

"Heroin: Naloxone as a Harm Reduction Technique"

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Abstract

Heroin is a synthetic opioid drug that is becoming the drug of choice among many opioid drug abusers. The recreational use of heroin has become a problem resulting in nearly two thousands deaths a year and costing the United States about \$22 billion each year due to medical costs, lost productivity, social welfare, and crime. This issue will only deteriorate further as the supply of heroin from south of the border continues to increase and as more individuals continue to become addicted to the drug. In an effort to address the problem, numerous overdose education and prevention programs have been launched around the country. Some of these nearly 200 programs also distribute a drug that can prevent heroin overdoses. This drug, naloxone, is an opioid antagonist that can reverse an opioid overdose by acting on the central nervous system and is used as a harm reduction agent. The U.S. Food and Drug Administration (FDA) approved a naloxone auto-injector, Evzio, to be available effective April 3, 2014 by prescription to those who may experience or witness an overdose. Opinion is divided, medically, legally, and ethically, as to whether this nationwide distribution of naloxone is providing a service or disservice to heroin users, as well as whether or not this distribution is a wise use of taxpayers' money.

INTRODUCTION

Heroin use and addiction is a major problem both internationally and nationally. The United Nations estimates that there are more than 50 million users of heroin, cocaine and synthetic drugs. Global users of opiates are estimated to be around 13.5 million people, 9.2 million of whom are heroin users. *According to the 2012 National Survey on Drug Use and Health (NSDUH), the number of people who have used heroin in the previous year rose from 373,000 in 2007 to 669,000 in 2012. It is also estimated there are 335,000 current heroin users in the United States, a significant increase from the 153,000 users in 2007.*^[i] *According to the 2008 National Survey on Drug Use and Health, approximately 3.8 million Americans aged 12 or older reported trying heroin at least once representing 1.5% of the population aged 12 or older. In New York City, accidental heroin overdoses is the fourth leading cause of early adult death, claiming more than 600 lives each year.*^[ii] *In addition, heroin use, particularly in those who inject the drug, is also responsible for spreading needle-related infectious diseases such as hepatitis and HIV/AIDS.*^[iv]

Heroin abuse is becoming an increasingly important issue throughout the country. According to the 2013 National Drug Threat Assessment Summary, "Heroin-related

overdoses and overdose deaths are increasing in certain areas."^[v] This increase in the number of heroin-related overdoses and overdose deaths can be explained by a number of reasons. First, high-purity heroin has become more readily available to heroin abusers. Second, prescription drug abusers are increasingly switching from abusing prescription drugs to abusing heroin and are more susceptible to overdosing due to their inexperience with using heroin and the varying purity of heroin. These abusers are known to use whichever drug is cheapest or easiest to obtain at that time, which is especially alarming because many of these drug users will ultimately convert to solely abusing heroin due to its addictive nature. Last, according to national data the number of new heroin users in the United States nearly doubled between 2002 and 2011 to 178,000 new users in 2011, while the average age of heroin users has steadily decreased. ^[vi] As more and more people are introduced to heroin at a younger age, the number of overdose related deaths will only continue to increase. This issue has been further escalated by a marked increase in the amount of heroin crossing the southwest border of the United States. This increase in heroin distribution into the United States is so large that the annual amount of heroin seized crossing the southwest border of the United States increased by 232% from 2008 to 2012.^[vii] Clearly, the availability of heroin is not likely to decrease any time soon.

Equally apparent is the need to find a way to decrease the number of heroin-related overdose deaths. Heroin use not only costs lives, it costs society serious amounts of money! It is estimated that heroin use costs the United States about \$5 billion in medical care costs, \$11.5 billion in lost productivity, \$5.2 billion due to crime, and \$0.1 billion from incurred social welfare.[viii]

Heroin, also known as diamporphine, is a synthetic opioid drug made from morphine, which is extracted from the Asian opium poppy plant. The drug most often appears in the form of white or brown powder or as a black, tar-like substance known as "black tar heroin" and can cost anywhere from ten to twenty five dollars on the street.[ix],[x] As with other opioids, heroin is used as both a painkiller and a recreational drug and has a high potential for abuse. A range of treatment options exists for heroin addiction, including medications and behavioral therapies. Treatment usually begins with medically assisted detoxification to help patients withdraw from the drug safely. Medications such as methadone, clonidine, and buprenorphine can be used to help minimize symptoms of withdrawal. The most effective treatment is behavioral treatment in combination with medication, which is usually delivered in residential or outpatient settings.[xi] Similarly, another drug, naloxone, is now available to help prevent deaths from heroin-related overdoses. Naloxone is an opioid antagonist that acts on the central nervous system to counteract the effects of an opioid overdose. This allows naloxone to reverse respiratory depression; the main cause of heroin overdose deaths, within five minutes.[xii] The drug can be administered via injection into the muscle or in the form of a nasal spray. The Food and Drug Administration (FDA) has recently approved a naloxone auto-injector, Evzio. Evzio is a single-use, credit card-sized prefilled naloxone auto-injector. This device comes with both visual and voice instructions that allow for easy administration of the drug by laypeople. It also includes a trainer device that can be used to practice how to properly administer the drug.[xiii]

Naloxone could be used as a harm-reduction technique to combat the increasing number of heroin-related overdoses. Proponents of such strategies argue that the distribution of the drug naloxone allows individuals to address his or her addiction while also decreasing the effects heroin abuse has on society as a whole. Opponents of these strategies, though, argue that implementation of such strategies only encourages users to use more while also

grossly wasting taxpayers' money.

The purpose of this article is fourfold. First, this article will provide a background on the history of drug policy in the United States. Secondly, this article will put forth a medical analysis of the use of the drug naloxone as a harm-reduction technique. Third, the arguments both for and against such use of naloxone will be examined. Lastly, this article will provide an ethical analysis of the use of naloxone as a means to reverse heroin overdose and lessen the negative consequences of heroin use.

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HISTORY AND CULTURE OF THE U.S. DRUG POLICY

In the twentieth century, the United States of America's policy on drug possession and use has been varied, shifting between postures of prohibition, condemnation, treatment, incarceration and prevention. These principles sanctioned through legislation and moral ideology have been negotiated by the administrations of many presidents as well as governing bodies of states and municipalities. Social attitudes towards narcotics, especially heroin, have been prominently influenced by media coverage, depiction in television and cinema, and representation in popular songs. For almost a century, the governmental battle with drug addiction has been narrated in American culture through published music including "Roll a Little Pill For Me" (1911), "Smokin' Reefers" (1932), "Marahuana" (1934), "The Old Dope Peddler" (1953), "The Pusher" (1964), "King Heroin" (1972) and "I Want a New Drug" (1983). The songwriters provided public sentiment to the socio-cultural occurrence of drug usage that was stigmatized and celebrated. A history of the American policy on narcotics is augmented by the storied response in popular culture.

Prohibition

From 1900 to 1930, a series of laws were put forth to counter the unregulated period of patent drug medicines that circulated high amounts of opium, cannabis indica, heroin, cocaine and alcohol with no federal oversight. The most consequential legislation was the original Federal Food and Drugs Act of 1906 that instituted labeling of contents on foods and drugs, also it prohibited interstate commerce if these items were adulterated or misbranded. *In reporting the bill's debate in 1906, the New York Times reported that*

drugs were a greater menace than food. The Times quoted Representative Bourke Cockran's ire related to the crime of selling fraudulent medicines. "It seems there is a poison adapted to every age and condition of life."^[ii]

In subsequent years, additional laws were instrumental in curtailing drug importation and possession: Smoking Opium Exclusion Act of 1909, Harrison Narcotics Tax Act of 1914, Heroin Act of 1924 and Marihuana Tax Act of 1937. These laws taxed, regulated or banned the manufacture, distribution and use of specific substances.^[iii] By the mid-1920s, heroin addiction was measurable in large cities and linked to a growing crime wave of burglaries. A New York Times article of 1924 labeled heroin addicts the "living dead" due to their distressing predicament and insatiable search for relief.^[iv] Heroin usage was deemed a "menace more dangerous than war" with a major grip on the youth.^[v] In spite of extensive drug regulation, the unconstrained spread of heroin abuse and crime resulted in succeeding policies of fear that bypassed treatment strategies.

Condemnation

In 1933, the repeal of alcohol prohibition through the 21st Amendment advanced narcotics as enemy number one. A national plea for morality and lawfulness signified an administration plagued by illicit drug trafficking, organized crime and delinquency. Comparable to temperance efforts in the 1920s, officials waged warfare on drugs with ominous language and tighter controls. President Franklin D. Roosevelt urged state legislatures to act against the "ravages of the narcotic drug evil."^[vi] Warning of America's crime problem that was a social threat, Roosevelt argued for strict laws to obstruct the trading of illegal drugs.^[vii] In 1936, the film release of *Reefer Madness* directed by Louis Gasnier heightened the drug peril, equating marihuana to 'a violent narcotic, an unspeakable scourge'. Heroin was cited as a drug menace that triggers an incurable insanity. This language contributed to the nervous tone of narcotic discourse in America, equally to concealment tactics by users.

Narcotic imports remained a significant problem. In 1936, a seizure of heroin valued at \$10,000,000 was incinerated at the Bureau of Engraving and Printing.^[viii] Newspapers reported that large seizures of heroin had originated on ships and airplanes from Europe and South America during the 40s.^[ix] By 1950, Commissioner of the Federal Bureau of Narcotics Harry J. Anslinger specified a growth in heroin by thrill seeking "young hoodlums," who

had shifted from smoking marijuana.[x] A year later, Anslinger named "heroin as the greatest threat in the campaign against drug addiction." [xi]

In the mid-20th century, new bills, the Opium Poppy Control Act of 1942 and the Narcotic Control Act of 1956, were drafted to reinforce previous laws and impose greater penalties for transporting illegal narcotics. Jazz artists of the swing and modern movements became chief targets for narcotic surveillance. Heroin had become a drug of choice with a number of modern jazz performers. Miles Davis recalled in his memoir, '...all of us, started to get heavily into heroin around the same time.' [xii] Headlines of this period named and shamed performers, for instance "Krupa Sentenced on Dope Charge" (Washington Post 1943), "Singer Billie Holiday Jailed as Dope Victim" (Associated Press 1947), "Anita O'Day Convicted" (Long Beach Independent 1953) and "Jazz Musician Sentenced on Drug Charge" (Los Angeles Times 1953). These titles convey a policy of denigrating addicts due to uncontrollable narcotic trafficking and rising violence.

Treatment

In 1964, the New York Times alluded to a new approach to addiction that had been veiled for years. "Patients in test substitute 'good' addiction for 'bad'." [xiii] The article informed of experimental methadone for the treatment of heroin addiction. Having U.S. trials dating to 1948, the synthetic drug was used to mitigate the withdrawal symptoms of heroin users. It is important to note that this policy of addiction management and cure developed when the nation endured the instability of the Civil Rights Movement, Vietnam War and assassinations of key political leaders. In 1965, Senator Robert F. Kennedy proposed rehabilitation in controlled situations for the addict. [xiv] This open-minded attitude was echoed in the Narcotic Rehabilitation Act of 1966 that fostered treatment rather than jail time.

The persistent difficulty of curing addicts generated hostility for those favoring methadone treatment. Also, new demographics including individuals of affluence and veterans of the Vietnam War were linked to the consumption of heroin. In response to rampant crime, radical viewpoints of providing free heroin surfaced at the close of the 60s. Blighted neighborhoods and a lack of economic opportunity resulted in violent city streets, where drugs were pushed. The iconic film series *Death Wish* (1974) starring Charles Bronson replicated this urban condition that motivated

harsher narcotic controls in the 1970s.

Incarceration

Various narcotic regulations enacted over several decades resulted in the comprehensive Controlled Substances Act of 1970. Although inclusive of requirements to complete drug treatment upon conviction, the bill penalized individuals of federal benefits for a length of time, made it unlawful for selling drug paraphernalia and established a classification system of drugs based on abuse potential and medical use in treatment. [xv] Another rehabilitation-allied bill passed during the Richard Nixon administration was the Drug Abuse Office and Treatment Act of 1972 that concentrated resources for prevention and cure; as well the document recognized that "education, treatment, rehabilitation...and law enforcement efforts are interrelated." [xvi]

Taking a less supportive stance was New York Governor Nelson A. Rockefeller, who backed the toughest drug laws in the nation. These laws of 1973 provided mandatory life sentences for sellers of narcotic drugs and restricted plea bargaining, effectively treating all dealers the same. In an interview that same year, Rockefeller stated, "the arrests are down because the people are not at the old hangouts where they are pushing." [xvii] Much criticism came from these Rockefeller drug laws that seemed merely to impact small dealers and fill prisons. Nevertheless, Rockefeller claimed, "heroin seems to be disappearing drying up in the city." [xviii] By 1979 policy had shifted, the new Governor Hugh Carey sought a more balanced approach with decreased sentencing on small amounts of possession and stricter rulings on large traffickers. [xix] The failure of confinement was expressed in media reports regarding "polydrug" use, heroin epidemic at a runaway rate and increased narcotic deaths. [xx]

Prevention

In 1982, Nancy Reagan, wife of President Ronald Reagan, launched the phrase "Just Say No" as a retort to being offered drugs. The national campaign ignited a call to action through education programs, drug-free zones and firm moral grounding. She remained active in the cause throughout the 80s calling on Hollywood to reject screen characters that advocated drug use. By 1988, Nancy Reagan took a harsher stance equating the usage of drugs to being an "accomplice to murder." [xxi]

Legislation from the Reagan and Bush

administrations overlapped control and treatment objectives including the Drug Offenders Act of 1984, Analogue (Designer Drug) Act of 1986 and the Anti-Drug Abuse Act of 1986. The latter, similar to the Rockefeller laws, created mandatory minimum penalties for simple drug possession, allocated funding for new prisons and provided for deportation of convicted aliens.[xxii] This bill led to higher rates of imprisonment for minorities. Positing a moral imperative, Reagan professed benevolence "to fight the evils of drugs," also to stem the "cost of suffering and unhappiness." [xxiii]

Concluding the century, societal alarms were elevated by needle exchange programs, marketing of the heroin chic aesthetic in the fashion industry, ultra-realistic depictions of heroin use on film and a swelling rate of young, affluent heroin users. Experts assembled in a 1997 conference on the nation's drug abuse problem affirmed that the social policy of incarceration without treatment had failed. A consequence was a relapse rate of almost 100 percent among heroin addicts.[xxiv] In the 21st century, similar accounts on narcotics are palpable from years earlier. For instance, "experts trace the spike in heroin use to its widespread availability and low cost...cheap and accessible, the drug is driving up the rates of addiction and fatal overdoses." [xxv] These high rates of addiction and overdose call for social action to help guide users through their battle with addiction and prevent those users from overdosing while they work to break their addictions.

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MEDICAL ANALYSIS

Heroin use is a serious problem largely due to the effects the drug imparts on the user's body in a short period of time. There are a number of ways to use heroin, each of which quickly delivers the drug to the brain. However, the main methods employed by heroin users are injection into a vein or muscle, smoking, or snorting. Intravenous administration of the drug allows it to act on the individual in less than two minutes, while subcutaneous and intramuscular administrations take slightly longer to cause an action.²¹ Users of heroin feel an initial euphoric rush and impaired mental functioning, before entering an alternately wakeful and drowsy state known as "going on the nod."

"Heroin enters the brain, where it is converted to morphine and binds to receptors known as opioid receptors. These receptors are located in many areas of the brain (and in the body), especially those involved in perception of pain and in reward. Opioid receptors are also located in the brain stem—important for automatic processes critical for life, such as breathing (respiration), blood pressure, and arousal. Heroin overdoses frequently involve suppression of respiration."[ii] *Heroin acts as a pro-drug that allows rapid and complete central nervous system absorption; this accounts for the drug's euphoric and toxic effects.*[iii]

While the drug produces euphoric effects in the short-term, long-term heroin use has serious consequences for the user's health. Chronic abusers of heroin often suffer from "collapsed veins, infection of the heart lining and valves, abscesses, cellulites, and liver disease."^[iv] Regular heroin users develop a tolerance in which the user's physiological and psychological response to the drug decreases, and additional heroin is needed to achieve the same intensity of effect. Heroin users are at a high risk for addiction. In fact, it is estimated that about 23% of individuals who use heroin become dependent on it.^[v] This physical dependence means the user will experience severe withdrawal symptoms, such as drug cravings, insomnia, and vomiting, when his or her heroin usage is decreased or stopped altogether. Some users become so dependent on the drug that these withdrawal symptoms can even become fatal.^[vi] The overall poor health of a heroin abuser and the

depressive effects of heroin on the respiratory system may also result in pulmonary complications, such as pneumonia. Furthermore, some additives that will not completely dissolve in the blood stream may be present in the heroin dosage, leading to clogging of the blood vessels that supply vital organs. ^[vii] These blockages can lead to infection or death of cells in these vital organs.

As mentioned above, heroin is an opioid. Opioids act at three G-protein coupled receptor subtypes, Mu, Kappa, and Delta. The ligands that bind these receptors "are encoded by three different genes and are expressed heterogeneously throughout the CNS and in peripheral tissues." ^[viii] These ligands are distributed similarly to opioid receptors. Agonists that act at these three receptors sites cause analgesia, agonists acting at Mu or Delta receptors cause respiratory depression. Heroin, which is converted into morphine in the body, acts as an agonist at Mu Opioid receptors and can therefore result in respiratory depression. ^[ix] To understand how heroin can result in respiratory depression, we must first understand the processes of respiration. Respiration is carried out to control the levels of oxygen and carbon dioxide in the body through inspiration of oxygen and exhalation of carbon dioxide. Respiration is dependent on external neuronal input from the CNS to the lungs and associated musculature. Breathing is largely controlled in the brainstem via two major neuron groups located in the medulla region, the dorsal respiratory group (DRG) and the ventral respiratory group (VRG). It is believed that the DRG plays a more controlling role and influences the VRG, while the VRG most likely deals with influencing motor output. This is supported by the fact that "efferent fibres emanating from the VRG innervate the muscles of respiration."^[x] This rhythm of inspiration and exhalation requires activation and inhibition. Excitation is carried out via amino acid receptors, while GABA receptors facilitate inhibition. However, other neurotransmitters, such as serotonin and opioid peptides, may also affect this rhythmic process. Heroin disrupts this process, causing respiratory depression, by acting at the opioid receptors and decreasing neuronal activity. It also diminishes the system's capacity to sense changes in oxygen and carbon dioxide levels and bring these concentrations to optimum levels, which, as mentioned above, is the main function of respiration.^[xi]

The drug naloxone reverses the above effects on the respiratory system, as it is an opioid antagonist, meaning the drug blocks the brain's opioid receptors. Naloxone reverses

the effects of morphine by binding the Mu receptors where this opioid acts, blocking the morphine from binding to these receptors. Naloxone is able to do this due to its higher affinity to bind the Mu receptors than opioids. Blocking the opioid results in the reversal of respiratory suppression since the opioid can no longer affect the respiratory process. A limitation on this use of naloxone, though, is its relatively short period of action. This is not a problem when heroin is the only drug present in the dosage taken by the individual, as the period of action of heroin is shorter than that of naloxone. However, if another opioid agonist with a longer period of action on the body than that naloxone is present in the patient's body, the effects of that agonist will eventually return and again cause respiratory depression. Furthermore, administration of naloxone results in the individual experiencing withdrawal. Therefore, the use of naloxone should be followed by administration of a drug, such as buprenorphine, to control these withdrawal symptoms. However, when naloxone is administered in the absence of opioids or any other similar antagonists, the drug has no pharmacologic effect whatsoever. [xii] The amount of time the drug acts on the individual also varies based on the type of administration used. Because this length of action may be shorter than the action of the opiate, multiple doses of naloxone could be necessary. While naloxone does not produce a tolerance or dependence to the drug, it will cause the patient to experience withdrawal symptoms within a few minutes if the individual is already physically dependent on the opioid.[xiii]

The form of naloxone that will be available to the public, Evzio, can be administered via muscular or subcutaneous injection from a credit card-sized auto-injector.[xiv] The FDA approved this Evzio device on April 3rd, 2014 via its Priority Review program.[xv] This fast-tracked approval process is one of four routes the FDA has implemented. The reasoning behind the FDA's implementation of such processes is that "Speeding the development and availability of drugs that treat serious diseases are in everyone's interest, especially when the drugs are the first available treatment or have advantages over existing treatments." [xvi] The Priority Review Model used for the approval of Evzio was designed to "direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications." [xvii] The aforementioned significant improvement can be shown in a number of ways:

- Evidence of increased effectiveness in treatment, prevention, or diagnosis of condition.
- Elimination or substantial reduction of a treatment-limiting adverse reaction.
- Documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes.
- Evidence of safety and effectiveness in a new subpopulation.[xviii]

While this model speeds up the approval process, it does not alter the scientific/medical standard for approval or the quality of evidence necessary. The Evzio device was then granted access to the Fast-Track Model after passing the Priority Review process. "Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier." [xix] This process aids the drug company through the development of the drug and during its review process by offering and encouraging frequent communication between the FDA and the drug company to ensure all issues throughout the process are resolved quickly.[xx] Evzio also passed through this process and was approved ahead of its original timetable.[xxi] The American Medical Association (AMA) has lauded this expedited approval; "The American Medical Association (AMA) applauds the Food and Drug Administration (FDA) for approving the automatic injector of opioid overdose antidote naloxone for prescription by physicians. We commend FDA for expediting the approval process to quickly increase access to this medicine, which will undoubtedly save lives by reducing death from opioid-related overdose. The AMA has been a longtime supporter of increasing the availability of naloxone for patients, first responders, and bystanders who can help save lives and has provided resources to bolster legislative efforts to increase access to this medication in several states. Additionally, we have worked with several national groups, including the National Governors Association, the National Conference of Insurance Legislators and the National Safety Council to increase support for the increased availability of and access to naloxone. The AMA's dedication to reducing deaths from overdose is a part of the organization's broader effects to combat prescription drug abuse and diversion while at the same time preserving access to medically necessary treatments for pain." [xxii]

There is another form of naloxone administered intranasally that has been in use by emergency medical professionals. This form, known as Narcan, can be

administered by following just a few simple steps: from a nasal naloxone kit, attach the nasal applicator to the needleless syringe, screw a capsule of naloxone to the barrel of the syringe, and insert cone at the end of the syringe into the patients nose before giving a short push on the end of the device to spray the naloxone up the nostril of the patient.[xxiii] This method has been shown to be similarly effective as administering naloxone intravenously or subcutaneously, as one study found only 10% of patients required a second dosage of naloxone after receiving intranasal administration.[xxiv] Furthermore, the cost of an intranasal naloxone kit is significantly cheaper than the Evzio device. While Evzio may cost a few hundred dollars, an intranasal naloxone kit costs just \$42.[xxv]

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LEGAL ANALYSIS

While the FDA's approval of Evzio is an important step, the legal aspect of administering naloxone is also vital to the effort. As of 2014, there are 25 states that have a law regarding the use of naloxone. Of these 25 jurisdictions, 22 require a third-party prescription to be used. There are also 17 jurisdictions in which the prescribers of naloxone have no criminal liability. Two of these 17 jurisdictions also require that a naloxone distribution program must be involved in order for a naloxone prescription to be issued. Similarly, there are 14 states in which the prescribers of naloxone are free of civil liability and 17 jurisdictions where the layperson that administers naloxone is also free from criminal

prosecution. There are also 10 jurisdictions that have authorized prescriptions made by a standing order.

Depending on the specific order, this means that employees for a naloxone distribution program or individuals who might witness an overdose can easily obtain and administer naloxone to a patient. Two noteworthy examples of this standing order model are the Drug Overdose Prevention and Education (DOPE) project in San Francisco and the Massachusetts standing order. In the DOPE project model, the state has authorized this project to "to maintain supplies of naloxone and allow the project's overdose prevention educators to possess and distribute the medicine to potential responders who have completed overdose training.

Furthermore, it authorizes trained employees of the DOPE Project to administer naloxone in an emergency." [ii] The state also allows individuals who successfully completed an approved DOPE project overdose training session within the last two years to administer naloxone in emergencies. The individuals facilitating these training sessions, DOPE educators, are required to have completed a training session facilitated by the DOPE Project Manager and overseen by DOPE's Medical Director. This training session for DOPE educators is required to address:

- Risk factors for opioid overdose
- Prevention strategies
- Recognizing overdose
- Signs of an overdose
- Calling 911
- Rescue breathing
- Administering nasal naloxone
- Completion of proper documentation
- Proper storage of naloxone
- Post-overdose care
- Refill procedure [iii]

These training sessions must last at least 3 hours and cover all of the above topics in detail. [iv] The DOPE Project Manager will examine each DOPE educator annually and provide necessary feedback to the educator, while also reviewing documentation carried out by the educator monthly to ensure accuracy. Furthermore, any medical issues reported regarding use or distribution of naloxone will be referred to the DOPE Medical Director.[v] These DOPE educators can then provide training sessions for individuals who want to be approved to administer naloxone emergently. The following requirements are the cornerstones of these training sessions:

1. DOPE Project Overdose Prevention Educators shall be responsible for training Responders using the DOPE Project training curriculum.

2. Trainings may be conducted in a variety of settings, including on the street or in a more conventional private indoor setting. The trainings may be in small groups or conducted one-on-one. The duration of the training shall depend on the number of responders in the class and their familiarity with drug administration and overdose.
3. Responders shall be given a naloxone kit upon successful completion of the curriculum and practical demonstration of an understanding of the subject matter.
4. An Overdose Prevention and Narcan Registration will be completed with each overdose responder as part of the training session. The DOPE Educators will conduct a brief overdose risk assessment as part of the Registration process and will ensure that all paperwork is completed accurately.[vi]

These training sessions also are in accordance with California law, which requires the training program of an opioid overdose program to educate individuals on what causes an overdose and how to carry out mouth-to-mouth resuscitation, correctly contact emergency medical personnel, and administer a naloxone dosage. This law also allows licensed health care providers to issue standing orders to "a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose." [vii] Massachusetts law similarly allows naloxone to be prescribed to "a person at risk of experiencing an opiate-related overdose or to a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose." [viii] The standing order in Massachusetts allows state-registered naloxone programs to keep supplies of naloxone and allows approved opioid overdose trainers to carry and distribute naloxone to responders, while also allowing these responders to administer naloxone to a patient believed to be experiencing an overdose. [ix] While this is similar to California's requirements, Massachusetts law does not state that individuals must go through overdose training to be prescribed naloxone as it is in California. Law enforcement officers are gaining more access to naloxone around the country because law enforcement officers can often respond to emergencies before emergency medical personnel. Currently, there are law enforcement naloxone programs in 13 states, Georgia, Illinois, Indiana, Massachusetts, Maryland, Michigan, New Jersey, New Mexico, New York, North Carolina, Ohio, Rhode Island and Wisconsin, covering nearly 70 counties.[x] This number is expected to nearly double in the coming years.[xi] Emergency Medical Technicians (EMTs) and firefighters are also gaining more

access to naloxone, though, as around 2,000 firefighters and EMTs have gained access to naloxone kits in New York City alone.[xii] This increased access is vital as firefighters can respond within 10 minutes, law enforcement in 10 minutes and EMTs in 6 minutes.[xiii], [xiv], [xv] This increased access is vital as these trained individuals can correctly identify whether or not an individual is truly overdosing and in need of treatment, significantly increasing the chance for a successful overdose reversal. Steps to increase access to naloxone must continue to ensure the drug can be used to save lives. The harm reduction approach would be one way to justify its use.

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NALOXONE AS A HARM REDUCTION TECHNIQUE

The driving force behind the push for naloxone to be distributed to the public is the drug's potential to be used as a harm reduction technique. Harm reduction is an approach focused on minimizing the negative results that go hand-in-hand with drug abuse. *Harm reduction techniques have both a medical and ethical impact on the individual and society as a whole. Harm reduction techniques accept the individuals as they are, while also tailoring that person's treatment to fit his or her needs. [ii] Furthermore, there are certain principles that are quintessential to an understanding of harm reduction, as listed by the Harm Reduction Coalition:*

- Accepts, for better and or worse, that licit and illicit drug use is part of our world and chooses to work to minimize its harmful effects rather than simply ignore or condemn them.
- Understands drug use as a complex, multi-faceted phenomenon that encompasses a continuum of behaviors from severe abuse to total abstinence, and acknowledges that some ways of using drugs are clearly safer than others.
- Establishes quality of individual and community life and well-being—not necessarily cessation of all drug use—as the criteria for successful interventions and policies.
- Calls for the non-judgmental, non-coercive provision of services and resources to people who use drugs and the communities in which they live in order to assist them in reducing attendant harm.
- Ensures that drug users and those with a history of drug use routinely have a real voice in the creation of programs and policies designed to serve them.
- Affirms drugs users themselves as the primary agents of reducing the harms of their drug use, and seeks to empower users to share information and

support each other in strategies which meet their actual conditions of use.

- Recognizes that the realities of poverty, class, racism, social isolation, past trauma, sex-based discrimination and other social inequalities affect both people's vulnerability to and capacity for effectively dealing with drug-related harm.
- Does not attempt to minimize or ignore the real and tragic harm and danger associated with licit and illicit drug use. [iii]

Naloxone's ability to reverse the effects of a heroin overdose gives it the potential to be used as a harm reduction agent in itself as it will save lives. Furthermore, many individuals who die from opiate overdoses did not receive necessary medical treatment in time to save them; allowing more lay people access to naloxone can then save many preventable deaths. If we as a society value human life as sacred, we must find a way to prevent these deaths. Distributing naloxone to trained personnel as a harm reduction agent could present a way to solve this problem and save thousands of lives.

Many naloxone distribution programs are already in existence. In fact, at least 188 of these programs are currently operating.[iv] So many that, according to the Harm Reduction Coalition, over fifty thousand people were trained and given naloxone for reversing the overdoses of others between 1996 and 2010. This distribution of naloxone has resulted in over ten thousand reported overdose reversals. [v] Clearly, naloxone distribution programs have been effective and can continue to be so. There are, however, arguments against such programs; one of which being that nationwide distribution of naloxone through government programs would be a gross misuse of taxpayers' money. Contrary to this criticism, the distribution of naloxone has actually been proven to be extremely cost-effective. One study has concluded this using a mathematical form of analysis, the Incremental cost-effectiveness ratio (ICER), often used in healthcare economic evaluations. ICER is "the ratio of the change in costs of a therapeutic intervention (compared to the alternative, such as doing nothing or using the best available alternative treatment) to the change in effects of the intervention...The change in effects is usually measured in terms of the number of life-years gained or quality-adjusted life years gained by the intervention." [vi] This study has found that "Naloxone distribution increased costs by \$53 (CI, \$3 to \$156) and quality-adjusted life-years by 0.119 (CI, 0.017 to 0.378) for an ICER of \$438 (CI, \$48 to \$1706)... Naloxone distribution was cost-effective in all deterministic and probabilistic sensitivity and scenario analyses, and it was cost-saving if it resulted in fewer

overdoses or emergency medical service activations. In a 'worst-case scenario' where overdose was rarely witnessed and naloxone was rarely used, minimally effective, and expensive, the ICER was \$14 000. If national drug-related expenditures were applied to heroin users, the ICER was \$2429." [vii] The ICER values produced from this study are relatively low and therefore show how cost-effective the distribution of naloxone can be.

However, there are criticisms of both the harm reduction approach and the use of naloxone as a harm reduction agent. First, many argue that the use of a harm reduction technique like naloxone only encourages people to continue their destructive action. In the case of naloxone, critics believe its use will only lead drug abusers reusing heroin in even more dangerous ways. Similarly, critics argue these approaches lead people away from seeking treatment since they now have a safety net of sorts for their risky behaviors. Some critics also believe that we would be wasting valuable money on treating criminals, when that money could be spent helping more highly contributing members of society. Lastly, there is the cost issue of the approved Evzio device. While a dosage of naloxone would cost less than five dollars, experts believe that the Evzio device may cost as much as five hundred dollars. [viii] Because of the clear-cut effectiveness of the distribution of naloxone, it should be made available to the public at a reasonable cost. Therefore, if the cost of Evzio is in fact as high as some fear, something must be done to either reduce the cost of Evzio or find a cheaper, more cost-effective solution, such as the use of the intranasal Narcan product. To strengthen the arguments for this harm reduction approach, it must be determined whether or not broader access to naloxone would promote more good than harm, not only for heroin users but also for their associates and communities at large.

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ETHICAL ANALYSIS

Society, in general, has always recognized that in our complex world there are times when we are faced with situations that have two consequences--one good and the other evil. The time-honored ethical principle that has been applied in these situations is called the principle of double effect. As the name itself implies, the human action has two distinct effects. One effect is intended and good; the other is unintended and harmful. As an ethical principle, it was never intended to be an inflexible rule or a mathematical formula, but rather it is to be used as an efficient guide to prudent moral judgment in solving difficult moral dilemmas. *This principle focuses on the agent in terms of intentions and accountability, not just contingent consequences. The principle of double effect specifies four conditions, which must be fulfilled for an action with both a good and a harmful effect to be ethically justified:*

- 1) The action, considered by itself and independently of its effects, must not be morally harmful. The object of the action must be good or indifferent.
- 2) The harmful effect must not be the means of producing the good effect.
- 3) The harmful effect is sincerely not intended, but merely tolerated.
- 4) There must be a proportionate reason for performing the action, in spite of the harmful consequence.[ii]

The principle of double effect is applicable to the issue of naloxone because it has two effects, one good and the other harmful. The good effect is that this drug has the potential to save lives and hopefully encourage the heroin user to seek rehabilitation. The harmful effect is that some believe that it may send a wrong message that illegal drug use is condoned and even encouraged. To determine if naloxone is ethical, this issue will be examined in light of the four conditions of the principle of double effect.

The first condition allows for naloxone because the object of the action, in and of itself, is good. The moral object is the precise good that is freely willed in this action. The moral object of this action is to save lives by reversing the effects of a heroin overdose and hopefully getting these individuals into drug rehabilitation. The immediate goal is not to endorse illegal drug use or to encourage it. Rather, the direct goal is to have naloxone readily available to save the lives of those who overdose on heroin because of their drug addiction. Former New York Mayor Michael Bloomberg made this same point when he talked about implementing the Take Charge, Take Care: Ten Tips for Safer Use of Heroin program in New York City. He stated, "Using hard drugs is just not a smart thing to do. But we have an obligation no matter what people do in this city to make sure they do it as safe as they can." [iii]

The second condition permits making naloxone available at various sites in a city because the good effect of saving lives from an overdose is not produced by means of the harmful effect. The two effects are completely independent. Making naloxone available throughout a city at various sites with proper supervision has no intention of encouraging drug abuse. In fact, the opposite is true. To argue that public health officials are encouraging or condoning drug abuse is illogical. This is "like suggesting that air bags and seatbelts encourage unsafe driving." [iv]

The third condition is met because the direct intention of making naloxone available is to protect and preserve human life and to encourage drug rehabilitation, social support, professional counseling and medical care. The direct intention of this program is to preserve the lives of the most vulnerable that is, the poor and the minorities, by stopping heroin overdoses and indirectly, through rehabilitation decreasing illegal drug use. The foreseen but unintended consequence of this may be the belief by some that this is condoning and even encouraging illegal drug use. One might also argue that it could give heroin users a "false" sense of security that if they overdose they will be revived.

Nevertheless, there is no scientific evidence that proves this will encourage or even increase heroin abuse.

Finally, the argument for the ethical justification of making naloxone available by the principle of double effect focuses on the fourth condition of whether there is a proportionately grave reason for allowing the unintended possibility of scandal and the possibility of increased drug usage. Proportionate reason is the linchpin that holds this complex moral principle together.

Proportionate reason refers to a specific value and its relation to all elements in the action.[v] The specific value in allowing for naloxone is to preserve human life by reversing the effects of heroin overdoses and encouraging drug rehabilitation to the most vulnerable members of society. The harm, which may come about by trying to achieve this value, is the foreseen but unintended possibility that some may view this as condoning and even encouraging illegal drug use. The ethical question is whether the value of preserving human life outweighs the harm of the foreseen, but unintended, possibility of scandal and possible increased drug usage? To determine if a proper relationship exists between the specific value and the other elements of the act, ethicist Richard McCormick, S.J. proposes three criteria for the establishment of proportionate reason:

- 1) The means used will not cause more harm than necessary to achieve the value.
- 2) No less harmful way exists to protect the value.
- 3) The means used to achieve the value will not undermine it.[vi]

The application of McCormick's criteria to making naloxone available supports the argument that there is a proportionate reason for allowing this program. First, according to public health officials, the use of naloxone, as part of a comprehensive drug prevention program, can decrease overdose deaths and could increase heroin addicts to seek drug rehabilitation. New York City's health department is in the process of conducting "a large study following people who get naloxone to assess how frequently the antidote is used to reverse overdose. In 2012, the health department filed a public letter to the Food and Drug Administration (F.D.A.) recommending that the F.D.A. approve naloxone for over-the-counter use. The letter stated that more than 20,000 kits had been distributed in New York City. It also noted that more than 500 overdose reversals had been reported by civilians who had administered the

antidote."[vii] If making naloxone readily available, as part of a comprehensive program, saves lives and does not increase drug usage or condone drug use, then, this program does not cause more harm than necessary. To verify these facts, the program must be initiated on a wide-scale basis in order to collect the appropriate data.

Second, at present, there does not appear to be an alternative that is as effective as naloxone. It is true that other means exist such as drug treatment and prevention efforts, but according to the most reliable public health and medical sources, the use of naloxone is the best means presently available for reducing overdose deaths among intravenous drug users.[viii] The American Medical Association (A.M.A.) endorsed the distribution of naloxone on April 7, 2014. In addition, the A.M.A. is working with several national groups, including the National Governor's Association, the National Conference of Insurance Legislators and the National Safety Council to increase support for the increased availability of and access to naloxone.[ix] Most experts contend that few drug addicts, especially those within the 13-24 age range, will take advantage of drug treatment programs and educational resources on their own, because their addictive behavior stands in the way.

The critical aspect that cannot be overlooked in making naloxone readily available at various sites in a city is the element of human contact. Human contact is with an individual who saves your life through reversing the effects of a heroin overdose. This human contact allows outreach workers to form personal relationships with the addicts and thus provide the opportunity to offer them appropriate health care, personal counseling and referrals to treatment centers. Various scientific studies have confirmed that intravenous drug users reduce risk-laden behaviors when pertinent information and services, such as counseling are made available, and especially when they are offered by peers who are members of the drug-using subcultures.[x] "The human contact of having individuals trained to reverse the effects of a heroin overdose communicates a powerful message to addicts that their lives and well-being are still valued by the community, even though they may not yet be able to break the cycle of addictive behavior."[xi] Making naloxone available to trained individuals not only has the potential to save human lives but also to foster human dignity and respect.

Third, naloxone does not undermine the value of human life. One can argue convincingly that the intention of

making naloxone readily available to trained individuals is to save human lives. This program has the potential to decrease drug overdoses and to increase referrals to drug rehabilitation centers. The purpose of making naloxone readily available to trained individuals is to save lives and from the current data it appears to be quite effective. This is a public health issue that must be addressed because innocent lives are being lost. It seems clear that there is a proportionate reason to allow naloxone to be made readily available to trained individuals in a city using taxpayer money. Naloxone contributes to the well-being of those affected because it has the potential to preserve the lives of those individuals who overdose on heroin. It also offers those addicted the opportunity to realize that they are valued as persons and that with the appropriate assistance addiction can be overcome. Therefore, it is ethically justified under the principle of double effect to allow for naloxone to be made readily available to trained individuals. Ethically, the greater good of addicts and the common good of society are advanced by financially supporting the use of naloxone in major cities in the United States.

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CONCLUSIONS AND RECOMMENDATIONS

Heroin is clearly a life and death issue, as the supply of heroin in our country grows and the addictive nature of the drug causes more and more individuals to become addicted to it. This drug affects thousands of lives and costs society billions of dollars each year. Evidence has shown that naloxone will be beneficial both at the individual level and the societal level. For the individual, it has been proven to effectively reverse heroin overdose and save lives. On a societal level, the use of naloxone can ultimately decrease the strain on the medical system as more individuals will be educated on the use of heroin, which will lead to heroin users using the drug more safely and, over time, working to break their addictions.

Based on the information we have provided we have the following recommendations:

1. Naloxone kits should only be distributed to individuals who have gone through proper education and training programs, similar to the method outlined in the DOPE model in California. All individuals granted access to naloxone must be educated on the responsibility they have when administering the drug.
2. A licensed physician or physician's assistant should oversee these training programs.
3. Naloxone kits should be distributed to trained law enforcement, firefighters, and EMTs nationwide.
4. The price of the FDA-approved Evzio device may

be far too expensive for many people to have access to the device. For this reason, either distribution programs must find a way to lower this cost to a more reasonable level or we, as a nation, will have to find a cheaper alternative, such as an intranasal Narcan product.

5. The administration of naloxone should be followed by the administration of a medication that manages the withdrawal symptoms of the user. This follow-up medication should be included in the naloxone kit that trained individuals are given. This will both provide better care for the patient and take away the fear some users have of going into withdrawal.

It is clear that the widespread distribution of naloxone kits to

trained personnel can and will save lives. If we as a society value human life, we must continue to increase access to naloxone and work to effectively serve drug abusers in their fight to beat addiction. A comprehensive approach that includes a preventative strategy, a treatment strategy, and a harm reduction strategy could serve as a new paradigm to guide our decisions regarding drug addiction. We cannot allow the appearance of scandal to stand in the way of proven scientific evidence. Human lives are hanging in the balance.

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