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ETHICS AND COST-EFFECTIVENESS OF NALOXONE

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LRCM-200-LC-F: Learning Community

ECON 225: Health Economics & RELG 326: Medical Ethics

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Table of Contents

I. Introduction

II. The Opioid Epidemic

III. Naloxone

IV. Controversy about using Naloxone

V. Current Uses of Naloxone

VI. Ethics

VII. Responding to those who disagree with Naloxone on the basis of ethics

VIII. Cost-Effectiveness Analysis of Naloxone

IX. Responding to those who disagree with Naloxone on the basis of economics

X. Suggested plan for Naloxone distribution

XI. Conclusion

I. Introduction

The United States is currently in an opioid epidemic, so severe that the death rate due to opioid overdose has increased 2.8-fold since 2002.[1] In 2015, death because of drug overdoses was the leading cause of accidental death in people aged 25 to 65.[2] Of all drug overdose deaths in 2016, opioid overdose was the highest.[3] Naloxone is a drug that has been developed to reverse an opioid overdose. The drug is available in some pharmacies and first responders and hospitals carry it. There is debate about the extent to which this lifesaving drug should be used. Questions have arisen if naloxone should be allowed to be bought without prescriptions, so it is more readily available to the public and those who would need to use the drug. There is a controversy if naloxone encourages drug abuse by minimizing the consequences and risks of drug abuse. There is also a question if we should be spending money on drug abuse education and prevention, rather than reversing overdoses. I think that increased use of naloxone to treat opioid overdoses should be done because it is cost- effective and an ethical treatment for opioid addiction and overdose.

II. The Opioid Epidemic

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[1] "Overdose Death Rates" *National Institute on Drug Abuse.* Date Published: September 2017. Date Accessed: September 30, 2017. https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates
[2] "Ten Leading Causes of Death" *Centers for Disease Control and Prevention.* Date Accessed: October 15, 2017. https://www.cdc.gov/injury/wisqars/LeadingCauses.html
[3] "Overdose Death Rates" *National Institute on Drug Abuse.*

Opioids are a type of drug commonly used to treat pain, but commonly used illegally. There are three types of opioids. Opioids exist as natural opium, like morphine and codeine, semi-synthetic opioids such as hydrocodone, oxycodone, and heroin, and synthetic opioids, which include fentanyl, methadone, and tramadol.[4] Opioids reduce pain, create euphoria, and cause drowsiness and sedation. The euphoric high and pain relief is what makes people use non-prescribed pain killers and heroin. Opioids are highly addictive, which creates a dependence and causes people to abuse the drugs. With dependence and continued use of opioids, a tolerance builds. This means that the usage intake increases, to get the same high. This leads to dangerous conditions, to the point where an overdose is possible.[5] Overdose happens when the drug overpowers the body and its systems, to the point where there is respiratory depression, brain damage, liver damage, vomiting, and a distended abdomen.

As mentioned earlier, we are in the middle of an opioid epidemic. Opioid abuse, overdose, and deaths have increased over the past 16 years, by passing the number of overdoses of all other types of drugs.[6] The overdose death rate for synthetic opioids and heroin has dramatically increased from 2013 to the present, as compared to other drug types. The opioid

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[4] Sara Bellum, "What are the Different Types of Opioids?" *National Institute on Drug Abuse for Teens.* Date Published: July 16, 2014. Date Accessed: September 30, 2017. https://teens.drugabuse.gov/blog/post/real-teens-ask-what-are-different-types-opioids-0

[5] "Prescription Drug Abuse: A Serious Problem" *Foundation for a Drug Free World.* Date Accessed: September 30, 2017. http://www.drugfreeworld.org/drugfacts/prescription-drugs.html

[6] "Opioids" *U.S. Department of Health and Human Services.* Date Published: June 15, 2017. Date Accessed: September 30, 2017. https://www.hhs.gov/opioids/about-the-epidemic/index.html

epidemic costs the United States. The cost is a whopping $78.5 billion spent in one year.[7] A possible way to cut costs, would be to utilize the cost-effective opioid reversal drug, naloxone.

III. Naloxone

Naloxone is a drug that has been developed that reverses opioid overdoses by reversing the respiratory depression in overdose patients. Naloxone can be administered intranasally, intramuscularly, intravenously, or subcutaneously. Evzio is an auto injectable naloxone product, that is given intramuscularly or subcutaneously to the outer thigh. Narcan is another naloxone product which is a nasal spray. Narcan can be bought over the counter in 35 states, without a prescription.[8] Given the easy administration of a nasal spray and autoinjector, naloxone can be used quickly and efficiently in an overdose emergency. The CDC reports that from 1996 to 2015 Narcan has saved 27,000 lives of people who have overdosed.[9] The success of naloxone and the push to get more people, like police, EMTs, drug addicts, and rehab centers to carry it, and the fact that not many companies manufacture it, has made prices rise. There is a 95% price increase in the nasal spray, a 129% increase for the autoinjector, and a monstrous 500% increase for the 2-pack autoinjectors.[10] There are some side effects associated with naloxone. After administering naloxone, there is quick onset of withdrawal symptoms.[11] Even with the withdrawal side effects, the lifesaving effects make the drug very valuable.

IV. Controversy about using Naloxone

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[7] "Opioids" *U.S. Department of Health and Human Services.*

[8] "Which States Offer Naloxone Over the Counter?" *Evolutions Treatment Center.* Date Published: December 2016. Date Accessed: September 30, 2017. https://evolutionstreatment.com/states-offer-naloxone-over-the-counter/

[9] "CDC Report: Narcan Saves 27,000 Lives" *CADCA Building Drug-free Communities.* Date Accessed: September 30, 2017. http://www.cadca.org/resources/cdc-report-narcan-kits-save-nearly-27000-lives

[10] Ravi Gupta, Shah D. Nilay, and Ross S. Joseph. "The rising price of naloxone—risks to efforts to stem overdose deaths." *New England Journal of Medicine* 375, no. 23 (2016): 2213-2215.

[11] Cara M. Renzelli and Capretto A. Neil. "Less pain, more gain: buprenorphine-naloxone and patient retention in treatment." *Journal of addictive diseases* 25, no. 3 (2006): 97-104.

There is some debate about the extent of how we use naloxone to treat opioid overdose, whether using naloxone and making it readily available to the public, such as opioid abusers and their friends and family, is a dangerous public health strategy. The reasoning behind this is that it could be seen as encouraging drug use, because it minimizes the risk of death from abusing opioids and heroin. There is also the question of whether we should be spending money on distributing naloxone to first responders and the community. Some say that this money could be better spent on detoxification efforts and drug abuse prevention and education. People who believe this, would believe solving the opioid crisis needs to be done by preventing people from using drugs in the first place. Opponents of this way of thinking would believe that while drug use prevention and education are very important, it is not enough to stop the opioid epidemic, because some people will always abuse drugs no matter what and we need a way to treat them when they overdose.

V. Current uses of Naloxone

Many states have made laws to regulate how naloxone is used. Naloxone is carried by first responders including hospitals, rehab centers, EMTs, and police. These people have been trained to administer naloxone. More controversy exists when it comes to third party and lay persons carrying and administering naloxone. People question whether lay persons, like friends and family of high risk people should be allowed to have naloxone and administer it in case of an emergency. The current policy on this varies from state to state. Forty-five states and the District of Columbia allow third party prescriptions.[12] Of those forty-six states and territories, forty-three of them do not require the third parties to participate in the naloxone program.[13] Participation in

[12] "Naloxone Overdose Prevention Laws" *Prescription Drug Abuse Policy System.* Date Published: June 30, 2017. Date Accessed: September 30, 2017. http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139

[13] "Naloxone Overdose Prevention Laws" *Prescription Drug Abuse Policy System.*

the naloxone program means that the third parties need to be trained to identify opioid overdos, how to administer naloxone, and the procedure following the administration of the naloxone.

VI. Ethics

Making naloxone readily available to high risk people, their friends and family, members of the community, and to first responders is an ethical decision concerning naloxone distribution. I think that naloxone should be distributed using the need based ethical decision model, not the merit-based decision model. The need based ethical decision-making model says that we should allocate things based on who needs the resource in question. This means, that if a drug addict needs naloxone treatment, because of an overdose, then we should administer it and have it readily available. Some people may say that the merit-based decision model should be considered with naloxone distribution, because people who abuse drugs created this situation for themselves. I do not think that this decision-making model should be applied here because even if drug abuse starts with a bad decision, addiction is a disease and people with this disease should not be treated any less than someone with other diseases. Another reason that the merit-based decision-making model should not be used is opioid addiction is unique from other types of drug abuse. Opioid abuse includes getting addicted to prescription pain killers for chronic pain. Drug abuse is not always malicious in the case of opioids and thus we cannot decide who gets naloxone treatment based on merit.

VII. Responding to those who disagree with Naloxone on the basis of ethics

Some believe that naloxone encourages drug abuse by minimizing the risk and consequences of drug abuse, thus it is unethical. An example of when this belief was seen is when the governor of Maine, Paul LePage said, “Naloxone does not truly save lives; it merely

extends them until the next overdose".[14] I see how one could believe that naloxone causes more issues in the fight against the opioid epidemic, but having naloxone easily available is a public health strategy called harm reduction.

Harm reduction is "a term that defines policies, programmes, services and actions that work to reduce the: health, social and economic harms to individuals, communities and society".[15] Naloxone is harm reduction, because it works to reduce the harm of drug abuse by reversing opioid overdose. Harm reduction is an ethical public health strategy because it does not break the four principles of bioethics.[16] The first principle of bioethics is patient autonomy. This means that the patient is informed of their health status and they can make informed consent on their treatment.[17] In the case of a drug overdose, the patient is in a state where they cannot make a conscious informed consent decision. "Autonomy requires competence and in emergency medicine time does not allow intimate exploration of patient competence and reasons for treatment refusal".[18] Given that in emergency medicine, one cannot gain informed consent, so the person giving care must use their judgement while giving treatment, it is not breaking autonomy, thus administering naloxone does not break autonomy. The second principle is non-maleficence, meaning that there is no intentional creation of harm or injury to the patient.[19] When someone receives naloxone, the possibility of creating harm is there by having adverse side effects of withdrawal symptoms. This is not intentionally causing pain to the patient,

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[14] Andrew Joseph. "Not just for medics: Drugs that reverse opioid overdoses are being pushed to the masses" *STAT*. Date Published: October 3, 2016. Date Accessed: September 30, 2017.
[15] Carmen Aceijas. "The ethics in substitution treatment and harm reduction. An analytical review." *Public Health Reviews* 34, no. 1 (2012): 16.
[16] Aceijas, *Public Health Reviews*, 16
[17] Thomas R. McCormick, "Principles of Bioethics" *Ethics in Medicine.* Date Published: October 13, 2013. Date Accessed: August 28, 2017. http://depts.washington.edu/bioethx/tools/princpl.html
[18]Anne-Cathrine Naess, Foerde Reidun, and Andreas Peter. "Patient autonomy in emergency medicine." *Medicine, health care and philosophy* 4, no. 1 (2001): 71-77.
[19] McCormick, *Ethics in Medicine*

because the primary goal is to save their life and saving a life outweighs the withdrawal symptoms that result. Harm reduction strategies' goal is to reduce maleficence. The third principle of bioethics is beneficence, meaning the healthcare provider needs "to take positive steps to prevent and to remove harm from the patient".[20] Beneficence is the main purpose of harm reduction. By making naloxone available to those who are high risk for overdose is an attempt to remove them from harm. Lastly, the last principle of bioethics is justice, which is to treat people fairly and giving them equal treatment.[21]

If we were talking about making EpiPens readily available, there would be almost no debate. There is actually a program, EpiPens4Schools, that provides four free EpiPens to schools and will replace any EpiPen that has been used in an anaphylaxis medical emergency for free.[22] A 2-pack of EpiPen costs more than $600[23] (more expensive compared to $150 for a 2-pack of Narcan[24]) and still EpiPen has a program that distributes the product in high risk places, like schools, yet people still question if naloxone, which is less expensive, should be distributed to high risk people. What makes someone with a severe allergy different than someone with addiction? They are both diseases and thus should both be treated equally, so naloxone should be available to those who need it and the basis of equality and justice.

VIII. Cost-Effectiveness Analysis of Naloxone

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[20] McCormick, *Ethics in Medicine*
[21] McCormick, *Ethics in Medicine*
[22] "EpiPen (epinephrine) Auto-Injector EpiPen4Schools Program" *DC.gov.* Date Published: August 2014. Date Accessed: October 15, 2017. https://osse.dc.gov/sites/default/files/dc/sites/osse/publication/attachments/Epipen-%20Discount%20Form-1.pdf
[23] Dan Mangan. "EpiPens cost just several dollars to make. Customers pay more than $600 for them" *CNBC.* Date Published: August 25, 2016. Date Accessed: October 15, 2017. https://www.cnbc.com/2016/08/25/epipens-cost-just-several-dollars-to-make-customers-pay-more-than-600-dollars-for-them.html
[24] Ravi Gupta, Shah D. Nilay, and Ross S. Joseph. " *New England Journal of Medicine* 2213.

Using naloxone is cost-effective way to treat opioid overdose.[25] A study conducted by the University of Toronto sought out to determine if prevented overdose death by naloxone treatment was cost-effective and what people were willing to pay per QALY gained. What resulted from the cost-effectiveness analysis was that "naloxone distribution increased lifetime costs by $53 and QALYs by 0.119 for an incremental cost of $438 per QALY gained".[26] From this we can determine that distributing naloxone to high risk people would increase QALYs and be cost-effective. It is also important to note that cost-effectiveness increases and QALYs gained increases the younger the demographic is.[27] For example, the case study determined QALYs gained for people aged 21, 31, and 41. The 21-year olds who received naloxone were the most cost-effective.[28] It was found that naloxone was cost-effective if a naloxone kit costs less than $4480 and relative increase in survival was less than 0.05%.[29]

IX. Responding to those who disagree with Naloxone on the basis of economics

People may disagree with the cost-effective analysis that was presented on the basis that drug addicts are usually a net cost to society. To respond to this, the University of Toronto adjusted their cost-effective analysis to the idea that drug addicts are costly to society. Applying the adjustment for the cost on society, it was found that "naloxone resulted in an incremental cost of $2429 per QALY gained".[30] Under the adjusted drug addict assumption, as compared to the

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[25] Phillip O. Coffin and Sullivan D. Sean. "Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal Cost-Effectiveness of Distributing Naloxone for Heroin Overdose Reversal." *Annals of Internal Medicine* 158, no. 1 (2013): 1-9.
[26] Phillip O. Coffin and Sullivan D. Sean. *Annals of Internal Medicine*, 4
[27] Phillip O. Coffin and Sullivan D. Sean. *Annals of Internal Medicine,* 4
[28] Phillip O. Coffin and Sullivan D. Sean. *Annals of Internal Medicine*, 4
[29] Phillip O. Coffin and Sullivan D. Sean. *Annals of Internal Medicine*, 6
[30] Phillip O. Coffin and Sullivan D. Sean. *Annals of Internal Medicine*, 7.

traditional economy assumptions, the willingness to pay per QALY is higher. This means that naloxone is even more cost-effective and is a good choice.

Another argument against naloxone distribution to high risk people could be that money could be better spent towards drug prevention. I agree 100% that money should be spent on drug education and prevention, although drug prevention does not seem to be enough. In 2017, the Office of National Drug Policy spent $1,507 billion on prevention and education[31] and it has been shown that drug prevention has only reduced non-marijuana drug consumption by 11%.[32] Drug prevention measures are not enough to help defeat the opioid epidemic in America. People will always do drugs, no matter how much public health prevention measures we take; it is inevitable. We need a way to help save those who have fallen ill to opioid addiction. Naloxone does this, so we cannot stop spending money on it to save these people.

X. Suggested plan for Naloxone distribution

Increased use of naloxone to treat opioid overdoses should be done because it is cost-effective and an ethical treatment for opioid addiction and overdose. This is easier said than done, because it can be hard to determine the extent to which naloxone is distributed. For example, there was a recent report that librarians have begun to have Narcan on hand just in case of an emergency.[33] At first glance, this seems unnecessary, but the location of the library in Philadelphia was one that had a lot of drug use and they found people outside the library in need of the overdose antidote, so it makes sense that the library would have Narcan. I think the answer to the extent of who should carry Narcan should be based on how likely they are to encounter

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[31] "Economics" *Drug War Facts.* Date Accessed: October 15, 2017. http://www.drugwarfacts.org/chapter/economics

[32] "The Benefits and Costs of Drug Use Prevention" *RAND Corporation.* Date Accessed: October 15, 2017. https://www.rand.org/pubs/research_briefs/RB6007/index1.html

[33] Anne Ford. "Saving Lives in the Stacks: How Libraries are Handling the Opiod Crisis" *American Libraries Magazine.org*. Date Published: September/October 2017. Date Accessed: October 1, 2017.

high risk people. For example, police, EMTs, chronic drug abusers, friends and family of high risk people, prisons, halfway houses, rehab centers, and bars and clubs in areas where there is a high rate of opioid abuse, should carry naloxone.

Another thing to consider when determining the extent to which naloxone is distributed, is its cost. As discussed earlier in section III, the prices of naloxone are increasing.[34] As long as the price of naloxone kits do not exceed the cost-effective limit that case study that the University of Toronto developed of $4480 per kit[35], I think that naloxone should be distributed as needed, because it will still be cost-effective.

Another component of a plan for naloxone use could be to require third party participation in the naloxone program, meaning that friends and family of high risk people need to be trained to use it. As seen in section V, only three states require lay persons to receive training.[36] Studies have shown that training lay people to have greater success in naloxone success and survival of the person who has overdosed.[37]

One more way to make naloxone use more effective is to mandate that people who were given naloxone, because of an overdose, should be required to have drug education and be given the opportunity for detoxification. Naloxone causes withdrawal symptoms, which is why it is advised for the person to go to the hospital after being given a naloxone dose. At the hospital, is where a social worker could be mandated to talk to the patient about detoxification measures. It has shown that when opioid addicts are treated with buprenorphine-naloxone, they are more

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[34] "Naloxone Overdose Prevention Laws" *Prescription Drug Abuse Policy System.*
[35] Phillip O. Coffin and Sullivan D. Sean. *Annals of Internal Medicine*, 6.
[36] "Naloxone Overdose Prevention Laws" *Prescription Drug Abuse Policy System.*
[37] Rebecca E. Giglio, Li Guohua, and DiMaggio J. Charles. "Effectiveness of bystander naloxone administration and overdose education programs: a meta-analysis." *Injury Epidemiology* 2, no. 1 (2015): 10.

likely to stay in treatment for longer lengths.[38] I think adding this point to the public health plan of distributing naloxone would get more people on board, who are wary if naloxone encourages risky behavior.

In conjunction with increased naloxone distribution, we should restrict the supply of opioid prescriptions. Doctors prescribe a lot and sometimes unnecessary pain killers, which can easily be abused. According to the American Society of Addiction Medicine, “in 2012, 259 million prescriptions were written for opioids, which is more than enough to give every American adult their own bottle of pills”.[39] This number is excessive and could easily be reduced with restricted supply. The high amount of prescriptions for pain killers is an issue and is contributing to the opioid epidemic because “four in five new heroin users started out misusing prescription painkillers”.[40] If we restrict the supply of opioid prescriptions, the number of people who are addicted to opioids could be reduced thus, it would be an effective strategy to take, alongside naloxone distribution and drug education and prevention, to fight the opioid epidemic.

XI. Conclusion

Overall, increased use of naloxone to treat opioid overdoses should be done, because it is cost-effective and an ethical treatment for opioid addiction and overdose. The opioid epidemic in America is stronger than ever, because more people are overdosing and dying because of opioids, including heroin and prescription pain pills. Naloxone is an opioid overdose antidote, which reverse the respiratory depression. Naloxone is available in various forms, autoinjectors

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[38] James Bell, Marian Shanahan, Carolyn Mutch, Felicity Rea, Anni Ryan, Robert Batey, Adrian Dunlop, and Adam Winstock. "A randomized trial of effectiveness and cost-effectiveness of observed versus unobserved administration of buprenorphine–naloxone for heroin dependence." *Addiction* 102, no. 12 (2007): 1899-1907.
[39] “Opioid Addiction 2016 Facts and Figures” *American Society of Addiction Medicine*. Date Accessed: October 15, 2017. https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf
[40] “Opioid Addiction 2016 Facts and Figures” *American Society of Addiction Medicine*.

(Evzio) or nasal spray (Narcan). Naloxone distribution to the community and lay people is a harm reduction public health strategy that is ethical and cost-effective, thus it should be used and readily available.

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Ford, Anne. "Saving Lives in the Stacks: How Libraries are Handling the Opiod Crisis" *American Libraries Magazine.org*. Date Published: September/October 2017. Date Accessed: 1 Oct 2017 on Academic Search Complete.

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