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I, Angela K Clark, hereby submit this original work as part of the requirements for the degree of Doctor of Philosophy in Nursing Research.

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A Feasibility Study of a Group-based Opioid Overdose Prevention Educational Intervention

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A Feasibility Study of a Group-based Opioid Overdose Prevention Educational Intervention

A Dissertation Presented to the Graduate School in Partial Fulfillment of the Requirements in the College of Nursing at The University of Cincinnati for the Degree Doctor of Philosophy

by

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Abstract

This dissertation study aimed to evaluate the feasibility of an innovative group-based opioid overdose educational intervention in individuals at high-risk for overdose. Opioid overdose is the leading cause of injury death in the United States and overdose fatalities have more than tripled in the past 25 years. Fatal opioid overdoses have been declared an epidemic by the Centers for Disease Control and Prevention and can be reversed by the timely administration of naloxone, brand name Narcan®. There are approximately 188 opioid overdose prevention programs (OOPPs) distributing naloxone to individuals at high-risk for witnessing an overdose and there is vital need to expand the dissemination of interventions that reduce the risk of overdose and expand access to naloxone. In 2013, the Substance Abuse and Mental Health Services Administration (SAMHSA) released the Opioid Overdose Prevention Toolkit to assist OOPPs in the development and implementation of opioid overdose prevention efforts. However, in its current format the toolkit is not amenable for use in the group setting. Therefore, the overall purpose of this feasibility study was to develop a group-based OOPP educational intervention and determine the implementation fidelity and intervention effect size. Specifically this study aimed to: 1) Modify the SAMHSA Opioid Overdose Prevention Toolkit for use in the group setting; 2) Determine whether clinicians, who have received training, can deliver the intervention with implementation fidelity in the group setting; 3) Determine participant responsiveness to the intervention; 4) Determine the intervention effect size. A total of 49 subjects, receiving inpatient treatment for opioid dependence, participated in the educational intervention. Participants completed a pre-test and a post-test to determine their knowledge about preventing overdoses, risk factors for overdose, and responding to overdoses, including the administration of naloxone. The end product of this study was an overdose prevention iBook, for
use in groups and implementation guidelines for program clinicians. Findings from this study will expand opportunities for educational interventions in other treatment settings. This study was a vital step in the development of practice guidelines and treatment initiatives for opioid overdose prevention.
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Lastly, I would like to dedicate this dissertation to the families who have lost loved ones to opioid overdose. Our work is not finished.
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Chapter 1: Introduction

Opioid overdoses are the result of an ingestion of too many opioids in the body and are a burgeoning public health issue. Opioid overdose is the leading cause of injury death in the United States; approximately 100 people succumb daily to fatal drug overdoses, half of which involve opioids (CDC, 2011; Jones, Roux, Stancliff, Matthews, & Comer, 2013; Paulozzi, Weisler, & Patkar, 2011). Opioid overdose fatalities have more than tripled in the past 25 years and overdoses associated with prescription and illicit opioids have reached epidemic levels (CDC, 2011). Potentially fatal respiratory depression is the most formidable outcome of opioid overdoses and is effectually reversible with naloxone (Sporer & Kral, 2007). Naloxone, brand name Narcan®, has the ability to reverse respiratory depression by competitively binding to mu-opioid receptor sites, temporarily reversing the effects of opioids providing an opportunity to reinstate adequate breathing (Boyer, 2012; Sporer & Kral, 2007).

Drug overdose deaths involving prescription opioids including hydrocodone, oxycodone, fentanyl, methadone have increased dramatically (Jones, Mack, & Paulozzi, 2013). In a study funded by the Substance Abuse and Mental Health Services Administration (SAMHSA), an estimated 52 million people were found to have used prescription drugs for nonmedical purposes during their lifetime and the number of fatalities related to nonmedical use of prescription drugs is climbing (Manchikanti et al., 2012; SAMHSA, 2013c; Volkow, 2011). Heroin use has also contributed to the increased drug overdose deaths in the last 10 years (CDC, 2012a).

Heroin is an opiate that is synthesized from morphine. Once in the body opioids bind to opioid receptors throughout the brain (Boyer, 2012). Initially users experience euphoria as the drug delivers potent central nervous system depressant effect to the body (National Institute on Drug Abuse, 2010). After repeat administrations over-time users build up a tolerance to the
central nervous system effects of opioids and require higher doses and more frequent uses signaling physical dependence. Depending on genetic factors and environmental stressors the increased use of opioids may foster opioid addiction (American Society of Addiction Medicine, 2001). While all users may not develop opioid addiction, frequent opioid users will build up a tolerance to the effects and will exhibit unpleasant symptoms associated with a withdrawal syndrome. To prevent these symptoms opioid users continue using opioids in increased amounts. As the amount of ingested opioids increases, so does the risk for opioid overdose.

Opioid overdoses are the result of high doses of opioids, used alone or in combination with other substances in the body that decrease the drive to breathe (Boyer, 2012). Opioids circulate through the body and bind to specific mu-opioid receptors that block pain sensations, cause euphoria, and in doing so inhibit the drive for respirations. Respiratory depression is the hallmark symptom of an opioid overdose; drug overdoses, in which a person has not taken opioids, infrequently cause respiratory depression (Boyer, 2012; Wermeling, 2010). When someone is experiencing an opioid overdose, a potentially fatal cyanotic cascade begins. Breathing slows, oxygen levels in the blood decrease, lips and fingers turn blue, oxygenation to vital organs like the heart and brain decreases. Within 3-5 minutes without oxygenation unconsciousness, brain damage, coma, and then death may follow (Boyer, 2012).

The cyanotic cascade is rarely instantaneous and there is usually a window of time to intervene. Surviving an opioid overdose depends entirely on breathing and oxygenation to vital organs. This pathway of fatal events is reversible if naloxone is administered in time. Naloxone is a FDA-approved medication with established efficacy that reverses opioid overdose and prevents fatalities (Boyer, 2012; Buajordet, Naess, Jacobsen, & Brors, 2004; Clarke, Dargan, & Jones, 2005; Dahan, Aarts, & Smith, 2010).
Naloxone has been used routinely in hospitals for over 40 years (Chamberlain & Klein, 1994) and in 1996, staff in community-based harm reduction programs began distributing naloxone to bystanders (friends and relatives of heroin users) and individuals at high risk for overdose to be administered during overdose events (Sporer & Kral, 2007; Wheeler, Davidson, Jones, & Irwin, 2012). Naloxone is harmless if administered accidently to someone who has not ingested opioids and/or is not experiencing an overdose. Naloxone, even if used at doses 700 times higher than what is recommended, will not produce adverse events (Terman, 2012).

Naloxone can be administered by intramuscular, intravenous, intraosseous, or intranasal routes. For intranasal administration a nasal atomizer is attached to the naloxone syringe and 1ml is sprayed into each naris. When naloxone is administered intranasally it may work immediately or take up to 8 minutes to produce an effect (Wanger, et al, 1998). Once in the system, the effects of naloxone will last approximately 30 to 90 minutes (Wanger, et al, 1998).

Providing opioid overdose education and naloxone to persons who may witness an opioid overdose has been shown to reduce mortality (Wheeler et al., 2012). The evidence from non-randomized studies suggests that bystanders can and will use naloxone when properly trained, and that this training can be done through Opioid Overdose Prevention Programs (OOPPs) (Clark, Wilder, & Winstanley, 2014; Doe-Simkins, Walley, Epstein, & Moyer, 2009). There are now over 188 OOPPs across the United States, operating in a variety of service venues, mostly needle exchange programs, detention centers and community clinics (Wheeler et al., 2012). OOPPs provide education and training in two key areas 1). how to identify the symptoms of an opioid overdose and 2). how to respond, including naloxone administration (Enteen et al., 2010). Over 53,000 persons have received training on naloxone, including a naloxone prescription, and naloxone administration has successfully reversed 10,171 overdoses (Wheeler et al., 2012).
Despite the ability of OOPPs to increase participant knowledge regarding overdoses and change participant behavior, published evaluations of OOPPs indicate that participants still have difficulty responding to overdoses, including difficulty with the mechanical attachment of the nasal adaptor to the naloxone, (Clark et al., 2014; Doe-Simkins et al., 2009; Walley, Xuan, et al., 2013) and hesitancy to notify first responders (Bennett, Bell, Tomedi, Hulsey, & Kral, 2011; Doe-Simkins et al., 2009; Tobin, Sherman, Beilenson, Welsh, & Latkin, 2009). Evaluations of OOPPs also suggest that the educational component of OOPP interventions varies widely (Clark et al., 2014).

In an ongoing evaluation of an OOPP in an addiction treatment setting, Winstanley and her research team have examined the use of a group setting to deliver OOPP content (E. Winstanley, personal communication, September, 13, 2013). Initially, the decision to utilize the group setting was based on resource optimization. However, throughout the course of the study, group facilitators observed that participant interaction encouraged open discussion about such topics as attachment of the nasal adaptor to the naloxone, victim responses after naloxone administration and concerns regarding police involvement on the scene. Together the groups generated solutions to the aforementioned barriers, which would not have been possible when learning individually. These findings support the over 1,200 studies conducted testing the theory of social interdependence, which holds that cooperative group learning (positive interdependence) facilitates the exchange of needed resources and assistance (promotive interaction) resulting in an increased effort to achieve the targeted goal (Johnson & Johnson, 2009; Johnson & Johnson, 2013).

In 2013, the Substance Abuse and Mental Health Services Administration (SAMHSA) released the Opioid Overdose Prevention Toolkit to guide educational interventions in OOPPs
(SAMHSA, 2013b, 2013d). However, the Toolkit has not been tested in OOPPs and in its current format is not amenable to facilitating group discussion despite the fact that several researchers have shown numerous advantages to using groups in substance abuse treatment (Center for Substance Abuse Treatment, 2005; Scheidlinger, 2000). Thus, there was a critical need to develop an opioid overdose prevention curriculum for use in the group setting.

The Study

Study Purpose

The overall purpose of this phase Ia/Ib feasibility study (Rounsaville, Carroll, & Onken, 2001) was to determine the implementation fidelity and intervention effect size, of a group-based OOPP educational intervention loosely based on the SAMHSA toolkit. The specific aims of the study were to:

1. Use the SAMHSA Opioid Overdose Prevention Toolkit as a guide to develop an educational tool for use in the group setting.
2. Determine whether clinicians, who received training, could deliver the intervention with implementation fidelity in the group setting;
3. Examine the relationship between the educational intervention fidelity and participant responsiveness to the intervention;
4. Determine the intervention effect size.

The end product of this study was the CARRY Narcan® iBook, for use in overdose prevention groups and implementation guidelines for program clinicians. This intervention was an important step in the development of practice guidelines for opioid overdose prevention. Findings from this study will be used to develop a randomized trial to test the efficacy and cost effectiveness of the CARRY Narcan® iBook educational intervention.
This research is innovative because it is the first study to empirically evaluate a manualized OOPP curriculum loosely based on the SAMHSA Opioid Overdose Prevention Toolkit and the first study to provide an educational manual specifically created to facilitate discussion in the group setting. A systematic review of 19 OOPPs yielded findings that the duration, setting, and participant composition (group or individual) varied widely across and within OOPPs (Clark et al., 2014). None of the published studies stated whether OOPP educational interventions were empirically tested. As such, the current study is the first study to empirically evaluate a manualized educational intervention based on the toolkit. In published studies, educational intervention settings also varied widely, the same educational intervention was utilized for the syringe exchange program, detoxification centers, opioid substitution clinics, HIV education centers and substance abuse treatment facilities (Enteen et al., 2010; Walley, Doe-Simkins, et al., 2013; Walley, Xuan, et al., 2013; Yokell, Green, Bowman, McKenzie, & Rich, 2011) to either a group or an individual (Galea et al., 2006; Gaston, Best, Manning, & Day, 2009; Leece et al., 2013; Piper et al., 2008; Sherman et al., 2008; Wagner et al., 2010; Walley, Doe-Simkins, et al., 2013; Walley, Xuan, et al., 2013). This current study was the first to provide an educational manual specifically created to facilitate discussion in the group setting.

Currently, NIDA has funded research aimed to increase OOPP educational resources (NIH Reporter, 2013). Investigators in one study are using a computer-assisted online approach targeted to ‘train the trainers’ of OOPPs through individual learning. Researchers in a second study aim to develop individual learning modules and do not include education regarding naloxone administration (NIH Reporter, 2013). Our study was an innovative study and was the first to develop an overdose prevention educational intervention for use in a group setting and the first to determine the feasibility of the intervention.
Assumptions and Definitions:

Assumptions. The primary investigator conducted the study operating under the following assumptions:

1. Reversing potentially fatal opioid overdoses has the potential to save lives and provides another opportunity for treatment.
2. In time, substance abuse treatment works.
3. Participants in OOPP groups have a direct interest in reversing opioid overdoses and are capable of assessing the signs and symptoms of an overdose and responding to opioid overdoses.

Definition. The following definition was applied throughout the study:

1. Opioid overdose prevention program (OOPP): A program that aims to prevent opioid overdoses through educational interventions including naloxone distribution and training.
Chapter 2: Review of the Literature

The aim of this dissertation study was to evaluate the feasibility of an innovative group-based opioid overdose educational intervention in individuals at high-risk for opioid overdose. In order to provide a foundation for the study, this chapter will examine the role of prescription opioids and heroin in the overdose epidemic, evaluate harm reduction strategies employed to reduce fatalities, and examine a theoretical framework to understand the use of group-based educational interventions.

**Epidemiology of Prescription and Illicit Opioid Use**

The purpose of this section is to present current epidemiological statistics on opioid use, opioid related-overdoses and associated economic impact at the global, national, regional, and community levels. Data were extracted from reports issued by the United Nations Office on Drugs and Crime, the Centers of Disease Control and Prevention, The Substance Abuse and Mental Health Services Administration and the Ohio Department of Health.

**Opioid Use from a Global Perspective**

An estimated 16.5 million people annually or 0.4 percent of the global population aged 15-64, report using opiates including heroin and opium (UNODC, 2013). A high prevalence of opioid use has been reported in Southwest and Central Asia, Eastern and Southeastern Europe and North America (UNODC, 2013). Currently, the United Nations Office on Drugs and Crime (UNODC) does not track the misuse of prescription medications, but the UNODC suggests increased reports of prescription opioid misuse from different regions signaling that the estimates of illicit opioid use are modest (UNODC, 2013).
Opioid Use in the United States of America

In the United States both prescription opioids and illicit opioids are on the rise in use, misuse, and dependence and have propelled an upsurge in overdose fatalities. Current estimates suggest that 12 million Americans use prescription drugs for non-medical purposes and use of illicit drugs, such as heroin, is significantly on the rise. The number of persons who were past year heroin users in 2011 was 44% higher than in 2007 and the reported number of persons with heroin dependence nearly doubled from 2007 to 2012 (SAMHSA, 2012, 2013c).

In 2010, approximately 22.5 million Americans reported having used or misused an illicit drug or medication in the past month and in the same year opioid-induced deaths accounted for 37,792 fatalities (SAMHSA, 2012). Opioid use has been on the rise and is associated with the rapid increase in unintentional drug poisoning and drug overdoses (CDC, 2011).

Regional Opioid Statistics

Rural America, such as the Appalachian region is experiencing overdose fatalities at high rates (CDC, 2013). In the state of Ohio, which is located in the Appalachian region, nearly five people die every day of unintentional drug overdose, and the rapid increase in unintentional drug poisoning has been linked to opioids (Ohio Department of Health, Violence, & Injury Prevention Program, 2013). The Ohio Department of Health (2012) reports that half of fatal overdoses involve prescription opioids while heroin-involved deaths account for 16 percent of drug overdoses. Ohio’s rate of unintentional overdose has increased 440 percent in the past decade (Ohio Department of Health, 2014). In 2007, unintentional drug poisoning surpassed motor vehicle crashes to become the leading cause of injury death in Ohio (Ohio Department of Health, 2014).
Economic Impact

According to Inocencio, Carroll, Read and Holdford (2013) opioid-related poisonings (fatal and non-fatal) cost the United States $20.4 billion dollars annually. The estimated direct costs of opioid-related poisoning, including emergency department and inpatient costs are estimated at 2.2 billion dollars per year (Inocencio et al., 2013). Prescription opioid poisoning accounted for 80% of the 2.2 billion in direct costs and was highest for oxycodone and hydrocodone (Inocencio et al., 2013). The average direct cost per poisoning event was $4,255 for prescription opioids and $3,198 for heroin. Total indirect costs included and were estimated by Inocencio and colleagues (2013) at $18.2 billion including an estimated $33,267 per opioid poisoning. In the State of Ohio fatal overdoses cost Ohioans $1.9 billion on average each year and non-fatal hospital-admitted related drug poisonings cost an additional $40 million (Ohio Department of Health, 2014).

Both heroin and prescription opioids are contributing to the opioid overdose epidemic and the consequences, although costly, are not just financial. Opioid fatalities have fractured families and changed the landscape of our communities. Opioid overdoses represent a significant public health concern and efforts to mitigate the opioid overdose epidemic are crucial to reduce the fatal discourse associated with opioid misuse.

Opioid Misuse and Heroin: An Overview

Prescription Opioids

Drug overdose deaths involving prescription opioids including: hydrocodone, oxycodone, and fentanyl, have yielded a dramatic upsurge since 1999 (Paulozzi, Jones, Mack, & Rudd, 2011). Accompanying the insurgence of overdose deaths, is an increase in the non-medical use
of prescription drugs and an increase in the sales of prescription opioids (Paulozzi, Jones, et al., 2011).

Nonmedical use of prescription opioids as defined by the Drug Abuse Warning Network (DAWN) includes both the misuse and/or abuse of any opioid medication. DAWN’s definition of nonmedical use of a pharmaceutical includes:

Taking more than the prescribed dose of a prescription drug; taking more than the recommended dose of an over-the-counter pharmaceutical or supplement; taking a drug prescribed for another individual; taking a drug obtained illegally or without a legitimate prescription; deliberate poisoning with a pharmaceutical by another person; and any use of a prescription drug, an over-the-counter pharmaceutical, or a dietary supplement that ED medical staff document in the patient's medical record as misuse or abuse.

(SAMHSA, 2013a, p.47)

As documented by the 2011 National Survey on Drug Use and Health (NSDUH) annual report, misuse of pharmaceuticals is estimated at over 14 million persons aged 12 or older (SAMHSA, 2012). According to the DAWN survey estimate 1,244,872 ED visits involved the nonmedical use of prescription medicines, over-the-counter drugs, or other types of pharmaceuticals (SAMHSA, 2013a).

**Contributory Factors**

There are multiple factors contributing to the high prevalence of prescription opioid misuse (Garland, Froeliger, Zeidan, Partin, & Howard, 2013). Factors include; increasing availability of prescription medications, misconceptions about the safety of prescription pain medications, and self-treating/self-prescribing medications (NIDA, 2011). In 2010, U.S. retail pharmacies dispensed 202 million opioid prescriptions with hydrocodone topping the list (Figure
1) (Volkow, 2011). During the same year, opioid-related overdoses crescendoed, surpassing motor vehicle accidents as the leading cause of injury death, further supporting researchers’ claims of a positive correlation between the pharmaceutical sales of opioid pain relievers and opioid overdose fatalities (Manchikanti et al., 2012; Volkow, 2011).

![Figure 1](image.png)

**Figure 1.** Number of opioid prescriptions dispensed. This figure illustrates the increased dispensing of opioid prescriptions by U.S. retail pharmacies. Source: NIDA, 2011b, Public Domain

SAMHSA released the sources where prescription opioids were obtained for the most recent nonmedical use among past year users aged 12 or older for 2011-2012 (see Figure 2). Among persons who used pain relievers nonmedically in the past year, 54.0 percent obtained pain relievers from a friend or relative free of charge and nearly 20 percent obtained the pain reliever from one physician (SAMHSA, 2013c).
Nonmedical use of prescription opioids is of concern because of the risks associated with neuroadaptation resulting in tolerance and withdrawal when the opioid is no longer used and the potential for initiation of heroin use (Garland et al., 2013). Researchers from the Center for Behavioral Health Statistics and Quality released a report indicating that nearly 80 percent of heroin initiates had a history of nonmedical use of prescription opioids and that people ages 12 to 49 who had used prescription pain medications non-medically were 19 times more likely to have initiated heroin use (Muhuri, Gfroerer, & Davies, 2013). Opioids and heroin are similar in chemical structure and bind to the same receptors in the brain. Therefore the substitution and transition between opioids (prescription to heroin) is common (Volkow, 2011).

Figure 2. Source where user obtained prescription opioid. This figure illustrates the most recent source where users obtained opioids for misuse. Source: SAMHSA, 2013c, Public Domain
Heroin

Results from the 2012 National Survey on Drug Use and Health: Summary of Findings indicate that heroin use has continued to rise in the United States and that 156,000 persons (ages 12 or older) initiated first-time heroin use in 2012 with an average age of first use estimated at 23.0 years (SAMHSA, 2013c). Heroin is a drug that is synthesized from morphine extracted from the seeds of poppy plants (NIDA, 2014). In its purest form heroin is a white powder and in this pure form can be snorted or smoked.

While Afghanistan is the number one producer of heroin globally, the majority of heroin found in the United States originates in Columbia and Mexico (UNODC, 2013). Heroin in the United States is seen in two formulations: The whitish powder form more commonly used in the Eastern United States; and black tar heroin which is a dark sticky sap like heroin originating from Mexico and commonly used West of the Mississippi (NIDA, 2014). Due to the processing and formulation of black tar heroin it is most often dissolved and injected intravenously, intramuscularly or subcutaneous (NIDA, 2014).

Once heroin enters the body, heroin binds to mu-opioid receptors in the brain activating a pleasure reward center, stimulating the release of dopamine. The intensity of the pleasure sensation depends on the amount of heroin used, route of administration, the purity of the heroin, and the person’s tolerance. As with prescription opioids, a person may initially feel calm and have heavy extremities, drowsiness may ensue and heart rate and respiratory rate decrease.

Over time repeated use of opioids change the structure and function of the brain creating long-term imbalances in the neuronal and hormonal systems (NIDA, 2014). The long-term effects of heroin use include: addiction, and complications for intravenous drug use such as infectious disease, collapsed veins, bacterial infections, abscesses, endocarditis, arthritis and
other rheumatologic problems, liver and kidney disease. Injection drug use also increases the risk of exposure to hepatitis B and C and HIV. Injection drug users are the group at highest risk for acquiring hepatitis C infection, accounting for approximately half of new hepatitis C infections in the United States (CDC, 2012b; NIDA, 2014).

The Pathophysiology of Opioid Dependence

While the full etiology of opioid use to opioid addiction, including the potential role of genetic implications, is not fully understood, the abnormalities that occur with the repeated use of opioids that produce opioid dependence are well established (Kosten & George, 2002). Once exogenous opioids (either prescription opioids or heroin) enter the body they attach to mu-opioid receptors in the brain signaling the release of dopamine, which satiates pain receptors decreasing pain perception (Wood, 2008). In the absence of pain, exogenous opioids trigger the mesolimbic rewards system (Kosten & George, 2002).

This neurophysiologic pathway involves the release of dopamine from the ventral tegmental area (VTA) onto dopamine receptors in the nucleus accumbens (NAc) producing reward and positive reinforcement (Kosten & George, 2002; Trachtenberg & Fleming, n.d.). With repeated use of exogenous dopamine and the subsequent activation of mesolimbic reward system other parts of the brain including the periaqueductal gray area, amygdala and locus corellas create a memory of the reward (Kosten & George, 2002; Trachtenberg & Fleming, n.d.). These memory centers lead to cravings for the drug and drive the feelings of compulsion that drive tolerance and dependence (Kosten & George, 2002).
Over time more endogenous opioids (increased amount) are needed to stimulate the VTA to release dopamine in the NAc (see Figure 3) to produce pleasurable feelings this concept of ‘more for the same’ signals tolerance. Once an individual has developed tolerance and stops taking exogenous opioids they will experience opioid withdrawal syndrome. Signs and symptoms of withdrawal syndrome include: restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, cold flashes and leg movements (NIDA, n.d.). Thus, physical dependence occurs when a state of adaptation, that is manifested by a drug-class-specific withdrawal syndrome, can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and or administration of an antagonist (American Society of Addiction Medicine, 2001).

The American Society of Addiction Medicine, the American Academy of Pain Medicine, and the American Pain Society recognize a discrete difference in the definitions of tolerance, physical dependence and addiction. The American Society of Addiction Medicine (2011) defines addiction as:
A primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death. (para. 1)

While physical dependence and tolerance are symptomatic characteristics of addiction, “addiction, unlike tolerance and physical dependence, is not a predictable drug effect, but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals” (American Society of Addiction Medicine, 2001). Due to the well-documented increased risk for opioid overdose associated with physical dependence, this study included individuals who have a diagnosis of opioid dependence (Paulozzi, 2012).

**Opioid Overdose**

An overdose is defined as too much of a substance. While an opioid overdose may be characterized by many symptoms such as miosis, stupor and apnea, the hallmark symptom of an opioid overdose is respiratory depression (Boyer, 2012). Overdoses involving polysubstances may produce mydriatic pupils, miosis, and coma but respiratory depression is usually not initially present (Boyer, 2012). The length of time for an opioid overdose to occur ranges and may be instantaneous or last up to 3 hours (Sporer & Kral, 2007). As such, there is often opportunity to intervene before the victim’s respiratory depression progresses resulting in coma
or death. Naloxone, brand name Narcan®, when administered in a timely matter, has the ability to reverse respiratory depression by competitively binding to mu-opioid receptor sites, preventing fatalities (Boyer, 2012; Sporer & Kral, 2007).

Prescription opioid use and misuse, as well as heroin use, is on the rise in the United States. As use increases, so do the number of fatal opioid overdoses. Fatal opioid overdoses have now reached epidemic proportions in the United States and are a burgeoning public health matter. The most proximal solution to combatting fatal opioid overdoses is the timely administration of naloxone hydrochloride. Efforts to combat fatal opioid overdoses now include the dispensing of naloxone hydrochloride to those at risk of witnessing an opioid overdose.

**Naloxone Hydrochloride: An Overview**

Naloxone hydrochloride, brand name Narcan®, is an opioid antagonist that, when administered in a timely manner, competitively binds to mu-opioid receptors temporarily reversing respiratory and central nervous system depression caused by opioids (Boyer, 2012; Wermeling, 2012). Naloxone is approved for use in the United States by intravascular, intramuscular, endotracheal, intraosseous and subcutaneous routes (Food and Drug Administration, 2004). While intravenous administration of naloxone produces the fastest therapeutic onset (3.7 minutes) intranasal naloxone is only slightly more gradual with a mean clinical response time of 4.2 minutes (Wermeling, 2012).

In a clinical trial comparing the effectiveness and safety of intranasal and intramuscular naloxone for the treatment of suspected heroin overdose Kerr et al. (2009) reported that concentrated intranasal naloxone (2mg) and concentrated intramuscularly administered naloxone (2mg) yielded the same time to clinical response (Kerr, Kelly, Dietze, Jolley, & Barger, 2009). Barton et al. (2005) reported that the advantage of intranasal naloxone is that is limits the risk of
needle-stick exposures while providing rapid reversal of opioid overdoses (Barton et al., 2005). In 1996, individuals began naloxone distribution to lay persons at risk for experiencing or witnessing an opioid overdose (Wheeler et al., 2012).

Over 50,000 doses of naloxone have been distributed and over 10,000 opioid overdose reversals have been reported, indicating that individuals who are trained to administer naloxone have the ability to reverse overdoses (Wheeler et al., 2012). These data further solidify prescription naloxone distribution as an efficacious approach to overdose prevention (Doe-Simkins et al., 2009; Sporer & Kral, 2007; Wheeler et al., 2012). In general, opioid overdose prevention programs include education around recognizing the signs and symptoms of an opioid overdose and how to respond to an opioid overdose. Some programs also include discussion of overdose prevention (Clark et al., 2014; Enteen et al., 2010; Sporer & Kral, 2007). In addition to education, programs provide participants with a naloxone kit.

**Opioid Overdose Prevention Programs**

In 1996, community-based programs, often referred to as opioid overdose prevention programs (OOPP), began naloxone distribution directly to patients at high risk for overdose (Sporer & Kral, 2007; Wheeler et al., 2012). Although bystander administration of naloxone by non-medical persons is considered an off-label use of the medication, some states have passed legislation protecting prescribing physicians and bystander administrators from civil and/or medical liability (Davis, Webb, & Burris, 2013; Sporer & Kral, 2007). There are now over 188 community-run programs operating across the United States in a variety of service venues including needle exchange programs, detention centers, community clinics, and drug-treatment facilities (Wheeler et al., 2012). OOPPs provide training to bystanders in two key areas 1) how to identify the symptoms of an opioid overdose and 2) how to respond, including administration
of naloxone (Enteen et al., 2010).

Because of the novelty of OOPPs, published information on them is limited. There are no published systematic literature reviews describing OOPPs or assessing their outcomes. This section reviews characteristics and outcomes of OOPPs as described in the current peer-reviewed literature. This section also describes demographic and clinical characteristics of OOPP participants, OOPP curricula, fatal and non-fatal overdose reduction rates among OOPP participants, non-medical bystander increase in knowledge of prevention, risk factors, and recognition of opioid overdose, and non-medical bystanders’ response to witnessed opioid overdoses.

A search was conducted in PubMed®, MEDLINE® and PsychINFO® online databases using the Boolean search query: (opioid OR opiate) AND overdose AND prevention, limited to English Language. This query yielded 360 unique citations which were imported into an electronic database (EndNote® X5; Thomson Reuters, Philadelphia, PA). We included original, peer-reviewed articles evaluating community OOPPs which reported a training outcome and/or a report of overdose reversal rate, overdose fatalities, or another measure of overdose rate among program participants. Articles could include a single program or a small group of affiliated regional programs. Articles were excluded if OOPPs did not incorporate training on the use of naloxone and naloxone distribution as part of their program. Articles based on conglomerate data were excluded due to the inability to extract program specific information. Finally, program evaluations that focused exclusively on healthcare personnel knowledge or training were excluded.

Thirty-three articles for full-text review were identified. Of these, nineteen articles were included in this review. Seventeen articles were excluded from the review for the following
reasons: 11 did not evaluate a community OOPP (Beletsky, Rich, & Walley, 2012; Darke & Hall, 1997; Jones, Roux, et al., 2013; Leece & Orkin, 2013; Lenton, Dietze, Degenhardt, Darke, & Butler, 2009; Neira-Leon et al., 2011; Seal et al., 2001; Thurmond & Bowman, 2007; Wright, Oldham, Francis, & Jones, 2006); two did not report a training outcome and/or measure of overdose rate among program participants (Piper et al., 2008; Strang et al., 2008); one did not include training on the use of naloxone and naloxone distribution as part of its program (Branagan & Grogan, 2006); two were based on conglomerate data (Bowman, McKenzie, & Rich, 2008; Green, Heimer, & Grau, 2008); and one focused exclusively on healthcare personnel knowledge or training (Mayet, Manning, Williams, Loaring, & Strang, 2011). Two additional articles (Heller & Stancliff, 2007; Worthington, Markham Piper, Galea, & Rosenthal, 2006) were excluded because they used samples duplicated in whole or part from other included studies. When articles contained duplicate or partly duplicate samples, the article which contained results most relevant to this review was included. If all articles contained relevant results, the article, which included the largest sample population, was selected. A quality appraisal was performed on all studies included in the review. Appendix A lists areas addressed in the quality appraisal, which was adapted from a pre-existing quality assessment scale (Jinks, Cotton, & Rylance, 2011).

**State of the Current Literature**

Of 19 published studies, 14 were cohort studies which included baseline and follow-up results based on some form of questionnaire administered at separate time points (Bennett et al., 2011; Bennett & Holloway, 2012; Doe-Simkins et al., 2009; Enteen et al., 2010; Galea et al., 2006; Gaston et al., 2009; McAuley, Lindsey, Woods, & Louittit, 2010; Piper et al., 2008; Strang et al., 2008; Tobin et al., 2009; Wagner et al., 2010; Walley, Xuan, et al., 2013; Yokell et al.,
Three studies were primarily descriptive, but included outcome information based on spontaneous self-report of OOPP participants (Dettmer, Saunders, & Strang, 2001; Leece et al., 2013; Maxwell, Bigg, Stanczykiewicz, & Carlberg-Racich, 2006). Two studies were qualitative and did not include follow-up (Lankenau et al., 2013; Sherman et al., 2008). There were no randomized studies. Study quality scores ranged from 4-7 (mean = 6.1, median = 6.5 and mode = 7) out of a possible 8. Most studies scored 0 for randomization and attrition, while all studies scored 1 for overview of intervention and outcome measures. Eighteen of 19 studies received full scores for sample size and clearly described outcomes. The overall descriptive quality of the included studies, none of which were randomized and most of which had low rates of follow-up, was fair.

**Demographics & Clinical Characteristics of Participants.** Fourteen studies included a total of 9,165 self- or purposively-selected OOPP participants (Appendix B). Five articles were not included in the calculation of sample size; four were excluded (Doe-Simkins et al., 2009; Gaston et al., 2009; Walley, Xuan, et al., 2013) because these studies included overlapping OOPP sites (Maxwell et al., 2006) and one was excluded because it did not report an exact sample size. The mean age of participants was 37.4 (based on 1,615 participants from 7 studies); the majority of participants were male (68.3%, based on 4,149 participants from 12 studies) and Caucasian (61.4%, based on 3,366 participants from 7 studies). Only one study reported serving primarily African American participants (Tobin et al., 2009).

Nearly half of OOPP participants reported experiencing an overdose during their lifetime (49.6%, based on 2,036 participants from 9 studies). Across eight studies, 79.2% of study participants reported witnessing an overdose during their lifetime. Doe-Simkins et al. (2009) reported that the median number of lifetime witnessed overdoses was five and Sherman et al.
(2008) reported participants witnessed a median of six overdoses in their lifetime. Two studies reported that nearly one third of participants witnessed at least one fatal overdose. The primary self-reported drug used prior to the overdose was heroin. Contrary to other studies, Bennett et al. (2011) reported high rates of overdose on both heroin (92.0%) and other opioids (93.4%).

**OOPP Curricula.** The primary components of reported OOPPs’ curricula included 1) recognizing overdose, 2) preventing overdose, 3) risk factors for overdose, 4) appropriate response to overdose, and 5) administration of naloxone. Interestingly, only one study provided an explicit definition of overdose (Piper et al., 2008) although 15 studies reported including recognition of overdose symptoms as part of their OOPP curriculum. Fourteen articles reported inclusion of overdose prevention in their curriculum and 12 explicitly reviewed factors that could increase the risk of overdose such as mixing drugs, using drugs alone, periods of abstinence that contribute to alterations in tolerance, and drug purity. Sixteen articles reported an OOPP curriculum that included appropriate responses to overdose events, such as contacting emergency medical personnel, instructions on rescue breathing/CPR, placing the person in the recovery position, and staying with the victim. All 19 articles also included naloxone administration as part of their curricula. Fifteen articles reported providing training on needle-based naloxone administration, with some programs providing additional features such as the opportunity to practice injection techniques using oranges (Bennett & Holloway, 2012). Three articles reported on programs that offered nasal naloxone, all of which were affiliated with the OOPP in Massachusetts and all of which provided the opportunity for participants to assemble the naloxone with the atomization device and demonstrate naloxone administration (Doe-Simkins et al., 2009; Walley, Doe-Simkins, et al., 2013; Walley, Xuan, et al., 2013). OOPP training sessions varied among programs from 10 minutes to 1 hour in length.
Most authors did not specify the qualifications of individuals who conducted the training sessions or the size of the sessions. Because laws for prescribing naloxone vary by state, physician involvement varied across the programs. Rhode Island’s pilot program participants completed the training curriculum, then the program staff notified the program physician by phone and the program staff distributed the prescribed naloxone (Yokell et al., 2011). The Skills and Knowledge on Overdose Prevention (SKOOP) program in New York City required participants to briefly meet with a physician for a targeted medical history prior to receiving a naloxone kit (Galea et al., 2006; Piper et al., 2008). Some articles did not discuss physician involvement or stated that providers prescribed and dispensed naloxone, but did not give specific details.

**OOPP Reduction of Fatal and Non-fatal Overdose Rates.** Naloxone was used successfully by participants in all but one reviewed study, for a total of 1,949 reported naloxone administrations across 18 programs. Eleven studies reported 100% survival rate post-naloxone administration; the remaining articles reported a range of 83%-96% survival. In two articles where lower rates of survival were reported, this finding was confounded by a greater number of unknown overdose outcomes (Enteen et al., 2010; Piper et al., 2008). Contrary to other researchers’ reports, Lopez-Gaston et al. (2009) found that naloxone was not used in any of the witnessed overdose cases for which data were available. Researchers examined, in two articles, whether OOPPs reduced opioid overdose mortality rates at a population level. Using an interrupted time series analysis, Walley et al. (2013) found that areas in Massachusetts with higher levels of enrollment in OOPPs had lower rates of opioid-related overdose death after controlling for other factors. Maxwell et al. (2006) suggest that the Chicago Recovery Alliance OOPP may have been associated with an observed decrease in heroin overdose deaths in
Chicago. They argue that the trend toward decreasing deaths began in the same year that the OOPP was instituted and has continued since then. However, they provide no detailed analysis to test this hypothesis.

Naloxone administrations were not successful in 12 known situations across five studies (Bennett et al., 2011; Bennett & Holloway, 2012; Enteen et al., 2010; Maxwell et al., 2006; Walley, Xuan, et al., 2013). For three unsuccessful administrations, victims received emergency care and survived (Walley, Xuan, et al., 2013), while in the nine other unsuccessful administrations, the victims died. The cause of death was not reported for these individuals and in one article, the authors speculated that witnesses might have arrived too late (Enteen et al., 2010).

Researchers reporting findings in nine articles reported adverse outcomes associated with the use of naloxone. The only common physiologic adverse event reported was vomiting or other symptoms of precipitated withdrawal (109 instances). Rare but serious adverse events included four reported seizures across two studies (Enteen et al., 2010; Maxwell et al., 2006). In one situation where a seizure was reported, it was noted that the patient had a history of concurrent alprazolam use (Maxwell et al., 2006). Other non-physiological adverse events included four arrests (Enteen et al., 2010; Wagner et al., 2010) and reports of problems with police, first responders, shelters, or treatment programs due to possession of naloxone (Doe-Simkins et al., 2009; Enteen et al., 2010; Galea et al., 2006; Lankenau et al., 2013; Piper et al., 2008; Wagner et al., 2010). Rescuers from one program using nasally-administered naloxone could not connect the mucosal atomization adapter to the naloxone syringe during four separate overdose response situations (Doe-Simkins et al., 2009).
**OOPPs Effectiveness at Increasing Non-medical Bystander Knowledge.** Researchers in eight studies reported pre-post measures of change in knowledge about opioid overdose. In a study of 525 Welsh opioid users, Bennett and Holloway (2012) reported statistically significant increases in knowledge of overdose risk factors, signs and symptoms of an overdose, appropriate responses to an overdose, and the use of naloxone in overdose events immediately following an OOPP training. However, these participants were not re-tested after an extended period of time, nor were these results linked with information from individuals who reported later witnessing or experiencing an overdose. Tobin et al. (2009) reported, in a population of injection drug users (IDU), only limited change in knowledge six months after OOPP trainings. Knowledge of risk factors for overdose was high both pre and post training, while post-training knowledge about naloxone improved on some questions but declined on others.

Retention of knowledge has been demonstrated in several studies. Among 239 British opioid users, Strang et al. (2008) noted statistically significant improvements in knowledge of risk factors for overdose, overdose signs, appropriate responses to overdose, and use of naloxone immediately following OOPP training. Three months after the initial training, 78% of participants demonstrated retention in overdose knowledge. In a subset of approximately 30% of Strang et al.’s (2008) original cohort, knowledge of overdose signs and response to overdose situations was still retained at the 6-month follow-up (Gaston et al., 2009). Wagner et al.’s (2010) 3-month follow-up sample (47 of an original 69 IDUs in Los Angeles who participated in an OOPP training) demonstrated a statistically significant increase on their overall knowledge score, which included questions on overdose risks, recognition of overdose, and naloxone use. McAuley et al. (2010) reported retention in cumulative knowledge scores at 2 and 6 months in 19 Scottish drug users regarding overdose risk factors, however the small sample size precluded
determination of whether this change was statistically significant.

In a qualitative study of 31 Chicago IDUs who had completed OOPP training, Sherman et al. (2008) found that they possessed extensive knowledge regarding overdoses. Their subjective reports also demonstrated increased confidence and comfort with naloxone administration following training. Among those who had administered naloxone, individuals reported initial apprehension replaced by a sense of comfort and achievement after witnessing a successful reversal (Sherman et al., 2008). Finally, Maxwell et al. (2006) noted anecdotal knowledge increase in overdose risks and signs of overdose.

**Trained Bystanders Respond Correctly to Opioid Overdoses.** There was some evidence that training is associated with an increased use of appropriate overdose strategies. Overall, participants used both OOPP-recommended and non-recommended strategies to deal with overdose (Lankenau et al., 2013; Sherman et al., 2008). Researchers from 11 studies reported on other strategies besides naloxone administration in response to an overdose. Among these studies 23–66% participants reported using rescue breathing or CPR (Bennett et al., 2011; Enteen et al., 2010; Lankenau et al., 2013; Piper et al., 2008; Tobin et al., 2009; Wagner et al., 2010); 9–31% reported using a sternal rub to try to arouse the victim (Bennett et al., 2011; Enteen et al., 2010; Lankenau et al., 2013; Tobin et al., 2009; Wagner et al., 2010), and 22–72% placed the victim in the recovery position (Gaston et al., 2009; Piper et al., 2008). Participants also reported using non-recommended strategies in response to overdoses such as using ice or cold water to try to revive the victim (Lankenau et al., 2013; Piper et al., 2008; Tobin et al., 2009; Wagner et al., 2010), shaking or hitting the victim (Lankenau et al., 2013; Wagner et al., 2010), or injecting salt or other drugs (Tobin et al., 2009).

Two large studies, collecting follow-up data only from patients who requested a naloxone
refill, reported that at least 75% of returning participants who used naloxone concurrently used at least one other appropriate overdose response strategy (Doe-Simkins et al., 2009; Enteen et al., 2010). A smaller study, with a higher follow-up rate, reported that about half of trained participants used only OOPP-recommended strategies while half used both recommended and non-recommended strategies (Wagner et al., 2010). In three studies (total n=66) that compared reported responses to actual overdoses prior to training and three to six months after training, there was a consistent increase in reported use of sternal rubs, rescue breathing, remaining with the victim until help arrived, and placing the victim in the recovery position (Galea et al., 2006; Tobin et al., 2009; Wagner et al., 2010), as well as a decrease in use of inappropriate responses such as shouting at the victim, using ice or cold water, walking the victim, or injecting the victim with salt or other drugs (Galea et al., 2006; Tobin et al., 2009). Bennett and Holloway (2012) compared an OOPP-trained group (n=28) with a non-trained comparison group (n=38) and found that the OOPP-trained individuals were more likely to place the victim in the recovery position and call an ambulance, but less likely to use CPR. The authors speculated that the decreased use of CPR was due to less perceived need for CPR given the efficacy of naloxone.

Alerting emergency medical services (EMS) is an OOPP-recommended action that is of particular significance because naloxone has a short duration of action and individuals may experience medical complications related to recurring inadequate respiration. Additionally, notification of EMS may simultaneously alert police to respond to the scene. The reported range of EMS notification varied from 29–100% among 9 studies which reported post-training EMS notification, with 6 studies reporting a rate of less than 50%. Two qualitative studies identified fear of police involvement as one of the main reasons that participants did not alert EMS (Lankenau et al., 2013; Sherman et al., 2008). Lankenau et al (2013) noted that participants were
more comfortable notifying EMS if they were in a public location and if naloxone was not available. Furthermore, in this study participants never called EMS when naloxone was administered in a private location. Bennett et al. (2011) reported that 71% of participants who did not notify EMS cited the reason as fear of police involvement, whereas only 22% cited the reason as perceiving medical assistance as unnecessary. Conversely, Tobin et al. (2009) reported only 16% of those who did not call 911 reported fear as the reason and 84% reported that medical assistance was not needed. Of note, two studies reported actual harassment of participants by EMS (Enteen et al., 2010; Sherman et al., 2008). In qualitative interviews participants reported fear of calling EMS, but most who did reported receiving positive feedback for their use of naloxone as well as four positive interactions with police accompanying EMS (Sherman et al., 2008). Five studies compared rates of EMS notification pre- and post-training: two reported a decrease in rates of notification (Bennett et al., 2011; Tobin et al., 2009), two reported an increase (Bennett & Holloway, 2012; Galea et al., 2006), and one reported no change (Wagner et al., 2010).

**Summary of OOPP Literature**

Several conclusions can be drawn from this review of the current literature on OOPPs. Specifically, conclusions can be made about: a.) the overall effectiveness of non-medical bystanders trained by OOPPs, b.) bystander use of additional recommended and non-recommended strategies in response to an overdose, and c.) common limitations of the OOPPs studies. One convincing indication that a participant has acquired OOPP knowledge is through the demonstration of that knowledge. Positive outcomes in actual overdose situations may indicate effective OOPP training, even without methodologically rigorous follow-up testing. By this measure, we can conclude that at least some trained individuals retained and made use of
their OOPP training by reversing opioid overdoses they subsequently witnessed.

Including only the reviewed studies, nearly 2,000 overdoses were reversed by lay bystanders who have received OOPP training. All but one of nineteen articles indicated that participants used and refilled their naloxone prescriptions at an appropriate rate, again suggesting that across different locations in the United States and Great Britain, current OOPP trainings consistently provide sufficient knowledge for individuals to effectively administer naloxone. Because most individuals who overdose recover even without medical attention (Darke et al., 2007), it is not possible simply to equate use of naloxone with reductions in overall mortality from overdose. However, Walley et al. (2013) provide evidence that a comprehensive OOPP may actually reduce population mortality rates from opioid overdose. Further studies of this type would better illustrate the public health impact of OOPPs in reducing the morbidity and mortality associated with the opioid overdose epidemic.

The current evidence suggests that individuals who use naloxone effectively also utilize both appropriate and inappropriate additional strategies in response to overdose. The high variation in rates of use suggests that different training programs may be more or less effectively reinforcing other lifesaving measures. Although several articles suggest that training improved the use of sternal rubs, rescue breathing, and use of the recovery position, it is discouraging that, in the most methodologically sound articles, the same individuals who were able to correctly administer naloxone used other appropriate overdose response strategies less than half the time. Additionally, ineffective and potentially harmful strategies, such as pouring ice or cold water on the victim, continued to be used after training.

This review of OOPPs confirmed that most OOPP participants do not call EMS when they witness an overdose. This finding is consistent with observational research conducted prior
to the availability of bystander-administered naloxone which showed that individuals who witnessed an overdose rarely contacted EMS (Tobin, Davey, & Latkin, 2005). On the other hand, rates of EMS notification were similar to the use rates of other appropriate overdose strategies such as rescue breathing. Several articles provided more detailed analysis of EMS utilization, suggesting that 1) participants fear negative consequences if they call for assistance, and 2) although there were a few cases of EMS harassment, most individuals who contacted EMS reported positive experiences. Trainings that directly addressed these two factors might improve rates of EMS notification. Future research may investigate whether laws that provide civil and/or criminal protection for bystanders, who call EMS in response to an overdose, result in increased notification of EMS by OOPP participants.

**Limitations of OOPP Studies.** The limitations of the OOPP articles include a lack of methodological rigor and challenges related to generalizability. Furthermore, there are limitations to the systematic review itself. Lack of methodological rigor is demonstrated in several ways in the reviewed studies. Currently published articles are of fair quality, as evidenced by the quality appraisal scores. None of the seventeen quantitative studies used randomization and all studies relied on participant self-reports. The lack of randomized controlled trials of OOPPs limits any conclusions that can be reached about their overall effectiveness, while the well-established efficacy of naloxone in reversing opioid overdose (Boyer, 2012) creates an ethical challenge that makes future randomized efficacy trials of OOPP unlikely. Effectiveness trials randomized by treatment program remain a viable option for study. The generalizability of reviewed OOPP studies is further limited because systematic prospective methods were infrequently used to follow-up with OOPP participants and when these methods were employed, the follow-up period was short (6 months) or the sample size was small (<75
Many of these studies reported findings from pilot programs that only collected follow-up data from participants returning for naloxone refills or other standard clinical services. Four of the studies made no systematic attempt to follow up with participants and 10 studies followed up with less than half of participants. The high rate of attrition observed in these studies could have resulted in under- or over-reporting of outcomes, particularly given that many studies only collected follow-up data on patients who requested naloxone refills. Finally, the methodological and measurement differences across studies make it challenging to synthesize the results and ultimately determine the effectiveness of OOPPs. The development of a standardized OOPP evaluation and outcome tool would allow consistent measurement across studies, enhancing the empirical evidence regarding the effectiveness of OOPPs.

Program curricula were fairly standard across studies, but there was no indication of whether curricula were manualized or empirically tested. While most studies did not include specific details of their curriculum, they usually did note that their curriculum addressed how to recognize overdose, risk factors for overdose and how to appropriately respond to overdose events. It is difficult to assess the effectiveness of these educational programs due to the lack of systematic measures and consistent follow-up. Two studies demonstrated improvement in knowledge immediately following OOPP training, but this is of limited value in determining retention of knowledge over time. The five studies in which researchers conducted three or six-month follow up findings indicated some improvement in at least some areas of OOPP knowledge. However, the results also suggest that researchers in these studies may have observed ceiling effects in their measurement instruments which make it difficult to accurately measure absolute increase in knowledge. A standardized approach to assessing changes in
knowledge, assessing retention in knowledge over time, and achieving higher follow-up rates would provide stronger support regarding the efficacy of OOPPs at increasing non-medical bystander knowledge of prevention, risk factors, and recognition of overdose.

One difficulty in generalizing the findings of this review of OOPPS is that heroin was identified as the drug reported as most frequently used prior to the overdose. This finding does not reflect national data from the United States and may be attributable to the high number of OOPPs delivering services in conjunction with needle exchange programs. According to the National Vital Statistics System, the leading cause of drug overdoses is opioid analgesics, not heroin (Paulozzi, 2012). Needle exchange programs are an excellent strategy to reach intravenous drug users and illicit drug users that are not likely to be receiving services from the addiction treatment specialty system. However, non-intravenous drug users (IDU’s) and patients across a variety of health care settings, including substance abuse treatment centers, pain clinics, dental offices, emergency departments, and primary care clinics may be at high risk for overdose.

The demographic characteristics of OOPP participants in the reviewed studies may not accurately represent all persons at high risk of overdose death based on epidemiological studies. For example, the majority of program participants were male (71.4%) and while males are at an increased risk for drug overdose deaths compared to females (Paulozzi, 2012), more than half of the estimated 2.4 million Americans initiating prescription drugs non-medically in the past year were female (SAMHSA, 2011). Research examining gender-specific needs in OOPPs as well as clinical consideration of how to improve OOPP participation by individuals misusing prescription opioids may be warranted.
This systematic review of OOPPs is subject to several limitations. Our review has a narrow focus and included a limited number of the total articles published on OOPPs. Because this review focused on OOPP outcomes, descriptive articles were excluded. The review included only peer-reviewed articles that were published in English and therefore may have missed important international differences in OOPPs. There are more than 188 OOPPs operating in the United States alone, but only a few have published peer-reviewed assessments or evaluations. Therefore, this report of the number of overdoses reversed is about an order of magnitude lower than that found in a more comprehensive recent survey of OOPPs nationwide (Wheeler et al., 2012). The survey by Wheeler et al. (2012) and others that included multiple OOPPs within one publication were not included in this review because the data could not be disaggregated at the program level.

This review was not able to determine the effectiveness of OOPPs in reducing fatal and non-fatal overdoses because of the methodological limitations of the studies. However OOPP participation is associated with overdose reversals, increased knowledge and ability to respond appropriately in an overdose situation, and the ability of non-medical bystanders to safely administer naloxone. While participation in OOPPs may not increase EMS notification, some participants do utilize other appropriate strategies including rescue breathing and placing victims in the recovery position. Although naloxone is a life-saving medication, other strategies are essential to prevent the occurrence of an overdose and it is necessary to provide response strategies if a naloxone kit is not readily available and/or there are any problems contacting EMS. Given that OOPPs provide training on overdose risk factors, prospective large-scale longitudinal studies are needed to determine whether participation is associated with a decreased risk of fatal and non-fatal overdose.
Testing the effectiveness of training requires a more standardized approach to evaluation, including tools to accurately measure change in knowledge, demonstration of achieved knowledge, and more careful follow-up. OOPPs have the potential to reduce opioid overdose morbidity and mortality, but their effectiveness is currently unknown. Well-designed studies are needed to evaluate the extent to which OOPPs reduce drug-related morbidity and mortality, examine strategies to implement OOPPs into existing clinical practices, and determine the population-level benefit of OOPPs.

**The Need for Empirically Tested OOPP Educational Interventions**

Findings from the literature review of OOPPs support that opioid overdose prevention programs have the potential to increase knowledge regarding overdose prevention and knowledge of how to respond during an overdose event. However, there is a need for educational interventions that have been empirically tested. In 2013, the Substance Abuse and Mental Health Services Administration released the SAMHSA Opioid Overdose Prevention Toolkit.

The toolkit is a 24-page document that includes: written facts for community members, essential steps for first responders, information for prescribers, safety advice for patients and family members and resources for overdose survivors (SAMHSA, 2013d). To best inform OOPP participants about preventing, recognizing, and responding to an opioid overdose, contents from the essential steps for first responders, information for prescribers, and safety advice for patients and family members were modified for use in the group setting.

The main purpose of this study was to develop a group educational intervention based on the SAMHSA toolkit and determine its feasibility in the clinical setting. The broad purpose of the study was to address the knowledge gap identified in the review of OOPP literature that includes a lack of efficacy studies due to a lack of educational interventions being empirically
based. This study utilized the theory of social interdependence to guide the implementation of a
group-based educational intervention in an inpatient OOPP.

**The Theory of Social Interdependence**

The intervention was guided by the social interdependence theory (SIT) which asserts that: a). group learning allows members to more frequently generate strategies and solutions than when working individually and b). group members have an increased ability to transfer learning from one situation to another (Johnson & Johnson, 2013). The SIT also supports that cooperative group learning, because of the strong relationship between theory, research, and practice, is a widely accepted and preferred method of instruction at all levels of education (Johnson, Johnson, & Smith, 2007).

Social interdependence occurs when outcomes are dually affected by the individual’s own actions and the actions of others (Johnson & Johnson, 2005). There are three variations of interdependence: positive social interdependence (i.e. cooperation), negative social interdependence (i.e. competition) and no social interdependence (i.e. individualistic) (Johnson & Johnson, 2008). Positive social interdependence (cooperation) occurs when an intervention is structured so that individuals’ goals are positively correlated and when individuals seek outcomes that are beneficial to all those who are in the group (Johnson & Johnson, 2008).

The underlying premise of the SIT is that type of interdependence (cooperative, competitive, or individualistic) indirectly determines outcomes. Positive social interdependence results in *promotive interaction*. Promotive interaction occurs as individuals encourage and facilitate each other’s efforts including the exchange of needed resources, assistance, challenging each other’s conclusions and reasoning (Johnson & Johnson, 2013). The main effect of promotive interaction is increased *effort to achieve*. Effort to achieve includes: actual
achievement, a willingness to take on difficult tasks despite challenges, increased intrinsic motivation, high commitment toward goal achievement, long-term retention of what is learned, higher-level critical thinking, creative thinking and process gain, transfer of learning from one situational setting to another, positive attitudes toward learning and increased time spent on task (Johnson & Johnson, 2005, 2008). Thus, the overall supposition of the social interdependence theory suggests that positive social interdependence fosters promotive interaction yielding an increased effort to achieve and that social interdependence is an important predictor of achievement (Johnson & Johnson, 2009; Onwueguzie & Daley, 1998).

In a meta-analysis of 168 studies examining the efficacy of cooperative, competitive, and individualistic learning, researchers indicated that cooperative learning (positive social interdependence and promotive interaction) promoted statistically-significant higher levels of individual achievement than both competitive and individualistic learning (Johnson et al., 2007). Research by Onwueguzie and Daley (1998) also supports the relationship between positive social interdependence and increased effort to achieve through an examination of the study skills of undergraduate students (n=154). Onwueguzie and Daley’s (1998) findings suggest that positive social interdependence affects effort to achieve; students’ scores on the cooperative subscale of the social interdependence scale were strongly, positively correlated with measures of actual achievement. In a study of male criminals in three samples from correctional facilities (n=123), researchers indicated that the more cooperatively oriented the inmates, the more positive their attitudes (James & Johnson, 1983). Inmates who were more cooperatively oriented, reported greater psychological health and less alienation (James & Johnson, 1983).

The SIT has been scientifically validated in numerous studies (Johnson & Johnson, 2013). Increased effort to achieve has been demonstrated to be related to: higher level reasoning,
process gain, group-to-individual transfer, intrinsic motivation and high commitment to achieve (Johnson & Johnson, 2013). Process gain occurs when group interaction increases new ideas, solutions to problems and are not generated when persons work individually (Johnson & Johnson, 2013). Group-to-individual transfer occurs when members of the group learn information and skills together and then have the ability to transfer the information and skills to future situations when group members are no longer present (Johnson & Johnson, 2013).

According to Johnson and Johnson (2013) more than 1,200 studies have measured the effects of cooperative, competitive, and individualistic efforts of individuals in a wide-variety of service organizations. Although the majority of studies evaluating the social interdependence theory examine school-aged children in the educational setting, there is evidence that cooperative predisposition increases with age and there is evidence of support for use of the SIT in public health settings (Choi, Johnson, & Johnson, 2011; James & Johnson, 1983).

Social Interdependence Theory as a Framework for Opioid Overdose Prevention

The social interdependence theory, as described by Johnson and Johnson posits that promotive interaction and positive interdependence results in higher effort to achieve making it the ideal theoretical framework to guide the study (Johnson & Johnson, 2013; Johnson & Johnson, 2005). The study aims to determine the feasibility and effect size of a group-based OOPP educational intervention and the tenets of SIT support: a). the use of a group to transfer knowledge and resources b). the use of group to increase actual achievement. In Figure 4 below, the SIT is illustrated as it will guide the study. The overall goal of the intervention is to prevent opioid overdoses (center) and effort to achieve (actual achievement) includes the surrounding spokes of the core: greater retention of opioid overdose prevention strategies, process gain,
higher level critical thinking, solutions for responding to overdose events, transfer of knowledge from the group setting to future settings.

**Figure 4.** The social interdependence theory. This figure illustrates how the SIT will guide the study. Source: Developed with permissions from David W. Johnson, 2014.

**Conclusion**

Opioid-related overdoses have reached epidemic proportions and are a burgeoning public health crisis in the United States. While the crisis is the result of multiple factors, the most-proximal intervention to decrease opioid-related overdose fatalities is the timely administration of naloxone. Opioid overdose prevention programs (OOPPs) have been distributing naloxone to individuals at high risk for experiencing or witnessing an opioid overdose for nearly twenty years. Research has demonstrated that bystanders have the ability to successfully reverse
overdoses after receiving education provided by opioid overdose prevention programs. A systematic review of OOPPs was conducted; findings indicate the lack of follow-up and wide-variation in interventions within and across OOPPs make it difficult to determine the true efficacy of OOPPs.

In 2013, SAMHSA released the Opioid Overdose Prevention Toolkit to assist OOPPs in the implementation and development of the educational interventions. However, in its current format the toolkit does not permit use in the group setting because it lacks the necessary prompts for group discussion. The aforementioned discussions have been powerful in assisting program participants to gain knowledge about responding to opioid overdoses including notifying emergency responders and troubleshooting naloxone administration. The SIT, as envisioned by Johnson and Johnson (2005), is a well-established theory grounded in educational principles that supports an increase transfer of knowledge when individuals learn in the groups. Due to the rigorous support of the theory by over 1,200 studies, it is an ideal theory to guide the group-based educational intervention. The SIT will guide the study by supporting the use of cooperative learning groups to promote the generation of new ideas and solutions regarding opioid overdose prevention and response including the administration of naloxone (Johnson & Johnson, 2013; Johnson & Johnson, 2005).
Chapter 3: Method

The purpose of this study was to determine the feasibility of an opioid overdose prevention educational intervention in the group setting. This chapter will provide insight regarding the research design in terms of how it was embedded within a larger ongoing evaluation of an OOPP in respect to each of the study’s four specific aims. This chapter will specifically provide an overview of the study methods, a breakdown of the sample size, inclusion/exclusion criteria, recruitment procedures, informed consent process and protection of human subjects.

Research Design

The educational intervention study was embedded within an ongoing program evaluation study of an opioid overdose prevention program at the Center for Chemical Addictions Treatment. The ongoing study entitled: Program Evaluation of an Opioid Overdose Prevention Program for Patients Receiving Addiction Treatment as conducted by Dr. Erin Winstanley. The ongoing evaluation aims to determine whether participation in the OOPP is associated with 1) increased knowledge of opioid overdose risk factors, 2) the utilization of naloxone, and 3) a reduction in the rate of fatal opioid overdoses among program participants. The protocol for the ongoing evaluation study includes 6-month and 12-month follow-up data collection.

The current study was based on Rousanville’s stage model of development and testing of behavioral therapies. Rousanville’s model outlines a scientifically rigorous process guiding initial innovative behavioral therapy development and subsequent intervention and efficacy studies, and eventually effectiveness research (Rounsaville et al., 2001). Stage Ia of Rousanville’s model, focuses on therapy development and manual writing and guided Aim 1 of the study (Rounsaville et al., 2001). Stage/Ib of Rousanville’s model guided Aims 2, 3, and 4 of
the study and involved pilot testing the manual and determining the feasibility of the manualized intervention (Rounsaville et al., 2001). The approach to each of the aims is described below.

**Setting**

This study was conducted at a Midwestern substance abuse treatment facility in a mid-sized city. The patient population includes adults, both male and female patients age 18 or older receiving treatment for drug and/or alcohol dependence. Staff includes a physician medical director, two staff nurses, a nurse manager, four counselors and various non-clinical support staff (cooks, patient care assistants, janitors and clerical workers). The facility has two inpatient treatment programs: a 5 to 7-day inpatient detoxification program and a 28-day inpatient treatment program. For this study, participants were recruited from the 28-day inpatient treatment program.

**Specific Aim 1: Modify the SAMSHA Opioid Overdose Prevention Toolkit for Use in the Group Setting**

**Approach.** Stage Ia in the stage model of determining feasibility included developing the intervention implementation guidelines for program clinicians (Rounsaville et al., 2001). Stage Ia was accomplished by convening an all-day meeting during which four key stakeholders assisted the PI to determine content and mandatory items for the educational intervention. Prior to meeting, the PI distributed the SAMHSA Toolkit and preliminary findings from the ongoing evaluation of the OOPP to key stakeholders. After thorough review and evaluation of the toolkit and other items individually, the group convened at an in-person, one-day meeting to determine and arrive at agreement on intervention components including: content organization, specific items for the adherence subscale (Aim 2) and method of delivery within the group setting. The PI then worked with a team of instructional design and pedagogy experts to synthesize the ideas.
generated from the meeting into an approximately 1-hour iBook intervention for use in the group setting. Key stakeholders were then given the opportunity to review the iBook and provide feedback. The outcome of Aim 1 was an interactive educational intervention in the iBook format entitled CARRY Narcan®.

**Participants.** Key stakeholders included: a clinician with five years’ experience as an addiction counselor who is well versed in facilitating groups and has experience training clinicians; a public health nurse experienced in drafting an OOPP curriculum and implementing harm-reduction programs; a person with opioid dependence who has previous experience receiving naloxone; a public health researcher who has extensive experience in harm reduction strategies and experience organizing community attempts to reduce harm. All key stakeholders demonstrated a previous working knowledge of opioid overdose prevention programs and were recruited from The University of Cincinnati College of Medicine, Ohio’s Prescription Drug Abuse Action Group and the Center for Chemical Addictions Treatment.

**Specific Aim 2: Determine Whether Clinicians, Who have Received Training, Can Deliver the Intervention with Implementation Fidelity in the Group Setting**

**Overview.** Implementation fidelity is the degree to which interventions are implemented in the manner intended by the developers and is an important source of variation that affects both the utility of interventions and the credibility of findings (Carroll et al., 2007; Kubiak, Fedock, Tillander, Kim, & Bybee, 2014). Implementation fidelity is determined by three factors: clinicians’ adherence to the manual; clinicians’ competency in skills supporting the intervention; and the participants’ responsiveness during the intervention (Aim 3) (Breitenstein et al., 2010; Carroll et al., 2007).
**Approach.** Inter-rater agreement was used to determine implementation fidelity. Two research assistants (RAs) attended all group sessions and completed The Modified Fidelity Checklist®. The Modified Fidelity Checklist® is composed of two subscales evaluating adherence and competence. The original version of this tool has been successfully used to evaluate educational interventions with reliability in the community setting (Breitenstein et al., 2010).

The adherence subscale of the original fidelity checklist is not transferable and requires modification to reflect the content of the intervention. Dr. Susan Breitenstein, who developed The Fidelity Checklist, served as a consultant on this study and worked with the PI to develop The Modified Fidelity Checklist® (Appendix C). The Modified Fidelity Checklist® is composed of two subscales evaluating adherence to the intervention and competence of the clinician’s skills when delivering the intervention.

**Participants.** The target sample size for Aim 2 was three clinicians (75% of current staff clinicians). Two raters, RAs, observed each clinician conducting the group-based educational intervention four times yielding a total of 12 group observations. Inclusion criteria for the clinicians included: English speaking staff members, who voluntarily consented to study participation. All clinicians were recruited in person by the PI who reviewed the consent forms with the clinicians and provided informed consent. The staff members were made aware that participation in the study was entirely voluntary and at no point would their decision affect their role in clinical care.

**Training of Clinicians.** The PI conducted a two-hour in-person training on how to use the CARRY Narcan® iBook. The training included instruction on mandatory adherence items as determined by the key stakeholders (Aim 1) and as outlined in The Modified Fidelity
Checklist©. The training also included discussion of possible participant questions. Clinicians were given an iPad with the iBook on it, The Modified Fidelity Checklist©, and nasal naloxone adaptors to practice hands-on simulation and application of naloxone administration content.

Data Collection. Two RAs attended all OOPP group interventions and completed The Modified Fidelity Checklist©, until each clinician had been observed conducting four educational groups (Carroll et al., 2007; Kubiak et al., 2014).

Data Management. Results of The Modified Fidelity Checklist were entered into REDCap™ data management software then transferred to SPSS® statistical analysis software for data analysis.

Data Analysis. Two estimates of inter-rater reliability were determined using intraclass correlation coefficients (ICCs). Dichotomous item cores under the subscales of adherence and competence on The Modified Fidelity Checklist© were used to determine inter-rater reliability using Kappa statistics. Internal consistency among items in sub-domains were evaluated using Cronbach’s alpha. Change of knowledge score (Aim 4) in relation to adherence and competence subscales were assessed using correlation coefficients.

Specific Aim 3: Examine the Relationship between the Educational Intervention Fidelity and Participant Responsiveness to the Intervention

Rationale. The third factor of implementation fidelity is participant responsiveness during the intervention (Breitenstein et al., 2010; Carroll et al., 2007). Participant responsiveness includes assessments of how useful and relevant an intervention is deemed and the level of engagement amongst participants (Carroll et al., 2007). Participant responsiveness was assessed through group leader report using the Engagement Form (Appendix H) (Garvey, Julion, Fogg, Kratovil, & Gross, 2006). The 7-item Engagement Form was used to determine the extent to
which group attendees participate in the group sessions. In a study measuring participant responsiveness to a community educational intervention, the Engagement Form was deemed both valid and reliable (Cronbach’s alpha was .92).

**Hypothesis.** Higher scores on the Engagement Form will be positively correlated with higher scores on The Fidelity Checklist (Aim 2).

**Approach.** After each group intervention the clinician who delivered the intervention to the group completed the Engagement Form (Garvey et al., 2006).

**Data Management.** Results of the Engagement Form were entered into REDCap™ database and imported into SPSS® statistical analysis software for data analysis.

**Data Analysis.** Pearson’s correlation coefficient was used to assess the linear correlation between the total score on the Engagement Form (Aim 3) and The Modified Fidelity Checklist© (Aim 2). In addition, measurements in the Engagement Form (Likert scores such as 0=not at all, 1=seldom, 2=some of the time, 3=most of the time) were compared to dichotomous groups “being engaged” versus “not engaged” using Wilcoxon’s rank sum tests.

**Specific Aim 4: Determine the Intervention Effect Size**

**Rationale.** The social interdependence theory as described by Johnson and Johnson indicates that promotive interaction and positive interdependence results in higher effort to achieve. Promotive interaction is defined as individuals encouraging and facilitating each other’s efforts to accomplish the group goal (Johnson & Johnson, 2013). This variable was operationalized using the Classroom Life Measure subscale cooperative learning. Positive interdependence is when the actions of individuals promote the achievement of joint goals and was operationalized by the Classroom Life Measure positive goal interdependence subscale and the Classroom Life Measure resource interdependence subscale on the Classroom Life Measure
The outcome of promotive interaction and positive interdependence is effort to achieve and is conceptually defined as higher-level reasoning strategies, generation of new ideas and solutions, transfer of what is learned from one situation to another, intrinsic motivation, and actual achievement (Johnson & Johnson, 2013). Effort to achieve was operationally defined as actual achievement and was evaluated using the mean change in knowledge score from the Knowledge Pre-test/Post-test.

**Instrumentation**

The Classroom Life Measure, as modified with permissions from Dr. David Johnson, is a 21 item, 5-point Likert scale, and was used to determine the degree to which subjects’ perceived promotive interaction and positive interdependence during the group intervention. The Knowledge Pre-Training Survey is a 34-question, Likert type scale, developed by the University of Cincinnati Opioid Research Team. The Knowledge Pre-Training Survey© is used to assess participant knowledge of the risk factors associated with opioid overdose, symptoms of an overdose and actions participants would take if someone overdosed. The Knowledge Post-Training Survey© is a 37-question, Likert-type scale, nearly identical to the Knowledge Pre-Training Survey© with the inclusion of the questions: Prior to this training, did you know that naloxone could reverse a heroin or prescription drug overdose? If yes, please check if: Narcan has been used to revive you in the past and/or You’ve seen someone who overdosed by given narcan. The Naloxone Program Baseline Survey© is a 51-question survey identifying participants’ demographics, living situation, status of employment, history of substance use, history of overdose, psychiatric mental history and physical history.
Table 1. Theoretical constructs of the social interdependence theory. This table describes data collection tools.

<table>
<thead>
<tr>
<th>Theoretical Construct</th>
<th>Measure</th>
<th>Items</th>
<th>Reliability (Cronbach’s alpha)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promotive Interaction</td>
<td>Classroom Life Measure Subscale</td>
<td>7 Likert-type items</td>
<td>0.83</td>
</tr>
<tr>
<td></td>
<td>Cooperative Learning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive Interdependence</td>
<td>Classroom Life Measure Subscale</td>
<td>5 Likert-type items</td>
<td>0.61</td>
</tr>
<tr>
<td></td>
<td>Positive Goal Interdependence</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Classroom Life Measure Subscale</td>
<td>5 Likert-type items</td>
<td>.74</td>
</tr>
<tr>
<td></td>
<td>Resource Interdependence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effort to Achieve</td>
<td>Knowledge Pre-Training Survey©</td>
<td>34 Likert-type items</td>
<td>Not assessed for reliability.</td>
</tr>
<tr>
<td></td>
<td>Knowledge Post-Training Survey©</td>
<td>37 Likert-type items, yes/no items</td>
<td></td>
</tr>
</tbody>
</table>

**Hypothesis.** Increased scores on the interdependence and promotive interaction subscales of the Classroom Life Instrument will be associated with higher levels of actual achievement, as indicated by an increased number of correct responses from the Knowledge Pre-training Survey© to the Knowledge Post-training Survey©.

**Approach.** The PI tested the hypothesis that a group-based OOPP educational intervention will increase actual achievement using a one-group pre-test/post-test quasi-experimental design. Subjects completed the Knowledge Pre-training Survey© (Appendix D) before the group educational intervention. After the intervention, subjects completed the
Knowledge Post-training Survey® (Appendix E), The Classroom Life Measure (Appendix F), and the Naloxone Program Baseline Survey® (Appendix G).

**Data Collection.** This study was conducted at a Midwestern substance abuse treatment facility where subjects are receiving inpatient treatment for opioid dependence. Forty-nine subjects completed the educational intervention. Forty-nine subjects was the sample size calculated prior to study initiation. It was estimated that a sample size of 49 subjects would yield a power of 90% to detect a correlation coefficient of 0.45, and a 86% power to detect an effect size of 0.45 to detect a change between the Knowledge Pre-training Survey® and the Knowledge Post-training Survey®, using a paired t-test at a 5% significance level.

**Participants.** The inclusion criteria for Aim 4 were: 1). opioid-dependent patients 18 or older; 2). clinically stable as determined by the physician utilizing the biopsychosocial assessment document; 3). able to comprehend English; 4). negative pregnancy test for females; 5). has sensory capacity (sight, hearing, cognition) to participate as determined by standard intake procedures; and 6). willing to participate in the group discussion.

**Consent and Recruitment.** Subjects were recruited by the research team in person and were given the opportunity to ask questions prior to study consent. All subjects completed informed consent prior to participation in the study. Subjects were made aware that participation was entirely voluntary, and that they could withdraw from the study at any point. Subjects were also informed that their decision to participate in the study would in no way affect their clinical care at the treatment facility.

**Data Management.** Data from the Naloxone Program Baseline Survey®, Knowledge Pre-training Survey® and Knowledge Post-training Survey® and The Classroom Life Measure
were entered into REDCap™ database and imported into SPSS® statistical analysis software for data analysis.

**Data Analysis.** Total scores from the Classroom Life Measure were correlated to the change of scores between the Knowledge Pre-training Survey© and the Knowledge Post-training Survey© using correlation coefficients. The interdependence and promotive interaction subscales of the Classroom Life Measure were compared to changes in knowledge scores using the correlation coefficients. Cohen’s d was calculated to determine the intervention effect size and to determine power for future studies.

**Importance of Knowledge to be Gained**

This study was the first to empirically evaluate a manualized OOPP curriculum based on the SAMHSA Opioid Overdose Prevention Toolkit and the first study to provide manualized intervention to facilitate discussion in the group setting. Findings from this study will contribute knowledge regarding the feasibility of OOPP interventions in the treatment setting, and the feasibility utilizing a group-based curriculum. This knowledge is highly beneficial to communities, governments, and public health stakeholders working to mitigate the opioid overdose epidemic.
Manuscript 1: Opioid Overdose Prevention iBook Increases Opioid Dependent Inpatients’ Knowledge

Opioid overdose is the leading cause of injury death in the United States and opioid overdose fatalities have more than tripled in the past 25 years (CDC, 2014). According to the Centers for Disease Control and Prevention, overdoses associated with prescription and illicit opioids have reached epidemic levels (CDC, 2012a). Approximately 46 fatalities from prescription opioids occur in the U.S. every day (Jones, Mack, & Paulozzi, 2013). In states such as Ohio, opioid overdose is a significant concern as fatal overdoses have nearly quadrupled in the past decade (Ohio Department of Health, 2014). It is estimated that five Ohioans die each day due to drug overdose (Ohio Department of Health, 2014).

Untreated respiratory depression is the most deleterious outcome of opioid overdoses and, if left unrecognized, overdoses are all too often fatal. However, opioid overdoses can be effectually reversed with the timely administration of Naloxone, brand name Narcan®. Naloxone reverses respiratory depression by competitively binding to mu-opioid receptor sites, temporarily blocking the depressive effects of opioids, averting fatalities (Boyer, 2012; Sporer & Kral, 2007). Medical professionals have long used naloxone routinely in hospitals (Chamberlain & Klein, 1994) and in 1996, community-based harm reduction programs began distributing naloxone to bystanders and individuals at high-risk for overdose to be administered during overdose events (Wheeler, Davidson, Jones, & Irwin, 2012).

The most recent report on opioid overdose prevention programs (OOPPs) states that there are 188 OOPPS in the United States providing overdose prevention education and naloxone, mostly through needle-exchange programs, public health clinics and jails (Wheeler et al., 2012). However, since the publication of these results, states such as Ohio have responded to the opioid
overdose epidemic by dramatically increasing the number of OOPPs. Ohio, for example had one OOPP at the time of Wheeler et al.’s. (2012) manuscript and currently has 24 documented OOPPs.

In 2013 a research team, including the first and third authors, conducted a systematic review of OOPPs and our findings suggested that the majority of OOPPs were conducted through needle-exchange efforts, not addiction treatment facilities. We also found that educational interventions primarily addressed recognizing overdoses and responding to overdoses, including the administration of naloxone, and many programs included discussion of overdose prevention. However, interventions varied widely in duration, setting, and were dually delivered to individuals and groups (Clark et al., 2014). Despite the ability of OOPPs to increase participant knowledge regarding overdoses and change participant behavior, published evaluations of OOPPs indicate that participants used both OOPP-recommended and non-recommended strategies to deal with overdose, (Doe-Simkins, Walley, Epstein, & Moyer, 2009; Walley et al., 2013) and despite training sometimes individuals were hesitant to notify first responders during an overdose (Bennett, Bell, Tomedi, Hulsey, & Kral, 2011; Doe-Simkins et al., 2009; Tobin, Sherman, Beilenson, Welsh, & Latkin, 2009). Furthermore, the research team determined that additional research was needed to describe educational interventions of OOPPs in the group with structured, consistent treatment dose.

In an evaluation of an ongoing OOPP in an inpatient addiction treatment setting, our research team examined the use of the group setting to deliver OOPP content. Initially, the decision was based on resource optimization. However, throughout the course of the study, the research team observed that participant interaction encouraged open discussion about issues surrounding overdose events such as victim responses after naloxone administration and
concerns regarding police involvement on the scene. Together the group generated solutions to real-life personal experiences with overdose and addressed barriers to responding to overdose events, including discussing thoughts and feelings about fatal overdoses, contacting police and first responders during an overdose, and what to expect after administering naloxone. Group conversations allowed participants the opportunity to process past overdose events and provided insight for how to respond in the future. This learning process would not have been possible if learning occurred outside the group setting (Johnson & Johnson, 2013). These findings support the over 1,200 studies conducted testing the theory of social interdependence, which holds that cooperative group learning (positive interdependence) facilitates the exchange of needed resources and assistance (promotive interaction) resulting in an increased effort to achieve the targeted goal, in this case opioid overdose prevention (Johnson & Johnson, 2013; Johnson & Johnson, 2009).

Thus, there was an opportunity for researchers to develop a novel Opioid Overdose Prevention Educational Intervention for use in the group setting. To develop the educational intervention, a team of four key stakeholders convened to determine critical components of the OOPP curricula. Key stakeholders included: a clinician with five years’ experience as an addiction counselor who also is well versed in facilitating groups and has experience training clinicians; a public health nurse experienced in drafting an OOPP curriculum and implementing harm-reduction programs; a person with opioid dependence who has previous experience receiving naloxone; a public health researcher who has extensive experience in harm reduction strategies and experience organizing community attempts to reduce harm.

The first author utilized all critical components identified by the stakeholders and developed the CARRY Narcan® iBook for use in the group setting. The CARRY Narcan®
iBook includes 23 interactive pages of video demonstrations, testimony, audio explanation, and animations aimed at instructing group members how to identify, prevent and respond to opioid overdoses.

The purpose of this one-group pre-test/post-test quasi-experimental study was to determine if the overdose prevention education could be delivered in the group setting using the CARRY Narcan© iBook and if the intervention improved participant knowledge around recognizing, preventing and responding to opioid overdoses. We hypothesized that when clinicians delivered the CARRY Narcan© iBook with a high level of treatment fidelity, participant knowledge about opioid overdose prevention would increase.

The theory of social interdependence as described by Johnson and Johnson (2005) indicates that promotive interaction and positive interdependence results in a higher effort to achieve an identified behavior (Johnson & Johnson, 2005). Promotive interaction is defined as individuals encouraging and facilitating each other’s efforts to accomplish the group goal (Johnson & Johnson, 2013). Positive interdependence is when the actions of individuals promote the achievement of joint goals. The outcome of promotive interaction and positive interdependence is an increased effort to achieve and is conceptually defined as higher-level reasoning strategies, generation of new ideas and solutions, transfer of what is learned from one situation to another, intrinsic motivation, and actual achievement (Johnson & Johnson, 2013). Effort to achieve was operationally defined as actual achievement and was evaluated using the mean change in knowledge score from the Knowledge Pre-training Survey©/Post-training Survey©.
Methods

Recruitment and Inclusion Criteria

Subjects were recruited by the research team in person at an overdose prevention group session and were given the opportunity to ask questions prior to study consent. All subjects completed informed consent prior to participation in the study. Subjects were made aware that participation was entirely voluntary, and that they could withdraw from the study at any point. Subjects were also informed that their decision to participate in the study would not affect their clinical care at the treatment facility.

The inclusion criteria for subjects were: 1). opioid-dependent patients at a Midwestern substance abuse treatment facility over the age of 18; 2). clinically stable as determined by the physician; 3). able to comprehend English; 4). negative pregnancy test for females; and 5). has sensory capacity (sight, hearing, cognition) to participate as determined by standard intake procedures.

Overdose Prevention Education Groups

Clinicians who had been trained by the first author, in a two-hour in-person training session, on how to deliver the iBook OOPP educational intervention delivered overdose prevention group sessions. Each of the three clinicians delivered the intervention four times. A total of 12 OOPP group educational sessions were conducted between August 15, 2014 and December 19, 2014. Two research assistants monitored all sessions for treatment fidelity using Clark and Breitenstein’s (2015) Modified Fidelity Checklist©. The Modified Fidelity Checklist© is composed of two subscales evaluating adherence to the designed intervention and competence in the delivery of skills and group management. Prior to the educational sessions, both clinicians
and research assistants were trained by the PI on how to use the iBook in the group setting and were given the opportunity to practice using the iBook.

**Data Collection Tools**

Prior to the overdose group training, subjects completed the Knowledge Pre-training Survey©. After the intervention, subjects completed the Knowledge Post-training Survey©, The Classroom Life Measure, and the Naloxone Program Baseline Survey©.

**Knowledge Pre-training/Post-training Survey©.** Knowledge Pre-training/Post-training Survey© was developed by the University of Cincinnati Opioid Research Team and was a revision of previous knowledge survey that had yielded ceiling effects. The Knowledge Pre-training Survey© contains 34 Likert-type items, 2 true/false items and is used to assess knowledge around overdose. The survey is divided into three sections: knowledge of overdose prevention and risk factors, recognition of opioid overdose signs and symptoms, and knowledge around how to appropriately respond to an overdose event. After the educational intervention, subjects completed the Knowledge Post-training Survey© that included all of the same questions as the Knowledge Pre-training Survey© with the addition of a question asking if the subject was aware that naloxone could reverse a heroin or prescription drug overdose prior to the training.

**Classroom Life Measure.** The social interdependence theory as described by Johnson and Johnson posits that promotive interaction and positive interdependence results in an increased effort to achieve the desired behavior. Promotive interaction is defined as individuals encouraging and facilitating each other’s efforts to accomplish the group goal (Johnson & Johnson, 2013). This variable was operationalized using the Classroom Life Measure subscale cooperative learning. Positive interdependence is when the actions of individuals promote the achievement of joint goals and was operationalized using the Classroom Life Measure positive
goal interdependence subscale and the Classroom Life Measure resource interdependence subscale on the Classroom Life Measure (Johnson & Johnson, 2002). Table 1 illustrates each of the subscales, items and previous reliability measures as reported by Johnson & Johnson.

Table 1: Classroom Life Measure

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<tr>
<td></td>
<td>Resource Interdependence</td>
<td>5 Likert-type items</td>
<td>0.74</td>
</tr>
</tbody>
</table>

Baseline Demographic Survey. The Naloxone Program Baseline Survey© is a 51-question appraisal requesting the subjects’ demographics including: race, ethnicity, living situation, status of employment, history of substance use, history of overdose, psychiatric mental health history and physical history. This instrument was also used to assess the quantity of drug use in the previous 30 days before entering substance abuse treatment.

The purpose of this study was to determine if a group-based OOPP educational intervention could significantly increase participant knowledge on overdose recognition, prevention and how to respond during an opioid overdose. Incorporating the Naloxone Program Baseline Survey© allowed the research team to assess the group demographics while dually allowing the research team to explore the relationships between demographic variables and changes in knowledge. The Naloxone Program Baseline Survey© also allowed researchers to determine the educational needs that are unique to this population.
Data Management

Data from the CCAT Naloxone Program Baseline Survey®, Knowledge Pre-training/Post-training Survey® and The Classroom Life Measure were entered into REDCap™ database. Data were cleaned using various data checks. Data were imported into SPSS® statistical software for data analysis.

Data Analysis

Descriptive statistics were used to describe the demographic composition of the groups and to provide an overview of program participants. Comparisons of knowledge scores from the pre-test to the post-test were performed using paired t-tests for numerical variables and McNemar tests for binary variables respectively. Changes in knowledge scores were calculated within subjects and across subjects to determine the overall change in scores. Cross-sectional comparisons of numerical and binary scores were performed using independent samples t-tests and Chi square tests. Item reliability was assessed using Cronbach’s alpha and inter-rater reliability (or agreement) on The Modified Fidelity Checklist® was determined using percent agreement. Cohen’s d was calculated to determine the intervention effect size.

Results

Demographic Characteristics

The sample included a total of 49 subjects; 55.1% (n=27) were male and 44.8% (n=22) were female. The mean age of study subjects was 32 years old and ages ranged from 19 to 71 years. Educational attainment of the subjects was 53.1% (n=26) reported completing some college, while 46.9% of subjects (n=23) report their highest level of education as high school diploma, GED, or less than high school. Approximately one-third of subjects reported currently living with parents or caregivers and 10.2% (n=5) reported being homeless. The majority of
subjects (87.8%) reported their race as White and 10.2% identified themselves as Black or African American. The majority of subjects, 75.5% (n=37) reported their relationship status as currently not married or single.

**Clinical Characteristics of Subjects.** Most subjects (77.5%) rated their physical health as good to excellent and 40.8% reported having a regular or family doctor. Twenty-one subjects (42.8%) reported experiencing mental health problems greater than half the time in the last month, while 38.8% (n=19) of subjects were prescribed a psychiatric medication in their lifetime. Nearly half (46.9%) of subjects report having a significant period of time in their lives in which they have experienced serious thoughts of suicide, 30.6% of subjects report attempting suicide in their lifetime. About one-third of subjects (30.6%) reported having serious conflicts with friends or family members 30 out the previous 30 days.

Lifetime injection drug use was reported by 69.6% of subjects (n=46). The age of first IV drug use ranged from 13 years to 55 years with a mean age of 26.4 years (SD=8.4). Past-month injection drug use was reported by 89.7% of subjects (n=29). Subjects reporting a history of overdose accounted for 43.5% (n=46) of the sample, with the mean number of times ever overdosing reported at 2.8 (SD=3.8). The mean age of first overdose was 28.0 years old (SD=14.2). Almost half of the study subjects (47.8%, n=46) reported witnessing an overdose, with the mean number of witnessed overdoses 5.1 times.

**Knowledge Change**

Study subjects’ scores on Knowledge Pre-training/Post-training Survey© were recoded to “correct response” and “incorrect response”. The mean ± standard deviation of total score on the knowledge pre-test was 21.71 ± 4.33 and significantly increased to 27.65 ± 4.33 in post-test (n=49, p<0.01). The mean net increase from pre-test to post-test was 5.94 points (p<0.01).
Section 1 of the knowledge survey assessed knowledge of risk factors associated with a heroin or prescription opioid overdose death. This section included 8 questions assessing tolerance, purity, using alone and injecting for the first time. The mean net gain from pre-test to post-test increased by 0.33 points and was found to be a statistically significant improvement in knowledge (p<0.05). While the majority of scores in section 1 on the pre-test were correct, nearly 20% subjects were unaware that using heroin/prescription opioids with some pre-existing medical condition placed them at a greater risk for a fatal overdose.

Section 2 of the survey included 8 questions assessing subjects’ knowledge of symptoms of a heroin/prescription drug overdose. The mean change in score from pre-test to post-test was 1.55 points (p<0.001) for this section. These findings indicate the educational intervention significantly increased subject knowledge of the signs and symptoms of an opioid overdose. Overdose symptoms subjects correctly identified during the pre-test were: shallow or slow breathing (91.8% of subjects), blue/grayish lips or skin (91.8% of subjects), and loss of consciousness & non-responsive (98.0% of subjects).

Section 3 of the knowledge survey included 17 questions assessing participant knowledge of how to appropriately respond during an overdose event including rescue breathing, sternal rub, calling 911, etc. The mean change in knowledge scores for this section was an increase of 3.00 points (p<0.001). These findings suggest that the opioid overdose group educational intervention significantly increased subject knowledge of how to respond during an overdose event.

Eleven of the 17 items yielded a significant (p<0.05) increase in mean scores. The largest increases in post-test scores were from subjects correctly identifying that naloxone can wear off before the effects of heroin/prescription opioids and correctly identifying that the recovery
position is on the left side. Table 2 provides a list of items from Section 3 of the Knowledge Survey and includes the mean increase in knowledge and level of significance.

Table 2: Knowledge Survey Section 3

<table>
<thead>
<tr>
<th>Responding to an opioid overdose item</th>
<th>Mean Increase in Points from Pre-Training to Post-Training</th>
<th>Significance (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walk the person around the room</td>
<td>15</td>
<td>0.000</td>
</tr>
<tr>
<td>Inject them with saline (salt) or water</td>
<td>15</td>
<td>0.001</td>
</tr>
<tr>
<td>Give stimulants (for example, coffee)</td>
<td>19</td>
<td>0.000</td>
</tr>
<tr>
<td>Slap, shake or use pain to wake the person</td>
<td>29</td>
<td>0.000</td>
</tr>
<tr>
<td>Shock the person with cold water or ice</td>
<td>26</td>
<td>0.000</td>
</tr>
<tr>
<td>*Perform rescue breathing</td>
<td>11</td>
<td>0.001</td>
</tr>
<tr>
<td>*Place the person the in the recovery position</td>
<td>9</td>
<td>0.004</td>
</tr>
<tr>
<td>*Administer naloxone (Narcan)</td>
<td>6</td>
<td>0.031</td>
</tr>
<tr>
<td>*Rub their sternum</td>
<td>28</td>
<td>0.000</td>
</tr>
</tbody>
</table>

* Items deemed appropriate when responding to an opioid overdose

**Classroom Life Measure**

Total scores from the Classroom Life Measure (CLM) were calculated using descriptive statistics and results indicate that participants prefer cooperative learning ‘some of the time to all of the time’ when compared to learning individually. Cronbach’s alpha for the CLM was 0.81. Total CLM scores were recoded to binary variables, 0= score less than 84 points on the CLM and 1= score 84 or greater on the CLM. Independent samples t-test was used to compare this score to total knowledge gain in points from the knowledge survey to determine if there was a correlation. There was no correlation between increase scores on the classroom life measure and increased mean knowledge scores or changes in knowledge scores. The binary coding cutoff was changed to 0= score less than 80 points on the CLM and 1= a score of 80 or greater on the CLM. Findings demonstrate that there was not a significant correlation between knowledge change and the CLM scores. However, the group learning environment allowed the opportunity for subjects
to share their personal experiences, ask questions, and share their concerns about contacting first responders, administering naloxone and receiving naloxone training while in substance abuse treatment. Table 3 lists the subscales of the CLM with the mean score across all subjects.

*Table 3: Classroom Life Measure Mean Scores*

<table>
<thead>
<tr>
<th>Theoretical Construct</th>
<th>Subscale</th>
<th>Mean Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promotive Interaction</td>
<td>Cooperative Learning</td>
<td>4.29 out of 5.00</td>
</tr>
<tr>
<td>Positive Interdependence</td>
<td>Positive Goal Interdependence</td>
<td>3.68 out of 5.00</td>
</tr>
<tr>
<td></td>
<td>Resource Interdependence</td>
<td>3.65 out of 5.00</td>
</tr>
</tbody>
</table>

**Discussion**

The present study examined the characteristics of 49 opioid-dependent individuals in order to determine the effectiveness of a novel overdose prevention iBook in the group setting. Findings from this study indicate that the study population has unique demographic attributes that can be used to guide and direct OOPP educational interventions, the group setting is a promising venue for future OOPP research and that the iBook educational intervention significantly increased participant knowledge of opioid overdose prevention.

Demographic findings from this study are very similar to findings in the recent systemic review of OOPPs. The population was slightly younger (mean age of 32) than the reported mean age of 37.4 years old in a systematic review of OOPPS (Clark et al., 2014). Researchers from the systematic review also reported that 68.3% of participants were male, while the current study was 55.1% male and 44.9% female. Similar to other evaluations of OOPPS the majority of subjects in this study were White (87.8%).

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The sample in this study reported witnessing a high number of overdoses (mean of 5.1); one individual reported witnessing 50 overdoses in his lifetime. This report is of particular concern because evidence from a study of drug users in New York City suggests a high number of witnessed overdoses as indicative of being in high-risk situations and increases the risks of self-overdose (Bohnert, Tracy, & Galea, 2012).

Findings from this study support that individuals who use opioids do not fully understand the risks associated with mental health and overdose risk. While subjects correctly identified mixing drugs as a risk factor for opioid overdose death 91.8% of the time on the Knowledge Pre-training Survey©, subjects only recognized using heroin/prescription opioids with a medical condition, such as anxiety or depression as a risk factor for opioid overdose death 81.6% of the time. This finding indicates that while subjects know that mixing illicit drugs (both heroin and opioids) increases the risk for overdose death, if a physician prescribes the medication for a medical condition, they may not recognize the use of both prescribed medications and illicit drugs as “mixing drugs”. When this topic was discussed in group as a risk factor, subjects (38.8% who have been prescribed psychiatric medications) asked numerous questions about the pharmacokinetics and pharmacodynamics of medications. The above findings support the evidence that individuals with a history of injection drug use who have witnessed many overdoses are a target audience for overdose prevention training (Bohnert et al., 2012).

**Overdose Prevention in the Group Setting**

While no correlation was found between increased scores on the CLM, which is indicative of participants’ support of the group learning environment, and the knowledge survey post-test, participants reported a positive response to cooperative learning (mean of 4.3 out of 5.0 points across all groups). The group setting was advantageous for discussing strategies for
responding to overdoses and allowed group participants to gain feedback on how to better prevent overdoses.

Other positive findings regarding the group setting were related to site. Because this particular intervention was conducted in an inpatient substance abuse treatment facility that promotes abstinence, group participants asked the obvious question: “Why are you giving me Narcan, I’m sober?” This question provided a platform for the clinician to elicit discussion on several key factors to preventing overdose.

First, it provided segue for discussions about the importance of not using alone. The CARRY Narcan® iBook has a brief video introduction of an individual in recovery who shares her story of how naloxone saved her life. She talks candidly about how grateful she is to her family for finding her and notifying responders. Had she been home alone, no one would have been able to get help. It allowed participants the opportunity to question if it is even possible to self-administer naloxone and also illustrated why it is important to tell others to never use alone. For example, participants would say “You can’t use Narcan on yourself” it is for you to use on other people.

Second, group members would also share stories of how they had administered Narcan in the past to someone and were grateful to have had it. One participant explained it as, “We are more likely to see someone overdose later and now we can be prepared.” Participants who had seen naloxone used or who had been “narcanized” also shared their stories of what to expect. Their accounts allowed participants to ask more in-depth questions such as, “What happens if somebody mixes heroin and other drugs, would the Narcan work?”

The group also allowed for participants to share their experiences with overdose. Over 47.8% of subject in the study reported witnessing an overdose and many group participants had a
lot of grief and sadness over the loss of their friends and family members. The group allowed participants to share these feelings, and dually allowed clinicians the opportunity to follow-up individually with patients to address their grief.

**CARRY Narcan® iBook Increases Knowledge of Opioid Overdose Prevention**

Like other evaluations of overdose prevention programs, this study demonstrates that a brief educational intervention can significantly increase knowledge of overdose prevention for program attendees (Clark et al., 2014; Gaston, Best, Manning, & Day, 2009; Jones, Roux, Stancliff, Matthews, & Comer, 2013; Strang et al., 2008). In the present study, the mean knowledge score increased 5.9 points from pre-test to post-test. During data analysis, level of education, “college” vs. “no college” was compared to total Knowledge Pre-training Survey© scores. The mean total score on pre-tests was significantly higher (p<.001) for subjects reporting their education as “college”. However, there was not a significant difference on the mean Knowledge Post-Training Survey© scores between groups. This finding supports the versatility of the iBook to reach all educational levels, supporting research that the training itself improved the performance on the Knowledge Post-test (Jones, Roux, et al., 2013).

Our findings also suggest that subjects’ knowledge pre-training scores reflect that subjects have a high level of knowledge regarding the risk factors of opioid overdose, but despite having a high level of knowledge continue to engage in high-risk behaviors. For example 20% of subjects reported weekly to daily concurrent use of alcohol, street opioids, prescription opioids and/or sedatives/benzodiazepines. Over 91.8% of subjects correctly identified using heroin/prescription opioids and other drugs at the same time as a risk factor associated with opioid overdose on the knowledge survey pre-test yet. These findings support published research
that among patients who received addiction treatment, overdose is the leading cause of premature death (Jimenez-Treviño et al., 2011).

While few published evaluations of OOPPS specify who delivered the OOPP educational intervention, clinicians in this study (mostly social workers) delivered the manualized intervention as intended by the research team. This is an important finding because the CARRY Narcan© iBook includes demonstration and discussion of skills that often times are not part of substance abuse and abstinence-based treatment programs including: rescue breathing, sternal rub, recovery position and administration of nasal naloxone. Previously, the site where this study was conducted delivered the OOPP content in two parts. The first part was a general discussion of overdose and was led by counselors/clinicians. Then, the entire group would attend another training provided by a nurse to learn how to administer naloxone, assess breathing, and provide rescue breathing. Using the iBook videos allowed for clinical content to be delivered by skilled nurses, who did not need to be present. This also allowed the participants to complete their training during one session. This not only reduced the length of the educational program, but it also assisted with resource optimization at the site.

The mean age of subjects in the present sample was younger and reported a high rate of currently living with parents or caregivers (34.7%). This finding supports continued outreach education to individuals who are not opioid-dependent, but are at high-risk for witnessing an overdose such as parents and friends.
Limitations

Findings from this study are limited because this was the first testing of the intervention. Throughout the five months of data collection, the first author recorded ideas about how to modify the iBook to meet the groups’ needs. These findings have been incorporated into an updated version of the CARRY Narcan© iBook. Furthermore, the sample size was small (n=49). The sample size was large enough to show significant increases in knowledge.

Future Research

Future research around this intervention includes determining the efficacy and effectiveness of the manualized iBook intervention with more participants and in different settings. Due to the flexible, yet individualized nature of the iBooks platform, there is an opportunity for the iBook introductory videos to be tailored to different audiences. This intervention was conducted in an inpatient substance abuse treatment facility but could be easily modified for use in the outpatient setting for clients receiving Suboxone® or Methadone® therapy. There is also an opportunity for the iBook to be modified for use in overdose prevention support groups, attended by friends and family members of individuals at high-risk for opioid overdose. Research demonstrating the importance of educating bystanders (friends and family members) about overdose prevention is well documented and is a priority area for future testing with the iBook (Doe-Simkins et al., 2009).

Conclusion

Findings from this study indicate that the CARRY Narcan© iBook can be delivered with high level of treatment fidelity by clinicians in the group setting and significantly increases participant knowledge of opioid overdose prevention. Our data also suggest that opioid-dependent individuals can be trained to respond to an opioid overdose event and prove a valuable
audience for overdose prevention efforts. Future research should include larger-scale studies of
the iBook in the addiction treatment setting and in other settings for those who are at high risk
for witnessing an opioid overdose.
Manuscript 2: Implementation of an Inpatient Opioid Overdose Prevention Program

In 2012, drug overdose surpassed motor vehicle accident fatalities as the leading cause of injury death in the United States (Centers for Disease Control and Prevention, 2014). Opioid overdoses have more than tripled in the past decade leaving communities and families fragmented and in need of overdose prevention services (CDC, 2014). In 1996, opioid overdose prevention programs (OOPPs) began distributing naloxone hydrochloride, brand name Narcan® to individuals at high-risk for witnessing or experiencing an opioid overdose (Wheeler, Davidson, Jones, & Irwin, 2012). Naloxone competitively binds to opioid receptors and reverses the effects of opioids increasing chances of survival (Boyer, 2012; Sporer & Kral, 2007).

In addition to naloxone, OOPPs provide education on how to recognize and respond during an opioid overdose and some programs include information on how to prevent opioid overdoses (Enteen et al., 2010). OOPPs deliver educational services from a variety of settings including: syringe exchange programs, detention centers and jails, community and public health clinics, harm reduction programs, and in substance abuse treatment centers. OOPPs have now distributed over 50,000 doses of naloxone and contributed to over 10,000 overdose reversals (Wheeler et al., 2012).

In response to the opioid overdose epidemic and the documented success of OOPPs, there has been an increase in the demand for overdose prevention education. In 2014, the Substance Abuse and Mental Health Services Administration (SAMHSA) released the Opioid Overdose Prevention Toolkit. However, in its current format the tool kit is not readily available for use in the group inpatient substance abuse treatment setting. Furthermore, although the tool-kit provides a rich array of information regarding opioid overdose prevention, the toolkit is not a one-stop resource for clinicians needing to conduct group educational sessions. For example, to
provide education on how to respond during an overdose event, it is important for course participants to learn rescue breathing, and the recovery position but these topics are not part of the tool-kit. Furthermore, basic life support skills are often not part of substance abuse counselors’ skill sets. Thus, there was a need for an innovative OOPP intervention that included all aspects of overdose prevention to guide group discussions.

The purpose of the original study, entitled “A Feasibility Study of An Opioid Overdose Prevention Educational Intervention,” was to develop a manualized education tool for OOPP groups, determine the feasibility of the intervention and to determine if the intervention increased OOPP participant knowledge of overdoses in three areas: overdose prevention, overdose recognition, and responding to an overdose. The aim of this article is to briefly describe the findings from the Phase Ia/Ib Feasibility Study, introduce the CARRY Narcan® iBook educational tool for OOPPs and to provide an explanation of how clinicians can adopt the iBook for use in the inpatient treatment setting.

**The Need for Manualized Overdose Prevention Training**

Before the implementing the CARRY Narcan® iBook, the Midwestern OOPP clinicians used the Project Dawn Opioid Overdose Prevention Video (available on youtube) as the core component of the educational group intervention. Group members included all patients, both male and female, age 18 and older, who were in their residential long-term treatment program. Clinicians introduced the video and provided an opportunity for group participants to discuss their experiences with overdose. During this time, it was noted by the research team that group participants had a very high level of knowledge around opioids and asked high-level questions about how opioids work in the body. These questions often went unanswered since clinicians did not have the resources available in the group to answer the questions. After the group members
viewed the video, a nurse would take opioid-dependent patients to a different group room and demonstrate the recovery position, rescue breathing and nasal naloxone administration. The OOPP delivered in this manner, required additional staffing and often resulted in fragmented delivery of concepts. It was apparent that program delivery required modification since the nurse-led group required additional staffing, and other types of clinicians were either not trained or did not feel comfortable demonstrating the recovery position, rescue breathing and nasal naloxone administration. To better serve OOPP participants that CARRY Narcan© iBook educational intervention was developed. The following sections summarize the development and use of the educational intervention.

**A Feasibility Study of OOPP Educational Intervention**

To develop the intervention, the first author organized a team of key stakeholders to inform the development of the intervention. Then the first author distributed current research articles and OOPP materials to the key stakeholders for review. Key stakeholders included: two nurses with previous public health nursing experience; one nurse with experience in planning large initiative wellness programs, a substance abuse counselor, a public health researcher who served as the content expert in overdose prevention and a community member who has experienced two overdoses, has experience with naloxone and works as a peer navigator at a Midwestern substance abuse treatment facility.

The first author and the stakeholders convened at an all-day meeting to determine the mandatory items of the educational intervention and to determine the best platform to deliver the items. The first author kept a written record of all items deemed mandatory for the intervention and developed them into an iBook entitled CARRY Narcan©. An iBook is an e-book application by Apple Inc. that allows contents to be enhanced by video, animations, quizzes, music, etc.,
increasing the potential for interaction with the audience. The CARRY Narcan© iBook includes three main sections: a). how to recognize the signs and symptoms of an overdose, b). how to prevent an opioid overdose and c). how to respond during an overdose event; including implications for nasal naloxone and instructions on how to assemble and administer nasal naloxone. The 23-page iBook utilizes videos, interactive animations, definitions and a formative quiz to assist clinicians to lead a well-informed group discussion on overdose prevention.

**Clinician Training**

Prior to the initiation of the study, the first author trained three clinicians (substance abuse counselors) in an intensive two-hour session. During this time, clinicians had the opportunity to practice using the iBook and to ask questions about the iBook content. There was also in-depth discussion on possible patient/client questions. It is important to note that the clinicians’ knowledge and familiarity of the iBook platform and iPads varied widely. One clinician had never used an iPad or the iBook platform and by the end of the training could maneuver through the iBook on the iPad with ease.

**Group Session Activities**

The research team discussed options about optimal group membership and decided to include both opioid-dependent clients and clients with other addiction diagnoses in the same group. This decision was based on the fact that in the pilot group, a client with an alcohol-dependent diagnosis appropriately responded to an opioid overdose after attending one of the OOPP groups. Prior to the initiation of the group, participants completed a knowledge survey pre-test consisting of 34 questions assessing patient/client knowledge of overdose prevention/risk factors, signs and symptoms of an overdose, and how to respond to an overdose event. After the iBook intervention, patients completed the knowledge survey post-test. Participants also
completed the Classroom Life Measure; a tool used to assess if patients preferred learning in the group setting and if it increased their ability to learn the iBook course content (Johnson & Johnson, 2005). During the group sessions, two research assistants completed The Modified Fidelity Checklist, a modified version of The Fidelity Checklist (Breitenstein et al., 2010). This measure was taken so the research team could assess that the iBook was being delivered by the clinicians in accordance with the developers' guidelines about proper CARRY Narcan® iBook use.

**Introduction to the CARRY Narcan® iBook**

The iBook is a 23-page interactive educational tool that provides a one-stop resource for individuals conducting educational groups on how to prevent, recognize and respond to opioid overdoses. The book includes instructions on how to use the interactive components to generate group interaction. Learning outcomes of the iBook interaction include that at the end of a 30-60 minute group session in which the iBook is used group participants will be able to:

- Define opioids and provide an example of different types of opioids;
- Define overdose and identify the signs and symptoms of an opioid overdose;
- Define respiratory depression;
- Name factors that can contribute to an overdose;
- Define naloxone and identify how it works in the body;
- Demonstrate the appropriate response to an overdose event.

The above learning outcomes have been previously demonstrated with a high level of success. Preliminary data, from a small study of 49 subjects from a Midwestern opioid overdose prevention program attended a group session that was led by a clinician who had been trained by the first author to deliver the iBook. Subjects completed a pre-test before the intervention and
a post-test after the intervention. The mean ± standard deviation of total score on the knowledge
pre-test was 21.71 ± 4.33 and significantly increased to 27.65 ± 4.33 in the post-test (n=49, p<0.01). The mean net increase from pre-test to post-test was 5.94 points (p<0.01),
demonstrating that the iBook significantly increases group participant knowledge around opioid
overdose.

**Introduction Section.** The introduction section of the iBook includes facts about the
prevalence of opioid overdoses in the United States. Given the ease of modification of the iBook
platform, there is opportunity to have the introduction modified to include regional facts about
opioid overdose. This section also includes a movie entitled Jackie’s Story. Jackie’s story is a
brief, 7-minute account of how Jackie
journeyed into substance use, her experience
in treatment, jail, overdose and eventually
how she achieved long-term recovery. Her
message is one of perseverance and she sends
the message that every life is worth saving.

After showing the video, clinicians ask
participants to share the parts of Jackie’s story
that resonate with them. Participants connect
with Jackie’s emotional story and candidly
share how they identify with her statements
that she was scared of being ‘dope sick’ and
that they are too young to die and feel invincible while they are using. Participants also share
how they feel inspired to learn more about both Narcan and maintaining sobriety. Jackie’s story
is the perfect segue for clinicians in the inpatient setting to discuss, a frequently asked patient/client question, “Why Narcan if I am in an abstinence based program?” While there is not one answer to this question, the group often answers it for each other, “You can’t give Narcan to yourself, you’ve overdosed.” Also, it is important to note that in a previous study, group members discussed how they used naloxone to save friends and family members.

**Opioids.** The Introduction to Opioids section includes questions and answers about: what opioids are, a description of how they work in the body and a list of different kinds of opioids. This section speaks to both those with an extensive knowledge of opioids and those who are just learning about opioids. The interactive cartoon, “Opioids in the Body” provides a visual of opioids in the body, binding to mu-opioid receptors. This section lays the foundation of how opioids work, so that as the iBook session progresses, participants will have knowledge of how naloxone counteracts the effects of opioids.

**Opioid Overdose.** This section begins with two group-discussion questions. The questions are used to elicit discussion about the group participants’ experiences with overdoses, either self or witnessed. These questions are important for the group because they allow the clinician to determine the level of experience in the subject matter and participants to share their stories. Participants in the group often have witnessed many overdoses, some of which have been fatal. There is a lot of grief, guilt, and even anger associated with these experiences and the group setting allows participants who are dealing with similar experiences to offer support. It also allows participants to draw from previous experiences and to teach each other about what an overdose is and what it looks like. Definitions of overdose and the characteristics of an overdose are provided.
This section also provides a definition of respiratory depression, the hallmark symptom of an opioid overdose and provides a play-by-play account of “what happens when breathing stops or slows.” This is an important discussion piece for the group because participants, who often have extensive knowledge of opioids, often do not understand how the effects of opioids progress to death.

After a thorough explanation of overdose is provided, risk factors associated with preventing overdose are introduced. This section includes group discussion of situations that place someone at an increased risk for overdose. This is important because participants often think of overdose as happening by chance, but do not think about factors that place the body at an increased risk for overdose. Risk factors, such as, mental and physical ailments or using while taking prescribed medications for these ailments are presented. Opioid overdoses are preventable and sending this message to participants affords them the opportunity to ‘prevent’ overdoses from happening.

The iBook has an entire interactive section explaining factors that contribute to overdoses. Before clicking through the interactive section, clinicians often ask participants to think of as many factors as they can. While they will say “tolerance” and describe changes in tolerance such as not using for a brief period, participants often are not aware that being dehydrated or having the flu affects tolerance. This interactive section helps to bridge the gap from hypothetical to relatable terms and demonstrates that overdoses really are preventable.

The next section of the iBook is about naloxone. The section begins with a group discussion about naloxone. Group members often share their experiences with naloxone. Previous group members had been misinformed about Narcan being a safety net to use but as group members tell each other “being narcanized” is not a pleasant experience, it sends you into
immediate withdrawal. After the group discussion, the CARRY Narcan© iBook presents a
definition of naloxone and an explanation of how naloxone works in the body. There is a brief
animation with a narrator explaining how naloxone competitively binds to mu-opioid receptors,
temporarily misplacing opioids. This is a very important animation because participants, even
those with extensive experience with naloxone, are generally not aware of the short half-life of
naloxone compared to that of longer acting opioids such as fentanyl.

The maneuverability of the iBook, allows clinicians to pause and play the videos and
animations at a pace that is appropriate for all participants. The animation of naloxone binding to
opioid receptors allows participants to obtain a visual understanding of why multiple doses of
naloxone may be needed to reverse the overdose and why it is important to contact emergency
responders during an overdose. The iBook video explains that naloxone has a short half-life and
two doses may not be enough and further treatment, related to the effects of opioids, may be
necessary.

After participants are provided with an overview of naloxone, using naloxone is
described as a viable method for responding to an opioid overdose. Responding to an overdose is
presented in two parts. The first part is to demonstrate appropriate ways to determine if a
participant is responsive. A video demonstration of the sternal rub is presented so that
participants have a clear visual understanding of how to determine responsiveness. The second
part of the presentation introduces the CARRY Narcan© sequence for responding to an opioid
overdose. This section demonstrates the immediacy of required action to prevent complications
from the lack of oxygen to the brain and vital organs. The CARRY Narcan© sequence is
explained fully and a discussion of each of the
components of the acronym is described.

Figure 2: CARRY Narcan© Sequence
Along with the introduction of the sequence, a full explanation of why participants should complete each action is included. For example, participants in treatment often are hesitant to call 911 for fear of prosecution or harassment. Examples of how participants can describe the signs and symptoms of the overdose to responders are included. The iBook provides group participants the opportunity to share their concerns about responding to overdoses, including the exploration of previous overdose events.

A video demonstration of how to administer nasal naloxone, including assembly of the nasal applicator to the naloxone vial is provided. A narration providing more in-depth information about naloxone is also included. A video demonstration of a registered nurse providing rescue breathing including tips for rescue breathing is provided. There is also pop-up window that provides a step-by-step breakdown of the how to provide rescue breathing for the clinician to review with participants after watching the rescue breathing video. This allows the steps to be reviewed by the group at their own pace.

An explanation of when to use the recovery position and a video demonstration of how to place someone in the recovery position is included. The final message of the Carry Narcan sequence is “You can save a life!” This slogan is important because, now that participants have the knowledge and skills required to appropriately respond to an overdose, it is important for them to have reinforcement.

The next section of the CARRY Narcan© iBook provides an overview of the “Do’s and Don’ts of Responding to an Overdose.” This section is another recap of how to respond to an overdose. The Do Not box includes real life participant accounts of how they previously responded to overdoses in the past including injecting the person with cocaine or inflicting force to get the victim to “wake-up”.
The iBook concludes with a 9-question quiz including multiple-choice and matching items, assessing participants’ knowledge of the iBook content. The quiz allows clinicians to check participant understanding before concluding the group. Thus, clinicians can allow incorrect answers to be discussed and correct answers to be appropriately reinforced.

**Results of the Group Intervention**

The CARRY Narcan® iBook was tested in weekly inpatient groups to obtain a preliminary assessment of whether it was useful. These weekly groups included on average 22 group members (inpatients) at a chemical dependency treatment center in a Midwestern city. The mean age of study participants was 32 years old and ages ranged from 18 to 71 years. The mean time of the iBook group intervention was 48 minutes. However, given the format of the iBook and the variable opportunities for group discussion, the intervention time can be adapted to meet the needs of the group and adjusted to comply with agency needs. Patient knowledge was assessed by calculating the mean change in knowledge score from the Knowledge Pre-test/Post-test. The mean net increase from pre-test to post-test was 5.94 points (p<0.01). While no correlation was found between increased scores on the Classroom Life Measure, which is indicative of participants’ support of the group learning environment, and the knowledge survey post-test, participants reported a positive response to cooperative learning (mean of 4.3 out of 5.0 points across all groups).

Despite varying levels of familiarity with the iBook and iPad, all three clinicians consistently demonstrated a high level of ability to deliver the iBook to the group in the way it was intended to be used by the developers. Across 12 groups in which the CARRY Narcan® iBook was used, the intervention was delivered with a high level of treatment fidelity, as indicated by a adhering to the mandatory components of the iBook intervention 96.78% of the
time. Findings from this study indicated that clinicians delivering the iBook in the group setting could assist group participants to increase knowledge about opioid overdose and could assist clients to discuss strategies for responding to overdoses. They were also able to assist group participants to gain feedback on how to better prevent overdoses.

**Discussion**

The manualized format of the CARRY Narcan® iBook provides the opportunity for clinicians to conduct well-informed discussion on how to recognize, prevent, and respond to opioid overdoses. The iBook also allows clinicians to adapt the length of time spent on each topic and enables them to adjust for varying levels of audience knowledge. Clinicians delivering the iBook educational intervention can drastically increase the patient/client knowledge on how to prevent overdoses, how to recognize overdoses and how to respond during an overdose event. Increasing the reach and dissemination of knowledge around naloxone will decrease the number of fatal opioid overdoses.

Fatal opioid overdoses are plaguing our communities and there is a great need for education on overdose prevention including naloxone administration, the most proximal means of reversing the opioid overdose. The aim of this article was to provide an overview of the CARRY Narcan® iBook and discuss how clinicians can use the iBook to provide overdose prevention education in the inpatient group setting. As previously stated, the iBook provides clinicians with a valuable resource that encompasses all aspects of overdose prevention and still generates rich group discussion. The iBook can be easily modified and implemented in practice.
Manuscript 3: Modifying The Fidelity Checklist for use in a Community-Based Opioid Overdose Prevention Program

The degree to which behavioral interventions can transcend the research setting and be successfully and effectively implemented in patient treatment settings with larger populations, yielding similar outcomes is largely dependent on fidelity (McHugh, Murray, & Barlow, 2009). As such, it is important for researchers to provide confirmation that control of the variables occurred as intended (Moncher & Prinz, 1991). Without confirmation, prematurely adopted behavioral interventions may result in lost resources and a decrease in the adoption and reach of behavioral interventions (Glasgow et al., 2004). Researchers using fidelity measurements can establish validity, one of the major components for calculating effectiveness and later efficacy in behavioral interventions (Glasgow et al., 2004).

Assuring fidelity by standardization of provider training and treatment delivery during behavioral interventions has been shown to minimize treatment contamination, thus increasing the validity and reliability of behavioral treatment findings (Breitenstein et al., 2010; Moncher & Prinz, 1991). The evaluation of behavioral interventions relies on methods of accurately quantifying treatment components (Monroe-DeVita et al., 2011). When conducting research measuring behavioral change, it is important to assess the true relationship between the independent and dependent variable, while identifying and minimizing the modifying and extraneous effects associated with intervention delivery (Resnick, Inguito, et al., 2005).

Treatment fidelity is the degree in which interventions are delivered as outlined by the program developers (Bellg et al., 2004; Carroll et al., 2007).

A lack of fidelity to the program model has the potential to be a large source of type I and type II error (Breitenstein et al., 2010). Low fidelity may also be the source of a type III error,
which occurs when an intervention appears ineffective, when in fact; if the intervention was delivered with fidelity it has the potential to be efficacious (Breitenstein et al., 2010; Dobson & Singer, 2005; Sánchez et al., 2007). How interventionists deliver interventions, their competence and their adherence to the prescribed intervention greatly affects the validity, reliability, and general credibility of findings (Moncher & Prinz, 1991).

While the use of fidelity monitoring and fidelity checklists have been documented in behavioral intervention research (Leeuw, Goossens, de Vet, & Vlaeyen, 2009), there have been no publications documenting a systematic process for modifying fidelity checklists. The purpose of this article is to describe the systematic adaptation of The Fidelity Checklist (TFC) (Breitenstein et al., 2010) – a valid and reliable tool for measuring treatment fidelity – for fidelity assessment of a group-based community opioid overdose prevention program.

Specifically, we will:

- Define treatment fidelity and describe the need for measuring treatment fidelity in behavioral change interventions.
- Provide an overview of The Fidelity Checklist (Breitenstein et al., 2010) including a description of the tool, a discussion of its purpose and a report of initial findings from early testing of the tool.
- Describe the modification of The Fidelity Checklist for use in a group-based community opioid overdose prevention program.

Fidelity measurement is an important methodological step that will lead to more structurally sound behavioral interventions. Findings from this article will assist researchers to measure fidelity in a variety of interventional research settings.
Background

Treatment fidelity is the degree to which interventions are implemented in the manner intended by the developers and is an important source of variation that affects both the utility of interventions and the credibility of findings (Carroll et al., 2007; Kubiak, Fedock, Tillander, Kim, & Bybee, 2014). Fidelity is determined by three factors: a). clinicians’ adherence to the manual or protocol, b). clinicians’ competency in skills supporting the intervention and, c). the participants’ responsiveness during the intervention (Breitenstein et al., 2010; Carroll et al., 2007). Monitoring treatment fidelity allows researchers to better control for extraneous variables during the intervention that have the potential to greatly affect findings of behavioral interventions (Moncher & Prinz, 1991). Researchers have used various terms to describe treatment fidelity including but not limited to: intervention fidelity, implementation fidelity and integrity fidelity all with the purpose to describe the standardization of the intervention. For the purposes of this article the term treatment fidelity will be used and the processes associated with ensuring the integrity of treatment delivery will be discussed.

Researchers have suggested differing and similar components of treatment fidelity. The NIH Behavioral Change Consortium (BCC) describes five components of treatment fidelity: design, training, delivery, receipt and enactment (Bellg et al., 2004). Similarly, Gearings et al. (2011) discuss the “major ingredients” of fidelity as: design, training, delivery, and receipt, and provide definitions for each of the elements. The focus of the present work is the fidelity component of delivery and is defined as the processes that monitor and improve the delivery of the intervention so that it is delivered as intended by the developers.

Determining treatment fidelity is an important methodological step that is necessary to determine the validity and reliability of treatment interventions and outcomes. Internal validity,
external validity and reliability of study findings have a complex cyclical relationship to treatment fidelity that is well-documented. Internal validity is the accepted truth of research findings. When outcomes of behavioral interventions yield significant findings, treatment fidelity increases the likelihood that significance is related to an effective treatment versus unknown confounding variables (type I error) (Moncher & Prinz, 1991). When an intervention yields non-significant findings, treatment fidelity monitoring can support that the treatment was in fact ineffective versus the treatment being inadequately administered (type II error) (McHugh et al., 2009). External validity is the extent to which findings from the study sample can be generalized to infer predictions in larger populations and is supported by the replication of internally valid studies (Moncher & Prinz, 1991). When larger studies are used, researchers can determine the true effectiveness of the treatment and increase the widespread dissemination of effective interventions, advancing the science of behavioral interventions research. Thus, treatment fidelity monitoring decreases the risk of rejecting effective interventions or accepting ineffective programs bolstering evidence-based practice.

The ability of the interventionist to skillfully deliver the treatment and engage participants can also affect the outcome (knowledge or other measured behavior change) associated with the intervention. As such, both adherence and competence assessments are necessary for an inference of validity (Santacroce, Maccarelli, & Grey, 2004), and can be measured using subscales of The Fidelity Checklist (Breitenstein et al., 2010).

The Fidelity Checklist

The Fidelity Checklist (TFC) was developed to measure group leader implementation of the Chicago Parent Program (CPP) (Breitenstein et al., 2010). The CPP is a 12-session, group-based behavioral parenting program delivered in community settings. The Fidelity Checklist was
established to assess group leaders’ maintenance of the weekly CPP protocol (adherence) and their group facilitation and process skills (competence). The adherence scale is session dependent and includes 16 dichotomously-scored items coded as yes or no to determine if the group leader performed the desired behavior for that group session. The adherence scale includes items that are key components of the intervention believed to be essential to ensure intervention effectiveness.

The competence scale is composed of 15 items with a 3-point scale rating “of skill rarely or never demonstrated”, “skill emerging, needs further development”, or “skill demonstrated and done well” (Breitenstein et al, 2010). The competence scale is used to determine group leaders’ delivery of intervention components and is consistent across group sessions. The competence scale is intended to rate group leaders on delivery of skills, response to challenging situations, and the overall response to the process, dynamics, and needs of the group members.

The Fidelity Checklist can be coded in two ways. Initially, the checklist was developed to be coded using audio recordings of group sessions but has also been successfully used with live observations. Fidelity raters are independent observers and are trained using a detailed coding manual. Training includes (a) an overview of fidelity monitoring, (b) a review of the coding manual and procedures, and (c) practice rating sessions until the coders reach 80% agreement on the adherence and competence scales.

Breitenstein and colleagues (2010) indicate that TFC is a reliable and valid measure of group leader treatment fidelity in a group-based parenting intervention. Reliability estimates for TFC show high interrater agreement (adherence scale = 94%, competence scale = 85%), intraclass correlation coefficients (adherence scale = .69; competence scale = .91) and Cronbach’s alpha reliability was .70 for the competence scale (Breitenstein et al., 2010). Positive
correlations were found between group leader adherence and parent attendance and engagement in the intervention and between group leader competence and parent satisfaction.

Although the adherence scale is specific to the CPP intervention, the competence scale is more generalizable to other group-based interventions and has been adapted for use in several behavioral interventions, including a physical activity intervention, a substance abuse curriculum, and a co-parenting intervention (S. Breitenstein, personal communication, 2014).

**The Need for Treatment Fidelity in Opioid Overdose Prevention Programs**

Due to the epidemic of fatal opioid overdoses, there has been a rapid increase in overdose prevention programs in the United States but, to date, no programs have reported fidelity measures evaluating the interventions (Clark, Wilder, & Winstanley, 2014). Opioid overdose prevention programs provide education to individuals at-risk for witnessing an opioid overdose. Researchers conducting a systematic review of community-based opioid overdose prevention programs examined the educational intervention associated with opioid overdose prevention programs (Clark et al., 2014). Researchers concluded that the educational intervention within and across programs varied greatly (Clark et al., 2014). For example, one program reported that the same intervention lasted 5 minutes in some cases and up to an hour in other cases.

Across programs, the same intervention was delivered in a group setting and individually, which affects the amount of group participation, potentially decreasing process gain, and engagement offered by interventionists (Johnson & Johnson, 2005). The adherence and competence variations were reflected across several studies. Another source of variance across programs was the reported outcomes. Although the intended behavior change, naloxone administration was high, it is difficult to know if other behaviors for preventing and responding to overdoses such as: calling 911, rescue breathing, and preventing overdose by the elimination
of high risk behaviors were associated with the educational intervention or related to other factors not specified by program participants (Clark et al., 2014). As such, it is difficult to assess the true efficacy of the educational interventions associated with opioid overdose prevention programs.

In an ongoing evaluation of a Midwestern opioid overdose prevention program (OOPP), the research team noted that, depending on which clinician delivered the prescribed intervention, the intervention structure and group participation varied greatly (E. Winstanley, personal communication, 2014). For example, some interventionists would use a video to lead the entire group session, while others would begin with an overview of overdose and solicit group interaction. The team also noted that clinicians periodically omitted key points of overdose prevention and items pertaining to responding to an overdose. Participants attending the (OOPP) group also had questions requiring sophisticated knowledge of overdose and medications involved in overdose, as well as used to reverse an overdose. Interventionists who could answer the questions were able to deliver more information to the participants. Interventionists who could not answer the questions and did not have the sources to provide participants with answers were missing out on participant learning opportunities. Due to the large amount variability during intervention delivery, it was difficult to understand which items related to overdose were covered in group and also difficult to measure the association between the intervention and outcomes.

To increase the fidelity of the intervention, the research team made several changes to the aforementioned Midwestern OOPP groups’ treatment intervention. Study design is one of the major components of treatment fidelity (Bellg et al., 2004; Gearing et al., 2011). Activities surrounding study design provide built-in safeguards to ensure that the behavioral intervention
appropriately reflects theoretical tenets, supports program goals and that researchers are testing the intended hypothesis (Bellg et al., 2004; Gearing et al., 2011).

First, the research team selected the theory of social interdependence (TSI) as the theoretical framework for the study. The overall premise of the TSI is that positive social interdependence fosters promotive interaction yielding an increased effort to achieve (Johnson & Johnson, 2013; Johnson & Johnson, 2002, 2005, 2008). The theory of social interdependence was selected since the ongoing pilot intervention yielded findings that the group members, when working together in an environment that supports positive interaction, were able to provide each other with useful information about responding and preventing opioid overdoses. Johnson and Johnson’s (2013) (TSI), which has been scientifically validated, supports the idea that the desired outcomes of educational groups include an increased effort to achieve, higher level reasoning, improved problem solving, group-to-individual transfer, intrinsic motivation and high commitment to achieve (Johnson & Johnson, 2013).

The research team also chose to manualize the intervention. This step was taken to decrease variation in group content and promote a more uniform treatment dose across groups. To accomplish manualization of the intervention, the research team established a group of key stakeholders, all well versed in community overdose prevention, to identify subject matter that was essential for opioid overdose prevention. Stakeholders convened for a one-day meeting that was video recorded. Video recording was done to ensure that the first author captured all content and stakeholder-discussion. Stakeholders included: a clinician who worked in the addiction treatment setting who has experience training clinicians to facilitate education groups, a public health nurse with experience creating opioid overdose prevention programs, a public health researcher with experience evaluating opioid overdose prevention programs, a member of the
community who has personally experienced two opioid overdoses and who received naloxone in both circumstances to reverse the overdoses, and finally the first author, who was developing the opioid overdose prevention program iBook.

Prior to the stakeholder meeting, stakeholders reviewed the following documents: The Opioid Overdose Prevention Toolkit (SAMHSA, 2013d), materials from the Harm Reduction Coalition, and findings from a community-based opioid overdose prevention program evaluation. A structured agenda was used to guide the stakeholder meeting in an effort to ensure coverage of the following topics: opioid overdose prevention, recognition of an opioid overdose and responding to an opioid overdose. To ensure that the stakeholders guided the content development, stakeholders were provided the opportunity voice their thoughts about each of the agenda items and any other tenets relating to opioid overdose experiences or content.

The outcome was a 23-page iBook with group discussion prompts. The opioid overdose prevention iBook provides clinicians delivering the treatment a one-stop tool for delivering both the didactic information on how to identity, prevent and respond to an opioid overdose, while also equipping them with video demonstrations of higher-level skills that clinicians previously did not cover in the course. The iBook format also allowed pathophysiological mechanisms that were identified by key stakeholders as mandatory for the participants to learn to be taught by clinicians or counselors working in the addiction treatment setting who may not have a medical background. The iBook format supports and promotes group interaction and discussion. The iBook also had the increased benefit of prompting the interventionist to cover all the prescribed content ensuring that the treatment dose was the same for each of the bi-weekly groups (Bellg et al., 2004; Gearing et al., 2011). The aforementioned actions represent attention to the design component of treatment fidelity (Bellg et al., 2004; Gearing et al., 2011). Careful attention to the
design component increases treatment structure and warrants that theoretical constructs and the treatment promote the accurate testing of hypotheses (Resnick, Bellg, et al., 2005).

Finally, an in-depth training for interventionists included instruction on how to deliver the iBook contents, the importance of group interaction in behavioral interventions, and opioid overdose prevention. For this particular OOPP treatment, counselors were going to be delivering the iBook content during bi-weekly afternoon groups. Due to variation in clinical skills and medical knowledge surrounding overdose, training the clinicians on how to appropriately deliver the treatment was of crucial importance. As recommended by the Behavioral Change Consortium and Gearing et al. (2011), all clinicians were trained with a standardized training and had the opportunity to role play the iBook, troubleshoot the technology and ask questions regarding content (Bellg et al., 2004; Gearing et al., 2011). Clinicians also had the opportunity during the training session to make recommendations to change the order and content of the iBook.

After careful attention and safeguards were embedded within the treatment design and clinician training, the next operational step of fidelity involved monitoring treatment delivery. Processes initiated to monitor the intervention delivery as intended by the developers coincide with the ‘delivery’ component of treatment fidelity. Monitoring treatment delivery is the gold standard to ensure optimal delivery of the intervention but prior to monitoring, delivery measurement tools such as The Fidelity Checklist must be developed in accordance with the intervention (Bellg et al., 2004). The overall goal of this study was to systematically modify the TFC for use in a community-based opioid overdose prevention program.
Methods

Instrument Development and Modification

The research team used a biphasic approach to modify TFC for use in the community opioid overdose prevention program. Phase 1 included utilizing key stakeholder meetings to determine adherence subscale components. Phase 2 included the modification of the competence subscale and TFC manual so that all components of the fidelity checklist were clearly explained to interventionists and fidelity raters.

Phase 1: Modifying the Adherence Subscale of The Fidelity Checklist

Because the adherence items on TFC are specific to the intervention, the modified adherence subscale could not be drafted until after the iBook was complete. To determine adherence items, an expert panel of key stakeholders, who assisted with the iBook content development, identified items that were deemed mandatory for clinicians to cover during the intervention. These mandatory items were then used to develop the adherence subscale. Through in-person discussion, key stakeholders arrived at 100% agreement on the relevance of each item of the adherence subscale ensuring the content validity of both the intervention and the adherence subscale.

The first author then met with the second author, at a day-long retreat, to develop a modified adherence subscale, using the format of the original TFC, which includes 18 detailed questions specific to the iBook intervention. Items measuring adherence were subdivided into three sections, as identified by the key stakeholders, and include: 1. Introduction, 2. Recognizing Signs and Symptoms of an Opioid Overdose, and 3. Responding to an Opioid Overdose. Items were coded as “yes” for completion, “no”, for non-completion and short-answer text space was provided for rater comments.
Phase 2: Modifying the Competence Subscale, The Manual for the Fidelity Checklist and the Facilitator Checklist

The second phase of the study included modifying the competence subscale and modifying The Manual for the Fidelity Checklist. Careful attention was paid to developing separate measures for adherence and competence since the iBook intervention has the potential to be delivered by clinicians and non-clinicians in a variety of settings in the future (Cross & West, 2011).

Competence Subscale

Competence or quality of program delivery is defined as the extent to which the interventionist has displayed behaviors that typically engage participants in the intervention (Cross & West, 2011). The iBook included videos demonstrating skills such as rescue breathing and assembly of nasal naloxone, in addition to definitions and animations fully explaining pathophysiological mechanisms, allowing interventionists to rely heavily on the manualized treatment during the intervention. However, since this was a group-based intervention, it was important for the research team to determine if the iBook could be skillfully integrated into the group setting. The competence subscale, as developed by Breitenstein et al. (2010), was developed specifically for behavioral interventions in the group setting so only slight modifications were necessary.

The Modified Fidelity Checklist

The Modified Fidelity Checklist (MFC) is comprised of the newly developed adherence and competence subscales and also includes a cover page for raters to provide information about the intervention setting, treatment dose, number of group participants and name of facilitator. The modified adherence subscale is comprised of 18 items, specific to the OOPP iBook, for the
interventionist to complete during the OOPP group. All items are coded “yes” or “no” and a comments section is provided in the subsequent column. The first three items on the adherence subscale reflect basic “housekeeping” requirements of the group and intervention. For example, action item #3 “Distributes Knowledge Survey Pre-Test for participant completion before course initiation” and item #18 “Administers Knowledge Survey Post-Test” were added to cue the interventionist to the study protocol. The knowledge survey pre-test/post-test was administered to participants to determine knowledge gain related to the iBook intervention. Items #4 through #17 on the adherence subscale reflect the content in the OOPP iBook. [See Figure 1]

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<table>
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<tbody>
<tr>
<td>4. Plays iBook OOPP course introduction (video link).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>5. Defines opioids (provide examples of prescription and illicit opioids).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>6. Discusses the pathophysiological mechanisms of opioids on the brain using the animation.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>7. Defines opioid overdose and hallmark symptom of respiratory depression.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>8. Discusses all risk factors for overdose using the iTunes bold links (Tolerance, Mixing Drugs, Physical/Mental, and Using Alone).</td>
<td>Yes ☐ No ☐</td>
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**RECOGNIZING SIGNS AND SYMPTOMS OF AN OVERDOSE**

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<tbody>
<tr>
<td>9. Presents signs and symptoms of an opioid overdose (uses iBook chart to discuss the difference between opioid overdose and “really high”).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>10. Introduces the sternal rub (using iBook video).</td>
<td>Yes ☐ No ☐</td>
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**RESPONDING TO AN OPIOID OVERDOSE**

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<tr>
<td>11. Presents and defines CARRY naloxone acronym.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>12. Discusses reasons for contacting 911 and participant’s concerns regarding notifying authorities.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>13. Introduces narcan (Naloxone Hydrochloride) including pathophysiology animation.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>14. Asks participants about their experiences with overdose and narcan.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>15. Allows participants to practice assembling nasal adaptor.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>16. Introduces rescue breathing (iBook video).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>17. Introduces recovery position (iBook video).</td>
<td>Yes ☐ No ☐</td>
</tr>
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*Figure 1: Modified Adherence Subscale*
The original competence subscale included 17-items rating the group leader, the modified subscale includes 14 items. Coding on the revised competence subscale remains unchanged from the original. Code ratings range from 1-3 and are defined as follows, 1= skill rarely or never demonstrated, 2= skill sometimes/occasionally demonstrated, 3= skill consistently demonstrated. The subscale also includes a place for raters to determine if the interventionist was particularly skilled in an item or if there was a missed opportunity. The purpose of the competence subscale is to determine if the group leader demonstrates skills that foster a group environment and promote an increased effort to achieve by participants.

The majority of items were altered to reflect the change in group participants and the change in subject matter under investigation [See Figure 2]. For example, the term ‘parent’ was changed to ‘participant’ in the modified tool. The wording of item #13 on the original TFC was changed from “using role-play or group activity” to “group discussion”, due to the time allotted for the overdose prevention group (Item #12 on the Modified Competence Subscale). Item #15 on the TFC was changed from “helps parents anticipate challenges using the new skills at home” to “helps participants anticipate challenges using new skills after discharge”. This item was changed for two reasons, first it needed to reflect the participant population, second, in accordance with the theory of social interdependence, participants working together in the group setting have an increased ability to transfer behaviors learned in the group into other environments (Johnson & Johnson, 2013).

Item #6 on Breitenstein et al.’s (2010) competence subscale was removed since it was not applicable to the opioid overdose prevention group. Item #14 was also removed since the parenting intervention included nine group educational sessions, while the opioid overdose prevention intervention was a one-time group. Item #17 on the TFC was not included in the
modified competence subscale since the intervention design included one interventionist, as opposed to a co-leader.

Clark et al. (2014) noted that participants in OOPPs were instructed to contact emergency responders during an overdose event, however, participants reported several barriers to contacting emergency responders, such as fear of arrest, legal prosecution, harassment, etc.. As such, item #13 was added to reflect the need for participants to discuss these challenges so that participants can provide each other with real life experiences and solutions regarding how they avoid legal infraction, while still notifying responders.

<table>
<thead>
<tr>
<th>The Original Fidelity Checklist Competence Scale</th>
<th>The Modified Fidelity Checklist Competence Scale</th>
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<tr>
<td>13. Effectively uses role-play or group activity to teach a principle or strategy.</td>
<td>12. Effectively uses group discussion to teach principles or strategies for overdose prevention.</td>
</tr>
<tr>
<td>14. Builds on parents’ knowledge by incorporating strategies discussed in previous sessions into this session.</td>
<td></td>
</tr>
<tr>
<td>15. Helps parents anticipate challenges using the new skills at home.</td>
<td>13. Helps participants anticipate challenges using new skills after discharge.</td>
</tr>
<tr>
<td>17. Overall quality of co-leader interactions and work together.</td>
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*Figure 2: Modified Items of Fidelity*

The Manual for the TFC, as developed by Breitenstein et al., provides in-depth guidelines for coding competence and adherence subscale items. The manual in its entirety was altered to reflect the change in population and subject matter. After thorough review, the manual was adapted for the current study by replacing all terms “parent” and “parents” with “participant” and “participants.” Then, items were re-numbered to reflect the altered components of the competence subscale. Finally, any “decision rules” at the bottom of the pages were changed to coincide with changes in the competence subscale. “Footnotes” were also reviewed and were all modified to accurately reflect the modified competence subscale.
The Manual for the TFC was also modified by removing the “All Sessions” guide to reflect the one-time group opioid overdose prevention intervention. The “role-play or group activity” section was removed due to time limitations for the overdose prevention content. In addition to the above modifications, the adherence subscale was amended to create a guide for the interventionists during group as a checklist of mandatory discussion items. Creating a facilitator checklist assisted interventionists during the training of the iBook intervention and as a guide during delivery of the intervention.

Results

The outcome of this project included the Modified Fidelity Checklist (MFC), composed of a modified adherence and competence subscale, a Modified Manual for The Fidelity Checklist [Contact first author for more information], and a Modified Facilitator Checklist.

The MFC was used to determine delivery fidelity and inform the feasibility of the iBook intervention in the group in-patient setting. The iBook intervention was delivered in the group setting to patients with a diagnosis of opioid dependence. Three interventionists delivered the iBook four times each for a total of twelve (OOPP) group interventions. The first author, using the Modified Manual for The Fidelity Checklist, trained two graduate research assistants, with previous data collection experience, on how to rate the interventionists. Both research assistants attended all iBook intervention group sessions and completed the adherence and competence subscales of the MFC. After each group intervention, interventionists completed the Modified Facilitator Checklist.

Data from the MFC were entered by the first author into REDCap™ data management software, and then exported to SPSS statistical software for statistical analysis. Fourteen items on the adherence subscale received 100% total agreement between raters across all 12-intervention
groups. Items 9, 12, and 15 were coded with 91.7% total agreement across the 12 groups. Item 2, “Reviews group discussion ground rules” with coded with 67% agreement across the 12 groups.

**Discussion**

Fidelity monitoring tools are informative for training development, refinement of the intervention and assisting with the identification of training needs. Before the intervention was delivered to the group, clinicians were trained to deliver the iBook content by using the MFC as a training guide. As clinicians were practicing with the iBook, they would use the modified Facilitator Checklist as a guide to ensure that they did not skip any of the content in the iBook. The Facilitator Checklist also allowed clinicians to see which content was coming up next until they became familiarized with the intervention. This is an important finding because not only did the tools assist with training but they allowed for an increased ease of delivery and ultimately increased the skillfulness of the clinicians and flow of the group sessions.

The importance of implementation fidelity monitoring development early on in the intervention development process appropriately allowed for intervention refinement. When the intervention began in August of 2014, the three interventionists had little experience using iPads and the Opioid Overdose iBook intervention was novel and in a pilot phase. Through careful review of rater comments on the MFC, it was noted that clinicians were not allowing participants to practice assembling the nasal naloxone adapter. Item #15 on the MFC was continually coded as “no” by raters and clinicians also coded “no” on the facilitator checklist item #15. The first author met with both the raters and the clinicians and determined that the site no longer had a naloxone ampule available to practice assembling, so clinicians were not completing this task. This is important because this item and the skill of assembling naloxone was deemed mandatory.
by key stakeholders and research shows that in cases where naloxone administration was
difficult, it is often due to the assembly of the nasal adaptor (Clark et al., 2014).

This also allowed clinicians the opportunity to voice their concerns over whether the
naloxone kit could potentially be a “trigger” for someone in recovery. The clinicians met with
their supervisor and medical director and determined that as long as the naloxone kit was
needleless, the chance for an adverse reaction from patients was low and that in the event that it
was a “trigger”, the clinicians were now prepared to discuss this concept with the group and use
it as a learning opportunity.

Another finding from this study was that the MFC allowed for treatment flexibility and
did not require rigid adherence. During one group session, several attendees were returning for
substance abuse treatment, so they had already completed the OOPP group session. The
interventionist covered all of the content of the iBook and adhered to the protocol, but increased
the number of participant discussions in the group so that participants were teaching each other
through personal experiences rather than relearning the content in the iBook. This is an important
finding because there is a need for clinicians to be able to adapt treatments for clients/patients’
needs. McHugh et al. (2009) purport that flexibility in manualized treatments allows for greater
heterogeneity of clinical presentation and provides opportunities to adapt the intervention to the
patient.

Our findings support the idea that establishing content validity is a key process in both
the development of the intervention in the development of fidelity measures. For this study, key
stakeholders arrived at 100% agreement on mandatory items that were added to the (MFC)
adherence subscale. While this study utilized content experts arriving at 100% agreement, future
attempts to modify the TFC could potentially utilize a content validity index (CVI), and rate
items of relevance to determine which items of should be added to the adherence subscale (Polit & Beck, 2006).

**Conclusion**

The overall goal of this study was to systematically modify the TFC for use in a community-based opioid overdose prevention program. Our findings indicate that the MFC is a valid and reliable instrument and suggest that TFC can be modified for future behavioral group interventions to determine treatment fidelity. Findings also support the importance of implementation fidelity monitoring early on in the intervention and that monitoring tools such as fidelity checklists are informative for clinician training and clinical development. Lastly, our findings suggest that establishing content validity is critical in the process of developing the adherence items.
References


Centers for Disease Control and Prevention. (2012b). *Viral hepatitis surveillance-United States, 2010.* Atlanta, GA.


http://dx.doi.org/10.1080/10826080701801261


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*Journal of Substance Abuse Treatment, 44*(2), 241-247. doi: http://dx.doi.org/10.1016/j.jsat.2012.07.004


*Drug Delivery and Translational Research*. doi: 10.1007/s13346-012-0092-0


DOI: 10.1586/14737175.8.5.781


## APPENDIX A
### QUALITY RATINGS OF REVIEWED ARTICLES

<table>
<thead>
<tr>
<th>Authors &amp; Publication Year</th>
<th>Research questions/ objectives/ hypothesis are clear &amp; appropriate</th>
<th>Clear overview of intervention is given with use of appropriate outcome measures</th>
<th>Sample size is given</th>
<th>Randomization method used in sample selection*</th>
<th>Attrition rate is recorded &amp; discussed</th>
<th>Data analysis is adequately described &amp; rigorous</th>
<th>Outcomes are clearly described</th>
<th>Ethical issues are suitably addressed</th>
<th>TOTAL score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bennett et al. 2011</td>
<td>1</td>
<td>1</td>
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<td>0</td>
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<td>0.5</td>
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<td>0</td>
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<tr>
<td>Dettmer et al. Al 2001</td>
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<td>Doe-Simkins et al. 2009</td>
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<td>Enteen et al. 2010</td>
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<td>1</td>
<td>0</td>
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<tr>
<td>Galea et al. 2006</td>
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<tr>
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<td>1</td>
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<tr>
<td>Lankenau et al. 2013</td>
<td>1</td>
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<td>1</td>
<td>0*</td>
<td>N/A</td>
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<tr>
<td>Leece et al. 2013</td>
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<td>McAuley et al. 2010</td>
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<tr>
<td>Sherman et al. 2008</td>
<td>1</td>
<td>1</td>
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<td>1*</td>
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<tr>
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<tr>
<td>Tobin et al. 2009</td>
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<tr>
<td>Wagner et al. 2010</td>
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<td>Walley et al. 2013</td>
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<td>1.0</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Walley et al. 2013</td>
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<td>Yokell et al. 2011</td>
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<td>0.5</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>5</td>
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</tbody>
</table>

* Randomization was a criterion for non-qualitative studies; for qualitative studies, the alternative criterion was “Recruitment of participants is adequately described.” Lankenau et al. 20013 and Sherman et al. 2008 were qualitative studies.
**APPENDIX B**
**ARTICLES INCLUDE IN LITERATURE REVIEW**

<table>
<thead>
<tr>
<th>AUTHORS (YEAR)</th>
<th>PROGRAM NAME</th>
<th>PROGRAM SITE (LOCATION)</th>
<th>SAMPLE SIZE</th>
<th>TIME FRAME</th>
<th>OUTCOMES</th>
<th>TRAINING CONTENT (DURATION/SETTING)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bennett et al. (2011)</td>
<td>Prevention Point Pittsburgh</td>
<td>Syringe exchange program (Pittsburgh, PA)</td>
<td>426</td>
<td>07/2005-12/2008</td>
<td>249/89/ NR</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses 96%/ NR</td>
</tr>
<tr>
<td>Bennett et al. (2012)</td>
<td>Take Home Naloxone Demonstration Project</td>
<td>Multiple sites including community settings &amp; prison sites (Wales)</td>
<td>525</td>
<td>09/2009-09/2010</td>
<td>28/ NR/ NR</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses 96% Stat. sig. increased knowledge of risk factors/ Confidence with nal. admin. increased from 67% to 92%; Mouth to mouth resuscitation increased from 69% to 88%</td>
</tr>
<tr>
<td>Dettmer et al. (2001)</td>
<td>NR</td>
<td>Mobile services for drug users (Berlin, Germany) &amp; local drug service locations (Jersey, UK)</td>
<td>Berlin= 124, Jersey= 101</td>
<td>01/1999-04/2000, 10/1998-02/2000</td>
<td>100% in both locations/ NR</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses 33% (Berlin) &amp; NR (Jersey)/ Spontaneous self-report (Berlin &amp; NR (Jersey))</td>
</tr>
<tr>
<td>Doe-Simkins et al. (2009)</td>
<td>NR</td>
<td>Syringe exchange program (Boston, MA)</td>
<td>385</td>
<td>09/2006-12/2007</td>
<td>74/ 50/ NR</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses 72%/ NR</td>
</tr>
<tr>
<td>Enteen et al. (2010)</td>
<td>NR</td>
<td>Syringe exchange programs, re-entry programs, opioid substitution clinics, pain management clinics, &amp; single room occupancy hotels (San Francisco, CA)</td>
<td>1,942</td>
<td>09/2003-12/2009</td>
<td>399/ 310/ NR</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses 89% / 75% of participants who used nal. also used complementary overdose prevention strategies</td>
</tr>
<tr>
<td>Galea et al. (2006)</td>
<td>NR</td>
<td>Syringe exchange program (New York, NY)</td>
<td>25</td>
<td>06/2004-01/2005</td>
<td>10/ NR/ 26</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses 100% / Increase from 58% to 82% of respondents called ambulance from last witnessed overdose at FU</td>
</tr>
<tr>
<td>Lopez Gaston et al. (2009)*</td>
<td>NR</td>
<td>Detox. center &amp; community drug treatment teams</td>
<td>70</td>
<td>01/2006-01/2007</td>
<td>0/ NR/ 16</td>
<td>% survived after nal./ Indiv. Used Nal./ Num. Witnessed Overdoses NA/ Stat. sig. mean increase from 82.8% at 3 mos. &amp; 65% at 6 mos./</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Location</td>
<td>Sample</td>
<td>Trainings</td>
<td>Surveys</td>
<td>Knowledge Improvement</td>
<td>Strategies</td>
</tr>
<tr>
<td>-------------</td>
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<td>------------</td>
</tr>
<tr>
<td>Lankenau et al. (2013)</td>
<td>Los Angeles, CA</td>
<td>30</td>
<td>2010-2011</td>
<td>15/ NR</td>
<td>100%/ NR</td>
<td>-</td>
</tr>
<tr>
<td>McAuley et al. (2010)</td>
<td>Lanarkshire</td>
<td>19</td>
<td>NR</td>
<td>2/ NR</td>
<td>100% / Knowledge &amp; Confidence scores improved</td>
<td>-</td>
</tr>
</tbody>
</table>

- **Birmingham & London, England**
- **Baseline to 6 mos. FU in knowledge of overdose signs & in knowledge of actions to take in an overdose event**
- **Pre-post training survey & FU surveys at 3 & 6 mos.**

- Recognize overdose
- Activate EMS
- Recovery position
- Needle-based nal. admin. (30 min./ group of 3-10 or indiv.)
- Recognize overdose
- Activate EMS
- Rescue breathing
- CPR
- Needle-based nal. admin.
- (NR/ NR)
- Overdose prevention
- Recognize overdose
- Activate EMS
- Chest compressions
- Needle-based nal. admin.
- Aftercare
- Nal. kit care & logistics (20 min./ indiv. or small group by RN or counselor)

- Pharmacology of opioids & nal.
- Opioid neurophysiology
- Overdose prevention
- Risk factors for overdose
- Recognize overdose
- Rescue breathing
- Prevention of choking & aspiration
- Needle-based nal. admin.
- Aftercare
- “Educational & practical skills”

(NR/ NR)
<table>
<thead>
<tr>
<th>Studies</th>
<th>Community</th>
<th>Syringe exchange programs</th>
<th>Duration</th>
<th>N-Al/ NR</th>
<th>Follow-up/ Training Details</th>
<th>Nal. distribution methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sherman et al. (2008)</td>
<td>Chicago Recovery Alliance (Chicago, IL)</td>
<td>31</td>
<td>3 months in 2004</td>
<td>18/ NR/ NR</td>
<td>NA/ Qualitative interviews</td>
<td>100% / Subjective reports of increased sense of ability to help peers &amp; comfort level with nal. admin.</td>
</tr>
<tr>
<td>Strang et al. (2008)</td>
<td>NR</td>
<td>20 drug treatment facilities (England)</td>
<td>239</td>
<td>10/ 10/ 18</td>
<td>78% Pre-post training survey &amp; 3 mos. FU survey</td>
<td>100% / Knowledge composite scores increased stat. sig. from 16.7 pre-training to 21.4 post-training</td>
</tr>
<tr>
<td>Tobin et al. (2009)</td>
<td>Staying Alive Program (Baltimore, MD)</td>
<td>250</td>
<td>10/2004-04/2005</td>
<td>22/19/51</td>
<td>34% 6 mos. FU assessment</td>
<td>100% / Knowledge of risk factors for OD did not change; knowledge about naloxone improved for 46% of sample</td>
</tr>
<tr>
<td>Wagner et al. (2010)</td>
<td>Homeless Health Care Los Angeles Center for Harm Reduction, Skid Row (Los Angeles, CA)</td>
<td>Community health care program including syringe exchange</td>
<td>66</td>
<td>28/ NR/ 35</td>
<td>NR/ Stat. sig. increase in overall knowledge index from a baseline mean of 77% to 3 mo. mean of 91%</td>
<td>71% / Nal. refill form &amp; 3 mos. FU interview</td>
</tr>
<tr>
<td>Walley et al. (2013a)</td>
<td>MA Opioid Overdose Prevention Pilot Program (MA)</td>
<td>Addiction treatment programs, HIV prevention programs, syringe exchanges, emergency departments &amp; homeless shelters (MA)</td>
<td>1,553</td>
<td>92/62/ NR</td>
<td>51% Nal. refill form</td>
<td>100% / Nal. refill form</td>
</tr>
<tr>
<td>Walley et al. (2013b)</td>
<td>MA Overdose Education &amp; Naloxone Distribution Program</td>
<td>HIV education centers, syringe exchanges, substance abuse treatment programs, emergency &amp; primary health care centers, &amp; community meetings (MA)</td>
<td>4,857</td>
<td>545/ NR/ NR</td>
<td>11% Nal. refill form</td>
<td>98%** / Nal. refill form</td>
</tr>
<tr>
<td>Yokell et al. (2011)</td>
<td>Preventing Overdose &amp; Naloxone Intervention (RI)</td>
<td>Syringe exchange, HIV education center, substance abuse treatment programs, &amp; homeless shelters</td>
<td>120</td>
<td>5/5/ NR</td>
<td>8% Nal. refill form &amp; 3 mos. FU survey</td>
<td>100% / Nal. refill form</td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

*6 month follow up of a subset of participants from Strang et al., 2008
** Naloxone was 98% effective but the 2 individuals for whom it was not effective were subsequently treated by EMS and survived; therefore survival rate was 100%

NOTES: num. = number; admin. = administrations; FU = follow-up; mo(s). = month(s); NA = not applicable; NR = not reported; min. = minutes; hr. = hour; nal. = naloxone; indiv. = individuals; stat. sig. = statistically significant; detox. = detoxification
## APPENDIX C

THE MODIFIED FIDELITY CHECKLIST©

The OOPP Fidelity Checklist

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group facilitator:</td>
<td></td>
</tr>
<tr>
<td>Observer/coder:</td>
<td></td>
</tr>
<tr>
<td>Date of group:</td>
<td></td>
</tr>
<tr>
<td>Site/location:</td>
<td></td>
</tr>
<tr>
<td>Number of participants in group session:</td>
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</tr>
<tr>
<td>Start time of tape/group session:</td>
<td></td>
</tr>
<tr>
<td>End time of tape/group session:</td>
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</tr>
<tr>
<td>Total time of tape/group session:</td>
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</table>
Adherence Subscale

**OPIOID OVERDOSE PREVENTION EDUCATION**

Please answer yes or no whether the group leader performs the following actions:

**The Group Leader**

<table>
<thead>
<tr>
<th>Action</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
</tr>
<tr>
<td>1. Introduce the course/group (see training manual).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>2. Review group discussion “ground rules”.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>3. Distribute <strong>Knowledge Survey Pre-Test</strong> for participant completion before course initiation.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>4. Play iTunesU OOPP course introduction (video link.)</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>5. Define opioids (provide examples of prescription and illicit opioids).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>6. Discuss the pathophysiological mechanisms of opioids on the brain using the animation.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>7. Define opioid overdose and hallmark symptom of respiratory depression.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>8. Discuss all risk factors for overdose using the iTunes bold links (Tolerance, Mixing Drugs, Physical/Mental, and Using Alone).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td><strong>RECOGNIZING SIGNS AND SYMPTOMS OF AN OVERDOSE</strong></td>
<td></td>
</tr>
<tr>
<td>9. Present signs and symptoms of an opioid overdose (use iTunes animation to visually demonstrate while discussing).</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>10. Do they respond to sternal rub? Are they breathing?</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td><strong>RESPONDING TO AN OPIOID OVERDOSE</strong></td>
<td></td>
</tr>
<tr>
<td>11. Present and define CARRY NARCAN acronym.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>12. Discuss reasons for contacting 911 and participant concerns regarding notifying authorities.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>13. Introduce Narcan (Naloxone Hydrochloride) including pathophysiology animation.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>14. Ask participants about their experiences with narcan.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>15. Allow participants to practice assembling nasal adaptor.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>16. Support breathing by placing victim in the recovery. Show recovery position video link.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>17. Practice putting each other in recovery position or live demonstration.</td>
<td>Yes ☐ No ☐</td>
</tr>
<tr>
<td>18. Administer <strong>Knowledge Survey Post-Test</strong>.</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>
### Competence Subscale

Please rate the group leader on the following scale:
1= skill rarely or never demonstrated (skill demonstrated <25% of the time)
2= skill sometimes/occasionally demonstrated (skill demonstrated 25-75% of the time)
3= skill consistently demonstrated (skill demonstrated >75% of the time)

*Place a ✓ if this is a particular strength or missed opportunity for the group leader.*

<table>
<thead>
<tr>
<th>Skill</th>
<th>Rating</th>
<th>Strength</th>
<th>Missed opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Actively engages all group members in the discussion.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Actively listens when participants are talking.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Communicates with all participants in a respectful, positive, and non-judgmental manner.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Appropriately reinforces participants’ ideas and opinions.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Correctly conveys/communicates components of opioid overdose prevention.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Facilitates problem solving.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Facilitates sharing of ideas among participants.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Does not impose his/her ideas on participants.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Effectively responds when participants are resistant to new strategies or ideas.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Effectively manages challenging behavior from participants in the group.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Maintains a good pace for group discussion.</td>
<td>1 2 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
12. Effectively uses group discussion to teach a principles or strategies for overdose prevention.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
</table>

13. Helps participants anticipate challenges using the new skills at after discharge.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
</table>

14. Over the tone of this group (quality and affective tone of discussion) was: (circle one)

<table>
<thead>
<tr>
<th>Negative (1)</th>
<th>Neutral (2)</th>
<th>Positive (3)</th>
</tr>
</thead>
</table>
APPENDIX D
KNOWLEDGE PRE-TRAINING SURVEY

Overdose Prevention PRE-Training Survey

Today’s Date: _____/____/201__  Your Name:

1) Which of the following risk factors are associated with a heroin or prescription opioid overdose death?

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>NO</th>
<th>YES</th>
<th>UNSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Taking an opioid prescribed for pain more often or at a higher dose than prescribed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Using heroin/prescription opioids &amp; other drugs (like downers/benzodiazepines/barbiturates/alcohol) at the same time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Changes in the purity of heroin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) Using heroin/prescription opioids without others around</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Using heroin/prescription opioids with some medical conditions (lung, heart, or liver problems, sleep apnea, or advanced AIDS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Injecting heroin/prescription opioids for the first time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) Using heroin/prescription opioids after a week or more of not using</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2) Which of the following are symptoms of a heroin/prescription opioid overdose?

<table>
<thead>
<tr>
<th>Symptom</th>
<th>NO</th>
<th>YES</th>
<th>UNSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Bloodshot eyes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Shallow or slow breathing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Blue/Grayish lips or skin</td>
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<td>d) Slurred speech</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) Loss of consciousness &amp; non-responsive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) “Nodding off”, but still responsive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g) Snore-like gurgling noise during sleep</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h) Small pupils that don’t enlarge with light</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3) What things would you do if someone overdoses?

<table>
<thead>
<tr>
<th>Action</th>
<th>Definitely Would Do</th>
<th>Don’t Know</th>
<th>Definitely Would NOT do</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Call 9-1-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Stay with person until they came around</td>
<td></td>
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<td>c) Walk the person around the room</td>
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<td>d) Inject them with saline (salt) or water</td>
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<tr>
<td>e) Give stimulants (for example, coffee)</td>
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<td>f) Slap, shake or use pain to wake the person</td>
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<td>g) Shock the person with cold water or ice</td>
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<td>h) Perform rescue breathing</td>
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<td>i) Place the person the in the recovery position</td>
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<tr>
<td>j) Administer naloxone (Narcan)</td>
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<td>k) Stay until the paramedics arrive</td>
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<tr>
<td>l) Rub their sternum</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
m) Call their name to try to wake them up  
   □ (0) □ (1) □ (2) 

n) Take the person to the hospital  
   □ (0) □ (1) □ (2) 

o) Do nothing  
   □ (0) □ (1) □ (2) 

4) Naloxone (Narcan) can wear off before the effects of heroin/prescription opioids wear off.  
   □ (0) False □ (1) True □ (2) Unsure 

5) To put someone in the recovery position, you place them on their left side.  
   □ (0) False □ (1) True □ (2) Unsure 

STOP HERE – DO NOT COMPLETE THE QUESTIONS ON BACK UNTIL YOU’VE COMPLETED THE TRAINING SESSION
### Overdose Prevention POST-Training Survey

#### 6) Which of the following risk factors are associated with a heroin or prescription opioid overdose death?

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>NO (0)</th>
<th>YES (1)</th>
<th>UNSURE (2)</th>
</tr>
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<tbody>
<tr>
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#### 7) Which of the following are symptoms of a heroin/prescription opioids overdose?

<table>
<thead>
<tr>
<th>Symptom</th>
<th>NO (0)</th>
<th>YES (1)</th>
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#### 8) What things would you do if someone overdoses?

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<th>Don’t Know (1)</th>
<th>Definitely Would NOT do (2)</th>
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<td>n) Take the person to the hospital</td>
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<td></td>
</tr>
<tr>
<td>o) Do nothing</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
9) Naloxone (Narcan) can wear off before the effects of heroin/prescription opioids wear off.
   [ ] (0) False   [ ] (1) True   [ ] (2) Unsure

10) To put someone in the recovery position, you place them on their left side.
    [ ] (0) False   [ ] (1) True   [ ] (2) Unsure

11) Prior to this training, did you know that naloxone (Narcan) could reverse a heroin or prescription drug overdose?
    [ ] (0) No   [ ] (1) Yes → IF YES, please check if:
    [ ] (11a) Narcan has been used to revive you in the past
    [ ] (11b) You’ve seen someone who overdosed be given narcan
### APPENDIX F
### CLASSROOM LIFE MEASURE

**Classroom Life Measure**

<table>
<thead>
<tr>
<th>Today’s Date: <strong><strong>/</strong></strong>/201__</th>
<th>Participant Name:</th>
</tr>
</thead>
</table>

**Directions:** Next to each statement, check the corresponding box that tells how true each of these statements are of you.

<table>
<thead>
<tr>
<th></th>
<th>False All The Time</th>
<th>False Some of the Time</th>
<th>Neither False Nor True</th>
<th>True Some of the Time</th>
<th>True All of the Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In this class, I like to share my ideas and materials with other students.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>2. I learn more from other group members who are similar to me.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>3. In this class, I can learn important things from other students.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>4. In this class, I like to help other students learn.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>5. When we work together in small groups, everyone’s ideas are needed if we are going to be successful.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>6. When we work together in small groups, I have to find out what everyone else knows if I am going to be able to do the assignment.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>7. When we work together in groups, we cannot complete an assignment unless everyone contributes.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>8. When we work together in groups, the teacher divides the material so that everyone has a part and everyone has to share.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>9. I would like to be in a learning group with students who are different from me.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>10. I have more fun when I work with students’ who are different from me.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>11. I learn more from students who are different from me.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
<tr>
<td>12. When we work together in groups, we have to share materials in order to complete the assignment.</td>
<td>[ ] (1)</td>
<td>[ ] (2)</td>
<td>[ ] (3)</td>
<td>[ ] (4)</td>
<td>[ ] (5)</td>
</tr>
</tbody>
</table>
13. In this class, I like to share my ideas and materials with other students.

14. When we work together in groups, everyone’s ideas are needed if we are going to be successful.

15. In this class, it is a good idea for students to help each other learn.

16. In this class, I like to help other students learn.

17. In this class, I try to share my ideas and materials with other students when I think it will help them.

18. When we work together in small groups, we try to make sure everyone in our groups learns the material.

19. In this class, it is a good idea for students to help each other learn.

20. In this class, I like to cooperate with other students.

21. In this class, students learn a lot of important things from each other.

*Permissions for use granted by Dr. David W. Johnson*
### Naloxone Program Baseline Survey

<table>
<thead>
<tr>
<th>Your Name: _______________________________</th>
<th>Admission Date: _<strong>/</strong><strong>/201</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Today's Date: _<strong>/</strong><strong>/201</strong></td>
<td>Date of Birth: <em><strong>/</strong><strong>/</strong></em>___</td>
</tr>
</tbody>
</table>

**Program:**
- [ ] (0) Residential
- [ ] (1) Suboxone

**Gender:**
- [ ] (0) Male
- [ ] (1) Female

1. **What is your highest educational degree you have earned?** *(check only one box)*
   - [ ] (0) Less than high school, enter last grade completed: (a) _____
   - [ ] (1) High school diploma or GED
   - [ ] (2) Some College
   - [ ] (3) Associates Degree/Trade or Tech School
   - [ ] (4) BA/BS/Other 4-year college degree
   - [ ] (5) Some graduate school
   - [ ] (6) Graduate Degree (MD/PhD/MA/MS)

2. **What is your current living situation?**
   - [ ] (0) Alone
   - [ ] (1) Parents/Caregivers
   - [ ] (2) Spouse/Significant Other/Family Members
   - [ ] (3) Roommates (Non-family members)
   - [ ] (4) Supported or transitional housing
   - [ ] (5) Nursing Home/Assisted Living Facility
   - [ ] (6) Transient/Stay Where you Can
   - [ ] (7) Homeless
   - [ ] (8) Other, specify: (a) __________________

3. **What is your race?** *(check all that apply)*
   - [ ] (a) White
   - [ ] (b) Black or African American
   - [ ] (c) Some Other Race, please specify: (a) ____________________
4. **What is your ethnicity?**
   - (0) Not of Hispanic, Latino or Spanish origin
   - (1) Mexican, Mexican American or Chicano
   - (2) Puerto Rican
   - (3) Cuban
   - (4) Other Hispanic, Latino or Spanish origin,
   - (5) Other, please specify: __________________________

5. **What is your current marital status?** *(check only one box)*
   - (0) Single
   - (1) Divorced
   - (2) Separated
   - (3) Widowed
   - (4) Married/Cohabitating
   - (5) Other, please specify: __________________________

6. **What is your current or usual work/employment status?** *(check all that apply)*
   - (a) Employed *(full or part-time)*
   - (b) Unemployed
   - (c) Student
   - (d) Retired
   - (e) Homemaker
   - (f) Disabled
   - (g) Other, specify: __________________________

7. **How many days in the past month were you paid for working?** *(Include "under the table" work, paid sick days and vacation. If you are receiving residential treatment, count the 30 days before you entered residential treatment)*
   ___ ___ Number of days (0-30)

8. **How many days in the past month have you experienced employment problems?** *(Include inability to find work, if you are actively looking for work, or problems with your present job in which that job is jeopardized. If you are receiving residential treatment, count the 30 days before you entered residential treatment)*
   ___ ___ Number of days (0-30)

9. **Have you been in a controlled environment in the past 30 days?** *(If you are receiving residential treatment, count the 30 days before you entered residential treatment)*
   - (0) No
   - (1) Jail/Prison
   - (2) Alcohol/Drug treatment *(residential program)*
   - (3) Medical treatment *(hospitalized overnight)*
   - (4) Psychiatric treatment *(hospitalized overnight)*
   - (5) Other, please specify (a) __________________________
10. In general, would you say your mental health is:
☐ (4) Excellent  ☐ (3) Very Good  ☐ (2) Good  ☐ (1) Fair  ☐ (0) Poor

11. How many days in the past month have you experienced mental health problems?
   [include days that you felt sad, anxious, depressed, etc.]
   ___ ___ Number of days (0-30)

12. Have you ever been prescribed a medication for a psychological problem during your lifetime?
   ☐ (0) No  ☐ (1) Yes  ➔ if yes, ☐ (a) are you currently taking a medication for your psychological
   Problem(s)?  ☐ (0) No  ☐ (1) Yes, medication name:
   (a) ___________________

13. Have you had a significant period of time in which you have experienced serious thoughts of suicide?
   (check only one box)  ☐ (0) never  ☐ (1) in my lifetime  ☐ (2) in the past 30 days

14. Have you attempted suicide?  (check only one box)
   ☐ (0) never  ☐ (1) in my lifetime  ☐ (2) in the past 30 days

15. Do you currently live with anyone who has a current alcohol or drug problem?
   ☐ (0) No  ☐ (1) Yes  ☐ (2) Don’t know

16. How many days in the past month have you had serious conflicts with your family, friends or other people?
   ___ ___ Number of days (0-30)

Physical Health

17. In general, would you say your physical health is:
   ☐ (4) Excellent  ☐ (3) Very Good  ☐ (2) Good  ☐ (1) Fair  ☐ (0) Poor

18. During your lifetime, how many times have you been hospitalized for medical problems?
   [Exclude detoxification, alcohol/drug problems including overdose, psychiatric treatment and childbirth (if no complications).]
   ___ ___ ___ Number of times

19. How many days in the past month have you had serious medical problems?
   [for example, Hepatitis, HIV, diabetes, asthma, cirrhosis of liver, abscesses from needles]
   ___ ___ Number of days (0-30)

20. Do you have a regular or family doctor?
   ☐ (0) No  ☐ (1) Yes

21. Do you have a chronic medical problem? (check all that apply)
   ☐ (a) Kidney disease  ☐ (b) Liver disease  ☐ (c) HIV/AIDS  ☐ (d) Heart disease  ☐ (e) Emphysema
   ☐ (f) Asthma  ☐ (g) Hepatitis C  ☐ (h) Hepatitis B  ☐ (i) Other, please specify:  ☐ (j) ___________________
22. List any current medications that you are taking (include prescription & over the counter):

a. ____________________________
e. ____________________________

b. ____________________________
f. ____________________________

c. ____________________________
g. ____________________________

d. ____________________________
h. ____________________________

Criminal Behavior

23. How many times in your life have you been arrested? _____ _____ Number of times

24. Are you presently awaiting charges, trial or sentencing? □ ( ) No □ ( ) Yes □ ( ) Don’t know

25. Are you on currently parole or probation? □ ( ) No □ ( ) Yes  
   → if yes, (a) parole/probation officer name: ____________________

26. How many days in the past month ……...

   …..(a) have you had legal problems? (for example, were arrested, were on probation or parole)  
   _____ _____ (0-30) 

   …. (b) were you detained or incarcerated? (Include being arrested and released on the same day)  
   _____ _____ (0-30)

Substance Use: In the left column list the age you first used each drug. In the right column, list the number of days, ranging between 0-30, that you used the drug in the past month. [If you are receiving residential treatment, count the 30 days before you entered residential treatment.]

<table>
<thead>
<tr>
<th>Substance/Drug</th>
<th>Age of First Used</th>
<th>Num. of days used in the past 30 days (0-30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>27. Alcohol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Cannabis (marijuana, pot, grass, hash)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. Cocaine (coke, crack)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. Prescription stimulants (Ritalin, Concerta, Dexedrine, Adderall, diet pills)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31. Methamphetamine (speed, crystal meth, ice)</td>
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<td></td>
</tr>
<tr>
<td>32. Sedatives or sleeping pills (Soma, Valium, Serepax, Ativan, Xanax, Librium, Rohypnol, GHB)</td>
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</tr>
<tr>
<td>33. Street opioids (heroin, opium)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. Prescription opioids (fentanyl, oxycodone, OxyContin, Percocet, hydrocodone, Vicodin, methadone, buprenorphine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. Other – specify: ( )</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
35a. Thinking back to the very first time you used a prescription opioid (fentanyl, oxycodone, OxyContin, Percocet, hydrocodone, Vicodin, methadone, buprenorphine), did you get it from:

☐[0] A physician for pain, (35a1) if yes please specify whether you got the prescription from:

☐[0] Friend or family member
☐[2] Bought it from someone
☐[3] Other, please specify: ___________

36. During the past 3 months, how often has your use of opioids (heroin, opium, fentanyl, oxycodone, oxycontin) led to health, social, legal or financial problems?


37. In the past three months, how often have you used the substances?

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Once or Twice</th>
<th>Monthly</th>
<th>Weekly</th>
<th>Daily or Almost Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Alcohol</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>b) Cannabis</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>c) Cocaine</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>d) Prescription stimulants (Ritalin, Concerta, Dexameth, Adderall, diet pills)</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>e) Methamphetamine (speed, crystal meth, ice)</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>f) Sedatives or sleeping pills (Soma, Valium, Serapax, Ativan, Librium, Xanax, Rohypnol, GHB)</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>g) Street opioids (heroin, opium)</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>h) Prescription opioids (fentanyl, oxycodone, OxyContin, Percocet, hydrocodone, Vicodin, methadone, buprenorphine)</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
<tr>
<td>i) Other – Specify:</td>
<td>☐[0]</td>
<td>☐[1]</td>
<td>☐[2]</td>
<td>☐[3]</td>
<td>☐[4]</td>
</tr>
</tbody>
</table>

38. Have you ever injected drugs during your lifetime? ☐[0] No ☐[1] Yes

⇒ If yes … (a) age first used IV drugs: _____ years old

⇒ If yes … (b) have you injected drugs in the past month? ☐[0] No ☐[1] Yes

39. Which drug(s) are the major problem(s) or the reason that you sought treatment?

(1) _______________________________

(2) _______________________________

(3) _______________________________

40. Have you ever overdosed during your lifetime? ☐[0] No ☐[1] Yes

If yes … ….. (a) How many times have you overdosed? _____ Number of times

……. (b) How old were you when you first overdosed? _____ Years old

……..(c) Was narcan used to revive you? ☐[0] No ☐[1] Yes ☐[2] Don’t know

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41. Have you ever witnessed someone overdose? □ (1) No □ (0) Yes
   If yes … (a) How many times have you witnessed someone overdosing? ____ Number of times
   (b) What was your relationship with the person who most recently overdosed?
   □ (0) Friend □ (1) Family member □ (2) Girlfriend/Boyfriend/Significant other
   □ (3) Spouse □ (4) Neighbor □ (5) Acquaintance □ (0) Stranger □ (7) Other, specify:
   ____________________________
   (c) What did you do in response to the most recent overdose?
   ________________________________
   (d) What happened to the person that most recently overdosed?
   □ (1) Woke-up without any help
   □ (2) Taken to the hospital
   □ (3) Paramedics came & revived the person
   □ (4) Paramedics came & don’t know what happened next
   □ (5) They died
   □ (6) Don’t know
   □ (7) Other, please specify: ____________________________

Addiction Treatment History

42. How many times have you been treated as an inpatient for alcohol or drugs during your lifetime? _____ Number of times

43. How many days have you been treated for alcohol or drugs in the past 90 days?
   ________ (a) Number of days treated as an outpatient
   ________ (b) Number of days treated as an inpatient (addiction treatment program or hospital)

44. How many times have you been treated in an emergency department for alcohol or drugs:
   __________ (a) during your lifetime? _____ Number of times
   __________ (b) in the past 90 days? _____ Number of times

45. How many times were you treated by emergency responders (EMTs/EMS) for alcohol or drugs and were not transported to the emergency department:
   __________ (a) during your lifetime? _____ Number of times
   __________ (b) in the past 90 days? _____ Number of times

46. How many days in the past 30 have you had drug problems? [Include only: craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and not being able to] _____ Number of days
(0-30)

47. I have felt cheerful and in
   □ (5) All of the time
   □ (4) Most of the Time
   □ (3) More than half of the time
   □ (2) Less than half of the time
   □ (1) Some of the time
   □ (0) At no time

Over the last two weeks........
### Mark the statement that best describes how you have been feeling for the past week, including today.

52. □ (0) I have a moderate to strong wish to live  
   □ (1) I have a weak wish to live  
   □ (2) I have no wish to live

53. □ (0) I would try to save my life if I found myself in a life-threatening situation  
   □ (1) I would take a chance on life or death if I found myself in a life-threatening situation  
   □ (2) I would not take the steps necessary to avoid death if I found myself in a life-threatening situation
### Engagement Form

**Date of session:** ___/___/20___

**Clinician Name:** _______________________________

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>Seldom</th>
<th>Some of the time</th>
<th>Most of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In your opinion, how much did this group seem to “pay attention” and think about online content shown in the group?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. In your opinion, how much did this group seem to “pay attention” and think about the group discussions?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. In your opinion, how often was this group supportive to other group members?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. In your opinion, how much did this group actively participate in the discussion (asked questions, gave their opinions, offered ideas to other group members)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. In your opinion, how much did this group disclose about personal experiences or events in their lives during the group?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. In your opinion, how often was this group resistant to new ideas discussed in the group the attended (argued against principles, made negative facial expressions related to new ideas)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. In your opinion, how often did the group seem to correctly apply principles learned during group? □(1) □(2) □(3) □(4)

*Permissions for modification provided by Dr. Susan Breitenstein*