention activities meant that they could be revised as needed**. Likewise, implementers were able to try out new strategies. For example, one CHC with a pharmacy standing order recently piloted a primary care-based OEND initiative with pre-purchased naloxone rescue kits and posted local overdose data to engage clinic staff. Upon implementation, the team realized that the naloxone kits could not be reimbursed and discontinued the purchases. Likewise, the introduction of pharmacy standing orders also offered new access strategies for some CHCs that had already implemented other distribution strategies.

The “adaptable” nature of OENA activities enabled CHCs to respond to changes in either the inner or outer settings. For example, the availability of a pharmacy standing

order in Massachusetts in March 2014, plus CDC’s release of chronic opioid prescribing guidelines in March 2016, offered new opportunities to introduce novel program options. During all of the interviews, participants reflected on planned future enhancements and ways to streamline their programs, including whom they wanted to reach, additional outreach strategies, clinic staff engagement activities, and ways to decrease stigma related to requesting or receiving naloxone (Table 26).

Table 26. Examples of CHC OENA Program Adaptations

- Obtaining a standing order for nurses to order naloxone
- Utilizing the behavioral health team to conduct OEND
- Expanding the program to serve patients on chronic opioid therapy
- Working with senior administration to create a standing order with CHC pharmacy
- Making preparations to utilize the CHC pharmacy standing order if needed
- Adding signage at the clinic to increase overdose and naloxone awareness
- Designing request cards so patients can easily ask for naloxone at the pharmacy

Trialability

The degree to which a health services intervention can be piloted first (“trialability”) has been shown to support implementation.⁷⁵ OENA activities typically **started on a small-scale in a particular program within the CHC and were then modified or expanded over time.** The CHCs’ OENA activities operated in the HIV programs, a primary care clinic, the buprenorphine program, or across the whole CHC. One nurse practitioner commented on the transformation of her clinic’s pilot OENA initiative, *“So it’s not so much a pilot anymore. It’s supposed to be like a process that we are doing and are going to continue to do.”*

Starting OENA activities on a small scale aided the early adoption phase. An intervention pilot within a particular care team or targeted to specific patients allowed

CHCs to figure out what worked, demonstrate success, and identify program elements needing improvement before moving toward broader implementation. Demonstrated success was then used to galvanize leadership and colleagues in expanding the reach of the CHCs' naloxone access activities.

Costs

Overall, the **investment and supply costs related to OENA activities were minimal**, though cost does become a major consideration if naloxone is distributed in-house. A summary of cost consideration appears in Table 27. Note that these costs do not include staff time, training, or clinic space, which are discussed later the “Available Resources” construct in the “Inner Setting” domain.

In terms of supplies, educational materials and signage were mostly available for free through the websites for the Massachusetts DPH and Prescribe to Prevent. Several of the participants spoke about the importance of having a naloxone rescue training kit on-hand for patients to practice assembly.

Table 27. Cost Considerations for CHC OENA Initiatives

- Printing of patient-friendly, linguistically appropriate education materials
- Posters and signage for the clinic
- Naloxone rescue kit supply, if the CHC is using in-clinic distribution
- Co-payment or full cost of the kit at the pharmacy, depending on patients' health insurance coverage

For the majority of the CHCs using a pharmacy to dispense naloxone, the cost of the naloxone rescue kits was covered by patients' health insurance. In-house naloxone rescue kit distribution required long-term institutional or grant resources. External referrals to OEND programs relied on naloxone rescue kits paid for and made available

by the Massachusetts DPH.

Five of the sites with a pharmacy partnership indicated that **cost for naloxone was not a barrier for the patients**. A pharmacy director at one of the study sites explained:

I can't even remember a time when it wasn't completely covered. And if it's not, it's usually a co-pay of \$3.65 or something minimal. And if they can't afford it then we put it on the pharmacy account and write it off. Because we would rather have the patient leave with Narcan versus lose a co-pay. Because we are a FQHC, we are able to get great benefits in the pharmacy where we are able to do special things like that.

Even so, a program manager at a CHC with an OEND pilot program and a pharmacy standing order, which had not yet been utilized, expressed concern about the potential costs to patients of providing naloxone through a pharmacy standing order if insurance were not to cover it fully. *“It's the cost barrier for those people who have anything but Mass Health...the cost that is incurred. Our clinical manager has been in communication with the pharmacist to try and figure out how we can encourage pharmacy distribution.”*

Complexity

Overall, **participants who regularly conducted overdose education and distributed naloxone to patients did not find it to be complicated**, and reported that OEND was typically integrated into existing assessment and follow-up appointments, such as HIV or buprenorphine visits with a nurse.

For prescribers, integrating OENA activities into patient visits was more difficult. Participants continually spoke about the challenge of covering multiple clinical issues during a short visit. One physician's description of the problem was echoed by

others:

Time and multiple competing demands: patients have ten different things that they want to talk about. And I have so much time, and so I probably under-prescribe naloxone simply because I'm not always thinking about [it]. There are other things I am thinking about.

Time constraints were often exacerbated by the need to address both primary care and HIV-specific care during the same visit. Training other staff members who had more time with patients to provide education was a common strategy for addressing this issue.

Yet for some prescribers, a busy clinic flow impaired their ability to utilize other team members' expertise. One physician who was a naloxone champion in her clinic shared her experience, *"I hardly ever do it [refer to a case manager], I have to say. It's one more thing, and it ends up making my visit longer in reality. I have to find that case manager. I have to page them. There is a back and forth. So often times I'm doing it myself."* The utilization of other team members worked best when it was built into the existing workflow. For example, if a nurse already saw patients as part of her regular buprenorphine treatment assessment, and overdose education was conducted as part of that visit, then that would be a natural fit.

Summary: Intervention Characteristics Domain

Regarding intervention characteristics (Table 28), CHCs identified different strategies based on the clinic's structure and existing programs, staff roles, and internal and external partnerships. Starting small, such as with a particular group of patients, allowed staff to see what works and what changes are needed. Finding ways to make the intervention as simple as possible also seemed to support implementation. Examples included utilizing staff that could spend more time with patients, building overdose

education into regular visits, and adding prompts to the EMR system. Most implementation-related costs seemed to be low, but the cost of naloxone rescue kits mean that it is not sustainable for a clinic to distribute naloxone in-house in the absence of patient insurance coverage. Accordingly, it is important for clinics exploring OENA options to investigate the extent to which different insurers cover the cost of naloxone.

Table 28. Summary of Strategies Related to CFIR Constructs within Intervention Characteristics Domain	
Construct	Implementation Strategies
Adaptability	<ul style="list-style-type: none"> • Adapt model based on patient needs, interest of implementation team, staffing model, clinic structure, and internal and external partnerships • Modify the program as needed based on experience, including who conducts the education, which patients are reached, and ways of engaging clinic staff and patients • Adapt approaches, practices, and policies from other programs
Trialability	<ul style="list-style-type: none"> • Start with a pilot project within a particular program or department and scale back or expand the program based on experience • Start where it makes the most sense, based on the clinic staff and patient needs
Complexity	<ul style="list-style-type: none"> • Utilize non-provider staff to implement the intervention • Minimize steps for implementers and patients by integrating OENA activities into regular visits • Ensure availability of staff for a “warm hand-off” to ease provider burden and patient waiting time • Build overdose risk assessment, education, and naloxone into the EMR
Cost	<ul style="list-style-type: none"> • Create a partnership with a pharmacy to minimize cost barriers • Use or adapt free, readily available patient education materials • Determine the financial costs incurred by patients with various health insurance plans and ways to remove costs barriers

Domain 2: Outer Setting

The following three constructs from the “Outer Setting” domain were found to influence implementation: needs and resources of patients, cosmopolitanism, and external policies. Each of these constructs is described below.

Needs and Resources of Patients

Individual patient assessment activities and community outreach helped clinic staff understand patients' needs. One nurse talked about the patient assessment process in the buprenorphine program: *"It is through our reassessment that we do every six months and also our base knowledge of patients. We typically know what's going on with them, and their historical situation."* Participants from a few of the CHCs talked about the importance of having staff spend time in the community. One pharmacy director described her process:

Our clinical pharmacists have gone out with the homeless providers. Once you see what is going on, you are like, "Wow, we need to do something." Most pharmacy directors probably aren't there. They got to get in it. Whenever there is any kind of community outreach or program, the clinic continuity of care director will tell me about it, and I will have someone on my team go to it. Just get out there.

For many participants, clinic staff's **personal experience heightened awareness about the opioid crisis**. A nurse program manager spoke about her CHC being in a community experiencing high opioid overdoses as a factor in facilitating clinic staff sensitivity to opioid use disorder:

Most people who live in this community are affected by opioid addiction, whether it is themselves or someone they know. I think we have less resistance than maybe there would be in other communities. And I think that makes the providers, staff, and pharmacists more on board because we see this, and we know it's a problem, and it needs to be addressed. And this is one thing we can do to try to help.

Another participant at a different CHC echoed this sentiment:

You know, I don't know what the statistics are, but I can guarantee you that every patient who walks in this door has been affected by addiction in some way, shape, or form, and I'm sure a large number of them have been connected to somebody who has had an overdose or has lost somebody to an overdose.

Just as awareness of the opioid crisis in the community facilitated responses, **lack of awareness of patient needs outside the confines of the clinic setting** was reported as a barrier to implementation. One participant expressed frustration: *“It’s what we see in the community... When I came here I was surprised... What people were not realizing was the community perspective, and as a healthcare provider seeing what’s going on outside the doors.”*

Resistance to using a harm reduction model posed another barrier to addressing patients’ needs by inhibiting open discussions about overdose risk, naloxone use, and the potential for relapse while in recovery. Conversely, a **harm reduction approach to substance use disorder treatment facilitated the integration** of OENA activities into the clinic’s work. A nurse who underwent harm reduction training spoke about how this helps her support her patients:

It’s about taking the stigma out of it. You know, I brought it up with a patient: talking about the risk of relapse, overdose, and the importance of naloxone. I was worried that she would not want to hear it from me. And the patient said to me, “I come here because I’m not judged.” So I was glad I brought it up. I just talk about it now, and let people know we are here for them no matter what and recognize that relapse may be a part of the recovery process, and there are some ways for them to stay safe.

Some participants spoke about **patients’ resistance to receiving naloxone based on their perception that they do not need it**. This belief is common among patients who are in treatment for opioid use. One participant explained:

A lot of them are very resistant. They are like “I’m not going to use that stuff, I don’t need that stuff [naloxone].” So it is hard to convince them [they] should have this because they are in the mind frame of “I’m not going to do that anymore.”

One participant shared how she addresses this barrier:

I've had a couple of patients say, "Why do I need this? I'm not using drugs. I'm not hanging around with people who use drugs anymore." We kind of just say, "Oh we want to get more of this out there in the community. You never know where you might be when someone you know might need it." I say, "Well, I have it. I carry it with me." [I] try to kind of normalize it.

Another CHC HIV program manager outlined his message: *"I remind them that relapse is part of the disease— there is a 60% chance of relapse."*

Stigma was frequently reported as a barrier to OENA activities. Participants observed, for example, that it was difficult for patients to ask for naloxone at the pharmacy for this reason. Additionally, a few participants stated that patients are concerned about having naloxone listed on their health insurance or medical record.

Across all of the interviews, clinic staff expressed compassion towards patients with an opioid use disorder and spoke about ways to remove stigma. As demonstrated by some of the participant statements reported above, the clinic staff's **recognizing opioid use disorder as a brain disease and having knowledge of the recovery process seemed to enhance clinic staff members' communication with patients about overdose.** One physician identified this as a facilitator to OENA in his CHC; *"It is recognition that this is a chronic disease of the brain, and it's not a moral failing."* An HIV program director from another CHC noted the benefit to offering naloxone to persons struggling with an opioid use disorder: *"There is the empathetic message— by offering someone Narcan, you are letting them know, and 'You are worth it. You deserve to make it.'"*

Cosmopolitanism

A list of study site external partnerships can be found in Table 29. As Figure 6

shows, the CHCs established partnerships with multiple programs to ensure that patients had access to the continuum of opioid treatment services, including detoxification methadone treatment, and outpatient counseling. Some CHCs established formalized referral processes with these agencies.

Two of the CHCs partnered closely with the pharmacy vendor serving the CHC to stock and distribute naloxone through a standing order. Communication and partnerships with commercial pharmacies was limited. One nurse discussed the need for a commercial pharmacy partnership in order to expand OENA activities to a CHC without an in-house pharmacy:

Table 29. CHC External Partners Supporting OENA

- Detox programs
- Methadone treatment programs
- Outpatient counseling services
- Residential programs
- Behavioral health agencies
- HIV service organizations
- Harm reduction programs
- Homeless service providers
- Pharmacies
- Hospitals and their EDs
- EMS department
- Police departments

Once I roll out the addictions program up there and integrate it with the HIV program, the next step is to integrate the Narcan piece into it and figure out how we implement it without a pharmacy on-site..... If we are unable to keep Narcan in stock at the clinic to distribute and bill for, then patients would be given a script that is sent to that CVS, but then I would work to meet, along with the nurse and one of the physicians, along with the CVS pharmacist and make sure they are doing the teaching, and make sure we can have that streamlined referral process. We may teach the patient[s] how to do it and then have them go pick it up. That would be the next phase.

Three participants represented their health center on a **local coalition established to respond to the opioid crisis**, which played a role in information gathering and coordinating a multi-sector response. One coalition was described as follows:

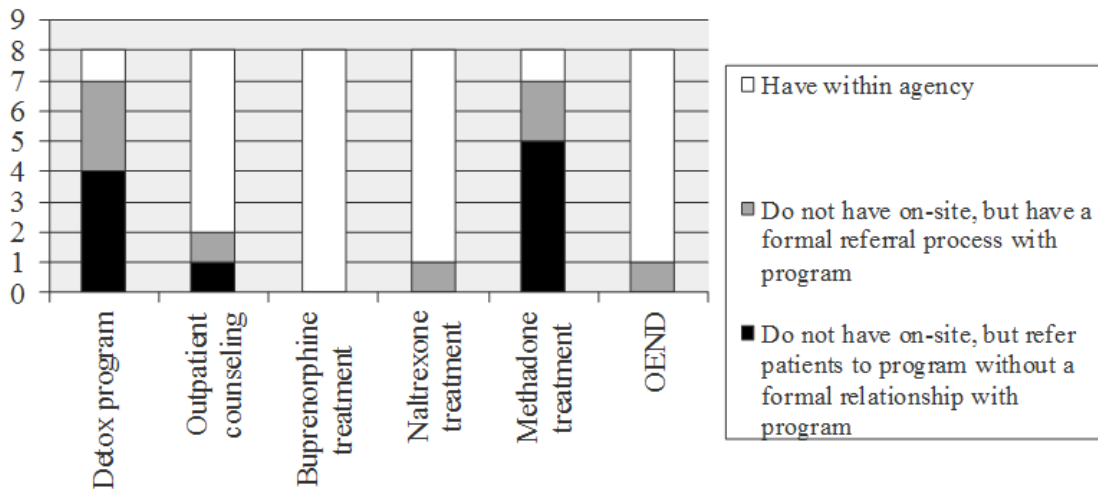
[It] brings together a variety of people— faith-based organizations, police departments, school representatives, treatment facilities, health centers.

These groups are useful in terms of disseminating information and pooling resources together.... They are trying to get more data from the ambulance service and hospital related to overdoses and track when naloxone is used. I am trying to get all of the outreach workers from the different agencies together so we can train them all in Narcan and make sure they know what resources each individual town has available.

Another CHC physician who attends an opioid community coalition takes the information from these meetings directly back to his clinic:

We talk about the overdoses and what we are seeing in the community, and the rates, and we discuss the police report. We get the data from the police. So that is what you saw on the board in the clinic. That just helps hit it home to the folks, to just say, “Hey, you know this is a patient of ours.” So everyone should be offering everyone a kit.

Figure 6. Availability of Opioid Treatment Services Across Study Sites



CHC connections with EDs were limited to physicians who had hospital privileges at the ED’s hospital. Although hospitals were a part of the local opioid coalitions, formal strategies to coordinate overdose follow-up with patients were lacking. One physician shared his success with getting a local ED to distribute naloxone to persons who visited the ED because of an overdose. Another nurse practitioner talked

about her expectation for additional collaboration with the local ED:

I would love to see more of the patients discharged from the hospital with Narcan. We are trying to work with the hospital on that because we will get the ER reports, and we can't find the patient. And everyone is like, "Can someone get a Narcan kit in that person's hands?" Well, if he is the one overdosing he's not going to be able to use it on himself anyway. We need to find out where he's going or where he's hanging out.

To address overdose response beyond the CHC, one CHC implemented an innovative pilot with the local EMS to identify patients who had an opioid-related ambulance transfer. Through this arrangement, primary care providers were made aware of patients who had overdosed.

Several of the CHC participants named specific harm reduction agencies and organizations serving the homeless population as being instrumental in helping initiate their clinic's OEND activities or serving as a program model. For example, one of the physicians spoke about his CHC's early partnership with a needle exchange van to distribute naloxone rescue kits to patients. Another CHC partnered with a local CBO to jointly conduct outreach activities, and used a naloxone policy from a healthcare organization serving homeless populations to draft the CHC's policy.

External Policies

There were external policies, funding mechanisms, and recommendations or

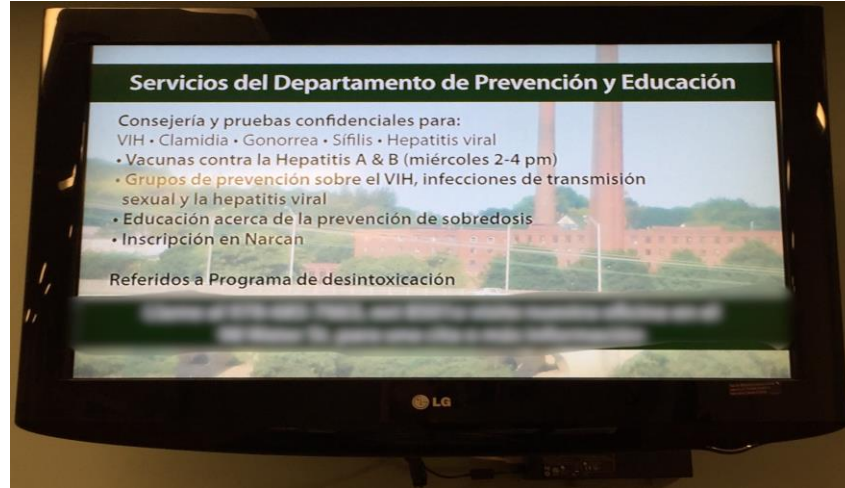
<p>Table 30. External Policies Influencing CHC OENA</p> <ul style="list-style-type: none"> • DPH-funded OEND pilot grants • Pharmacy standing order • MassHealth (Massachusetts' Medicaid program) naloxone reimbursement • Chronic opioid prescribing guidelines • Opioid treatment funding in CHC primary care settings

guidelines that influenced the adoption of OENA activities by the CHCs, as listed in Table 30.

The **Massachusetts DPH-funded OEND pilot grants** provided naloxone rescue kits to select HIV programs in the state, including some clinical sites (see Image 4). Three of the CHCs in this study had an OEND pilot program, and two partnered with a local community agency that had an OEND pilot grant. These programs, particularly when located at a CHC, facilitated the development of clinic-based OENA activities; all three of those CHCs implemented pharmacy standing orders to increase naloxone access for patients, though one CHC had not yet begun referring patients to the pharmacy. The OEND pilot program served a supportive function by making overdose prevention a priority during regular HIV team meetings. Concrete supports, such as training, educational materials, and referrals were also provided by these programs. One OEND program manager articulated the supportive role of the OEND pilot grant program:

We have worked really hard...to remind all of the physicians, if they have someone with a substance use problem, they should be prescribing a naloxone kit because you can pick it up at any of our pharmacies. We have always had referrals, especially when the doctors have a patient with a substance use problem, they will send them over to us to find a detox spot. When they are over with us, we will always make sure they get naloxone if it is an opioid substance abuse program. The doctors will also prescribe naloxone and sometimes refer them to us for education.

Image 4. CHC Primary Care Waiting Room Screen Promoting Massachusetts DPH OEND Program



Source: Author, 2016.

In addition, the **network of Massachusetts DPH-funded OEND grant programs played a role in disseminating best practices**. One HIV and OEND grant manager explained:

Getting involved in the [DPH OEND pilot] Narcan meetings and going to those meetings has really broadened my understanding of it. And a lot of the discussion and watching what was happening in [other parts of the state] with the overdoses was good for me to see, so I felt like we were prepared and had all of this information about the Narcan even though we weren't yet getting the issues... in terms of the overdoses. So when it hit us we had all of that available. I think we were definitely involved by the state OEND program and policies. It was also really great in encouraging our pharmacy to get Narcan....So the [CHC] administration was really supportive of that, and it was really easy for me to get the policies and procedures because I had access to all of these other programs that were doing this in the state.

While the DPH OEND pilot programs may have facilitated clinic-based naloxone expansion in two of the CHCs, **having an OEND pilot program at the clinic was not a necessity**. In fact, four of the CHCs implemented activities without such a program. One

Image 5. CHC Pharmacy Sign Promoting Standing Order (Available in Spanish)



of these CHCs partnered with the community-based OEND pilot grant program to bring education and distribution in the clinic entrance area. One referred patients to the OEND program as the CHC itself did not implement OENA activities. It is important to note that for two of the CHCs without an OEND program, identifying training resources for the clinic staff posed an initial barrier, as the external OEND pilot programs were limited in their training capacity, and clinical sites were not a priority for them.

For some of the CHCs, the **Massachusetts pharmacy standing order**, promoted on a pharmacy sign in Image 5, was vital to expanding access to naloxone. One physician credited this policy change as follows: *“At the state level, having the ability to prescribe freely on demand... the standing order. When [Dr. Alexander Walley] pushed that through that was big— really critical to expanding access for people.”* The pharmacist at this CHC explained how the standing order works in their clinic:

We have a standing order [with the pharmacy at the CHC] where anyone can come off the street and buy naloxone. Because of the standing order you can actually use your insurance. So we have the kits already set up. We have all of the pharmacists trained. We met with DPH to get approval

for this. We are on a website or database that we are one of the pharmacies that people can go to for Narcan. The prescription is pre-filled out. We do our best to get the patient in and out.

Further supporting pharmacy access by removing cost barriers, MassHealth (Massachusetts' Medicaid program) provides full coverage of naloxone without requiring a co-payment.²⁹²

Despite their awareness of the state's standing order that allows for distribution of naloxone by certain commercial pharmacies, **CHCs did not refer patients to commercial pharmacies for naloxone.** One participant expressed doubt about the degree to which clinic staff and colleagues promote this option:

I don't know how much people are utilizing, "Go to Walgreens. Even if you don't have a prescription from the doc, you can just buy it and use your insurance." I know that, but I don't know that message is going out to everybody.

A few participants talked about negative experiences reported by patients, making the interaction with the pharmacist *"difficult and humiliating for them."* One participant discussed his concerns regarding the retail pharmacies, including space constraints:

I'm not sure what environment they are teaching them [in], if they are teaching them with that one-foot wall that kind of protects your conversation, but you are still showing somebody how to use Narcan. But here it isn't done in the pharmacy; it is done in a private consult room with the patient, and the patient is allowed to play with the equipment and get a feel for it.

A participant from another CHC discussed the stigma that patients might experience if they sought naloxone from a retail pharmacy:

I think we work really hard in our setting to remove barriers. We have certainly heard from people in other parts of the state [that] when they go to a commercial pharmacy they haven't been treated very well when

asking for Narcan. I think we try to have a different approach here so they don't feel like they are getting judged here or we are getting into their business.

Finally, a pharmacist expressed her concern about the co-payment requirement at commercial pharmacies in contrast to CHC pharmacies, noting:

If it is a co-pay issue, we are a CHC, we are a 340b pharmacy, so we get cheaper rates. It shouldn't be a reason to deny someone. I am adamant with pharmacy services that cost is not a reason to deny a patient medications or a life-saving drug like Narcan. Our pharmacy never has. Everybody in the pharmacy really gets it. We are fortunate. You may not be able to find someone who cares at CVS.

Several of the study participants spoke about the impact of their health center's revised **chronic opioid therapy prescribing guidelines** in response to the recommended guidelines released by the state and then by CDC in the past year. One physician explained the positive impact of these guidelines on her CHC's practice,

The other big prong and big push in this program has been safer opioid prescribing. For every patient on chronic opiates, we have totally overhauled our clinical guidance around that. We have now templated [sic] into the EMR a risk tool before we prescribe...Based on the score, it guides us to more or less intensive monitoring. So that has been super helpful.....The other thing I would say related to that is we have also just increased requirements around monitoring in general. Even the patient who is a "good" candidate for opioid prescribing, we are reminded every three months [that], minimally, urine tox's have to be done. We have to check the PMP quarterly. But if they are high risk you have to do those things more frequently. So it will prompt you monthly-- you should do urine tox and [a] PMP check.

Two of the CHCs prioritized naloxone access for patients on chronic opioid therapy, but at the other four study sites, naloxone co-prescribing was not uniformly done for these

patients. One barrier to this was the increased monitoring requirements and time demands imposed by the new guidelines:

Well, the chronic opioids, there are a lot of things that kind of catch up and meet the current recommendations. Checking that— state pharmacy exchange, contracts, and urine testing. I think folks with patients on chronic opioids are struggling to kind of keep up with all the things that need to happen over the past couple of years.

While some of the CHCs did not prioritize patients on chronic opioid therapy as candidates for naloxone, two of the CHCs were in the process of expanding naloxone efforts to include these patients. One study participant outlined the benefit of co-prescribing naloxone with opioids: *“They are working on that in the chronic pain program to make it part of the program. Part of the agreement when the patient is being prescribed opioids chronically...is you need to have naloxone just in case of an emergency.”* At another site, the nurse program manager highlighted his vision of the overdose education and naloxone program’s future direction:

We also want to have a more centralized program for our patients on chronic opioid therapy, like our Suboxone program, with an addictions nurse, education, Narcan provision. So the whole clinic functions with this model. Champion providers came up with this idea— we want to hire another nurse who is part of the team.

Finally, the scale-up of **opioid treatment programs**— specifically, buprenorphine (Suboxone) programs— at the CHCs played a major role in the provision of OENA activities. Several of the sites received grants from the Massachusetts DPH to implement Office-Based Opioid Treatment Programs (OBOT)— a Massachusetts-developed nurse case manager model for primary care-based MAT delivery. In addition, recommendations to integrate OENA into opioid treatment programs were issued by

SAMHSA, ASAM, and the Massachusetts DPH in spring 2015.²⁹³ One participant explained how the buprenorphine program served as the focal point for OENA activities within her CHC:

Our Suboxone program really is the motivating factor of keeping this relevant. They are the ones that are seeing this on a regular basis and working with patients who are at highest risk, making sure that patients are getting access to Narcan, and making sure they are following up with them. That has been supportive— and keeping it going, rather than it being a hot topic and then going away.

Implementation Strategies by Outer Setting Domain

Regarding the **Outer Setting** (Table 31), federal and state policies and funding streams for naloxone access, opioid prescribing, and medication-assisted treatment provision greatly influence the opportunities for program adoption, expansion, and maintenance. Providing CHC staff the opportunity to talk about the impact of the opioid crisis with other medical professionals and community leaders also served as an impetus for CHC response. As described above, connections with external agencies broadened naloxone access through outreach partnerships and patient referral mechanisms. CHC participation in community opioid coalitions played a key role in coordinating a comprehensive local response.

Construct	Implementation Strategies
Needs and Resources of Patients	<ul style="list-style-type: none"> • Identify opportunities for the clinic staff to discuss the impact of the opioid crisis in the community • Partner with community-based organizations and conduct community outreach events to learn more about the community's needs outside the clinic • Conduct training for providers and staff on addiction, treatment, and recovery science, and on the role of naloxone in the treatment and recovery process
Cosmopolitanism	<ul style="list-style-type: none"> • Join a community coalition to coordinate the local opioid response • Identify new partnership opportunities (e.g., ED) to expand naloxone access for patients.
External Policies	<ul style="list-style-type: none"> • Document and share naloxone access laws with clinic and pharmacy leadership and staff at the start of the initiative, and outline those laws in the clinic's policy document • If needed, partner with community-based OEND programs to support naloxone access • Build a relationship with the clinic's pharmacy to establish a standing order for increased naloxone access • Create new partnership with commercial pharmacies when the CHC does not have an affiliated pharmacy • Integrate naloxone co-prescribing into revised chronic opioid prescribing guidelines • Build OENA into buprenorphine treatment

Domain 3: Inner Setting

The following six constructs were found to influence implementation within this domain: networks and communications; implementation climate; tension for change; readiness for implementation; leadership engagement; and available resources.

Networks and Communication

The team-based care model at the CHCs facilitated internal networks and OENA-related communication. Table 32 lists various internal stakeholders at the CHCs who were involved in implementation. One CHC nurse described her perception of the integrated, team-based environment and how that works to support the multiple needs of a patient or families who may be struggling with addiction:

I think that is part of the team model, too. A patient walks in here and gets all of the services they need in one building. This area in general is a resource-rich community, but what I have seen there is an integrated model approach where it's about pulling in different skill sets so that a patient can really feel well supported. From our end, from a clinical standpoint, you know that a patient is going to be well cared for, that some of those barriers that could potentially prevent someone from actually taking that action, you are setting them up so they can be successful in whatever that next step is.

This team approach, in turn, was reported to support the provider, as explained by one physician: *“It’s so great not carrying this by yourself, to have the addictions nurse, health educator, recovery coach, our social workers, our case managers.”* While particular team members played a greater role than others, all team members shared a vision for the program and worked together to ensure that patients had this service. All of the participants talked about how the **weekly and monthly HIV and Suboxone team meetings** facilitated coordination and communication about patient cases and reinforced the need for supports including naloxone access.

Table 32. OENA Implementation Team Members Identified at the CHCs

- Prescribers, including physicians, physician assistants, and nurse practitioners providing HIV, primary care, and buprenorphine
- Nurses providing HIV, buprenorphine, and primary care
- Case managers and health educators
- Behavioral health providers
- Pharmacists

Within the integrated care team model, several participants talked about the **important role that the behavioral health team members play** in terms of screening and counseling for mental health and substance use issues. One physician endorsed their involvement in overdose prevention initiatives:

The behavioral health team and the role of behavioral health integration have been huge. Having that team be on board with all of these initiatives is really important.”

A CHC director spoke about the role that the behavioral health team plays in the overdose education and referral process:

We do two screenings in primary care for mental health and substance abuse... When the screening is positive, they should be making a referral to behavioral health staff who would handle the overdose education or referral. So the provider themselves probably doesn't do a lot of the overdose education... because of the 15-minute visit.

Participants at other CHCs talked about the future promise of involving the behavioral health team in overdose education initiatives, given that they have more time and are already interacting with patients who may be at risk of an overdose.

The HIV care teams' OENA activities matched what was being done in primary care generally, and sometimes the HIV care team took the lead in implementation. In most cases, in fact, OENA activities originated and were often managed within the HIV departments. Given that all of the CHCs deliver HIV care in the context of a primary care clinic, participants explained that the activities they were describing pertained to the primary care clinic overall. In the majority of sites, the HIV programs were instrumental in the beginning stages of implementation, after which the CHCs focused their attention broadly on all of their patients at greatest risk.

This resulted in varying organizational options. If a CHC saw a high number of PLWH who also had a substance use disorder or an overdose history, then the OENA activities would be tied to the HIV program. The CHCs that received Massachusetts DPH

OEND grants through the HIV programs primarily managed their OENA activities out of those programs. In two of the CHCs, OENA activities were managed by a HIV program manager who also managed the CHC's opioid treatment (OBOT) program. In two other CHCs, OENA activities had diffused throughout the center, without a direct tie to the HIV program. In another CHC, however, OENA activities were piloted by a primary care team not focused on HIV care and were in the process of being brought to the CHC's HIV team. Expansion of buprenorphine treatment programs and involvement of a CHC-affiliated pharmacy further broadened naloxone access throughout the clinic for patients with and without HIV.

The buprenorphine programs reached patients across the HIV and primary care programs with overdose education and naloxone. A program manager overseeing both the HIV and buprenorphine treatment programs facilitated staff communication between the two programs. The buprenorphine treatment program reached patients from across the clinic, including primary care and HIV programs. One participant explained how his CHC identifies patients for overdose education and naloxone as follows:

When it's clear they have an addiction and it's identified, or when the patient comes in and asks to be referred to the addictions program. That's mainly the primary care pool, but if we talk about the HIV care pool that we have here, our services are so integrated that the nurse practitioners that have been here—and they have been here for years and know the patients and know when they need to refer them over—they really work closely with our addictions team to make sure a patient is on our Suboxone program, and making sure they do the naloxone teaching, have a prescription for Narcan, or have Narcan on hand.

The CHC-affiliated pharmacies played a crucial role in expanding OENA.

Well-defined and understood roles for the clinic and pharmacy staffs facilitated the

process. One example of this was described as follows by a nurse, “*The pharmacy has a standing order for naloxone so it doesn't need to be prescribed here. I answer questions and talk about it... but the pharmacy does most of the training at this point.*” Another CHC without a standing order employed a different model that required open and regular lines of communication between the pharmacy and CHC, as explained by the nurse program manager:

So we have a process set up where the provider, we have general scripts in the system that are simplified to click and you can get a prescription for a naloxone kit from the pharmacy for any patient or family member that requires it. And we have an agreement with our pharmacy that they will not fill a script until the patient had had a demonstration from the addictions nurse or the nurse on our HIV team. So for any of our HIV patients, it functions the same way. It's just the addictions nurse is part of the HIV team so it streamlines the process that the providers can call in. One of the nurse practitioners who does HIV primary care can actually get the patient in, get them the prescription, and have them talk to someone about how to use naloxone immediately. So once they get their teaching, the nurse then lets the pharmacist know that they can now pick up their naloxone prescription.

A CHC nurse manager at a different CHC described how first-time Suboxone patients are reached: “*So there is a standing order so it isn't actually a prescription. We work closely with the pharmacy and they know the person is getting Suboxone for the first time and so the pharmacist would offer Narcan to the patient.*” In this case, the role of the pharmacist was expanded to further extend access to patients and support the clinical team in the process.

CHC Culture

Many of the participants recognized that the **organizational culture at their CHC set the stage for initiating OENA activities**. This culture was manifest in the staff

commitment to community health and patient-centered care, the team-based model of care, and having a mission-driven organization. Repeatedly, the sentiment expressed by one nurse was heard across the interviews:

The biggest piece is the mission. It's the administration and mission of the agency. It's the recognition that this is a huge problem that we deal with, and we face not only in our professional lives but many of us in our personal lives. There's a lot of conversation about it. That's a huge support.

Participants from one CHC that was affiliated with a large hospital noted that the hospital's commitment to addressing the opioid crisis enabled them to purchase and stock naloxone rescue kits in their clinic's medicine cart. A physician from another site indicated that integrating opioid overdose into clinical care is a natural part of working at a CHC located in a neighborhood with high opioid use:

It's been part of what the doctors do in their day-to-day practice, thinking about overdose risk and prevention, prescribing treatments for addiction, and making sure patients who are at risk and family members of patients at risk have naloxone in their household to prevent overdose... You wouldn't choose to work here or stay working here if you didn't have this a part of what you do... It's just part of where we are and what we do.

Implementation Climate

The degree to which OENA was expected and supported within the clinics varied. In some CHCs, OENA activities had diffused across the clinic and in one place was included as a quality of service measure. The degree of leadership engagement and the involvement of a champion also influenced the implementation climate. One of the CHC physicians with a supportive working environment reported the following:

There are things that we are incorporating to make it better and better, but I think what we have is extremely useful. If people are willing to get everyone on board—that is the main goal, to have everyone feel

passionate about the same outcome....It's not going to work unless everyone is on board. And that is the case here and that's why it is so successful.

A participant from another CHC reflected on the domino effect of leadership support and how this permeates the implementation climate: *"It comes from the top down being supportive of the whole program. It starts with a pharmacist director being ultra-supportive and a great resource. It works its way down to everyone else being supportive."*

The tone set from leadership was important in a CHC pharmacy. One pharmacist explained the expectation in her pharmacy as follows:

We can fill up to 1,500 prescription in 10 hours, but even if one person comes in [for naloxone] and someone needs to step away to counsel them, the pharmacy director expects that comes first rather than filling the thousands of dollars that are coming in. She would rather the person step away and provide this to the patient and actually save someone's life.

Within other CHCs where OENA activities were more sporadic or conducted on a case-by-cases basis, study participants were not as effusive about the level of CHC-wide support. One champion leading an initiative within her primary care clinic lamented, *"I'm honestly a little disappointed that it hasn't really caught on at the rest of the health center. I am hoping it will continue to grow and be offered."*

Tension for Change

Study participants continually spoke about the **need for an urgent response to the opioid crisis** in their communities, and the visible impact of overdoses among their CHC's patients as an impetus to OENA. One physician assistant at a CHC serving a population at high risk of overdose explained:

The providers— the openness of it all, it's not a taboo to us — we are used to it. We unfortunately have several overdoses a month where we are administering Narcan here in the clinic— in the bathrooms, people are using in the bathrooms and overdosing in the bathrooms. Things I wouldn't necessarily do if I worked in a private practice. When I go to the waiting room to call someone, I scan, and if someone is slumped over, I'm going to walk over to them. People are watching how the bathrooms are used— who is in there, how long have they been in there? We have just incorporated it into every aspect of our daily lives here... You can see people overdosing on the street and that is at 7:00 in the morning when you are just coming into work.

Several participants attributed the location of the CHC in a community with high overdose rates as a call-to-action for the health center. One physician noted:

Most people who live in this community are affected by opioid addiction, whether it is themselves or someone they know... And I think that makes the providers, staff, and pharmacists more on board because we see this, and we know it's a problem, and it needs to be addressed. And [overdose education and naloxone provision] is one thing we can do to try to help.

Other participants spoke about the staggering opioid overdose data in their local city or town, and used this as a way of engaging their clinic colleagues in a response. One nurse practitioner charged with clinical outreach emphasized, *“It's so prevalent in [name of city] and on the streets. From what we've seen in our program, I think trying to just drill that into the health center and say this is what's happening outside our doors.”* In addition, participants spoke about the personal toll of the opioid crisis on CHC staff:

It's affected everyone in our clinic— all the providers and staff members and many of the, not only the doctors and nurses, but many of the front desk staff and medical assistants are from the town, and it's affected their family members... [and] patient's children or grandkids.

This articulated tension for change seemed to be the impetus for all of the CHCs to stock naloxone in clinic emergency carts and to train clinic staff— from the front desk

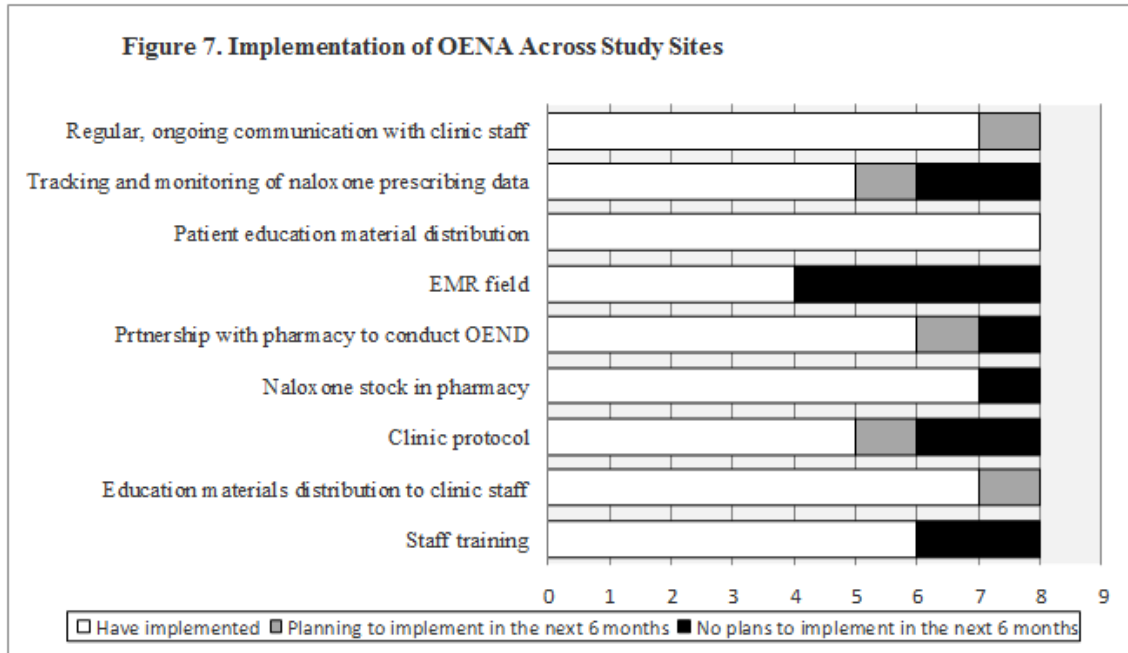
staff to the CHC leadership— on how to respond if an overdose occurred in the clinic. This often served as a first step in the CHCs recognizing that they needed to respond more broadly to the reality of the opioid crisis in their community.

Readiness for Implementation

As illustrated in Figure 7, the study sites were at varying stages of implementation with regard to certain OENA activities. At the start of this study, the presence of these activities was thought to signal a CHC's commitment to implement OENA activities. For example, all of the CHCs reported distributing patient education material about overdose and naloxone. Seven of the eight sites distribute education materials to clinic staff, hold regular discussions with clinic staff, and stock naloxone in the affiliated clinic pharmacy. Six of the CHCs have conducted staff training and established a partnership with the pharmacy. Five have established a clinic policy or protocol and track and monitor data on naloxone prescribing, dispensing, or distribution. Half of the CHCs record information about a patient's receipt of naloxone in the EMR.

These indicators, along with others identified during the course of the qualitative data collection, served as visible, concrete indicators of a CHCs decision to implement OENA activities. It is important to note that these indicators emerged from a review of eight CHC models. Not all of these activities were in place at each CHC, nor are they all necessary in order to begin OENA implementation.

Some of these activities were necessary initial steps, such as figuring out how patients would get naloxone. For example, if a CHC chose to use its affiliated pharmacy for naloxone access, the clinic would need to create a standing order or establish an



agreement with the pharmacy, and easy electronic prescribing would need to be set up to support prescriber implementation. Other activities, such as creation of a policy or protocol, were not required for implementation to begin, but their later development improves service quality and bolstered implementation rates.

Leadership Engagement

Communication by the CHC's leadership about the need to address the opioid crisis was reported to be vital in initiating and sustaining OENA implementation, including leadership at the senior administrative, medical, and pharmacy levels. One physician at a CHC that has been implementing OENA activities for several years stated:

I think the key is having leadership being involved and taking their role very seriously. Our medical leadership took this on. We didn't have a choice; it was the way to do it. We weren't seeing the overdoses when we first got this data. We got this going and then you start seeing it, and no one is questioning the value of it anymore.....The one thing I would say to other CHCs is you have to get your

medical leadership to take this on and take it seriously and then the rest of the staff follow.

Though not engaged at the implementation level, CHC leadership played an important role in the initial program implementation activities, including the development of the standing order, naloxone stocking, and later, the approval of CHC-wide policies.

Furthermore, they helped keep overdose prevention as a priority by raising the topic during management meetings.

Available Resources

Resources include physical space, staff training, and staff time. All of the individuals who conducted overdose education with patients participated in **training**. As can be seen in Table 33, the majority of the study participants received OEND training, with most of them receiving it at the CHC. This was often a part of the health center training when naloxone was added to the emergency kits, but also may have been delivered by the in-house OEND pilot grants or an external expert.²⁹⁴ Other participants were trained at a community-based organization or through an online webinar.

Table 33. Study Participant Receipt of OEND Training

	Number (Percentage)
Receipt of OEND training (N=29)	
Yes	22 (76)
Location of OEND training (N=22)*	
Current workplace (CHC)	17 (77)
Community-based organization	4 (18)
Previous employer	2 (9)
Online webinar	3 (14)
Other (e.g., DPH and community college)	2 (9)

*Multiple responses allowed.

For clinic staff training sessions, educational materials were often provided, including the Massachusetts DPH Naloxone Pamphlet, PowerPoint slides, and a CHC

naloxone distribution policy. One program manager talked about her CHC's staff training activities:

We have done in-services with groups at a few of the OBOT programs. We do it with the clients of the OBOT programs, and the nurses will sit in on it which is almost like an entire training on it. We've done that with the pharmacy staff especially at the beginning phases of when they were implementing pharmacy access. We did a lot of in-services with them to help them be comfortable if they were going to be explaining how to use Narcan to others.

Frequent, ongoing training sessions were reported to be beneficial, not only for the new staff, but to keep the issue salient and increase the comfort level of existing staff, particularly those who may have only attended one brief training when naloxone was added to the emergency kits. One pharmacist noted that the trainings do not need to be time intensive or burdensome, *“I think especially with turn-over. For a pharmacy where we have new pharmacists coming in at a healthy rate, having more trainings for them— it is such an easy and fast training. It can be done super easily.”*

Lack of dedicated, private space for patient education in the pharmacy was noted as a barrier by several of the participants with a pharmacy model. As noted earlier, **most prescribers reported that not having time to provide overdose education was a barrier**. For some nurse and case management staff, providing overdose education was often integrated into regular patient visits. Likewise, pharmacists conducting the education component did so as part of their patient education activities.

Implementation Strategies by Inner Setting Domain

Regarding the **Inner Setting** (Table 34), recognizing that OENA requires a team approach supported implementation, as did including a pharmacy as part of the response

team. Ongoing articulation of overdose prevention as a priority by CHC and pharmacy leadership contributed to a facilitating implementation climate, and tangible, visible activities across the CHC demonstrated leadership's commitment to respond. Ongoing training on how to conduct overdose education and provide naloxone to patients, plus the role that naloxone plays in the treatment process provided clinic staff with the knowledge and skills they needed to discuss naloxone with patients effectively. Identification of staff with available time and space to conduct education activities was also essential to successful implementation.

Construct	Implementation Strategies
Networks and Communications	<ul style="list-style-type: none"> • Set up weekly and monthly interdisciplinary team meetings where overdose risk is discussed • Establish clinic and pharmacist partnership with defined roles and responsibilities • Integrate program activities into the buprenorphine treatment program • Engage behavioral health team in overdose OENA activities
Culture	<ul style="list-style-type: none"> • Connect mission-driven focus of CHC with the CHC's overdose prevention response
Implementation Climate	<ul style="list-style-type: none"> • Find opportunities for implementing teams to share their experiences with other clinic staff
Tension for Change	<ul style="list-style-type: none"> • Discuss the impact of overdose in the community with CHC staff • Train clinic staff on naloxone use and stock naloxone in clinic emergency kit
Readiness for Implementation	<ul style="list-style-type: none"> • Identify clinic team implementation roles • Set up a pharmacy standing order • Train staff and providers • Write overdose education and naloxone policy
Leadership Engagement	<ul style="list-style-type: none"> • Articulate leadership support and expectations in regard to naloxone access
Available Resources	<ul style="list-style-type: none"> • Create staff training plan, including provision of patient education materials and refresher training • Identify staff who can be available to provide real-time overdose education, including nurses, behavioral health providers, and other staff who can include this function in their sessions with patients • Determine what private space(s) will be used for education

Domain 4: Characteristics of Individuals

The following individual-level constructs were found to influence OENA implementation: knowledge and beliefs about the intervention and the individual's stage of change.

Knowledge and Beliefs about Intervention

Study participants were knowledgeable and believed naloxone would be a beneficial intervention for patients at risk of overdose. One participant summarized this in the following way:

As far as the pain management and drug use is concerned, I think most of the providers are aware of opioid addiction and long-term narcotic use, and the benefits of using Narcan, because of the patients we see on a daily basis— we have so many patients on narcotics, we have a Suboxone program here. People are well aware.

Not every study participant agreed. Two prescribers questioned the utility of providing naloxone to patients at risk of an overdose since they cannot administer naloxone to themselves. Another clinic manager explained his clinic's prescribers' reaction to co-prescribing naloxone with chronic opioid therapy:

...they thought it was interesting, then saying, "But if you overdose on something I prescribe you, here is something that might help." They were struggling with that concept. But I like it as a harm reduction public health concept. But we don't do that here.

Other CHC leaders were able to engage prescribers in reaching patients on chronic opioid therapy, as they were persuasive in stating that these patients could benefit from having a naloxone rescue kit.

Clinic staff **knowledge and believing in a harm reduction approach facilitated OENA activities**. Participants across the clinics talked about the transformation in knowledge and beliefs that several staff had to go through as they changed their thinking about the role of naloxone for people in treatment. A program manager at another CHC commented on the change his program had gone through:

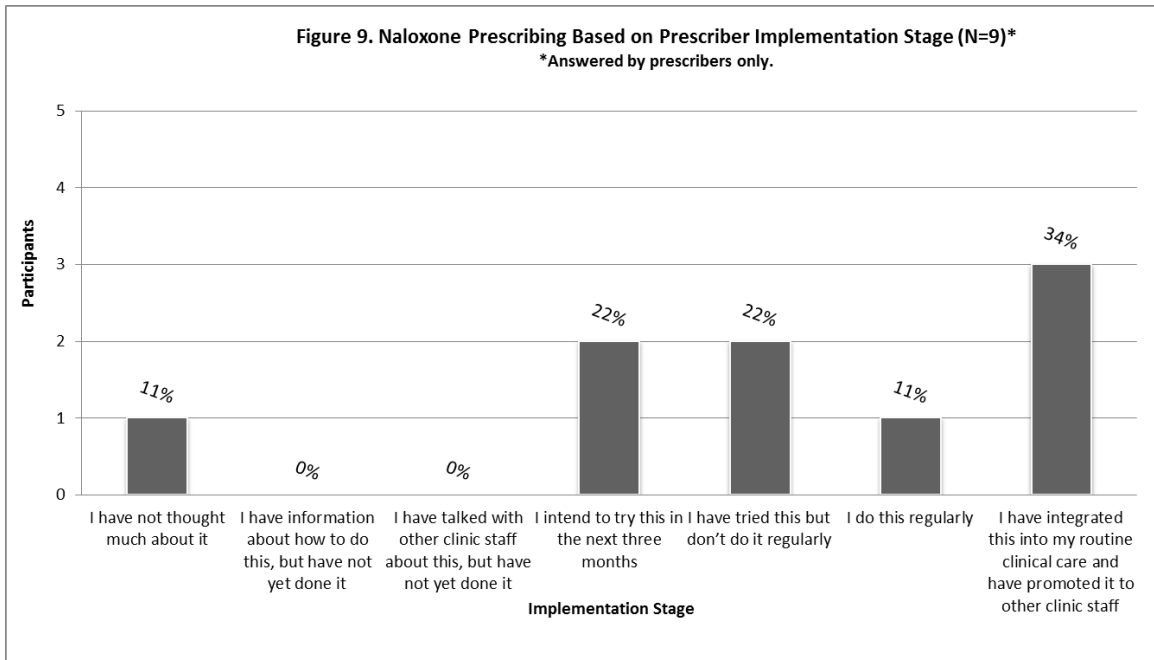
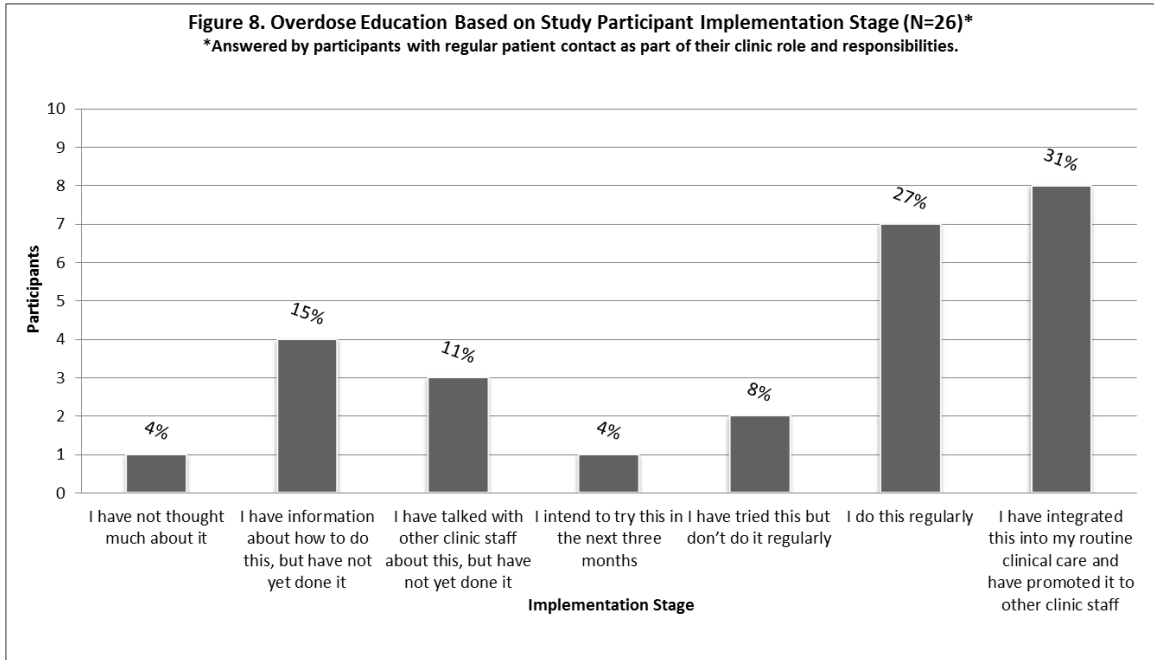
Our program has really evolved from an abstinence model to more of a harm reduction model. We are not doing a lot of kicking people out for using. That will put them at a higher risk of overdose. You are still in our narcotics program; if you are using, you should have Narcan. And we refer them to other levels of care to help get them to recovery, but not everyone is going to get there immediately.

Several participants talked about the need for staff training on this new treatment paradigm:

It's really about educating staff— some people may be set in their ways about the old models of behavioral health and substance use treatment care, but those are going away. I have seen the change in our behavioral health [group] in the past nearly 18 years, seeing the changes in people's attitudes. People had to change to a more harm reduction approach. People are accepting [this] as the right way to do it.

Individual Stage of Readiness for Change

Study participants **spanned the continuum of stages of readiness for change in regards to OENA activities**. The participant survey asked study participants to self-assess their stage of readiness for providing overdose education to participants, and if a prescriber, their stage of readiness for prescribing naloxone to patients. The findings are presented in Figures 8 and 9 below.



Given that anyone trained could provide overdose education, 26 of the 29 participants who had patient contact as part of their role answered this question. More than half of the participants reported that they conduct overdose education regularly, with about one-third

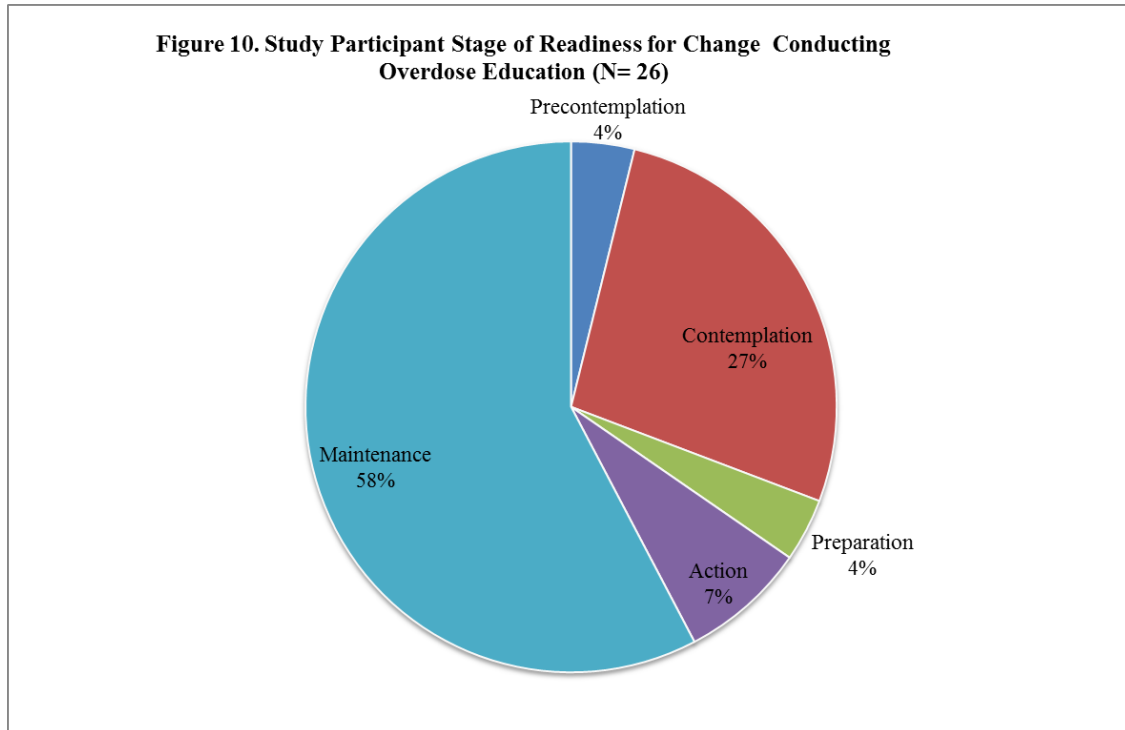
indicating that they have fully integrated overdose education into their practice. Less than a tenth of the participants reported having tried overdose education. One-third of participants had not conducted overdose education activities. An alternate view of this data can be seen in Figure 10 which categorizes participant responses to provision of overdose education into the Stages of Change Model's readiness categories.

Similar to the survey findings, participants reported a range of comfort levels with OENA activities. Participants who regularly see patients with an opioid use disorder were reported to conduct overdose education more frequently and with greater comfort compared to those who rarely care for such patients. One participant explained:

We have a lot of providers who are super-comfortable doing this, especially our Suboxone providers who are also primary care providers here. They are really great doing all of that and comfortable with the kits, they all carry kits. We have a bunch of providers here that are provider champions around things like this and are really comfortable talking with patients. And there are providers who maybe don't have a lot of experience doing it and maybe have to learn it on an annual basis. So not everybody is in that place; everybody is in a different place.

Another CHC program manager talked about how some nurses in the buprenorphine clinic were uncomfortable in the beginning, *"And there was discomfort [among the nurses] with doing the education at the beginning, and I think that is still the case for some providers."* This same relationship between experience and increased confidence was heard during interviews with the pharmacists, as one explained:

It varies. Some people are not as comfortable as others, especially those who are newer. The pharmacists who focus on clinical services are used to seeing patients and are offering education. So a lot of this is done by our clinical pharmacy team.



The participant survey also asked prescribers to rate their stage of readiness for naloxone prescribing. This question did not take into consideration the fact that many of the CHCs had standing orders in place, thus limiting the necessity for a prescription. That being the case, four of the nine prescribers interviewed reported prescribing naloxone “regularly,” two have “tried it, but don’t do it regularly,” and two “plan to try it in the next three months.” Only one prescriber reported not having “thought much about it.” As described earlier, prescribers perceived this intervention to be complex due to a variety of barriers (i.e., limited time, competing priorities) so this range of stages is not unexpected.

Implementation Strategies by Characteristics of Individuals Domain

With the **Characteristics of Individuals** domain (Table 35), it was clear that participants were aware of the benefits of naloxone, though some thought about overdose

risk differently for people receiving treatment for opioid use disorder compared with those on chronic opioid therapy. It is important to recognize that clinic staff are likely to be at different stages of readiness in implementing overdose education and naloxone prescribing or dispensing. Different strategies are needed to reach CHC based on the staff’s stage of readiness and on the role they play when the program is implemented.

Table 35. Summary of Strategies Related to CFIR Constructs from Characteristics of Individuals Domain	
Construct	Implementation Strategies
Characteristics of Individuals	
Knowledge and Beliefs about Intervention	<ul style="list-style-type: none"> • Integrate harm reduction principles into the CHC’s approach • Increase provider and staff perceptions of overdose risk for persons on chronic opioid therapy • Discuss risk of overdose among patients on chronic opioid therapy, particularly in the context of new guidelines issued by CDC
Individual Stage of Readiness for Change	<ul style="list-style-type: none"> • Find opportunities for implementers to regularly practice overdose education discussions with patients • Utilize in-house peer support • Conduct booster training sessions • Keep OENA activities on the agenda for team meetings • Build in a mechanism to give providers data reports on naloxone ordering/prescribing

Domain 5: Process

The following CFIR constructs were found to influence the implementation process domain: engaging, champions, external change agents, and reflecting and evaluating.

Engaging

Different strategies were used across the study sites to engage clinic staff and patients in OEANA activities, depending on the program’s implementation stage.

Strategies for reaching both of these groups are described below.

Engaging clinic staff. Community overdose statistics were used as a call to action by some of the health centers. One CHC primary care clinic posted statistics on the number of overdoses in the city and the number of naloxone rescue kits provided to patients that week. A staff member reported “*sending emails and reminding people how many overdoses we had in the city, how many deaths— these are our patients.*” CHCs also found ways to begin implementation that resonated with clinic staff. For example, a nurse practitioner explained why they started with patients on chronic opioid therapy:

...a way to really get into the docs who aren't into this and aren't aware of it is to start with the pain management because everyone is embracing that. Say, “Okay, well someone is on chronic pain pills, let's make sure they have a Narcan kit.” Kind of introducing it that way.

Integrating OENA activities into buprenorphine programs seemed to help engage nurses given the obvious connection between opioid use disorder and the potential for relapse and overdose.

Modeling how to use naloxone was reported to be an important component in helping nurses to feel comfortable. A pharmacist also used this technique to train her pharmacy staff: “*As part of our trainings, we always do demos...Having the practical, hands-on [experience] and you trying it also helps you be able to train others. So this is what it's going to feel like.*” Peer support was also noted as an important component to engaging clinic staff. One nurse practitioner champion at another CHC planned to have the nurses in her clinic who had successfully adopted OENA share their experiences with others who were less engaged.

In addition to basic overdose education and naloxone use training, two participants talked about the **importance of conducting training on substance use**

disorder, addiction, and the treatment process as a way to increase their comfort with participating in OENA activities. One participant explained her clinic's process:

We had to do a lot of education around feeling comfortable talking about abuse. I think it is a very uncomfortable topic to broach. I think given my background and the patient population I work with it is pretty normalized in a way, the discussion and talking and asking those questions. I think that has been challenging for some staff. So we did a lot of education around that.

Identifying strategies to support individuals along the continuum of readiness to change was found to be important. In particular, maintenance of OENA activities was reported to be a challenge for staff that had been doing it regularly, but not consistently. At one CHC, where the expectation is to provide naloxone to everyone over 18 years of age, one physician acknowledged the following:

Even though we have the leadership behind us, there are policies in place, there are helpful tools in the medical record, we are following this in terms of quality, I think I had the highest score for prescriptions and I am only at 53%. Even though I feel like I'm doing it for everybody, I'm only doing it for about half my patients. So it is taking a while to roll out."

Clinic staff engagement was not seen as a one-shot activity, but as an ongoing process.

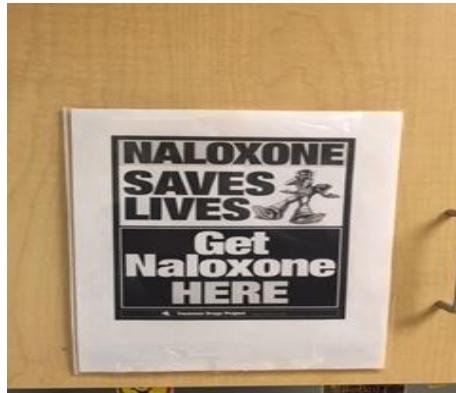
The physician continued to talk about the challenge of maintaining a sustained effort:

Keeping the fire underneath it. There is often alert fatigue and we are onto the next big initiative. Just continuing to keep it a priority. Continuing to remind people it is our goal to have everyone have a naloxone prescription. We probably do need to put an emphasis on getting prescribing percentages higher.

Participants also spoke about the challenge of keeping opioid overdose a priority when there are so many competing priorities. One nurse manager commented, *"That is one thing that I am contending with, getting our message out when there are a lot of*

other different messages that everybody else wants to get out as well.” Building discussions into team meetings and data sharing helped keep clinic staff engaged over time.

Image 6. Sign on Exam Room Cabinet



Source: Author, 2016.

Image 7. Sign in Waiting Room



Source: Author, 2016.

Engaging patients. Strategies to engage patients facilitated implementation success. **Visual cues** in the clinic or pharmacy in the form of posters and signage seemed to be effective strategies for engaging patients who might be at risk of overdose or who may be friends or family members of persons at risk. In several CHCs, posters about overdose and naloxone could be seen in the waiting room, exam rooms, clinic walls, and pharmacy walls, such as the ones depicted in Images 6 , 7, and 8.

A physician shared a recent experience with naloxone signs in the main area of the primary care clinic: *“We had another patient who saw the sign out here by the desk. And it was the first time he informed his primary care provider that he was struggling with opioid dependence.”* One pharmacist noted how the presence of signs in her

pharmacy heightened patient awareness about naloxone access via a standing order. These posters and signs let patients know that the CHC or pharmacy is a safe place to seek overdose prevention services.

Image 8. Sign on Exam Room Bulletin Board



Source: Author, 2016.

In recognition of the challenge of requesting naloxone at the pharmacies, two of the CHCs had also discussed ideas for how to increase naloxone access for patients. One pharmacist explained what her CHC is considering:

Sometimes the patients who come to the pharmacy, just telling someone they want Narcan can be difficult. So we are trying to come up with a voucher that just says, “Hand this to the pharmacist,” and it says, “Please give me Narcan per the standing order,” or something like that. They don’t even need to discuss what they want, they can just hand it to someone which would be much more comfortable. We would put a stack of those vouchers in the clinic. Also sometimes people don’t remember the name of it, so to describe it becomes more uncomfortable.

A few of the health centers spoke about **community outreach activities**, such as health

fairs, that clinic and pharmacy staff participated in. One CHC utilized a local cable network station to market the availability of naloxone at the CHC-affiliated pharmacy after a spike in opioid overdose deaths in the city:

We recently had a rash of overdoses. We had eight deaths in [name of city]. Our pharmacy is really awesome. We have really great people dedicated to our patients and community. They called the local news and asked them to get the word out that people can get Narcan at the pharmacy [through a standing order]. They did a couple of news stories. There was a short uptake and then it leveled out again.

Another CHC brought up the role of a health center consumer board as a key element in both engaging the patient population and informing OENA activities. A physician explained:

The other important piece of this is the consumers. We have a Consumer Advisory Board (CAB). Both at the program level and an HIV CAB that is a sub-committee. They have been interested in [OENA]. They did a big event last summer for International Overdose Awareness Day. They had tables and were doing naloxone education, showed people how to put the kits together.

Champion

As referenced throughout this chapter, the presence and ongoing, active involvement of a **champion inside the CHC was instrumental to implementation success**. These champions included nurse practitioners, nurses, program managers, and physicians. They were not formally appointed OENA champions, but assumed this role out of a desire to change the situation, and started with their own patients and then their own clinic teams. They were clearly recognized as a champion by others, and served as a resource for CHC staff that were at different levels of comfort with the intervention.

Given the multitude of clinical and public health priorities that CHC primary care settings face, and the need to assess clinical practice on a continuing basis, having a champion dedicated to overdose prevention activities was a major factor in clinics adopting and implementing OENA activities long-term. Having such a person in place was particularly beneficial during the early stages of adoption when the champion served as a point-of-contact for OENA activities. In this role, the champion facilitated training, internal and external partnerships, and data sharing. In addition, the champion helped overcome identified barriers, such as procuring naloxone rescue kits or suggesting that an experienced nurse help a more novice implementer. In many cases, the champion connected the CHC to external change agents, such as innovators in the field, and made staff aware of promising practices from other settings. Finally, the champion helped sustain activities by continuing to model sound OENA practice and advocating for the program to be an ongoing priority at the administrative and management levels of the CHC.

External Change Agents

Participants spoke about the influence of external change agents in paving the way for their clinic's OENA activities. These individuals were often leaders in the harm reduction response, such as a street outreach advocate or a physician overseeing the state's OEND program. The **external change agents were most instrumental during the early stages** of OENA activities by increasing CHC clinic staff awareness of the needs of persons with substance use disorder, connecting CHC patients with harm reduction services, and explaining how a clinic-based OENA program might work. One

participant championing activities in her CHC explained, *“That’s how I kicked this all off. I had [name of a physician OEND leader] come out and give a talk....that was the kick-off.”*

As discussed previously, the presence and growth of buprenorphine programs was seen as contributing to the need for and expansion of OENA activities. The leader of the state’s nurse-led OBOT response was mentioned by a few of the clinics as an important influence.

Reflecting and Evaluating

Quantitative and qualitative data documenting OENA activities varied across the CHCs. Four of the CHCs reported having an EMR field that collected data on overdose education and naloxone provision. At most CHCs, a referral for naloxone was documented in an open text field in the EMR. One CHC developed a comprehensive EMR system that systematically prompted and allowed for prescriber documentation regarding receipt of overdose education and a naloxone prescription (see Images 9 and 10).

Naloxone prescribing was then included as a services quality measure. As one physician at the CHC stated, *“Another big programmatic piece is actually making Narcan prescribing a quality measure, developing quality measures around substance use disorder— so, screening, treatment, and provision of naloxone.”*

Image 9. EMR Template Prompt for Overdose Prevention Counseling

Tobacco Use	Alcohol Use	Alcohol SOC	Drug Use	Drug SOC	OD Hx / Risk Behavior
<input type="radio"/> Tobacco Use	<input type="radio"/> Alcohol Use	<input type="radio"/> Alcohol SOC	<input type="radio"/> Drug Use	<input type="radio"/> Drug SOC	<input checked="" type="radio"/> OD Hx/High Risk Beh
<p>Overdose History</p> <p><input checked="" type="checkbox"/> History of OD</p> <p>Date of last overdose: <input type="text"/> <input type="button" value="View Previous"/></p> <p>Circumstances surrounding overdose: <input type="text"/></p> <p><input type="button" value="Add Hx of Overdose to Problem List"/></p>					
<p>Other High Risk Behaviors</p> <p>These questions are not intended as screening questions for the patient, but are used by clinical staff to inform clinical decision-making. Please note any of the following, if present:</p> <p><input type="checkbox"/> Credible report of diversion of abusable medications</p> <p><input type="checkbox"/> Forged prescriptions</p> <p><input type="checkbox"/> Prescriptions for abusable medications or potentiators from multiple prescribers</p> <p><input type="checkbox"/> Opioids previously denied by any BHCHP prescriber</p>					
<p>OD Prevention</p> <p>Naloxone Rescue Kit Naloxone Rescue Kit not found on patient's active med list. <input type="button" value="Update Kit Rx"/></p> <p><input type="checkbox"/> Naloxone rescue kit offered and refused.</p> <p>Education No OD Prevention Education on record.</p> <p><input type="checkbox"/> Pt educated about overdose prevention - risks of OD, signs of OD, and response to OD (including use of nasal naloxone rescue kit, if prescribed).</p>					

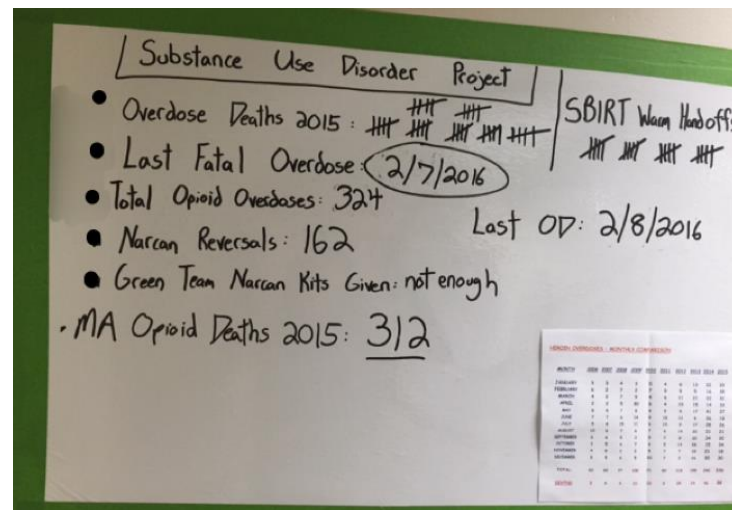
Image 10. EMR Template for Naloxone Prescribing

New Medication	
<p>Name: Emily Test</p> <p>Birth: 06/12/1975</p> <p>Age: 41 Years Old</p> <p>Sex: Female</p> <p>Height: 60 in (152.40 cm)</p> <p>Weight: 188 lb (85.45 kg)</p> <p>BSA: 1.82 sqm</p> <p>Insurance: Not insured-ZZ00</p> <p><input checked="" type="checkbox"/> Eligibility: Pending</p> <p><input checked="" type="radio"/> Allrgs(7) <input type="radio"/> Meds(20) <input type="radio"/> Probs(58)</p>	<p>Find Medication</p> <p>Custom List: NaloxoneRescueKit-BMH Pharm ONLY <input type="button" value="Reference List..."/></p> <p>NALOXONE HCL 1 MG/ML SOLN If overdose suspected, CALL 911 first. Attach nasa</p> <p>Formulary: BMC Outpatient Formulary</p> <p><input checked="" type="radio"/> NALOXONE HCL 1 MG/ML SOLN is off formulary. <input type="button" value="Search Formulary..."/></p> <p><input checked="" type="radio"/> There are no alternatives. <input type="button" value="Select Formulary..."/></p> <p><input type="button" value="Status..."/></p> <p><input type="button" value="Choose Alternative"/></p> <p>Define Medication</p> <p>Medication: NALOXONE HCL 1 MG/ML SOLN (NALOXONE HCL)</p> <p>Instructions: If overdose suspected, CALL 911 first. Attach nasal device, spray half the contents into each nostril, repeat <input type="button" value="Dosing Calculator"/></p> <p>Start Date: 08/16/2016 <input type="button" value="Stop Date:"/></p> <p>Duration: <input type="text"/> <input checked="" type="radio"/> Days <input type="radio"/> Weeks <input type="radio"/> Months <input type="button" value="Monograph"/></p> <p>Prescription</p> <p>Quantity: 2 syringes syringe Refills: 2 <input type="checkbox"/> Brand medically necessary <input type="checkbox"/> Print Pt. Handout necessary</p> <p>Pharmacy: Barbara McInnis House Pharmacy* (retail) <input type="button" value="Select..."/> Authorized By: Brody MD, Jennifer K</p> <p>780 Albany Street Prescribing Method: Electronic</p> <p>Boston, MA 02118 State: Massachusetts</p> <p>Ph: (857) 654-1791 Note to Pharmacy: <input type="text"/></p> <p>* indicates the calculated values of weight or height.</p> <p><input type="button" value="Save & Continue"/> <input type="button" value="OK"/> <input type="button" value="Cancel"/></p>

The other four CHCs indicated they had “no plans” to add such a field to the health center’s EMR in the next six months due to logistical constraints on modifying the EMR. Several CHC participants talked about the gaps in documenting OENA-related data. One participant described his CHC’s documentation needs as follows:

There is not currently an overdose and naloxone field in the EMR. I'm not sure of the feasibility of getting a general primary care provider to have it too high on their radar. What I do think is any nurse, case manager, and behavioral health clinician within the medication-assisted treatment program certainly could, on their template, have a field, like we have a nursing Suboxone template. I honestly don't know if naloxone is on there, but it should be, at least to document that we discussed and offered a referral.

Image 11. Primary Care Clinic Whiteboard Tallying Overdose Deaths in City and Naloxone Kits Distributed



Source: Author, 2016.

One of the **challenges with relying on a pharmacy standing order or referral method was not knowing if the patient actually obtained naloxone.** The pharmacy directors played an important role in sharing aggregate naloxone dispensing data, though

there did not seem to be any relationship between this data and actual prescriptions or referrals from the CHC.

Weekly and/or monthly HIV and Suboxone team meetings offered the opportunity for clinic teams to share updates and experiences related to OENA. One CHC pilot project had an interesting approach where a whiteboard in the primary care clinic kept track overdose deaths in the city (Image 11), the date of the last overdose, and the number of naloxone reversals, SBIRT “warm hand-offs” to nurses, and naloxone kits provided. This board was continually seen by all staff who worked in the clinic.

Stories from patients about how they used naloxone had a powerful effect on the participants. One physician explained how patients share their experience with naloxone: *“We aren't doing any formal tracking now. We certainly have patients who share that they reversed overdoses, but I don't have a number.”* A nurse added, *“A lot of patients give feedback. They say they had to use it, ask for another one.”* A nurse at another CHC shared a story based on feedback she received from a patient who had administered naloxone:

A couple of times, we have had people come back and report the use of Narcan. And that is powerful. I had this one particular patient who ...lives in a rooming house, and he had Narcan and used it on someone who overdosed in his apartment building. And he reversed the overdose. The man told me this story with tears in his eyes. And I was like, I have to hug you. Do you know what you did? You saved this person's life. That moment was so profound. I think for him, and for me— like, oh good, this really does work. We know the drugs work, and that people are actually using it.

A nurse practitioner from another CHC talked about the role of patient feedback in helping sustain OENA activities among the primary care clinic team nurses:

They [the nurses] come to us, a patient is worried, “I don't know what to do for her, she is using, should we offer it to her?” That is how it was in the beginning....and the feedback that came back—“I helped her, I gave her something concrete that she could do. That is so powerful and life-changing....I'm going to do this again.”

Implementation Strategies by Process Domain

For the **process** domain (Table 36), strategies included engaging staff through ongoing training, technical assistance, providing job aides, and sharing data. A champion was important for organizing implementation activities, coaching staff, and overcoming hurdles. While tracking and monitoring of overdose education and naloxone provision was sporadic across the sites, building data updates from the EMR or pharmacy records into team meetings helped demonstrate the degree of OENA uptake across providers and patients. Alongside this, sharing of clinic staff experiences with OENA helped reinforce the impact of the intervention.

Table 36. Summary of Strategies Related to CFIR Constructs with Process Domain	
Construct	Implementation Strategies
Engaging	<u>Engaging Clinic Staff</u> <ul style="list-style-type: none"> • Increase awareness of providers and staff in the early stages • Build in ongoing supports for providers and staff, including an agenda item in regular meetings • Provide job aides for clinic staff including EMR templates, patient education materials, and a written policy • Have peers share their experiences with other clinic staff and model education sessions • Share data on naloxone access with clinic staff <u>Engaging Patients</u> <ul style="list-style-type: none"> • Conduct outreach events • Partner with community-based organizations • Utilize signage in the CHC and the affiliated pharmacy • Identify barriers and implement strategies to address patient-level barriers
Champions	<ul style="list-style-type: none"> • Draw on the passion of a provider or staff team member who is on the ground implementing and has emerged as a champion
External Change Agents	<ul style="list-style-type: none"> • Utilize the expertise, reputation, and influence of external change agents to bring senior leadership, providers, and staff on board or to

	model program delivery policies and protocols
Reflecting and Evaluating	<ul style="list-style-type: none"> • Build in basic data collection systems and monthly reporting and data sharing • Offer the opportunity for implementing staff to share personal stories related to OENA implementation • Share success stories in meetings as a way to reinforce the benefits of OENA activities

Chapter Summary

Table 37 lists questions that CHCs can consider when planning or altering an OENA program, which are based on the CFIR’s implementation science constructs. Deliberation on these questions may help expedite the clinic’s implementation efforts.

CFIR Domain	Questions to Consider
Intervention Characteristics	<ul style="list-style-type: none"> • What aspects of the different models resonate with our setting? • Where might we begin an initiative in the clinic? • How can activities be integrated into the existing workflow, thus minimizing implementation barriers? • What are the costs to the program, especially for naloxone?
Outer Setting	<ul style="list-style-type: none"> • What are the needs of our patients when it comes to opioid overdose? • What are the mechanisms in place for obtaining feedback from patients on the implementation strategy? • Whom should we partner with to initiate or expand our activities? • What pharmacy(ies) should we establish partnership(s) with in order to best support the needs of our patients? • How can we become engaged in community-wide overdose response activities? • What outreach opportunities are there for reaching patients in the community and giving the clinic and pharmacy staff an opportunity to see the patients’ needs first-hand? • What policies and guidelines exist— at a state or national level— that can support our efforts?
Inner Setting	<ul style="list-style-type: none"> • What is the sense of urgency around this issue for CHC providers and staff? • How can leadership get involved in communicating overdose as a priority issue? • What steps can we take as a clinic to demonstrate we are ready to begin activities? • What communication systems are in place to discuss activities on a regular basis? • What communication systems need to be established, particularly between the clinic and pharmacy?

	<ul style="list-style-type: none"> • What resources do we need to have in place to begin the program, in terms of staffing, time, training, and space?
Characteristics of Individuals	<ul style="list-style-type: none"> • What are the training needs of providers and staff, both initially and over the first year of implementation, to support practice change?
Process	<ul style="list-style-type: none"> • Who will be the champion of these activities, leading implementation on the ground and resolving any staff resistance? • What can we do to engage patients in this process? • How can we continue to engage providers and staff long-term? • What external change agents can we involve to support provider and staff participation? • How can we continually use qualitative and quantitative data to reflect on our process? What program changes could be made as a result of our experiences?

An understanding of the constructs and strategies found to support OENA implementation can be used to accelerate implementation in other settings. These constructs could be considered one by one, but it is the interplay of these factors that ultimately determines the implementation experience. For this reason, the next chapter provides an integrated presentation of the study's conclusions and recommendations regarding the uptake and maintenance of OENA efforts.

CHAPTER 5: DISCUSSION

The purpose of this study was to explore the overdose education and naloxone access (OENA) implementation experiences of CHCs in Massachusetts. This chapter discusses the major findings and conclusions drawn from this research. The degree to which the findings corroborate, differ from, or enhance relevant literature is also explained. This is followed by recommendations for practice and future research, and then a concluding section on the study's limitations.

This study is the first qualitative examination of OENA implementation in primary care settings that used an implementation science framework focused on multiple systems-level factors. In contrast, most past studies have focused on provider-level barriers and facilitators to naloxone prescribing.^{51,39,40,55,53,54} More recently, Drainoni et al. examined implementation barriers and facilitators in an ED setting²⁰⁹ and Coffin et al. assessed the feasibility of a standardized naloxone co-prescribing intervention for patients receiving chronic opioid therapy at primary care safety net clinics.²²⁴ The present investigation supplements this nascent literature by going beyond an analysis of individual-level factors to highlight system-level factors that support or hinder OENA implementation.

This section brings together the significant findings across the five domains and 20 constructs from the Consolidated Framework for Implementation Research (CFIR) that were found to influence implementation. Ideally, the study's "take-away lessons" will guide other primary care settings as they grapple with how best to ensure naloxone access for their patients.

Conclusions

Table 38 provides a summary of the study's eleven major conclusions, which are discussed in more detail below.

Table 38. Summary of Study Conclusions

1. A variety of OENA approaches are feasible in CHC primary care settings, with different approaches available to fit each clinic's particular context.
2. Effective OENA implementation requires a systems-level response that goes beyond addressing individual-level factors that inhibit adoption.
3. Successful implementation relies on a team-based care model, with nursing playing a major role in OENA implementation.
4. Pharmacy teams are vital partners for broadening and sustaining OENA activities.
5. Determining the best means of providing naloxone to patients should center on a workable reimbursement mechanism to minimize cost barriers and ensure sustainability.
6. A clinic culture that supports harm reduction approaches greatly facilitates implementation.
7. Stigma needs to be acknowledged as a barrier to naloxone access and proactively addressed by both CHCs and pharmacies.
8. CHCs play an important partnership role in the community's response to a local opioid crisis.
9. Integrating OENA activities into buprenorphine treatment and chronic opioid prescribing greatly expands the scope of OENA implementation.
10. Differing clinic staff's perceptions of patients' overdose risk differed for patients with opioid use disorder and those being prescribed chronic opioids need to be considered in training and technical assistance response.
11. Clinic training and technical assistance plans should be customized according to the staff members' potential OENA roles and their stage of readiness. An OENA champion on-site who coaches and supports members can motivate staff to implement the intervention and address barriers.

Conclusion 1: *A variety of OENA approaches are feasible in CHC primary care settings, with different approaches available to fit each clinic's particular context.*

Despite the many barriers to naloxone access in clinical settings that have been identified in the literature,^{39,40,53-55,266} this study demonstrated that a range of CHCs were in fact able to integrate OENA into primary care service delivery. In doing so, CHCs utilized different strategies based on patient needs, the CHC context, available resources, staffing, and overall readiness to adopt this innovation.

The adaptable nature of the OENA activities meant that CHCs could implement an approach that worked best for their setting, and then change or add to it based on experience. Starting on a small scale to determine what worked best also supported adoption. Several of the CHCs with established OENA activities were able to adjust to intervention-related changes with relative ease, such as the new chronic opioid prescribing policies or the integration of naloxone prescribing into the clinic's EMR.

Conclusion 2: Effective implementation requires a systems-level response that goes beyond addressing individual-level factors that inhibit adoption.

Studies have shown that greater knowledge, positive attitudes, and self-efficacy among physicians and residents regarding OENA correlate with a greater willingness to prescribe naloxone and conduct overdose education.^{51,53-55} In contrast to other studies, participants in the present study did not express concern about naloxone being a “safety net” drug or leading to high-risk substance use behavior.^{39,40,54,251} Rather, participants across nearly all of the study sites were well aware of naloxone's benefits.

Nevertheless, a 2016 study of barriers to naloxone prescribing among internal medicine residents found that despite high awareness of naloxone, a willingness to prescribe, and a large number of patients at risk of overdose, only a small percentage of residents actually prescribed naloxone.⁵³ Another 2016 study among ED physicians found a similar gulf between “willingness” and “action.”⁵⁵ Clearly, system-level supports need to be in place to bring about change, including leadership engagement, an enabling implementation climate, partnerships, ongoing clinic-wide staff engagement, and staff education to reduce stigmatization of persons with opioid use disorder.

Conclusion 3: *Successful implementation relies on a team-based care model, with nursing staff playing a major role in OENA implementation.*

The involvement of clinic staff in addition to the prescriber served to enhance OENA implementation. Physicians and other prescribers faced multiple challenges providing OENA to patients on their own, including limited time, competing clinical priorities, and the need to address patients' additional clinical needs. Of course, physicians and other prescribers do play an important role: they identify patients in need and can begin a discussion about naloxone, after which they can conduct a "warm hand-off" to other staff who have more time for patient education. A 2016 study of naloxone co-prescribing for patients on chronic opioid therapy also reported that intervention activities were shared across multiple healthcare team members, including the physician, pharmacist, nurse, and health educator.²²⁵

The present study also identified the importance of creating a positive implementation climate with shared goals and expectations among team members. Equally important was the identification of specific roles and responsibilities for different team members. Related to this, a 2016 study found that in an ED setting, making naloxone distribution every team member's responsibility resulted in confusion about who was actually accountable for making sure the protocol was implemented.²⁰⁹ Team-based care is common practice within most CHC primary care settings.²⁹⁵ Employing this approach for naloxone access is a natural fit.

In the context of a team-based care model, nurses emerged as vital OENA implementers. The expanded nursing role in opioid-related care is not new. Since 2007,

for example, the Massachusetts Office-based Opioid Treatment (OBOT) model successfully utilized nurses to assess and monitor patients receiving buprenorphine treatment in select CHCs.⁶⁴ Building on this program's success, a study is currently assessing the efficacy of having a nurse care manager in place to support CHC-based primary care prescribers in managing patients who are prescribed chronic opioid therapy.²⁹⁶ Likewise, the present study demonstrated that nurse involvement facilitated implementation, particularly when OENA activities were made part of their official duties during HIV case management visits or when working with patients being prescribed buprenorphine treatment or opioids for chronic pain management.

Conclusion 4: Pharmacy teams are vital partners for broadening and sustaining OENA activities.

This study found that pharmacists at the CHC-affiliated pharmacy also played a key role in supporting expanded naloxone access for CHC patients. At a national level, there was a 1,170% increase in naloxone dispensing from retail pharmacies over a 21-month period of time between 2013 and 2015, with 35% of the prescriptions coming from primary care physicians.²²³ Further expansion is possible, as a review of international studies assessing pharmacists' attitudes about participating in harm reduction interventions have generally found them to be supportive.²⁹⁷

The study also identified additional types of working partnerships between the CHC clinical teams and pharmacy teams to support OENA implementation. Forming these partnerships allowed the CHC and pharmacy staff to collaborate in new ways to determine the most appropriate methods for reaching patients and addressing access

barriers. Examples include creating a standing order with the pharmacy and having the pharmacist offer naloxone to patients prescribed buprenorphine treatment.

For CHCs without pharmacies, establishing a partnership with a commercial pharmacy would be an important step to expand naloxone access. Given the doubts expressed by the study participants regarding the ability of commercial pharmacies with standing orders to respond positively to patients requesting naloxone, innovative approaches for engaging patients in these settings are needed to enhance the viability of this naloxone access point.

Conclusion 5: Determining the best means of providing naloxone to patients should center on a workable reimbursement mechanism to minimize cost barriers and ensure sustainability.

Ensuring the financial sustainability of OENA activities is an important consideration for determining how patients will get naloxone. Only one of the CHCs referred patients to an external agency funded by the Massachusetts DPH to provide OEND. Relying on external referrals to a state grant-funded program for naloxone access does not guarantee long-term access, nor does it support the integration of naloxone access activities into clinical practice.

Even so, for CHCs that prescribe naloxone or have a standing order in place, a partnership with a community-based OEND program can contribute further to expanded naloxone access for the clinic's patients. This was demonstrated by one of the CHCs that partnered with a local OEND program to conduct naloxone distribution events both at the CHC and in the community.

Two of the CHCs in this study distributed naloxone rescue kits at the CHC in order to minimize patient access barriers. Finding funds to cover the cost of the kits is a major consideration in both the short- and long-term. To facilitate access, some state health departments have allocated funds to support community-based naloxone distribution, including at some CHC sites. It is unlikely, however, that state-level policymakers will be able to justify funding naloxone rescue kits for patients in clinical settings when there is pharmacy access with insurance reimbursement. Direct clinic distribution, however, may be the most effective means of naloxone access for some patients, particularly those without easy pharmacy access, who may never go the pharmacy, or who do not have health insurance coverage for naloxone.

Future innovations could explore additional ways for clinic's to acquire naloxone, such as through "buy and bill" where a clinic would buy naloxone directly from the manufacturer, a designated pharmacy, or specialty distributor and stock it on the clinic floor. The clinic would then bill the patient's insurance company for the cost of the naloxone. While this study did not identify any instances where this option had been implemented, precedent for this approach has been established through the provision of other pharmaceuticals in outpatient primary care settings.²⁹⁸ Examples include in-clinic provision of IUDs to allow for same-day insertion²⁹⁹ and antibiotics for chlamydia to prevent treatment delay and a greater risk of long-term complications.³⁰⁰ Other potential strategies can also be explored with a pharmacy partner to enhance real-time naloxone access at the clinic.

Finally, insurance-related barriers should be anticipated and worked out in

advance of implementation to prevent cost from being a barrier to patient access. The cost of naloxone, if insurance does not fully cover it, was cited as a potential patient barrier in both this study and a qualitative study with primary health care providers.⁴⁰ In Massachusetts, the Medicaid payer fully covers the cost of a naloxone rescue kit, and the state worked with the commercial insurers to include the kit in their drug reimbursement list. For the patient, however, an insurance co-payment could be a deterrent. Unlike 340B pharmacies located in safety-net CHCs that support drug access,³⁰¹ commercial pharmacies do not have the same flexibility to waive receipt of co-payment.

It is important for CHCs and pharmacies to be aware of various insurance limitations that could pose a barrier to patients receiving naloxone from commercial pharmacies so they can inform patients and customers. In addition, pharmacists themselves may need education related to third-party dispensing laws and reimbursement policies. For instance, third-party billing is not allowed if a person wants to get naloxone for a friend or family member.³⁰² This could result in a prohibitively high out-of-pocket cost (e.g., \$100 for the new single-stepⁱⁱ naloxone device).³⁰³

Conclusion 6: *A clinic culture that supports harm reduction approaches greatly facilitates implementation.*

This study found that a harm reduction treatment model rather than an abstinence-

ⁱⁱ After this study was conducted, mucosal atomizer devices for the naloxone rescue kits were recalled, and the single-step intranasal device was the formulation of choice in pharmacies.³⁰³ While more expensive, this new device is likely to save staff time at both CHCs and pharmacies as it does not require the ordering of the MAD, compilation of the naloxone rescue kits, and staff and patient training on how to assemble before administration. At the same time, it comes at a higher cost, borne by the consumer, health insurance company, or CHC depending on how the naloxone is purchased or reimbursed. Therefore, while this change may decrease the “complexity” of the intervention, which could facilitate adoption, it could also increase the “cost,” which may discourage uptake.

based treatment model facilitated the integration of overdose and naloxone education into both opioid treatment services and co-prescribing initiatives involving chronic opioid therapy. Supporting this integration, clinic-wide staff training on addiction theory and brain science, along with modification of treatment program protocols, led over time to a paradigm shift within the CHCs.

A clinic culture that embraced a harm reduction philosophy and approach helped engage both clinic staff and patients through non-judgmental discussions about the reality and risk of relapse, compassionate exchanges about the importance of having naloxone, and the need for opioid safety precautions when prescription opioids are in the house. In a study of naloxone co-prescribing with chronic opioids, the authors also noted that they recommended a “patient-centered approach that is empowering and non-judgemental.”³⁰⁴ Inclusion of language that clinic staff can use for framing naloxone discussions, reinforced through role-play exercises, can further support clinic staff and patient engagement in OENA discussions.

Conclusion 7: Stigma needs to be acknowledged as a barrier to naloxone access and proactively addressed by both CHCs and pharmacies.

Acknowledgement and proactive response to the stigma experienced by persons with a substance use disorder, which in many cases has been perpetuated by the healthcare system itself,²⁴⁸ is paramount to successful OENA efforts. Stigma has been shown to increase psychological distress and to impede PWID from seeking care.³⁰⁵ Several study participants in both this and another investigation⁵⁴ expressed concern about stigma as a barrier to naloxone access.

Finding ways for CHCs and pharmacies to address stigma proactively are essential for creating a partnership with patients in overdose prevention. Strategies that helped open the lines of communication about overdose included clinic and pharmacy signage about naloxone, patient education posters and other materials, and use of vouchers to facilitate pharmacy requests. Of course, clinic staff training should include a focus on how to show empathy and respect when working with patients. Along these lines, ASAM has called for changing the language used in clinical settings to discuss substance use disorder.²⁴⁸

There are different views about the effect of overdose education on provider-patient communication. The present study and past investigations have documented providers' fear of offending patients by bringing up the subject of overdose, especially those receiving chronic opioid therapy.^{40,51,54} There is preliminary evidence that properly framed overdose education and naloxone prescribing can reduce patients' concerns regarding stigmatization and enhance the patient-provider connection.^{221,250} Discussions about overdose and naloxone can communicate the following: the patient's safety is the clinic's top priority; the possibility of overdose is a major concern; and the patient has a role in preventing an overdose-related death. Through this discussion, patients can see the provider's concern, making them more receptive to what the provider needs to say and to using naloxone should they or someone in their social network have the need for it.³⁰⁶

Conclusion 8: *CHCs play an important partnership role in the community's response to the local opioid crisis.*

CHCs have played a critical role in improving population health,³⁰⁷ and this study

further demonstrated their commitment to that mission in their responses to the local opioid crisis. In addition to reaching patients likely to experience or witness an opioid overdose, CHCs have helped expand OENA in their communities by working in partnership with other local agencies and through community coalitions.

Studies have depicted the geographic concentration (“hot spots”) of opioid overdose cases.^{308,220,309} The mapping of overdose deaths in Massachusetts has uncovered several cities and towns with disproportionately high rates compared to the state overall.³¹⁰ Such data suggest that highly targeted, community-focused initiatives may be effective in curbing the overdose death rate. Recently released data from the city of Lynn, Massachusetts demonstrated the success of one such effort: while the number of opioid overdoses rose, the number of people who succumbed to an overdose significantly decreased due to increased naloxone administration. Lynn’s opioid overdose fatality rate was 35.6 per 100,000 residents in 2012 and then decreased to 15.7 in 2016.³¹¹

The present study found that CHC engagement in local coalitions supported the development and implementation of both new initiatives and more coordinated efforts. Specifically, two CHCs formed partnerships addressing the communication void between EDs and primary care providers found in this and other studies. A study among over 2,000 patients within a U.S. healthcare system who had at least one opioid overdose showed that less than 10% of those patients had a subsequent naloxone order, indicating the need for enhanced communication between EDs and improved naloxone access within follow-up primary care.⁸⁰ In addition, a national study of commercially insured patients found that nearly all patients prescribed opioids continued to receive them from

the same provider even after an overdose, suggesting the lack of communication between EDs and primary care providers about the overdose.³¹²

Clearly, then, shoring up communication lines and response systems between CHCs and EDs is an important step for coordinating across local care systems to prevent overdose fatalities. Through community coalition participation, one CHC worked with the local ED to provide naloxone to patients seen there for opioid overdose. Another partnered with their local EMS, which resulted in primary health providers being alerted when patients had an opioid-related ambulance transfer. Such efforts are crucial in addressing the complex systemic barriers to a coordinated response.

Conclusion 9: *Integrating OENA activities into buprenorphine treatment and chronic opioid prescribing greatly expands the scope of OENA implementation.*

The integration of naloxone access into CHC protocols for buprenorphine treatment and chronic opioid therapy prescribing came about because clinic staff saw the benefit to providing naloxone to these patients. In turn, making OENA a routine practice helped sustain naloxone as a CHC priority. These practices were also supported by state and national guidelines.

In 2015, the Massachusetts DPH issued practice guidance for integrating overdose education and naloxone into opioid treatment programs.⁷⁰ Federal funding has expanded the role of CHCs in providing medication-assisted treatment nationally,⁶³ thereby encouraging additional opportunities for future naloxone access. The *Prescribe to Prevent* website offers sample policies and guidance that could be useful to implementing agencies and other jurisdictions.²⁹³

Opioid prescribing guidelines issued by the CDC in March 2016 recommend the provision of naloxone for persons prescribed chronic opioid therapy for non-cancer pain management.⁴⁵ This is an area of tremendous opportunity. Two 2016 studies demonstrated the feasibility of naloxone co-prescribing interventions, one in San Francisco primary care safety net clinics, the other in an Albuquerque ambulatory pain clinic.^{224,225}

Conclusion 10: Differing clinic staff's perceptions of patients' overdose risk differed for patients with opioid use disorder and those being prescribed chronic opioids need to be considered in training and technical assistance response.

Clinic staff's perceptions of patients' overdose risk differed for patients with opioid use disorder and those being prescribed chronic opioids. Those patients perceived to be at low risk were less likely to receive OENA. A few of this study's physicians noted that they do not consider their patients on long-term chronic opioids to be at risk for an overdose, and one participant noted that these patients likewise do not perceive themselves to be at risk. Consistent with that finding, a 2016 survey of patients on chronic opioid therapy for pain management found that, despite their high rate of overdose, these patients had low knowledge about their overdose risk and naloxone.³¹³ This finding underscores the need for clinic-based interventions, as many of these patients do not perceive themselves to be at risk if they are taking medication as prescribed.

The different levels of risk appraisal may also contribute to provider fear of offending patients or being perceived of accusing them of substance abuse, which has

been identified in the literature.^{39,40,54,249} The different notions of risk for patients prescribed opioids compared to those with an opioid use disorder likely require different clinic staff training and patient communication strategies. For example, study participants spoke about the importance of discussing relapse as a potential part of the treatment process, and the likelihood of being a bystander around others who may overdose. For patients on chronic opioid therapy, a physician spoke to her patients about the importance of having naloxone on hand for the safety of other household members. Another study reported that several patients prescribed naloxone alongside chronic opioid therapy reported safer medication behaviors, such as taking their prescribed dose at the right time, suggesting the role of this intervention in heightening patient awareness of opioid use risk.²²¹

Framed as a universal clinic opioid safety measure for all patients receiving chronic opioid therapy— an approach that has been previously recommended²²⁶— was found to be acceptable to patients.^{221,250} Coffin, et al. also found that universal co-prescribing ultimately reached patients at highest risk of overdose (i.e., past opioid-related ED visit and higher doses of opioids).²²⁴ While it is not feasible or always appropriate to offer every patient naloxone, having a universal guideline in place may help remove the stigma associated with OENA and create an implementation climate where co-prescribing is expected.

Conclusion 11: *Clinic training and technical assistance plans should be customized according to the staff members' potential OENA roles and their stage of readiness. An OENA champion on-site who coaches and supports team members can motivate staff to implement the intervention and address barriers.*

The present study revealed that staff members, often based on prior experience, were at different stages of readiness for implementing overdose education and naloxone prescribing, a finding that should be considered during a program's early implementation phase. All team members need to be "on board"—that is, sharing supportive beliefs about the need for the intervention and being fully prepared to implement OENA according to their clinic role. Therefore, ongoing training and technical assistance that reaches all clinic staff is imperative. In fact, as a starting point, all of the CHCs in this study conducted clinic-wide training on how to respond if an overdose occurred at the CHC. Not surprisingly, participants reported the need for ongoing pharmacist training since they too have different comfort levels with overdose education and naloxone dispensing. Studies of pharmacist-based interventions for PWID have found that training can facilitate pharmacist engagement.^{236,314}

Some clinic staff and pharmacists who struggle with OENA delivery may need additional in-service trainings. Ongoing booster sessions can establish a foundational level of knowledge and greater comfort with the intervention regardless of staff members' degree of involvement in day-to-day patient education and naloxone access. Finally, given prescribers' focus on clinical priorities, electronic reminders and easy online naloxone prescribing were reported to facilitate involvement over the long-term.

The study showed that having an on-site OENA champion supported roll-out, a finding shared by studies assessing implementation of other interventions in primary care settings.^{315,316} A champion can help keep the staff motivated by modeling implementation and connecting staff with their more experienced peers. At the same time, they are available to field questions and trouble-shoot problems that arise.

Coffin, et al. outlined a one-year implementation plan for the NOSE intervention, which featured the co-prescribing of naloxone with chronic opioid therapy in primary care settings. While rolled out in the context of a research study, their plan can serve as a helpful roadmap for other settings,²²⁴ and, in fact, similar steps were taken by some of the CHCs in the present study. The NOSE plan includes the following activities:²²⁴

- 1) meeting to introduce the program to clinic leaders;
- 2) clinic-wide staff training that introduces the program to all staff;
- 3) distribution of materials including naloxone rescue kit components and patient education brochures;
- 4) prescriber trainings to review the protocol and answer questions, which were often conducted in pre-clinic “huddles”;
- 5) nurse and medical assistant trainings to review activities, conduct role plays, and answer questions;
- 6) emails to remind staff to follow the OENA protocol; and
- 7) ongoing technical support for staff.

This plan reinforces the point that implementing the intervention requires the involvement of multiple staff, and that a one-shot training is inadequate to support staff

longer term.

In addition to training and technical assistance, the present study highlighted the importance of building in opportunities for information sharing as a way to engage clinic staff. Information shared included both quantitative data (i.e., naloxone prescribing and standing order data) and clinic staff stories about patients' reports of naloxone use. The practice-feedback loop is a fundamental component of implementation science, meaning that practice experience is documented, assessed, and then revised as needed.³¹⁷ A study of the Australian naloxone pharmacy access program also found that ongoing use of data systems supported implementation over time.³¹⁸

Recommendations for Practice

The study's findings in Chapter 4 were organized according to the CFIR's five domains: Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process. The fact is, however, that these constructs are interrelated, and therefore focusing on any one of these domains on its own would accomplish relatively little to produce systemic change. The complex interplay of these domains must be addressed.

Implementation science frameworks reinforce the point that implementation experience is highly dependent upon context. As outlined above, this study identified a large number of contextual factors across multiple domains that may support or impede the uptake and implementation of OENA activities. In consideration of this, nine broad practice recommendations are put forth in Table 39, organized according to what CHCs may want to consider at different stages of program implementation— specifically,

adoption, implementation, and maintenance, as per the RE-AIM Model.³¹⁹ It is important to note that many of the listed activities can be engaged in across program phases.

Table 39. Recommendations for Various Phases of OENA Program Implementation

Adoption Phase

- Ensure senior leadership support and have leadership communicate importance of overdose prevention activities to CHC staff
- Document and disseminate naloxone access, prescribing, and Good Samaritan laws to all clinic and pharmacy staff
- Identify a champion within both the clinic and pharmacy, if a pharmacy model is used
- Identify clinic team members who will be involved in implementation
- Adapt the OENA model to fit the clinic's workflow and patients' needs
- Start small with one clinic team or with a particular patient group
- Determine the best method for purchasing naloxone
- Determine a mechanism for stocking naloxone in the pharmacy or clinic
- Create a clinic emergency overdose response plan and clinic-wide staff training

Implementation Phase

- Establish formal partnerships with external organizations as needed
- Recognize different stages of readiness among the implementing team and conduct ongoing trainings to support the staff
- Conduct staff trainings on creating a stigma-free clinic environment
- If using a prescription model, create an easy online prescribing process
- Review data and implementer and patient feedback to determine any needed changes to program
- Post signage in both the clinic and the pharmacy
- Conduct outreach events in the community
- Participate in a community coalition that addresses the opioid crisis in the community

Maintenance Phase

- Build in decision supports for providers and staff, and discuss the initiative in weekly and monthly team meetings
- Consider the long-term cost implications for naloxone access and plan for any changes to ensure sustainability
- Create a written policy and train new and existing staff on it
- Support the efforts of the champion by acknowledging impact of OENA activities across the CHC
- Continue to evaluate and reflect on progress as a team and make adjustments as needed

Recommendations for the Adoption Phase

- **Determine what costs and resources are needed.** While OENA is not a resource-intensive intervention for the CHC unless naloxone is purchased by the

CHC directly, certain resources need to be in place: physical space for patient education (at the clinic or pharmacy), training for staff, designated training time for staff, stocking of naloxone rescue kits, and patient education materials.

- **Identify how patients will access naloxone.** It is important to determine how patients will access naloxone. Various strategies can be utilized and are not mutually exclusive. These approaches can also change over time based on the clinic, patients' needs, and available resources. Table 24 summarizes the advantages and disadvantages of the various approaches.
- **Determine staffing capacity and workflow.** Finding ways to build OENA into the existing workflow, such as during buprenorphine assessment visits, can support routine service provision. In recognition of prescribers' competing clinical priorities and their limited time with patients, nurses and other staff such as health educators, case managers, and behavioral health providers can all play a role in the delivery of OENA. Standing orders can help remove the need for a prescription and create an opportunity to expand the role of the pharmacist as a key member of the OEND team. Clearly articulated staff roles in the OENA process helps ensure that the intervention actually occurs with fidelity.
- **To start, consider piloting OENA activities.** Starting with where CHC clinic staff perceives the need to be the greatest, and working with the support of an enthusiastic champion, can support the intervention's initial implementation. OENA activities can be modified or expanded over time as needed.

- **Engage staff throughout the CHC in OENA training and technical assistance activities.** There are several opportunities to engage clinic staff, including training, ongoing booster sessions, on-the-job peer support, and provision of job aides. The provision of training on addiction theory and science can also help equip clinic staff with knowledge and tools for they need to integrate discussions about naloxone into patient visits.

Recommendations for the Implementation Phase

- **Build a relationship with the pharmacy used by most of the CHC patients.** CHCs can forge new or expand relationships with pharmacies to provide coordinated care for persons in need of overdose education and naloxone. Together, the CHC champion and pharmacy director can create a strategy to increase naloxone access for CHC patients
- **Actively work to create a stigma-free environment at the clinic and pharmacy.** Training on the science of addiction and evidence related to the treatment and recovery process can help engage both clinic staff and patients in a productive dialogue about naloxone's role in the recovery process. Trainings on the best language to use when working with patients can further support a culture that helps destigmatize addiction. During these discussions, it is important to recognize that clinic staff and patients may perceive overdose risk differently for patients who are on opioid treatment and those who are prescribed opioids for chronic pain. After staff receive training, signage in the clinic and pharmacy can help communicate that those are safe spaces to discuss overdose prevention.

- **Offer ongoing training and technical assistance activities to staff.** A training plan that includes basic training for all staff, specific training for staff conducting patient education, and ongoing booster trainings can support implementation. Effective training and technical assistance plans should recognize that CHC and pharmacy staff— both veteran and new— will likely be at different levels of readiness for implementing OENA activities. A written policy developed at this point will be a useful tool for communicating expectations to staff and giving them increased guidance regarding their OENA responsibilities. Table 8 in Chapter 2 lists free online clinic staff, prescriber, pharmacist, and patient training and education resources.

Recommendations for the Maintenance Phase

- **Gather and share data about the CHC’s opioid overdose activities.** Data about OENA activities can be useful in measuring how frequently patients have received naloxone, documenting progress, and identifying barriers to improved implementation. Reviewing these data with the CHC staff, and with the pharmacy staff if that approach is used, provides the opportunity to provide feedback and to brainstorm solutions to enhance the program.
- **Leverage local partnerships in the opioid response.** Local partners are vital to ensuring that patients have access to the full continuum of opioid treatment services, as well as to supportive social services. CHCs are key partners in the community response and can collaborate with community-based organizations to conduct outreach events, including naloxone distribution. Finding ways to

coordinate with local EDs, EMS, and police departments, such as through local opioid coalitions, are a great forum for bringing multiple stakeholders together for a coordinated response.

Transferability of Findings

Qualitative research findings are rarely generalizable to other settings,⁷⁷ but can provide important guidance to a broader range of practitioners when those findings are organized according to implementation science concepts. An implementation science perspective looks for common underlying themes and constructs that can guide the transfer of findings from one setting to another. The present study's findings offer sufficient detail to inform OENA implementation in other settings.

At the same time, of course, context is also essential to identifying what might work most effectively in one setting and not in another. Important contextual elements identified in this study include whether there are facilitative state policies, and whether the CHC has a clinic culture that is mission-driven, patient-centered, team-focused, and open to innovative methods of healthcare delivery that might better address both patient and community needs.

The findings from other CFIR domains— namely Characteristics of Individuals, Inner Setting, and Process— should also be considered by other settings as they create or expand a naloxone program. For example, when the findings were shared with an HIV physician at a large urban hospital, she reflected on aspects of the findings that applied to her setting, such as the need to train all clinic staff and increase patient awareness through signage.

Similarly, findings shared with attendees at a New Hampshire behavioral health conference led to one CHC nurse practitioner planning to find out which staff at her CHC are giving out naloxone, which patients are getting it, and how OENA could be integrated more formally into the clinic's buprenorphine treatment program. Another conference participant who manages a network of treatment centers stated that he planned first to share the laws with his clinic leadership and then reach out to the health department to learn how to procure naloxone rescue kits. He spoke about his plans to start on a small scale at one center to see what works before expanding the program to all sites. A third participant reflected on ways to enhance her clinic's partnership with the pharmacy that has a standing order. Based on these reactions, the hope is that these study findings will trigger new ways of thinking about naloxone access for patients in different primary care settings and help guide their adoption.

Recommendations for Future Research

Evaluate the intervention's outcomes. Future studies can examine naloxone distribution, prescribing, and standing order data from the clinics. Such data could identify actual trends within CHCs, including prioritization of patient risk factors, extent of provider and staff involvement, and patterns of naloxone access. Furthermore, a comparison of the number of naloxone rescue kits prescribed or ordered and actually received by patients would be important, particularly given that the study identified this disconnect as a barrier to effective care. This type of analysis could help identify the effectiveness of different naloxone access models, as well as point to program areas in need of quality improvement.

Conduct a case study of exemplary programs. An in-depth examination of two CHCs could supplement the cross-site findings produced by this study by providing a greater level of implementation detail that could guide newly launched programs. Sites with exemplary practices can be selected based on the outcome measures described above, while ensuring that different settings and methods of delivery are represented. Such case studies could build upon case studies prepared by The Harm Reduction Coalition.³²⁰ When posted online, the case study description could include links to sample policies, EMR template screen shots, staff training curricula, and patient education materials.

Explore further the role of the CHC-based pharmacy partner. Future studies can explore the efficacy of different pharmacy arrangements for increasing naloxone dispensing, including new innovative models such as including adding a pharmacist to the CHC clinic team. Subsequent investigations could examine the factors that increase naloxone dispensing rates from the pharmacy. Some of the factors identified in this study that could be explored include the relationship between the pharmacy staff and clinic champions; the clinic's physical space; community outreach activities; and stigma reduction activities. Identifying specific implementation factors that facilitate pharmacy access models will be an important step in overcoming the barriers identified in this study.

Obtain the patient perspective. The patient perspective has been largely absent from studies exploring clinic-based OENA activities. In future research, hearing directly from patients through a mix of qualitative and survey research can help inform new clinic

strategies and quality improvement efforts. Two studies in 2016 assessed chronic pain patients' attitudes toward naloxone prescribing in primary care settings found that patients found it acceptable to be prescribed the medication,²²¹ though barriers could arise if the discussion was not framed well.³⁰⁴ Another 2016 study among ED patients using opioids found a two-thirds acceptance rate for a naloxone kit.³²¹

Future studies should strive to sample a wider range of groups, including patients receiving buprenorphine treatment, patients prescribed opioids for chronic pain management, and patients who are family members or friends of persons at risk of overdose. The patient perspective, combined with the existing literature and these implementation findings, could be used to inform future education messages and methods of naloxone delivery.

Limitations of the Study

While the proposed methodology was well suited for addressing the study aims, there are inherent limitations to the research design that warrant attention. A brief explanation of these limitations and how they were addressed is presented below.

Location of the study. This study was conducted with a sample of CHCs located in the Commonwealth of Massachusetts, a state with a highly facilitative political environment for OENA programs. While more and more states are moving in that direction, it is important to note that CHCs in other states may not be operating with fully supportive policies or may be at an earlier stage of policy implementation. Even so, this study's documentation of the Massachusetts CHC's implementation experience can inform practice in other states.

Timing of the study. Focus groups and interviews were conducted over a four-month period. It is important to note that the CHCs' OENA activities may have evolved during and after the data collection process, and that the study's findings represent only a snapshot in time of their implementation experience. The continued focus on national and state policies and the broader dissemination of promising clinic practices is likely to increase clinic-based implementation of OENA. Likewise, it would be important to assess the degree to which fatigue may be setting in as CHCs grapple with the opioid crisis in their communities.

Absence of outcome evaluation. It is not possible to say which OENA approach is the most effective for increasing naloxone access since process and outcome data collection was not part of the research plan. As this is a relatively new intervention, conducting an outcome evaluation would be premature. All statements regarding the effectiveness of each approach, plus the identification of promising practices and key considerations for intervention planning, stem from the participants' descriptions of their experience.

Response bias. Findings from the clinic staff interviews are not representative of all providers at the clinics.⁷⁷ Different clinic staff involved in oversight, management, and implementation roles were interviewed to get multiple perspectives regarding the implementation experience, including the challenges each CHC faced. In addition, data sources were triangulated for each study site to validate the interview data.

Researcher bias. Several steps were taken to minimize the potential impact of researcher bias during this study. First, a series of meetings with experienced qualitative

researchers and a Massachusetts subject matter expert were held during development of the data collection tool, site selection, and outlining the data collection processes. Second, code definitions were discussed with an objective qualitative researcher, and the codes were applied to a subset of transcripts until consensus was established. Throughout the coding process, queries and uncertainties were documented in memoranda to refer to during the data interpretation phase. Patterns and key themes were discussed with the qualitative researcher and a state expert, resulting in continuous feedback throughout the study. In addition, the findings were shared with state experts and conference participants at a New Hampshire Behavioral Health Conference workshop in an effort to assess the broader relevance of the study's findings.

Chapter Summary

The CHCs in this study played an important role in increasing access to naloxone, particularly given their role in providing primary care to PWID, providing opioid treatment to persons with substance use disorder, and in prescribing opioids for chronic pain management. The present study elucidated the variation in OENA activities implemented in these primary care settings. Beyond demonstrating the feasibility of OENA in these settings, the study highlighted important considerations to be taken into account when designing or modifying programs to suit a CHC's particular context.

Several activities were found to facilitate the implementation of OENA activities. Starting small and identifying an implementation team and key internal and external partners is essential. Providing ongoing training and technical assistance on naloxone-related laws, harm reduction approaches, and OENA with all CHC staff can create a

supportive implementation climate. Identifying opportunities to integrate OENA activities into existing care delivery avoids unnecessary complexity and supports staff engagement. Working continuously to eliminate the stigmatization of persons with an opioid use disorder supports patients and the goal of getting naloxone into the hands of persons likely to experience or witness a future overdose.

The study findings, combined with the existing literature, paint a comprehensive picture of what implementation entails, highlighting the fact that system-wide support is needed to overcome individual-level barriers. This study also revealed the overlapping influences that in many cases need to be in place simultaneously in order to bring about sustained programmatic change. These approaches and findings can be used by other CHCs seeking to expand naloxone access as a means to prevent opioid overdose deaths in their communities.

APPENDIX A: Letter to HIV Clinic Medical Directors Inviting Study Participation

[Clinic Name; Clinic Email/Address]

Dear [Clinic Medical Director]:

[Date]

I received your name from [NAME] who recommended that I contact you about a project that I am working on. I am conducting a qualitative research study on barriers and facilitators faced by clinical care settings when implementing overdose education and naloxone prescribing for persons living with HIV who are at risk of potential overdose. This study serves as my dissertation project at the Boston University School of Public Health where I am a Doctor of Public Health (DrPH) student.

I am selecting approximately five different clinical care settings in Massachusetts that have more than two prescribers, provide dedicated care to PLWH in Massachusetts, and have initiated opioid overdose education and naloxone prescribing. [NAME] thought [CLINIC NAME] would be a great addition as a potential study site. I am writing to see if your clinic would be interested in participating in this project.

The study has been approved by the Boston University Medical Center Institutional Review Board. Please see the attached research study summary. Your participation would entail the following, based on a discussion with you about what is most appropriate for your clinic's staffing model:

- Completion of a brief survey about your clinic
- Interview with you by phone or in-person lasting about 30-50 minutes
- Individual interview(s) and/or focus group(s) with your clinic staff involved in overdose education and naloxone prescribing, including physicians, nurses, social workers, pharmacists, case managers, and peer educators.

I am hoping to learn about different strategies for providing overdose education and naloxone prescribing in HIV clinical settings-- what works, what doesn't work, and what makes it challenging— or easier— in HIV clinical settings.

I would come to your clinic for the interview(s) and focus group(s) at times convenient for you and your staff sometime between [DATES]. Findings from this study will be useful in supporting HIV clinic-based opioid overdose prevention and response strategies.

Thank you very much for your consideration. I am happy to answer any questions about the study or your participation, and will follow-up with a call within the next week. You can reach me at mclark11@bu.edu or 617-997-2709.

Best regards,
Michele Clark, MPH

Attached: Research Information Summary

APPENDIX B: Study Information Summary Sheets [Pilot and Main Studies]

Research Information Summary

Title of Project: *Understanding the Context of Implementing Overdose Education and Naloxone Distribution (OEND) for Patients at Risk of Opioid Overdose in an Infectious Disease Clinic*

Principle Investigator: Michele Clark, MPH

Background

The _____ has recently decided to train its providers on overdose education and naloxone kit distribution (OEND) and suggest prescribing naloxone to patients at high risk of overdose. As a formative step to a Boston University School of Public Health Doctor of Public Health student's dissertation research in this area, we are interested in understanding what you and your colleagues think about implementing OEND in the clinic and what you anticipate as challenges and potential strategies.

Purpose

The goal of this formative study is to understand the context of implementing clinic-based overdose education and naloxone kit distribution for patients at risk of opioid overdose at the _____ clinic. We are interested in understanding your current thinking around OEND in the clinic, as well as what makes it challenging and easier in clinical settings.

You are being asked to participate in this research project because you work in the _____ clinic. Your voluntary participation will consist of taking part in an interview or focus group discussion lasting up to 50 minutes. If you chose not to participate, your job will not be impacted in any way. You are free to answer the questions in any way you choose. Again, your point of view or opinions will not impact your job in any way. You are free to not answer a particular question if it makes you feel uncomfortable. There is no cost to you for participation, and you will not receive anything in return. Your input will help guide future recommendations for opioid overdose prevention strategies in clinical settings.

Confidentiality

We will be audio-recording the conversation so that we can analyze the themes of what we discuss with you and the other staff we will be interviewing. After the taping is complete, the Principal Investigator will be transcribing the interview/focus group discussion. No identifying information will be associated with the audiotaped file. All audiotapes will be destroyed after we receive the transcripts.

Who to Contact

Please feel free to ask any questions you may have now, or at any time during the interview/focus group discussion. The contact information for the Principal Investigator of the study is Ms. Michele Clark, MPH (617-997-2709; mclark11@bu.edu). You may also contact the BUMC IRB at 617-638-7207 or medirb@bu.edu if you have questions about your rights as a research subject.

Research Information Summary

Title of Project: Implementation Study of Opioid Overdose Education and Naloxone Prescribing in Clinic Settings for People Living with HIV: Identifying Opportunities for Expanding Access and Saving Lives

Principle Investigator: Michele Clark, MPH

Background

Michele Clark, MPH, a doctoral student at the Boston University of Public Health, is conducting her dissertation research on clinical approaches to opioid overdose education and naloxone prescribing for patients living with HIV (PLWH) who are at risk of potential overdose.

Purpose

The goal of this study is to examine the barriers and facilitators faced by HIV clinics in Massachusetts that are implementing varying strategies for providing overdose education and prescribing naloxone rescue kits to PLWH.

Approximately five HIV clinic sites will be selected for participation. At each site, focus groups and interviews with clinic staff will focus on their current thinking and experiences regarding overdose education and naloxone prescribing in their clinic, plus any recommendations they might have for improving clinic-based overdose education and naloxone prescribing.

You are being asked to participate in this research project because you work as a clinical provider or clinic staff member who may be involved in overdose education and/or naloxone prescribing. Your voluntary participation will consist of taking part in an interview or focus group discussion lasting up to 50 minutes.

If you choose not to participate, your job will not be affected in any way. You are free to answer the questions in any way you choose. Your point of view or opinion will not impact your job in any way. You are free not to answer a question if it makes you feel uncomfortable.

There is no stipend for your participation. Your input is important in helping guide future recommendations for opioid overdose prevention strategies in clinical settings.

Confidentiality

Interviews and focus groups will be audio-recorded for future review and analysis. Ms. Clark will be preparing a transcript of the discussion, after which she will destroy the audio recording. Individual names will not be associated with the transcripts or mentioned in the dissertation.

Today's discussion will remain as confidential as possible. The results of this interview/focus group will be summarized thematically. Your name will never be shared or linked with anything that you say. Focus group participants are also asked to help maintain the confidentiality of the process by honoring the request to keep this focus group discussion confidential. You can do this

by not talking about the content of this discussion with others outside of this room. Please be advised that although the moderator will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents her from guaranteeing confidentiality.

Whom to Contact

Please feel free to ask any questions you may have now or at any time during the study by contacting information for the Principal Investigator of the study is Michele Clark (617-997-2709; mclark11@bu.edu). You may also contact the Boston University Medical Center IRB at 617-638-7207 or medirb@bu.edu if you have questions.

Approved by the Boston University Medical Center IRB #: H-33572, 12/22/2015

APPENDIX C: Pilot Study Data Collection Tools

Physician Interview and Focus Group Participant Information Questionnaire

Understanding the Context of Implementing Overdose Education and Naloxone Kit Distribution (OEND) for Patients at Risk of Opioid Overdose in an Infectious Disease Clinic Setting

1) What is your gender?

Male

Female

2) How old are you?

< 25 years

26-35 years

36-45 years

46-55 years

56-65 years

>65 years

3) How many years have you worked at this HIV clinic?

Less than 1 – 2 years

3-5

6-10

More than 10 years

4) On average, how many sessions per week do you work at this HIV clinic?

1 session

2 sessions

3 or more sessions

5) Have you ever received training on overdose education and naloxone kit distribution?

Yes

No

6) If yes, please indicate the setting(s) where you received this training (check all that apply):

Center for Infectious Diseases

Emergency Department

Community-based organization

Medical school

Other place → please specify: _____

7) Approximately what percentage of your patients at this HIV clinic do you think could be at risk of a future opioid overdose?

10% or less

11-25%

26-50%

- 4 51-75%
- 5 more than 75%

8) Approximately what percentage of your patients at this HIV clinic do you prescribe opioids for chronic pain management?

- 1 10% or less
- 2 11-25%
- 3 26-50%
- 4 51-75%
- 5 more than 75%

9) Have you ever prescribed Narcan to your patient(s) at this HIV clinic?

- 1 Yes
- 2 No

Physician Interview and Focus Group Discussion Guide

Understanding the Context of Implementing Overdose Education and Naloxone Kit Distribution (OEND) for Patients at Risk of Opioid Overdose in an Infectious Disease Clinic Setting

INTRODUCTION

10 MINUTES

- A. Hello and welcome to our discussion, or focus group, today. Thank you for taking time to participate. We will keep the meeting to 50/60 minutes so that we finish by #:## am/pm. You should also feel free to get up and stretch, go to the bathroom, or help yourself to refreshments during the group if needed.
- B. My name is Michele Clark and I will act as the moderator for today's discussion. As you may have heard, I am a Doctor of Public Health student at the Boston University School of Public Health and doing my dissertation research. Before we begin today's focus group, I'd like to give you some background on why I am here and what I hope to learn from this discussion.

I am conducting qualitative research on clinic approaches to opioid overdose education and naloxone rescue kit prescribing for patients living with HIV at risk of potential overdose. The study is taking place within different clinical settings in Massachusetts that have recently decided to implement overdose education and prescribe naloxone rescue kits.

In order to learn about different strategies, as well as barriers and facilitators to overdose education and naloxone prescribing in clinical settings, I am talking with providers and plan to talk with patients, as well.

The goal of this formative study is to understand the context of implementing clinic-based overdose education and naloxone kit distribution for patients at risk of opioid overdose at the ____ clinic. We are interested in understanding your current thinking around OEND in the ____ clinic, as well as what makes it challenging and easier in clinical settings.

You are being asked to participate in this research project because you work in the ____ clinic. Your voluntary participation will consist of taking part in an interview or focus group discussion lasting up to 50 minutes. If you chose not to participate, your job will not be impacted in any way. You are free to answer the questions in any way you choose. Again, your point of view or opinions will not impact your job in any way. You are free to not answer a particular question if it makes you feel uncomfortable. There is no cost to you for participation, and you will not receive anything in return. Your input is so helpful to guide future recommendations for opioid overdose prevention strategies in clinical settings.

Confidentiality

We will be audio-recording the conversation so that we can analyze the themes of what we discuss with you and the other staff we will be interviewing. After the taping is complete, the Principal Investigator will be transcribing the interview/focus group discussion. No identifying information will be associated with the audiotaped file. All audiotapes will be destroyed after we receive the transcripts.

ROLES AND LOGISTICS**5 MINUTES**

-
- A. As a facilitator, my role is to make sure that we stay focused on the topic, that all the issues are touched upon as fully as possible within the time frame, and that everyone gets a chance to participate and express his or her opinion. We are here to learn about your experiences. I know you all have a lot of information and personal experiences to offer. At times, I may have to either gently interrupt and/or change the direction of the discussion so we can cover everything in the time we have.
- B. As participants, your role is to give your ideas, and share your experiences related to my questions and to comments made by other members of the group. I will ask a series of questions related to the topic, and ask for your opinions and ideas. Please remember that there is no right or wrong answers, and it is okay to have differences in opinions. The goal of today's session is not to reach consensus, but to hear diverse perspectives. Everything you tell us is valuable. It is important that you speak loudly and clearly, and that one person speaks at a time. The first part of the group will focus on your understanding of the current challenges facing patients and the current role of health literacy and patient education in addressing those challenges. We will then shift to hearing what specific strategies— both with and without resources— that you would recommend to improve patient outcomes through health literacy and patient education interventions.
- C. I want to emphasize that the discussion today will remain confidential. The results of this focus group will be reported thematically. Your name will never be shared or linked with anything that you say. We also ask all participants to help us maintain the confidentiality of the process by honoring our request to keep this focus group discussion confidential. You can do this by not talking about the content of this discussion with others outside of this room.
- D. I also want to remind you that we are audiotaping the discussion group so we can remember the important ideas you have. The tape will give us the opportunity to review what you said at a later time when we prepare a summary report. Is this okay with you?

INTRODUCTIONS**5 MINUTES**

A. Let's start with introductions. We have a lot to cover so please keep your introductions brief.

B. Please tell us:

- Your name (first names are fine)
- What department or community health center you work at
- Briefly what your role is

QUESTIONS: CURRENT PRACTICE; DESCRIPTION OF CHALLENGES, SUCCESSES**35 MINUTES****I. Questions [40 minutes]****A. Role of Overdose Education and Narcan in Patient's Lives [20 minutes]**

1) What role do you see overdose education and Narcan playing in your patients' lives?

Probe:

- To what extent do you see a need for overdose education and Narcan prescribing with the patients you see in the clinic?

2) What patients could benefit the most from overdose education and getting a prescription for Narcan?

Probe:

- Approximately what percentage of your patients could benefit from overdose education and getting a prescription for Narcan?
- Who else might benefit? Who else would you consider for this?
- What about patients who are on opioids for chronic pain management? Could they benefit from this?
- What criteria should determine if a patient should receive overdose education and Narcan?

3) Thinking about patients on opioids for chronic pain management, what typically happens when opioids are prescribed?

Probe:

- What discussions, if any, happen with your patients related to their opioid use— both medical and non-medical?

B. Implementing Overdose Education and Narcan Prescribing within the Infectious Disease Clinic [20 minutes]

Let's talk about how feasible you think it would be to implement overdose education and Narcan prescribing in the ___ clinic—both what makes it difficult and could facilitate talking to patients about overdose education and prescribing Narcan in this clinic setting.

- 4) What do you see as getting in the way of conducting overdose education with your patients and prescribing those at risk Narcan in the infectious disease clinic setting?

Probes:

- BMC policies
- Work environment
- Concerns about naloxone increasing risk
- Overdose not seen as a risk
- Lack of comfort discussing topic
- Limited time/not the priority
- Concerns about patient reaction

- 5) What solutions can you suggest that might help overcome some of the challenges to implementing overdose education and Narcan in an infectious disease clinic setting?

- 6) What about other team members' roles in the infectious disease clinic (e.g., case managers and peer educators)— who could best provide overdose education and prescribe Narcan?

Probes:

- Who would best provide the overdose education?
- Who should prescribe Narcan?
- Who could offer referral and follow-up support?

- 7) What about new models that aren't in place, such as a nurse addictions specialist who provides the education and prescribing or the pharmacist? How would those models play out?

Probes:

- Let's talk about the nurse addictions specialist model— how do you see that working with your patients and in your clinic setting?
- What about the pharmacist? What if there was a standing order where patients could request Narcan from the pharmacist and/or a pharmacist could offer Narcan to patients on opioids— how do you see that model working?

Additional Ideas for Preventing Overdose and Overdose Deaths in the Clinic Setting

- 8) What further suggestions or recommendations do you have on how overdose education and Narcan prescribing might happen more in the ___ clinic?

Probes:

- Administrative/leadership support
- Additional provider training
- Patient education about overdose education and Narcan
- Staff training and support

- Job aides
- Integrated into EMR

9) Other than overdose education and Narcan prescribing, what other prevention tools or interventions do you think are useful to reduce the risk of a person overdosing or dying from an overdose?

II. Closing [2 minutes]

Is there anything you want to discuss that has not already been discussed?

- *Summarize what was heard and thank participants for their time and sharing their experiences/ideas.*

APPENDIX D: Pilot Study Findings

Overdose Education and Naloxone Access: Barriers and Facilitators Among HIV Physicians (January 2015)

The clinic site provided both HIV and routine primary care to PLWH. This setting differed from the study sample in several regards. First, it was an infectious disease clinic based within a large, urban academic medical center rather than a community health center. Second, the number of HIV patients seen (1,653 in 2015) was significantly greater than the average number of patients seen at the CHCs in the study sample. Third, in large part to the number of patients, the care team was much larger in both size (e.g., 13 FTE physicians compared to an average of 1.3 FTE), and composition, including infectious disease fellows, along with nurses, case managers, peer educators, and in-house pharmacist educators. About 25% of the patients were estimated to have injection drug use as a risk factor (compared to 32% of the study sample). Both the preliminary study and implementation study sites had an estimated 10% of patients prescribed opioids for chronic pain management. Approximately 15% of patients were thought to be misusing or abusing opioids, compared to approximately 20% of the patients in the implementation study sample.

Similar to the study sites, the clinic was currently implementing outpatient individual or group counseling, buprenorphine treatment, naltrexone treatment, and OEND. Along with most of the study sites, this clinic also referred patients outside the organization for detox and methadone treatment services.

Unlike the implementation study sites, the pilot study clinic had not yet implemented a plan for naloxone prescribing for patients. At that time, primarily one physician— a buprenorphine provider and a champion of OEND, was prescribing naloxone. A clinic provider and staff training had been offered a few months prior, though was only attended by a couple of physicians, nurses, and case managers. At the time of data collection, and at the end of the implementation study, an overdose education and naloxone prescribing policy, EMR field, and ongoing discussion during regular meetings had not yet been happened. A standing order had just been implemented within one of the hospital pharmacies to allow for naloxone dispensing by patient request or at the pharmacists choice. Given the nascent stage of naloxone access activities at the time of the study, one of the providers noted that “we are on the steep side of the learning curve.” This timing made it particularly interesting to explore barriers and potential facilitators to broader implementation.

Pilot Study Participants

A summary of participant characteristics from this preliminary study phase can be found in Table 1. Nearly one-third of the participants (69%) were female, varying in age with almost half (46%) between 36-45 years of age. Almost half (46%) of the participants

worked at the clinic for three to five years, with 38% of them working there for over six years. The majority of physicians interviewed worked one clinic session/week, with a quarter working two sessions per week. Additional characteristics of the preliminary study participants will be described in the “Findings” chapter.

Table 1. Summary of Preliminary Study Participant Characteristics, Physicians (N=13)

Gender	
Male	4 (31%)
Female	9 (69%)
Age	
26-35	3 (23%)
36-45	6 (46%)
46-55	3 (23%)
56-65	1 (0.8%)
Years worked at clinic	
Less than 2	2 (15%)
3-5	6 (46%)
6-10	2 (15%)
More than 10	3 (23%)
Number of clinic sessions/week	
8	8 (62%)
1	3 (23%)
2	2 (15%)
3 or more	

Pilot Study Participant Experience Related to Overdose Education and Naloxone Prescribing

Table 2 summarizes participant experience related to overdose education and naloxone prescribing (OENP). Among the pilot study participants, 8 of the 13 physicians had attended an OEND training— half of them had participated in the clinic-based training, and the others had received training through residency program, state and city health department, or an online training program. Nearly half of the participants estimated that 11-25% of their patients are at risk of a future overdose, whereas about a quarter estimated 26-50% and 15% estimated 51-75% of patients are at risk, a reflection of the patient panel seen by participating physicians. For example, one of the physicians oversees patients on Suboxone, an office-based medication treatment for opioid addiction treatment, and another treats several patients receiving methadone treatment. Note that these estimates of risk are higher compared to the implementation study participants’ estimates.

Table 2. Summary of Pilot Study Participant Characteristics, Physicians (N=13)

Past OEND training receipt	
Yes	8 (62%)
No	5 (38%)
Location of past OEND training (n=8)	
Current clinic	4 (50%)
Other place	4 (50%)
Percentage of patients perceived to be at risk of future opioid overdose	
10% or less	2 (15%)
11-25%	6 (46%)
26-50%	3 (23%)
51-75%	2 (15%)
Percentage of patients prescribed opioids for pain management	
10% or less	9 (69%)
11-25%	3 (23%)
26-50%	1 (8%)
Ever prescribed Narcan at clinic	
Yes	3 (23%)
No	10 (77%)

All of the participants prescribed opioids to at least some of their patients, but the majority (69%) prescribe opioids to 10% or less of their patients, while about a quarter of the physicians reported prescribing opioids to 11-25% and only one 26-50% of patients—similar percentages to the implementation study. Despite the training receipt and perceived risk of patients at risk of an overdose along with opioid prescribing to patients, less than one-quarter of participants ever prescribed Narcan to their patients at the clinic— a lower percentage compared to the implementation study which makes sense given that these sites theoretically were implementing naloxone access activities. At the time, other than the one nurse working with the provider who regularly prescribed naloxone, no other staff members in the clinic routinely provided overdose education or a naloxone prescription to patients.

Pilot Study Interview and Focus Group Findings

Several findings emerged from this preliminary study to inform the implementation study research aims and data collection tool development. Table 3 summarizes the identified barriers and current and potential facilitators to overdose education and naloxone prescribing in the clinic. A brief summary of the four major barriers and five major facilitators follows:

Table 3. Barriers and Facilitators to Physician Implementation of OENP	
<p>Current Barriers</p> <ul style="list-style-type: none"> • Minimal time with patient • Multiple clinical priorities • Coding and prescribing • Low knowledge on how to use naloxone • Challenging to have conversations with patients on chronic opioid pain medication 	<p>Potential Facilitators</p> <ul style="list-style-type: none"> • Internal champion • Awareness of opioid crisis and data • Provider and staff training on overdose education and naloxone use • Utilization of other team members to deliver intervention • Standardized screening tool in EMR • Clarification of coding • Easy electronic prescribing in EMR • Build alerts into EMR • Post signs in waiting room and/or exam rooms • Universalize education by framing discussions as “opioid safety”

Barriers to Opioid Overdose Education and Naloxone Prescribing

Limited time and competing clinical care priorities made it difficult for physicians to discuss overdose education and naloxone prescribing during the physician clinical encounter. All of the participants indicated that limited time and competing clinical priorities prevented them from talking about overdose risk and prescribing naloxone. “So I think why we haven't done it more is because of the time barriers...having the time to give the patients the education....We have a lot of time constraints. And there are a lot of administrative activities that are implemented at the same time, we have to push that button we have to complete this other piece of paper. We have a lot of competing priorities in that 20 minutes that we have with the patient. While I understand the benefits of it, it is yet another initiative that isn't done very easily.” Another physician spoke about the time barrier of raising overdose education, *“It's not an easy conversation. I can imagine it being a 15-minute conversation or more to talk about that. Usually I've got to talk about six other co-morbid conditions and then that. And then 'Oh, I'm going to just raise Narcan.' You can't just do that in the time. I think that's a major barrier.”*

The physician participants also indicated that they conducted more overdose education and naloxone prescribing in primary care compared to the HIV clinic. While the burden of addiction per patient is likely to be higher within the HIV clinic, the volume of persons with opioid addiction or other substance use disorders is likely to be higher in primary care. Furthermore, there are more patients on buprenorphine in the primary care clinic. Therefore, innovations for overdose education and naloxone are also occurring in the primary care clinic context and through the Suboxone program, including a standing order in the primary care clinic pharmacy for naloxone that started during the time of these interviews.

Furthermore, physicians providing both HIV and primary care to patients are faced with multiple tasks. One physician explained the challenge of prioritizing multiple patient clinical needs during a single visit, *“We do primary care for our patients, and that means that you have to do HIV and hepatitis C and everything else: cholesterol, hypertension, diabetes, meal sufficiency. And they are growing old, osteoporosis, vitamin D, and then addiction management-- sure it would be nice to do it, and STD testing and treatment-- but is there a real time for it? There really isn't. Because we see patients for HIV and primary care, that is a big difference from maybe a clinic where they do purely consultative work where they manage their HIV or hepatitis C and for everything else is say, ‘see your primary care doctor.’”*

Lack of clarity on how to bill, code, and prescribe for overdose education and naloxone impeded physician overdose education and naloxone prescribing.

Physicians talked about their lack of clarity on how to bill for overdose education and naloxone. Furthermore, they were not sure how to prescribe naloxone in the current electronic prescribing system. One physician talked about the challenges she faces in a brief clinical interaction, *“We are struggling to manage the medical side of things, so this is yet another thing that you should include in your visit, such as educating about how to use Narcan, taking the time to write the prescription, how do you write it, what's the dose, how do you prescribe it? We know it needs to be done and if it were one button click away, I think I would do it for everyone.”*

Discussing opioid overdose and prescribing naloxone is harder for patients prescribed chronic opioids for pain management.

There was consensus among the participants that patients with opioid abuse history, overdose history, who have witnessed an overdose, or who have friends or family members at risk of an overdose would be priority patients to receive overdose education and naloxone.

Patients prescribed chronic opioids for pain management were also identified as those who should receive overdose education and naloxone, yet were not the always mentioned as high priority patients. One physician explained, “People on chronic meds are not in the front of my head as needing this, not because they don't need it, but because it isn't my default. Because of background of addiction, it is very easy for a patient to take a couple too many pills.” Another noted, “Sometimes after an interaction I'm thinking 'Oh I should have had that conversation.’” Some physicians expressed difficulty in reaching these patients with overdose messages for fear of stigmatizing their patients.

At the same time, the focus on the opioid crisis in national and state news and policies has changed the practice environment for providers prescribing opioids for pain management. One physician explained, “In the past two years we have heard a lot more about it, so in effect I've changed my practice, my prescribing behavior...some of the testing that we do. My awareness has changed in the past two years so I'm kind of primed for a major intervention.”

Physicians not the most appropriate role to deliver and sustain overdose education and naloxone prescribing. The majority of physicians believed that physicians were not the most appropriate care team members to offer overdose education and prescribe or deliver naloxone. In fact, this strong sentiment was expressed by a few of the participants, and clearly stated by one participant as follows, *“Leaving this up to the doctor is a sure thing to kill the initiative.”* Many of the other barriers previously discussed, in part, explain this belief, including lack of time and need for ongoing training and education. One provider cautioned, *“I think the actual piece of education means let’s open up the kit and look at it and see how we are going to do it. I definitely would not be able to do that. I think the pharmacy that is dispensing it would be a good place to do it because they will have to explain how to use it. And if we had test kits in the clinic we could have the nurses, our addictions nurse, demonstrate to patients how to use it.”* While providers may do it sporadically, there was strong agreement that putting this initiative into the hands of other staff who could more universally implement this with patients (e.g., patients receiving chronic pain medication) would maintain and sustain naloxone access.

While physicians did not see themselves as the primary educators, it should be noted that without a standing order in place, physicians would still need to be involved in the naloxone prescribing and potentially the referral to a team member— which would require an assessment to determine who should get referred for OEND. A team-based approach to overdose education and naloxone prescribing was recommended, taking it out of the hands of the physician. *“I feel that the flu shot is a good corollary. So the flu shot in some ways has been taken out of the hands of the providers. Where they come to the clinic for any type of visit and they can get offered a flu shot and get it. I think something like that where not that we don’t do it but it’s more of a team-based approach like with the flu vaccination.”*

There were differing opinions about the best team members to provide overdose education and naloxone to patients. Suggestions included:

- HIV clinic pharmacists provide dedicated training to patients on a variety of medications. One provider explained, *“The pharmacists cover almost every session and conduct HIV adherence counseling, and they will also do polypharmacy discussions, diabetes, smoking cessation. They could add Narcan to the discussion.”*
- Peer educators and case managers could talk patients about overdose prevention and naloxone, particularly given that they are trained to provide support around the “emotional” aspects of overdose and addiction.
- A specialized addiction nurse on staff could offer overall prescription pain management education and monitoring for patients, along with overdose education and naloxone. One noted, *“I think practically it’s going to have to be a referral to a specialty teaching service, somebody who can train them, whose gets issues of expiration, technique, all that kind of stuff. It’s like sending somebody to weight loss clinic, that’s a specialty service which is really important but we can’t*

do that.” Another provider compared this specialist nurse educator role to nurse educators who conduct diabetes insulin or warfarin education to patients. Having a specialized educator would ultimately allow the providers to better manage pain medication. The challenges of prescribing opioids and managing addiction posed enormous challenges to one physician. She explained, *“If the medical director came and she said make it the rule that all pain medicine has to go through this doctor and nurse who specialize in pain medicine, I would be the happiest person.”* The provider did, however, acknowledge the current provider capacity issues with such a model and that patients would require patients to wait weeks to be seen. This is one of the challenges of the current model of having a solo provider champion who regularly integrates this into his practice.

- Mental health counselors were thought to be well suited to discuss overdose with patients. One provider explained her thinking, *“I would say the mental health counselors they do see the patients and interact with them a little bit more and have more time in general than the psychiatrists, so that may be another opportunity to at least bring it up under the category of safety at home.”* She also spoke about the role of psychiatrists prescribing benzodiazepines to patients on prescription opioids, and that this would be an opportunity to talk to patients about overdose risk and naloxone.

Facilitators to Opioid Overdose Education and Naloxone Prescribing

A champion who is passionate about overdose prevention plays a major role in opioid overdose and naloxone prescribing. In this clinic setting, one physician in particular prescribed naloxone regularly to his patients. The role of a champion seemed to have two effects. First, these individuals can demonstrate that this practice can be done despite the identified barriers. One provider explained, *“I think someone has to stand up and raise their hand and say, ‘I’m going to be the champion.’ That is what has happened elsewhere where it has been successful...It’s got to be somebody who thinks it’s important. The case managers to some degree specialize in different patient populations, all of the attendings have their niche of patients that they get excited about.”* This may mean that providers think of this one physician as the one to refer high-risk patients to, rather than trying the intervention themselves or diffusing the intervention across providers. One physician noted, *“If I could refer all of my high-risk opioid user patients to [name of champion], that would make my job so much easier.”* The challenge with this approach, as described by this same participant, is that patients are getting opioid-related support services based on one provider’s *“...individual relationships as opposed to a systemic response. And I think this institution needs a systemic response.”* Thus, strategies to diffuse a champion’s expertise and practice to the broader system are needed.

Second, champions can heighten awareness about the importance and benefits of prescribing naloxone to other providers in the clinic. Another physician explained, *“I think most physicians are not aware of the problem with overdoses, the solution for*

overdoses, the ability of having naloxone be used very easily in the field by people who are minimally trained or with very little training. I think most physicians are not aware that this is happening...and it makes a difference. When you see the numbers. After seeing [name of champion] present the numbers... they are so shocking. You also then begin to become more in tune to your patients' messages. This is how I kind of paid attention to the fact that a patient of mine that I see seldom told me how she basically overdosed in the street with her pain medicine, and then you realize this is happening, that people are probably using opioids, that other people in the household have access to their opioids."

Framing discussions with patients about opioid overdose risk in terms of “opioid safety” helps normalize risk. A couple of physicians spoke about the importance of addressing opioid safety rather than overdose risk with patients who do not have an acknowledged addiction: *“It is better to really emphasize opioid safety, instead of overdose...when you are talking about an individual's risk who doesn't acknowledge that they have an addiction, it's probably better to talk about opioid safety. We want to talk to patients about this as a safety issue and make it clear to patients that we are not assuming that they are going to overdose or that we are not assuming that they are not going to take their medication in anyway other than prescribed.”* Coming at the importance of having a naloxone kit on hand from the perspective of the patient's caregiver role was seen as particularly helpful in aiding communication—to protect their family members and friends. Physicians spoke about the importance of making overdose education a universal practice, *“...like we are talking to everyone who is on a pain med... I think if you universalize it makes it a little bit less uncomfortable.”*

Training and education initiatives could expand provider and staff participation in overdose education and naloxone prescribing. As seen from the participant characteristics data, less than a quarter of the participants received OEND training. One provider noted that physician awareness and knowledge is individually-driven based on their interest. As a result of not having seen what is involved in overdose education, a couple of providers expressed concern about what to tell patients. One noted, *“I mean I know what it does, and I know why it's important, but that's not the questions that patients will ask me, ...So actually I avoid it, which probably isn't constructive behavior.”* A couple of other providers talked about the complexity of naloxone administration, noting that it required ongoing, hands-on learning with a mannequin and knowledge of how to use the syringe. One provider explained, *“Epi-pen is easy, simple, not clinically complex like insulin, warfarin, or overdose.”* This lack of self-efficacy in understanding the mechanics of using naloxone during an overdose posed barriers for several of the providers. One provider explained, *“I have the education piece on my bulletin board, but I haven't gone to the training. And so I am kind of sketchy myself about what they are supposed to do in the field. I know it is something they are supposed to spray in the nose, but in fact the reason I still have that piece of paper there is because I am a little leery of how to do it myself. So currently I wouldn't be able to teach my*

patients what to do with it [naloxone]. Well it is something you need to spray in the nose, is the extent of my knowledge, but I haven't touched a kit, I haven't literally seen a kit."

The EMR could support standardized patient overdose risk assessment. Physicians talked about the need for more information from the EMR on patient's risk, naloxone prescription status, and overdose history. A structured assessment could support providers or provider teams in ensuring overdose risk was assessed in a standardized way across patients. One physician explained, *"We used to have a very structured intake process in the ID clinic, its morphed so many times that I don't know if tis done in a reliable way anymore over the past few years."* Another noted, *"We need a system in place...for data, for keeping any data on health maintenance or things like that."* In addition to guiding assessment and documenting findings, physicians talked about how these alerts could support their patient discussions.

Prompts may support providers in offering overdose education and prescribing naloxone to patients. Several participants talked about the need for decision tools to guide their patient overdose risk assessment activities. Different formats were suggested. Providers recommended an alert in the EMR to help identify need and/or past receipt of overdose education and naloxone. One explanation was, *"It would be nice if there was a like a Logician pop-up. Now that we have those things they print out for us with the vaccine status, lit could include patient on opiates, naloxone status, or something like that...you know It's hard to remember all these things when the patient comes in, with chest pain, they are bleeding, and you know. I think if there was some sort of automatic reminder system it would be helpful."* In fact, one provider explained how a patient's medication facilitated her conversation about naloxone with a patient for whom she was prescribing pain medication: *"I saw that she had naloxone on her list, and I asked if she had Narcan at home and do you know how to use it...She was very upfront about it. She answered questions and it was definitely this little alert that made me ask about it because it was in the record, in the medication list. It would be the kind of thing that would make me ask, 'Do you need refills? Do you have refills?' Kind of like an Epi-pen situation. Do you need refills? Have you used it? It's a discussion opener."* Providers also suggested putting posters in the waiting and exam rooms to help engage both providers and patients. As one provider noted, *"If you put a poster up that said 'would you like to learn how to save someone's life from an overdose?' That might catch a few people."* Others went on to talk about how such educational messages could engage patients who are not directly at risk, but may have a family member or friend who is at risk of an overdose. Furthermore, as another provider added to the discussion, such messages may help normalize discussions about overdose.

Several (n=11) constructs from the CFIR emerged from these preliminary study findings, as documented in Table 3 below. As can be seen in the next section, the findings from the implementation study both drew and expanded upon these initial findings due to the higher sample size and implementation experience of the selected sites.

Table 3. Relevant CFIR Constructs Emerged from Pre-implementation Study	
Construct	Finding
I. Innovation Characteristics	
<ul style="list-style-type: none"> • Complexity 	<ul style="list-style-type: none"> • Discussing overdose and naloxone perceived to be disruptiveness, lengthy in duration, and complicated
II. Outer Setting	
<ul style="list-style-type: none"> • Needs and Resources of Those Served by the Organization 	<ul style="list-style-type: none"> • Easier to talk with patients with current or past opioid substance use disorder compared to patients prescribed opioids for chronic pain management
III. Inner Setting	
<ul style="list-style-type: none"> • Structural Characteristics • Implementation Climate: Relative Priority • Readiness for Implementation: Available Resources • Access to Knowledge and Information 	<ul style="list-style-type: none"> • Utilization of interdisciplinary care team offers multiple opportunities for who can deliver intervention • Multiple clinical demands and priorities impede discussion • Limited time during patient encounter • Need for training on the mechanics of naloxone use; Decision tools, such as screening tools and prompts in the EMR
IV. Characteristics of Individuals	
<ul style="list-style-type: none"> • Self-efficacy • Individual Stage of Change 	<ul style="list-style-type: none"> • Provider lack of confidence in their ability to implement overdose education and prescribe naloxone • Variation in provider passion, skill, and sustained overdose education discussions with patients and naloxone prescribing
V. Planning	
<ul style="list-style-type: none"> • Champions • Key Stakeholders • Innovation Participants 	<ul style="list-style-type: none"> • Individual provider who prioritizes and focuses on overdose prevention within clinic • Availability of staff within clinic who could play a role in intervention delivery (e.g., nurses, case managers, peer educators, pharmacists) • Need for strategies (e.g., posters in exam rooms) to engage patients

APPENDIX E: Clinic Characteristics Survey

*Implementation Study of Opioid Overdose Education and Naloxone Prescribing
in Clinic Settings for People Living with HIV:
Identifying Opportunities for Expanding Access and Saving Lives*

Thank you for taking 10 minutes to complete this survey.

The survey asks about your clinic's characteristics with a focus on clinical care for persons living with HIV (PLWH) at your clinic. Specifically, this survey asks about opioid overdose and naloxone prescribing activities for patients with HIV at your clinic.

Completion of this is completely voluntary, and you may skip any questions you'd prefer not to answer. Please feel free to send this to someone else in your clinic to complete if helpful. Please note that no reports or presentations will provide any information identified by clinic name.

Thank you very much for participating in this project. The findings will be useful for supporting opioid overdose prevention activities within routine, outpatient clinical care settings for PLWH.

A. HIV Clinic Background Information

1. Which of the following best describes your clinic organization? (Select one)

- Academic medical center clinic
- Other hospital-based clinic
- Federally Qualified Health Center/Community health center clinic
- Other private, non-profit clinic
- Other, please specify: _____

2. Which of the following best describes how the majority of your HIV patients get primary and HIV care? (Select one)

- HIV patients get both primary care and HIV care at this clinic site
- HIV patients get primary care outside this HIV clinic, but within this organization
- HIV patients get primary care outside this organization, and are referred here for HIV care

3. What external funding sources, if any, does your clinic currently receive to support the care of patients with HIV? (Check all that apply)

- Ryan White (state or federal)
- Other federal, non-Ryan White
- Other state, non-Ryan White
- Private/foundation funding
- Our clinic does not receive external funding for HIV services
- Not sure

4. Please indicate the approximate full-time equivalency (FTE) of your clinic staff members, not including administrative staff, housed directly within your clinic, who support the care of patients with HIV. (Write “0” if staff type not providing HIV care at your clinic)

HIV Clinic Staff Type	FTE (0-1.0)
Physician	
Nurse practitioner	
Physician’s assistant	
Nurse	
Case manager	
Social worker	
Patient/peer educator	
Community education specialist/outreach worker	
Patient navigator	
Pharmacist based within HIV clinic	
Other→Please specify: _____	
Other→Please specify: _____	

5. Please indicate the availability of opioid substance use services for your clinic patients with HIV. (Check all that apply)

	Have within agency	Do not have on-site, but have a formal referral process with program	Do not have on-site, but refer patients to program without a formal relationship with program	Do not have on-site and do not refer patients
Detox program				
Outpatient individual or group counseling				
Buprenorphine treatment				
Naltrexone treatment				
Methadone treatment				
Overdose education and naloxone distribution program				

6. When did your clinic begin offering overdose education and naloxone prescribing to patients with HIV seen during routine clinical care visits?

- In the past 3 months
- In the past 4-6 months
- In the past 7-12 months
- In the past 13-18 months
- In the past 19-24 months
- More than 24 months ago

7. Please indicate the implementation status of various overdose education and naloxone prescribing-related activities within your clinic providing routine care to patients with HIV. (Select one per row)

	Have implemented	Planning to implement in the next 6 months	No plans to implement in the next 6 months
Staff training on opioid overdose and naloxone prescribing			
Distribution of education materials to clinic staff			
Development of clinic protocol including opioid overdose and naloxone prescribing			
Stocking of naloxone within clinic pharmacy			
Established partnership with pharmacy to conduct overdose education and distribute naloxone			
Added electronic medical record field for naloxone prescribing			
Distribution of patient education materials about overdose education and naloxone			
Tracking and monitoring of naloxone prescribing data within clinic			
Regular, ongoing communication (e.g., during monthly staff meetings) with clinic staff about overdose education and naloxone prescribing activities			

B. Patient Information

8. Approximately how many adult patients received HIV care at this clinic site in CY 2015? _____

9. Please list the top three cities or towns where the majority of your HIV patients reside. If the majority comes from two or one city or town, then only list those places.

1. _____
2. _____
3. _____

9. Please list the approximate percentage of your adult HIV patients covered by the following types of health insurance. Please provide your best estimate—percentages should add up to 100%.

- _____ % Medicare
- _____ % Mass Health
- _____ % Dually eligible for Medicare/Mass Health
- _____ % Commercially insured
- _____ % None/uninsured

100% Total

10. Please list the approximate percentage of your adult HIV patients in each of the following age categories. Please provide your best estimate—percentages should add up to 100%.

- _____ % 18-24 years
- _____ % 25-44 years
- _____ % 45-64 years
- _____ % 65 years and older
- 100% Total**

11. Please list the approximate percentage of your adult HIV patients in each of the following gender categories. Please provide your best estimate—percentages should add up to 100%.

- _____ % Male
- _____ % Female
- _____ % Transgender
- 100% Total**

12. Please list the approximate percentage of your HIV patients in the following racial/ethnic categories. Please provide your best estimate—percentages should add up to 100%.

- _____ % Black/African American (not Hispanic or Latino)
- _____ % White (not Hispanic or Latino)
- _____ % Asian (not Hispanic or Latino)
- _____ % Native Hawaiian/Pacific Islander (not Hispanic or Latino)
- _____ % American Indian/Alaska Native (not Hispanic or Latino)
- _____ % Multi-racial (not Hispanic or Latino)
- _____ % Hispanic/Latino
- 100% Total**

13. Approximately what percentage of your HIV patients has injection drug use as a risk factor? _____

14. Approximately what percentage of your HIV patients are currently on a chronic opioid prescription for pain management? _____

15. Approximately what percentage of your HIV patients are currently misusing or abusing opioids? _____

16. In the past six months, approximately how many HIV patients have been prescribed a take-home naloxone rescue kit from your clinic staff? _____

17. Please feel free to add any comments or questions to clarify any of the responses.

Thank you very much for taking the time to complete this survey. I look forward to meeting with you and your clinic team soon to learn more about your clinic's overdose education and naloxone prescribing activities.

APPENDIX F: Participant Survey

Clinic Staff Interview and Focus Group Participant Questionnaire

*Implementation Study of Opioid Overdose Education and Naloxone Prescribing
in Clinic Settings for People Living with HIV:
Identifying Opportunities for Expanding Access and Saving Lives*

3) What is your gender?

- Male
- Female
- Transgender

4) What is your age?

- < 25 years
- 26-35 years
- 36-45 years
- 46-55 years
- 56-65 years
- >65 years

10) What is your role at this clinic?

- Physician
- Physician Assistant
- Nurse Practitioner
- Registered Nurse
- Case Manager
- Social Worker
- Patient Navigator
- Peer Educator
- Other → *Please specify:* _____

11) How many years have you worked at this clinic?

- Less than 2 years
- 3-5 years
- 6-10 years
- More than 10 years

12) In a typical week, how many patients with HIV do you see at this clinic? _____

13) Have you ever received training on opioid overdose education and naloxone kit distribution?

- Yes
 No → *If no, skip to #8 below.*

14) If yes, please indicate the setting(s) where you received this training (check all that apply):

- Medical school or nursing school
 Current workplace
 Community-based organization
 Online webinar
 Other place → *Please specify:*

15) Approximately what percentage of patients with HIV whom you see at this clinic do you think could be at risk of a future opioid overdose?

- 10% or less
 11-25%
 26-50%
 51-75%
 more than 75%

16) Which of the following statements best captures your involvement with talking to your patients with HIV at this clinic about the risk of opioid overdose and prevention steps they can take?

- I have not thought much about it
 I have information about how to do this, but have not yet done it
 I have talked with other clinic staff about this, but have not yet done it
 I intend to try this in the next three months
 I have tried this but don't do it regularly
 I do this regularly
 I have integrated this into my routine clinical care and have promoted it to other clinic staff

17) For prescribers: Approximately what percentage of your patients with HIV who you see at this clinic do you prescribe opioids for chronic pain management?

- 10% or less
 11-25%
 26-50%
 51-75%
 more than 75%

18) For prescribers: Approximately how many naloxone prescriptions have you written in the past 12 months to patients with HIV in this clinic? _____

19) ***For prescribers: Which of the following statements best captures your involvement with prescribing naloxone to your patients at this clinic?***

- ₁ I have not thought much about it
- ₂ I have information about how to do this, but have not yet done it
- ₃ I have talked with other clinic staff about this, but have not yet done it
- ₄ I intend to try this in the next three months
- ₅ I have tried this but don't do it regularly
- ₆ I do this regularly
- ₇ I have integrated this into my routine clinical care and have promoted it to other clinic staff

Thank you!

APPENDIX G: Interview/Focus Group Guide

*Implementation Study of Opioid Overdose Education and Naloxone Prescribing
in Clinic Settings for People Living with HIV:
Identifying Opportunities for Expanding Access and Saving Lives*

INTRODUCTION/STUDY BACKGROUND/CONSENT

Thank you for taking time to participate in this study. We will keep the meeting to about [30-50 minutes] so that we finish by [#:## am/pm].

My name is Michele Clark and I am the interviewer/moderator for today's discussion. I am a Doctor of Public Health student at the Boston University School of Public Health, and I am talking to you as part of my dissertation study.

I am conducting qualitative research on clinic approaches to opioid overdose education and naloxone rescue kit prescribing for patients living with HIV who are at risk of potential overdose. The study is taking place at several primary care clinics in Massachusetts that provide routine, outpatient care to persons living with HIV.

I have circulated an information summary sheet about this study, which has been approved by the Boston University Medical Campus IRB. Please let me know if you have any questions at any time, either now or after our interview.

I am talking with providers and staff providing HIV care in order to learn about different strategies for providing overdose education and naloxone prescribing in clinical settings, plus the barriers and facilitators that affect your practice. In particular, I am interested in understanding your current thinking about opioid overdose education and naloxone prescribing— what works, what doesn't work— and what makes it challenging— or easier— to do this work in HIV clinical settings. Because I am not an expert in this area, I may ask you to clarify your comments.

Your participation is voluntary. If you chose not to participate, your job will not be impacted in any way. You are free to answer the questions in any way you choose, again with no impact on your job. You are free to not answer a particular question if it makes you feel uncomfortable.

There is no cost to you for participation, and you will not receive anything in return. Your input will be helpful in guiding future recommendations for opioid overdose prevention strategies in clinical settings.

I want to emphasize that our conversation today will remain confidential. The results of this interview will be summarized thematically. Your name will never be shared or linked with anything that you say.

[For focus groups] As a facilitator, my role is to make sure that we stay focused on the topic, that all the issues we need to cover are discussed as fully as possible within our allotted time, and that everyone gets a chance to participate and express their opinion.

I am here to learn about your experiences. I know you all have a lot of information and personal experiences to offer. At times, I may have to gently interrupt or change the direction of the discussion so we can cover everything in the time we have. Also, because I am not an expert in this area, I may ask you to clarify your comments.

As participants, your role is to share your ideas and experiences in response to my questions and comments made by other members of the group. Please remember that there is no right or wrong answers, and it is okay to have differences in opinions. The goal of today's session is not to reach consensus, but to hear diverse perspectives. Everything you tell me is valuable. It is important that you speak loudly and clearly, and that one person speaks at a time.

I want to emphasize that our discussion today will remain as confidential as possible. The results of this focus group will be summarized thematically. Your name will never be shared or linked with anything that you say. I also ask all participants to help us maintain the confidentiality of the process by honoring our request to keep this focus group discussion confidential. You can do this by not talking about the content of this discussion with others outside of this room. Please be advised that although I will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents me from guaranteeing confidentiality.

I also want to remind you that I am audiotaping the discussion group so I can remember the important ideas you have. The recording will give us the opportunity to review what you said at a later time when I prepare a summary report.

Do you have any questions about the study or process?

I wanted to confirm your consent for participating in this interview.

Is it okay for me to begin the audio recorder?

INTERVIEW/DISCUSSION QUESTIONS

10) Please describe **overdose education and naloxone prescribing activities currently going on** at [clinic name] for patients with HIV receiving care here. First, I'm interested in hearing about overdose education activities, and then I'll ask about naloxone prescribing.

A) Opioid overdose education

Probes:

➤ What staff (roles) are doing overdose education with patients?

- What patients receive the overdose education? What criteria do you use?
- How long does it take?
- What is typically covered during that discussion?
- Who is prescribing naloxone?

B) Naloxone prescribing

- Who in this clinic prescribes naloxone to patients?
- What patients receive naloxone prescriptions? What criteria do you use?
- Where do patients pick up their naloxone prescription [or if not a prescription approach, explain process for how patients access naloxone (e.g., in clinic, from pharmacy, from program)]?

11) **Thinking about your patients** with HIV at this clinic, who do you think could benefit most from overdose education and a naloxone prescription?

Probes:

- To what degree is overdose a concern for you among your patients?
- To what extent do providers know if patients have overdosed?
- How is overdose risk assessed with your patients?
- How frequently is that done with patients?
- What patients in particular do you see at risk of an overdose?
- How is overdose education and naloxone prescribing differently considered/implemented for patients who are using illicit drugs rather than patients on chronic opioid medicine for pain?

[Summarize model described]

12) Please summarize the **process** for how opioid overdose education and naloxone prescribing became introduced/integrated at this clinic. What were the key factors that went into the planning process and early stages of implementation?

Probes:

- Perceived need?
- Patient and caregiver engagement/request?
- Who participated in the decision to implement?
- How were clinic staff engaged in the process?
- How were patients engaged in the process?
- What determined the model your clinic uses?
- What supported implementation (e.g., training, champion provider, decision aides)?

13) To what extent have **policies**— both external to your organization and internal to your organization-- influenced your HIV clinic's adoption of overdose education and naloxone prescribing?

Probes:

- Federal policies, from SAMHSA, HHS, CMS?
- State policies, naloxone access laws in Massachusetts; Governor's Opioid Abuse Plan; prescribing guidelines?
- Organizational policies, including clinic, hospital, commercial insurance providers?

- 14) What has your/your clinic's **experience been— both positive and negative**— as you've worked to integrate overdose education and naloxone prescribing into your clinical care practice, particularly for PLWH?

Let's start with what has helped. What has supported your/your clinic's integration of overdose education and naloxone prescribing for your patients?

Probes:

- Staff training?
- Staffing models (e.g., case managers/peer educators/community outreach workers)
- Support from other providers/ other clinic staff?
- EMR prompts?
- Job aides for providers?
- Protocol/policy for all providers to follow?
- Educational materials for patients?
- In-house referral services for people addicted to opioids (e.g., buprenorphine program or other treatment services; OEND program)?
- Support from caregivers of patients?
- Partnership with pharmacist (in-house or community-based)?

- 15) What has been challenging to conduct overdose education and naloxone prescribing for your patients?

Probes:

- Time?
- Coordination across clinic staff?
- Prescribing in EMR?
- Cost?
- Provider confidence— need for more information about effectiveness of intervention and need skills in naloxone use and talking to patients (e.g., training)?
- Provider beliefs— concern of naloxone as “safety net”
- Concern of stigmatizing patients?
- Patient resistance?
- Need to educate caregiver/friend if patient is at risk of overdose?
- Board/community response?
- Legal concerns?
- Pharmacy process for getting naloxone?

- 16) Thinking about how your clinic functions, **who do you think should be providing overdose education and naloxone to your patients with HIV?**

Probes:

- Clinical providers?
- Case managers?
- Peer educators?
- Pharmacists?
- Other?

- 17) How, if at all, does your clinic **monitor** the implementation of overdose education and naloxone prescribing activities?

Probes:

- Feedback from patients?
- Feedback from providers?
- Review of prescribing data at regular clinic provider/staff meetings?
- Level of prescribing in clinic?

- 18) What have been the **outcomes** of overdose education and naloxone prescribing to patients at your HIV clinic? In other words, what have you learned?

Probes:

- Provider impact?
- Patient impact?
- Time?
- Costs?

RECOMMENDATIONS

- 19) What **solutions can you suggest or are you thinking about for the future** that might help overcome some of the challenges to implementing overdose education and naloxone prescribing in a routine primary care setting that provides care to PLWH?

Probes:

- Who would best provide the overdose education?
- Who should prescribe naloxone?
- Who could offer referral and follow-up support?

- 20) What **further suggestions or recommendations** do you have regarding overdose education and naloxone prescribing, particularly for other clinics beginning to implement a program?

Probes:

- Administrative/leadership support?
- Additional provider training?
- Staff training?
- Patient education about overdose education and naloxone?
- Job aides (e.g., protocol, education sheet; education and counseling code provision)?
- Integrated into EMR?
- Monthly data and case reviews?

- 21) Other than overdose education and naloxone prescribing, **what other prevention tools or interventions within your clinic do you think can be useful for reducing the risk of a person overdosing or dying from an overdose?**

Probes:

- Provision of medication-assisted treatment?

- In-house mental health and substance use counselors?
- Implementing chronic opioid prescribing guidelines?
- Use of PMP?

CLOSING

If relevant, ask: who else from your clinic would be appropriate for me to talk with to hear additional experiences about overdose education and naloxone prescribing within your clinical context?

Suggest based on model:

- Other clinical providers/prescribers
- Suboxone providers
- Social workers/peer educators/case managers/outreach workers
- Pharmacists
- Staff from other in-house program (e.g., OEND)

Thank you for your time and sharing your experiences about overdose education and naloxone prescribing in your clinical care setting. I hope to be able to learn about implementation strategies across multiple clinic sites that I am talking with during the course of my dissertation research.

APPENDIX H: Document Summary Form*

Study Site Code:

Document Number:

Date Received: _____

Document Date: _____

Name of Document: OENP Protocol

Type of Document:

- Clinic protocol
- Provider job aide
- Patient education material
- Other, specify:

Associated Event (if relevant):

Brief Summary of Document Contents:

Significance, Purpose, Use, or Importance of Document:

How Document Relates to Interview Questions and Study Constructs:

Additional Comments/Reflections/Issues:

*Adapted from: Miles MB, Huberman AM. *Qualitative Data Analysis: An Expanded Sourcebook, 2nd Edition*. 2nd edition. Thousand Oaks: SAGE Publications, Inc.; 1994.

APPENDIX I: Interview and Focus Group Summary Memo*

Date: _____ **Time:** _____ **Interview/Focus Group Code:** _____

Type of Data Collection

- Interview (In-Person)
- Interview (Telephone)
- Focus Group → **Number of Participants:** _____

- 1. What observations did you make during your visit to the clinic? Specify setting and duration.**

- 2. What were the main issues or themes that struck you after this interview or focus group? Identify the salient points made, organized by CFIR constructs.**

- 3. Summarize the information learned from the responses to each question that was asked.**

- 4. What else stood out as salient, interesting, illuminating, or important?**

- 5. What new or remaining questions exist for this site, including any items for follow-up in future interview(s) or focus group(s)?**

- 6. What questions/probes/ideas should be explored with the other study sites?**

*Adapted from: Miles MB, Huberman AM. *Qualitative Data Analysis: An Expanded Sourcebook, 2nd Edition*. 2nd edition. Thousand Oaks: SAGE Publications, Inc.; 1994.

APPENDIX J: CFIR Codebook** From www.cfirguide.org May 2016

Note: This template provides inclusion and exclusion criteria for most constructs. Please post additional inclusion and exclusion criteria, guidance, or questions to the [CFIR Wiki](#) discussion tab in order to help improve the CFIR.

This template only includes CFIR definitions and coding criteria; codebooks may include other information, such as examples of coded text, rating guidelines, and related interview questions.

I. Innovation**Characteristics**

A. Innovation Source	<u>Definition:</u> Perception of key stakeholders about whether the innovation is externally or internally developed.
	<u>Inclusion Criteria:</u> Include statements about the source of the innovation and the extent to which interviewees view the change as internal to the organization, e.g., an internally developed program, or external to the organization, e.g., a program coming from the outside. Note: May code and rate as "I" for internal or "E" for external.
	<u>Exclusion Criteria:</u> Exclude or double code statements related to who participated in the decision process to implement the innovation to Engaging , as an indication of early (or late) engagement. Participation in decision-making is an effective engagement strategy to help people feel ownership of the innovation.
B. Evidence Strength & Quality	<u>Definition:</u> Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes.
	<u>Inclusion Criteria:</u> Include statements regarding awareness of evidence and the strength and quality of evidence, as well as the absence of evidence or a desire for different types of evidence, such as pilot results instead of evidence from the literature.
	<u>Exclusion Criteria:</u> Exclude or double code statements regarding the receipt of evidence as an engagement strategy to Engaging : Key Stakeholders.
	Exclude or double code descriptions of use of results from local or regional pilots to Trialability .
C. Relative Advantage	<u>Definition:</u> Stakeholders' perception of the advantage of implementing the innovation versus an alternative solution.

	<p><u>Inclusion Criteria:</u> Include statements that demonstrate the innovation is better (or worse) than existing programs.</p> <p><u>Exclusion Criteria:</u> Exclude statements that demonstrate a strong need for the innovation and/or that the current situation is untenable and code to Tension for Change.</p>
D. Adaptability	<p><u>Definition:</u> The degree to which an innovation can be adapted, tailored, refined, or reinvented to meet local needs.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the (in)ability to adapt the innovation to their context, e.g., complaints about the rigidity of the protocol. Suggestions for improvement can be captured in this code but should not be included in the rating process, unless it is clear that the participant feels the change is needed but that the program cannot be adapted. However, it may be possible to infer that a large number of suggestions for improvement demonstrates lack of compatibility, see exclusion criteria below.</p> <p><u>Exclusion Criteria:</u> Exclude or double code statements that the innovation did or did not need to be adapted to Compatibility.</p>
E. Trialability	<p><u>Definition:</u> The ability to test the innovation on a small scale in the organization, and to be able to reverse course (undo implementation) if warranted.</p> <p><u>Inclusion Criteria:</u> Include statements related to whether the site piloted the innovation in the past or has plans to in the future, and comments about whether they believe it is (im)possible to conduct a pilot.</p> <p><u>Exclusion Criteria:</u> Exclude or double code descriptions of use of results from local or regional pilots to Evidence Strength & Quality.</p>
F. Complexity	<p><u>Definition:</u> Perceived difficulty of the innovation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.</p> <p><u>Inclusion Criteria:</u> Code statements regarding the complexity of the innovation itself.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding the complexity of implementation and code to the appropriate CFIR code, e.g., difficulties related to space are coded to Available Resources and difficulties related to engaging participants in a new program are coded to Engaging: Innovation Participants.</p>

G. Design Quality & Packaging	<p><u>Definition:</u> Perceived excellence in how the innovation is bundled, presented, and assembled.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the quality of the materials and packaging.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding the presence or absence of materials and code to Available Resources.</p> <p>Exclude statements regarding the receipt of materials as an engagement strategy and code to Engaging.</p>
H. Cost	<p><u>Definition:</u> Costs of the innovation and costs associated with implementing the innovation including investment, supply, and opportunity costs.</p> <p><u>Inclusion Criteria:</u> Include statements related to the cost of the innovation and its implementation.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to physical space and time, and code to Available Resources. In a research study, exclude statements related to costs of conducting the research components (e.g., funding for research staff, participant incentives).</p>
II. Outer Setting	
A. Needs & Resources of Those Served by the Organization	<p><u>Definition:</u> The extent to which the needs of those served by the organization (e.g., patients), as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization.</p> <p><u>Inclusion Criteria:</u> Include statements demonstrating (lack of) awareness of the needs and resources of those served by the organization. Analysts may be able to infer the level of awareness based on statements about: 1. Perceived need for the innovation based on the needs of those served by the organization and if the innovation will meet those needs; 2. Barriers and facilitators of those served by the organization to participating in the innovation; 3. Participant feedback on the innovation, i.e., satisfaction and success in a program. In addition, include statements that capture whether or not awareness of the needs and resources of those served by the organization influenced the implementation or adaptation of the innovation.</p> <p><u>Exclusion Criteria:</u> Exclude statements that demonstrate a strong need for the innovation and/or that the current situation is untenable and code to Tension for Change.</p>

	Exclude statements related to engagement strategies and outcomes, e.g., how innovation participants became engaged with the innovation, and code to Engaging: Innovation Participants .
B. Cosmopolitanism	<p><u>Definition:</u> The degree to which an organization is networked with other external organizations.</p> <p><u>Inclusion Criteria:</u> Include descriptions of outside group memberships and networking done outside the organization.</p> <p><u>Exclusion Criteria:</u> Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to Networks & Communications.</p>
C. Peer Pressure	<p><u>Definition:</u> Mimetic or competitive pressure to implement an innovation, typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.</p> <p><u>Inclusion Criteria:</u> Include statements about perceived pressure or motivation from other entities or organizations in the local geographic area or system to implement the innovation.</p> <p><u>Exclusion Criteria:</u></p>
D. External Policy & Incentives	<p><u>Definition:</u> A broad construct that includes external strategies to spread innovations including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.</p> <p><u>Inclusion Criteria:</u> Include descriptions of external performance measures from the system.</p> <p><u>Exclusion Criteria:</u></p>
III. Inner Setting	
A. Structural Characteristics	<p><u>Definition:</u> The social architecture, age, maturity, and size of an organization.</p> <p><u>Inclusion Criteria:</u></p> <p><u>Exclusion Criteria:</u></p>
B. Networks & Communications	<p><u>Definition:</u> The nature and quality of webs of social networks, and the nature and quality of formal and informal communications within an organization.</p>

	<p><u>Inclusion Criteria:</u> Include statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning.</p>
	<p><u>Exclusion Criteria:</u> Exclude statements related to implementation leaders' and users' access to knowledge and information regarding using the program, i.e., training on the mechanics of the program and code to Access to Knowledge & Information.</p>
	<p>Exclude statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation, and code to Engaging: Key Stakeholders.</p>
	<p>Exclude descriptions of outside group memberships and networking done outside the organization and code to Cosmopolitanism.</p>
C. Culture	<p><u>Definition:</u> Norms, values, and basic assumptions of a given organization.</p> <p><u>Inclusion Criteria:</u> Inclusion criteria, and potential sub-codes, will depend on the framework or definition used for “culture.” For example, if using the Competing Values Framework (CVF), you may include four sub-codes related to the four dimensions of the CVF and code statements regarding one or more of the four dimension in an organization.</p> <p><u>Exclusion Criteria:</u></p>
D. Implementation Climate	<p><u>Definition:</u> The absorptive capacity for change, shared receptivity of involved individuals to an innovation, and the extent to which use of that innovation will be rewarded, supported, and expected within their organization.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the general level of receptivity to implementing the innovation.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding the general level of receptivity that are captured in the sub-codes.</p>
1. Tension for Change	<p><u>Definition:</u> The degree to which stakeholders perceive the current situation as intolerable or needing change.</p> <p><u>Inclusion Criteria:</u> Include statements that (do not) demonstrate a strong need for the innovation and/or that the current situation is untenable, e.g., statements that the innovation is absolutely necessary or that the innovation is redundant with other programs. Note: If a participant states</p>

that the innovation is redundant with a preferred existing program, (double) code lack of [Relative Advantage](#), see exclusion criteria below.

Exclusion Criteria: Exclude statements regarding specific needs of individuals that demonstrate a need for the innovation, but do not necessarily represent a strong need or an untenable status quo, and code to [Needs and Resources of Those Served by the Organization](#).

Exclude statements that demonstrate the innovation is better (or worse) than existing programs and code to [Relative Advantage](#).

2. Compatibility

Definition: The degree of tangible fit between meaning and values attached to the innovation by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the innovation fits with existing workflows and systems.

Inclusion Criteria: Include statements that demonstrate the level of compatibility the innovation has with organizational values and work processes. Include statements that the innovation did or did not need to be adapted as evidence of compatibility or lack of compatibility.

Exclusion Criteria: Exclude or double code statements regarding the priority of the innovation based on compatibility with organizational values to [Relative Priority](#), e.g., if an innovation is not prioritized because it is not compatible with organizational values.

3. Relative Priority

Definition: Individuals' shared perception of the importance of the implementation within the organization.

Inclusion Criteria: Include statements that reflect the relative priority of the innovation, e.g., statements related to change fatigue in the organization due to implementation of many other programs.

Exclusion Criteria: Exclude or double code statements regarding the priority of the innovation based on compatibility with organizational values to [Compatibility](#), e.g., if an innovation is not prioritized because it is not compatible with organizational values.

4. Organizational
Incentives &
Rewards

Definition: Extrinsic incentives such as goal-sharing, awards, performance reviews, promotions, and raises in salary, and less tangible incentives such as increased stature or respect.

Inclusion Criteria: Include statements related to whether organizational incentive systems are in place to foster (or hinder) implementation, e.g., rewards or disincentives for staff engaging in the innovation.

Exclusion Criteria:

5. Goals & Feedback	<p><u>Definition:</u> The degree to which goals are clearly communicated, acted upon, and fed back to staff, and alignment of that feedback with goals.</p> <p><u>Inclusion Criteria:</u> Include statements related to the (lack of) alignment of implementation and innovation goals with larger organizational goals, as well as feedback to staff regarding those goals, e.g., regular audit and feedback showing any gaps between the current organizational status and the goal. Goals and Feedback include organizational processes and supporting structures independent of the implementation process. Evidence of the integration of evaluation components used as part of “Reflecting and Evaluating” into on-going or sustained organizational structures and processes may be (double) coded to Goals and Feedback.</p> <p><u>Exclusion Criteria:</u> Exclude statements that refer to the implementation team’s (lack of) assessment of the progress toward and impact of implementation, as well as the interpretation of outcomes related to implementation, and code to Reflecting & Evaluating. Reflecting and Evaluating is part of the implementation process; it likely ends when implementation activities end. It does not require goals be explicitly articulated; it can focus on descriptions of the current state with real-time judgment, though there may be an implied goal (e.g., we need to implement the innovation) when the implementation team discusses feedback in terms of adjustments needed to complete implementation.</p>
6. Learning Climate	<p><u>Definition:</u> A climate in which: 1. Leaders express their own fallibility and need for team members’ assistance and input; 2. Team members feel that they are essential, valued, and knowledgeable partners in the change process; 3. Individuals feel psychologically safe to try new methods; and 4. There is sufficient time and space for reflective thinking and evaluation.</p> <p><u>Inclusion Criteria:</u> Include statements that support (or refute) the degree to which key components of an organization exhibit a “learning climate.”</p> <p><u>Exclusion Criteria:</u></p>
E. Readiness for Implementation	<p><u>Definition:</u> Tangible and immediate indicators of organizational commitment to its decision to implement an innovation.</p> <p><u>Inclusion Criteria:</u> Include statements regarding the general level of readiness for implementation.</p> <p><u>Exclusion Criteria:</u> Exclude statements regarding the general level of readiness for implementation that are captured in the sub-codes.</p>
1. Leadership Engagement	<p><u>Definition:</u> Commitment, involvement, and accountability of leaders and managers with the implementation of the innovation.</p>

Inclusion Criteria: Include statements regarding the level of engagement of organizational leadership.

Exclusion Criteria: Exclude or double code statements regarding leadership engagement to Engaging: [Formally Appointed Internal Implementation Leaders](#) or [Champions](#) if an organizational leader is also an implementation leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline. Note that a key characteristic of this Implementation Leader/Champion is that s/he is also an Organizational Leader.

2. Available Resources

Definition: The level of resources organizational dedicated for implementation and on-going operations including physical space and time.

Inclusion Criteria: Include statements related to the presence or absence of resources specific to the innovation that is being implemented.

Exclusion Criteria: Exclude statements related to training and education and code to [Access to Knowledge & Information](#).

Exclude statements related to the quality of materials and code to [Design Quality & Packaging](#).

In a research study, exclude statements related to resources needed for conducting the research components (e.g., time to complete research tasks, such as IRB applications, consenting patients).

3. Access to Knowledge & Information

Definition: Ease of access to digestible information and knowledge about the innovation and how to incorporate it into work tasks.

Inclusion Criteria: Include statements related to implementation leaders' and users' access to knowledge and information regarding use of the program, i.e., training on the mechanics of the program.

Exclusion Criteria: Exclude statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation, and code to [Engaging: Key Stakeholders](#).

Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to [Networks & Communications](#).

IV. Characteristics of Individuals

1. Knowledge & Beliefs about the Innovation Definition: Individuals' attitudes toward and value placed on the innovation, as well as familiarity with facts, truths, and principles related to the innovation.

Inclusion Criteria:

Exclusion Criteria: Exclude statements related to familiarity with evidence about the innovation and code to [Evidence Strength & Quality](#).

2. Self-efficacy Definition: Individual belief in their own capabilities to execute courses of action to achieve implementation goals.

Inclusion Criteria:

Exclusion Criteria:

3. Individual Stage of Change Definition: Characterization of the phase an individual is in, as s/he progresses toward skilled, enthusiastic, and sustained use of the innovation.

Inclusion Criteria:

Exclusion Criteria:

4. Individual Identification with Organization Definition: A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.

Inclusion Criteria:

Exclusion Criteria:

5. Other Personal Attributes Definition: A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

Inclusion Criteria:

Exclusion Criteria:

V. Process

- A. Planning Definition: The degree to which a scheme or method of behavior and tasks for implementing an innovation are developed in advance, and the quality of those schemes or methods.
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	<p><u>Inclusion Criteria:</u> Include evidence of pre-implementation diagnostic assessments and planning, as well as refinements to the plan.</p> <p><u>Exclusion Criteria:</u></p>
<p>B. Engaging</p>	<p><u>Definition:</u> Attracting and involving appropriate individuals in the implementation and use of the innovation through a combined strategy of social marketing, education, role modeling, training, and other similar activities.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, i.e., if and how staff and innovation participants became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of engagement efforts determines the rating, i.e., if there are repeated attempts to engage staff that are unsuccessful, or if a role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of staff - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to specific sub constructs, e.g., Champions or Opinion Leaders.</p> <p>Exclude or double code statements related to who participated in the decision process to implement the innovation to Innovation Source, as an indicator of internal or external innovation source.</p>
<p>1. Opinion Leaders</p>	<p><u>Definition:</u> Individuals in an organization that have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the innovation.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, e.g., how the opinion leader became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage an opinion leader that are unsuccessful, or if the opinion leader leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the opinion leader here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.</p> <p><u>Exclusion Criteria:</u></p>

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2. Formally Appointed Internal Implementation Leaders
- Definition:** Individuals from within the organization who have been formally appointed with responsibility for implementing an innovation as coordinator, project manager, team leader, or other similar role.
- Inclusion Criteria:** Include statements related to engagement strategies and outcomes, e.g., how the formally appointed internal implementation leader became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage an implementation leader that are unsuccessful, or if the implementation leader leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the implementation leader here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.
- Exclusion Criteria:** Exclude or double code statements regarding leadership engagement to [Leadership Engagement](#) if an implementation leader is also an organizational leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline.
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3. Champions
- Definition:** "Individuals who dedicate themselves to supporting, marketing, and 'driving through' an [implementation]", overcoming indifference or resistance that the innovation may provoke in an organization.
- Inclusion Criteria:** Include statements related to engagement strategies and outcomes, e.g., how the champion became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage a champion that are unsuccessful, or if the champion leaves the organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the champion here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.
- Exclusion Criteria:** Exclude or double code statements regarding leadership engagement to [Leadership Engagement](#) if a champion is also an organizational leader, e.g., if a director of primary care takes the lead in implementing a new treatment guideline.
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4. External Change Agents	<p><u>Definition:</u> Individuals who are affiliated with an outside entity who formally influence or facilitate innovation decisions in a desirable direction.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, e.g., how the external change agent (entities outside the organization that facilitate change) became engaged with the innovation and what their role is in implementation, e.g., how they supported implementation efforts. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage an external change agent that are unsuccessful, or if the external change agent leaves their organization and this role is vacant, the construct receives a negative rating. In addition, you may also want to code the "quality" of the external change agent here - their capabilities, motivation, and skills, i.e., how good they are at their job, and this data affects the rating as well.</p> <p><u>Exclusion Criteria:</u> Note: It is important to clearly define what roles are external and internal to the organization. Exclude statements regarding facilitating activities, such as training in the mechanics of the program, and code to Access to Knowledge & Information if the change agent is considered internal to the study, e.g., a staff member at the national office. If the study considers this staff member internal to the organization, it should be coded to Access to Knowledge & Information, even though their support may overlap with what would be expected from an External Change Agent.</p>
5. Key Stakeholders	<p><u>Definition:</u> Individuals from within the organization that are directly impacted by the innovation, e.g., staff responsible for making referrals to a new program or using a new work process.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, e.g., how key stakeholders became engaged with the innovation and what their role is in implementation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage staff determines the rating, i.e., if there are repeated attempts to engage key stakeholders that are unsuccessful, the construct receives a negative rating.</p> <p><u>Exclusion Criteria:</u> Exclude statements related to implementation leaders' and users' access to knowledge and information regarding using the program, i.e., training on the mechanics of the program, and code to Access to Knowledge & Information.</p>

	<p>Exclude statements about general networking, communication, and relationships in the organization, such as descriptions of meetings, email groups, or other methods of keeping people connected and informed, and statements related to team formation, quality, and functioning, and code to Networks & Communications.</p>
6. Innovation Participants	<p><u>Definition:</u> Individuals served by the organization that participate in the innovation, e.g., patients in a prevention program in a hospital.</p> <p><u>Inclusion Criteria:</u> Include statements related to engagement strategies and outcomes, e.g., how innovation participants became engaged with the innovation. Note: Although both strategies and outcomes are coded here, the outcome of efforts to engage participants determines the rating, i.e., if there are repeated attempts to engage participants that are unsuccessful, the construct receives a negative rating.</p> <p><u>Exclusion Criteria:</u> Exclude statements demonstrating (lack of) awareness of the needs and resources of those served by the organization and whether or not that awareness influenced the implementation or adaptation of the innovation and code to Needs & Resources of Those Served by the Organization.</p>
C. Executing	<p><u>Definition:</u> Carrying out or accomplishing the implementation according to plan.</p> <p><u>Inclusion Criteria:</u> Include statements that demonstrate how implementation occurred with respect to the implementation plan. Note: Executing is coded very infrequently due to a lack of planning. However, some studies have used fidelity measures to assess executing, as an indication of the degree to which implementation was accomplished according to plan.</p> <p><u>Exclusion Criteria:</u></p>
D. Reflecting & Evaluating	<p><u>Definition:</u> Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.</p> <p><u>Inclusion Criteria:</u> Include statements that refer to the implementation team's (lack of) assessment of the progress toward and impact of implementation, as well as the interpretation of outcomes related to implementation. Reflecting and Evaluating is part of the implementation process; it likely ends when implementation activities end. It does not require goals be explicitly articulated; it can focus on descriptions of the current state with real-time judgment, though there may be an implied</p>

goal (e.g., we need to implement the innovation) when the implementation team discusses feedback in terms of adjustments needed to complete implementation.

Exclusion Criteria: Exclude statements related to the (lack of) alignment of implementation and innovation goals with larger organizational goals, as well as feedback to staff regarding those goals, e.g., regular audit and feedback showing any gaps between the current organizational status and the goal, and code to [Goals & Feedback](#). Goals and Feedback include organizational processes and supporting structures independent of the implementation process. Evidence of the integration of evaluation components used as part of “Reflecting and Evaluating” into **on-going or sustained** organizational structures and processes may be (double) coded to Goals and Feedback.

Exclude statements that capture reflecting and evaluating that participants may do during the interview, for example, related to the success of the implementation, and code to [Knowledge & Beliefs about the Innovation](#).

VI. Additional Codes

A. Code Name Definition:

Inclusion Criteria:

Exclusion Criteria:

B. Code Name Definition:

Inclusion Criteria:

Exclusion Criteria:

General Coding Rules:

When two codes are in question for a passage, consider the primary meaning of the passage to assign code; consider what the participant is truly saying. Analysts may wish to err on the side of inclusion or double coding.

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- Providing HIV Prevention Services for Injection Drug Users (IDUs) in Providence, RI. *Journal of Urban Health: Bulletin of the New York Academy of Medicine*. 2010;87(6): 942-953. doi:10.1007/s11524-010-9503-z.
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CURRICULUM VITAE

MICHELE N. CLARK, M.P.H.
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EDUCATION

- 2011-2017 **BOSTON UNIVERSITY**, Boston, MA
 School of Public Health
 Doctorate of Public Health
- Graduation: 2017
 - Dissertation Title: Qualitative Study of Opioid Overdose Education and Naloxone Access Strategies in Community Health Center Primary Care Settings: Opportunities for Expanding Access and Saving Lives
 - Boston University Women’s Guild Scholarship Recipient
 - Guest Lecturer: “Integrating Social Marketing Concepts into Public Health Program Planning”
- 1994-1996 **UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL**,
 Chapel Hill, NC
 School of Public Health
 Master of Public Health
- Concentration: Health Behavior and Health Education
 - Oberlin College Alumni Scholarship Recipient
 - Delta Omega Public Health Honorary Society Award Recipient
 - American Schools of Public Health Fellow, Centers for Disease Control and Prevention (CDC), Summer 1996
- 1987-1991 **OBERLIN COLLEGE**, Oberlin, OH
Bachelor of Arts
 Major: Anthropology
- Comfort Starr Prize for Excellence in Anthropology
 - Oberlin Shansi Fellowship, Tamil Nadu, India, 1991 - 1993

WORK EXPERIENCE

- 2008 to present **JOHN SNOW, Inc. (JSI)**, Boston, MA
 Health Services Division
Senior Consultant
Select Projects

Opioid Urgent Care Center Pilot Evaluation, MA Department of Public Health
Project Manager, July 2016 to present

Collaborate with Bureau of Substance Abuse Services and three Opioid Urgent Care Center Pilot sites to develop and implement mixed methods cross-site evaluation of new intervention to enhance treatment access.

Quality Improvement Network for Contraceptive Access, New York City
Department of Health and Mental Hygiene

Quality Improvement (QI) Coordinator, September 2015 to present

Coordinate QI process for hospitals by facilitating learning collaborative and technical assistance process to increase contraceptive access.

National Family Planning Training Center for Quality Improvement and Evaluation, Office of Population Affairs

Evaluator, December 2012 to August 2016

Developed and oversaw evaluation plan of national Title X family planning training program, including facilitation of cross-training center data collection, analysis, and presentation of findings with focus on training delivery improvement.

Data to Care Technical Assistance Project, CDC

Project Manager, October 2013 to September 2014

Managed technical assistance project to support health departments in using HIV surveillance data to link or re-engage persons living with HIV who are out of care. Major activities included needs assessment and resources development.

Evaluation of 115 Medicaid Wavier on Ryan White Programs, Health Resources and Services Administration (HRSA)

Evaluator, October 2012 to January 2013

Conducted qualitative case study on the impact of the Medicaid waiver on the Ryan White HIV/AIDS Program.

AIDS.gov Project, Office of HIV/AIDS Policy, U.S. Department of Health and Human Services (US DHHS)

Project Manager, January 2008 to January 2013

Managed national project utilizing media platforms to promote federal HIV policies and programs.

12 Cities Project Evaluation, Office of HIV/AIDS Policy, US DHHS

Evaluator, September 2011 to December 2012

Conducted site visits and qualitative data analysis as part of evaluation team to assess coordination, collaboration, and integration of federal HIV-related funding among the 12 jurisdictions in the U.S. with the highest HIV prevalence.

2006-2008**INTERNATIONAL TRAINING & EDUCATION CENTER****ON HIV**, Chennai, Tamil Nadu, India

University of Washington, Seattle, WA

Deputy Director of Field Office, 2006–2008

Managed PEPFAR-funded HRSA/CDC Global AIDS Program clinical training and technical assistance program with a team of 18 clinicians and staff. Led development of national medical doctor curriculum for year-long HIV Fellowship.

1997-2006**JOHN SNOW, INC. (JSI)**, Boston, MA*Consultant*Select Projects**OPTIONS Replication Evaluation**, HRSA*Project Director, 2005–2006*

Managed start-up research activities to evaluate an intervention for people living with HIV across 15 clinic sites.

Statewide HIV Prevention Evaluation, Rhode Island Dept. of Health*Project Director, 2001–2006*

Conducted evaluation of CDC-funded HIV prevention initiatives in Rhode Island, including the development of process and outcome measure documentation systems for programs conducting interventions with MSM, PWID, women and youth.

HIV Prevention Integration in Reproductive Health Settings for Region I, CDC*Project Director, 1998–2004*

Conducted assessment of Title X grantee HIV prevention training needs, designed training plan, oversaw curricula development, including HIV risk assessment guide. Implemented training activities and evaluated program activities.

Hepatitis C Case Management and Research Initiatives Statewide Evaluation,

MA Department of Public Health

Evaluator, 2000–2003

Evaluated cross-site statewide hepatitis C initiatives through qualitative in-depth site visits and outcome monitoring.

Focus Groups to Develop an Outreach and Education Program, MA Division of Medical Assistance*Project Manager, 1999*

Led focus group assessment with dually eligible Medicaid/Medicare seniors to inform statewide outreach program.

Ryan White Technical Assistance Contract, HRSA*Technical Assistance Coordinator, 1997–1999*

Oversaw technical assistance projects and materials development to support Ryan White HIV/AIDS Program grantees.

PRESENTATIONS AND PUBLICATIONS

Clark M & Sreedhara R. *Integrating Opioid Overdose and Naloxone Distribution into Community Health Center Settings*. New Hampshire Behavioral Health Conference. October 2016.

Green K, Taussig J, Jones R, Shouse L, Ortiz-Ricard A & **Clark M**. *Lessons Learned in the Provision of TA to Health Departments on Using HIV Surveillance Data to Improve the HIV Care Continuum*. International Conference on HIV Treatment & Prevention Adherence, May 2016, Ft. Lauderdale.

Amin K & **Clark M**. *Club Risky Business: A Zambian Television Series Challenges Multiple and Concurrent Sexual Partnerships*. AIDSTAR-One, JSI/USAID, December 2010.

Manoharan G, Somani J, Rajasekaran S, Charles B, Nadol P, Arivudainambi K, Sahu S, Friedman M, **Clark M** & Behrens C. *Creating Future HIV Clinical Leaders and Strengthening Institutional Workforce: An Innovative HIV Fellowship Program through a Private/Public Partnership at the Government Hospital of Thoracic Medicine, India*. International AIDS Conference, 2008, Mexico.

Clark M. *Developing Logic Models for Your HIV Programs*. CDC India Grantee Meeting. August 2007. Hyderabad, India.

Furtwangler T, Vijay P, **Clark M** & Manoharan G. *The Making of Opportunistic Infection Training Videos*. GHTM, India. Global Health Conference, 2007, Washington, DC.

Perlmutter D, **Clark M**, Mangione T, Ayotte. D & Kessler W. *Linking Prevention and Care for PLWH*. APHA, 2001, Atlanta.

Perlmutter D, **Clark M**, Prejean J, Ayotte D, Mangione T & Kessler W. *Positive Prevention: Opportunities for Linking Prevention and Care Services for PLWH Based on Needs Assessment Findings*. HIV Prevention Conference, 2001, Atlanta.

Thomas J, **Clark M**, Robinson J, Monnett M, Peterman T & Kilmarx P. *The Social Ecology of Syphilis*, Social Science and Medicine, April 1999.

Thomas J, Eng E, **Clark M**, Robinson J, & Blumenthal C. *Lay Health Advisors: STD Prevention through Community Involvement*, American Journal of Public Health, August 1998.