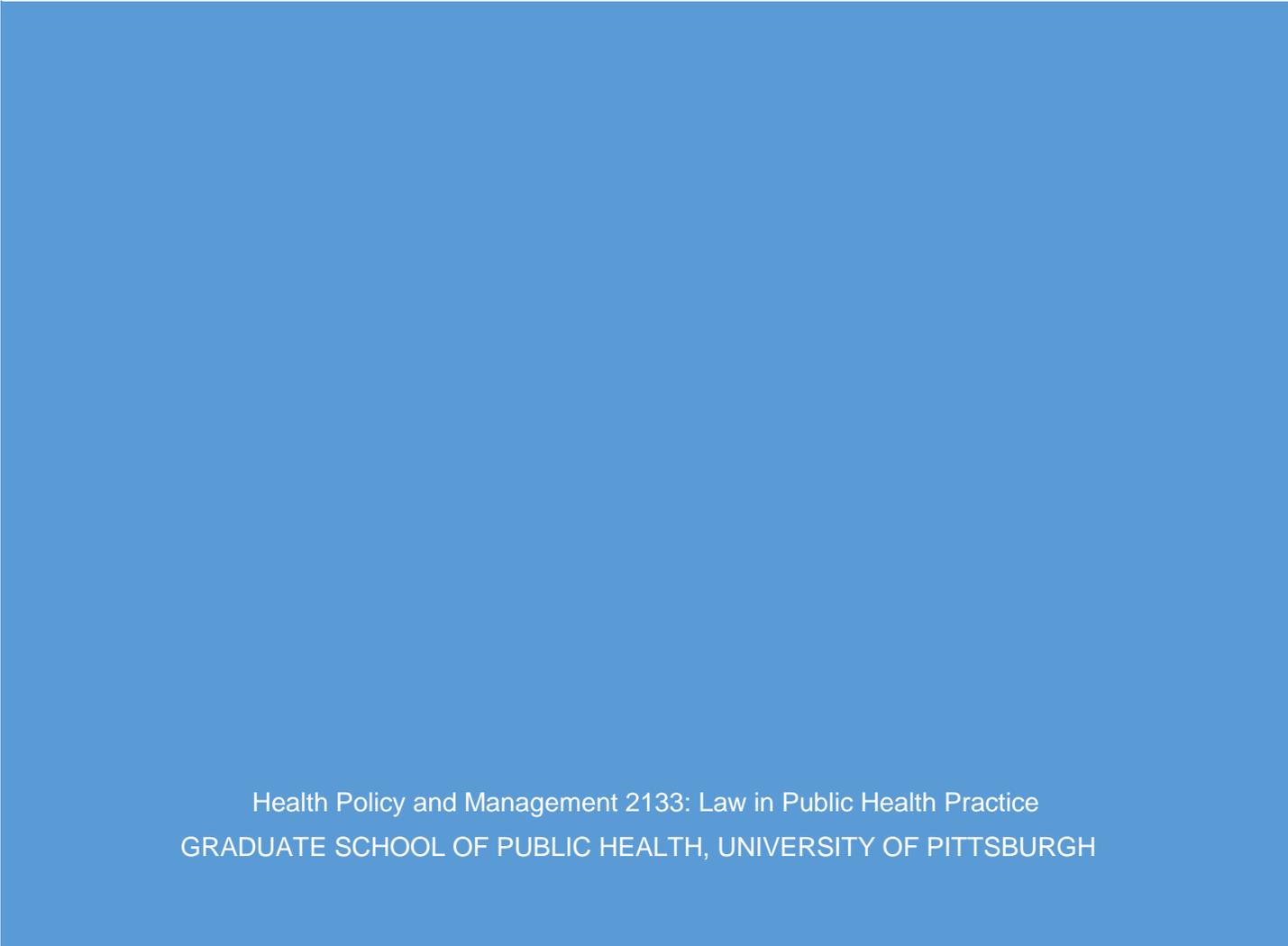




Addressing the Opioid Epidemic: Naloxone Availability as a Public Health Intervention in Allegheny County



Health Policy and Management 2133: Law in Public Health Practice
GRADUATE SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF PITTSBURGH

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Epidemic of fatal opiate overdoses persists amid deepening concerns



Photo: New York Times

LAW IN PUBLIC HEALTH PRACTICE: ENDING THE OPIATE EPIDEMIC

This interdisciplinary, practice-based course allows students to identify effective and ineffective interventions related to the opiate epidemic by exploring demographic and health outcomes data, analyzing criminal and civil laws, assessing policies and drafting model regulations. Students will work in collaboration with the executive leadership of the Allegheny County Health Department.

HPM 2133 is limited to 15 students

HPM 2133

Thursdays 3:50 – 5:20

G46 LAW

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EXECUTIVE SUMMARY

In 2014, overdose death surpassed motor vehicle death as the most common injury-related cause of mortality in Allegheny County, Pennsylvania as well as nationally, driven by opioid overdose. This report, compiled as part of an interdisciplinary public health law and practice course, contains an analysis of the factors influencing the opioid epidemic in Allegheny County, as well as recommendations to reduce the local burden of overdose death. The opioid epidemic has profound public health significance given its broad impact on diverse groups of people and communities. Immediate action, with a focus on vulnerable populations, is required to reduce this growing multidimensional problem.

This report also identifies effective local harm reduction methods that should be considered as a supplement to the efforts of local organizations like Prevention Point Pittsburgh. A broad economic analysis is discussed to demonstrate the cost and loss of productivity due to opioid abuse in Allegheny County. The cost-effectiveness of naloxone distribution is addressed, but the availability of public data sources limited this analysis. A legal analysis of Good Samaritan laws, including Pennsylvania's Act 139, is presented to identify similarities, strengths and shortcomings. Data on overdose death rates by state is used to create a model that demonstrates the efficacy of comprehensive Good Samaritan laws. Maps are also presented to create visual representations of the burden of the opioid epidemic in relation to pharmacy services.

Finally, a literature review is summarized to confirm the evidence base for harm reduction strategies in three vulnerable Allegheny County populations, including school-aged children, veterans, and incarcerated persons. Insufficient evidence exists to support stockpiling naloxone in schools for overdose prevention. The Veterans Affairs Pittsburgh Health System (VAPHS) is following the comprehensive national Veterans Affairs (VA) opioid overdose prevention strategy; however, collaboration between community partners and the VA is needed to enhance naloxone distribution to non-veteran family members of opiate-addicted VA patients. Medication-assisted treatment (MAT) provided during incarceration reduces opioid overdose mortality during the first year post-incarceration; however, naloxone distribution upon release from incarceration is vital to preventing opioid overdose death in the two-week period following release.

This report yielded the following actionable recommendations for the Allegheny County Health Department (ACHD):

1. Naloxone and appropriate training on naloxone use and overdose intervention should be offered to inmates with a history of opiate abuse upon release from the Allegheny County Jail. **Appendix A: Model Regulation** contains a model regulation to enforce this effort. Potential funding sources for this effort are discussed in the Recommendation section of this report.
2. Opiate-addicted Allegheny County Jail inmates should be offered opiate-specific MAT and community-based MAT referral upon release.
3. ACHD should work to ensure opioid overdose prevention for Allegheny County veterans by collaborating with the VAPHS and community partners on third-party naloxone distribution.

4. ACHD, in conjunction with the Allegheny County Department of Human Services, should conduct a large-scale in-person naloxone distribution and training program for first responders and Allegheny County bystanders.
5. ACHD should expand data-sharing initiatives with community and governmental partners as well as expand publically available data sources specific to the opioid epidemic.

The strongest evidence was found for interventions targeting the incarcerated population, who are at high risk of opioid overdose death following release. A considerable proportion of overdose deaths in Allegheny County occur in individuals who had been previously incarcerated in the Allegheny County Jail. Devoting resources to harm reduction strategies focused on the Allegheny County incarcerated population will substantially reduce the burden of opioid overdose death in Allegheny County.

We thank the Allegheny County Health Department for the opportunity to share this report and present our findings and recommendations.

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GLOSSARY

Abuse: *Refers to the use of illicit opioids, such as heroin.*

Allegheny County Health Department (ACHD) - *County health department in Western Pennsylvania that serves over 1.2 million residents*

Centers for Disease Control and Prevention (CDC)— *national governmental health protection agency located in Atlanta, GA*

Cognitive Behavioral Therapy (CBT)— *a short-term, goal-oriented psychotherapy treatment that takes a hands-on, practical approach to problem-solving. Its goal is to change patterns of thinking or behavior.*

Drug overdose mortality—*this implies deaths due to opioid overdose, but actually may include other drugs or toxicant-related deaths (Rudd et al, 2016)*

Ecologic study— *epidemiologic study design that uses aggregated population data or other large-scale metrics (such as average sales, pollution level, etc.) to draw conclusions (Morgenstern, 1995)*

Good Samaritan Law—*law or legal provision that provides protection for individuals who act in good faith to provide assistance and call 911 to report an overdose (even if they administer naloxone). (DDAP)*

Incident rate ratio (IRR)— *Ratio of two incidence rates (which is a measure that is indicative of risk). Incidence is the number of new events divided by the population at risk for the event, and the rate itself adds an element of time.*

Misuse: *Refers to the use of prescription opioids outside of a medical direction.*

Medication-Assisted Treatment (MAT)—*combines behavioral therapy and medications to treat substance use disorders.*

Network for Public Health Law (NPHL)— *network of lawyers, public health workers, advocates, government officials and organizations that promote the use of public health law and offer technical assistance and expertise in the area of law*

OEND - *Opioid and Overdose Education and Naloxone Distribution Program*

PCP - *primary care physician*

Pennsylvania Act 139— *Naloxone access and Good Samaritan Law in Pennsylvania*

Pennsylvania Department of Health (PADOH)— *state health department for Pennsylvania located in Harrisburg, PA*

Pennsylvania Virtual Training Network (PVTN)— *Online training resource for law enforcement that is developed by Pennsylvania law enforcement officers*

Pitt GSPH: *University of Pittsburgh Graduate School of Public Health*

Pittsburgh VA - *Pittsburgh Veteran's Affairs Healthcare System*

Poisson regression— *a statistical model used in the case of rare events. The data output illustrates a discrete distribution of the frequency of independent events occurring*

over a time t $p = \frac{e^{-\mu} \mu^x}{x!}$

PPP – *Prevention Point Pittsburgh*

Randomized Controlled Trial (RCT)— *experimental study design where individuals are randomly assigned to a treatment or control group (considered the gold standard in epidemiology)*

Recent releasee - *a term to describe former inmates who recently re-entered the community; formerly incarcerated individuals who were recently released from prison*

Standing order— *an executive action by a high-level medical appointee to provide a medical intervention to members in his/her jurisdiction that are otherwise only available through personal provider prescription.*

UPMC - *University of Pittsburgh Medical Center*

1.0 COURSE DESIGN

1.1 COURSE DESCRIPTION

HPM 2133: Law in Public Health Practice

Local health departments play increasingly pivotal roles in the provision of community public health services; however, they also are experiencing diminished funding and reduced workforces. This course is the first of its kind: a practice-based, interdisciplinary, collaborative learning experience. Together thirteen students developed legal and public health interventions to reduce morbidity and mortality attributable to the opiate epidemic for potential implementation by the Allegheny County Health Department, as requiring the expertise of both cohorts.

This course was developed during a Robert Wood Johnson Public Health Law Education fellowship. A full course syllabus is included in [Appendix B: Course Syllabus](#). Students represent the following department and university programs, and biosketches are included in [Appendix C: Biosketches](#).

The University of Pittsburgh

Dietrich School of Arts and Sciences, Economics Department (B.S.)

Graduate School of Public Health, Department of:

Behavioral and Community Health Science (MPH)

Environmental and Occupational Health (MPH)

Epidemiology (DrPH)

Health Policy and Management (MPH)

Human Genetics (MPH)

School of Medicine (M.D.)

Carnegie Mellon University

H. John Heinz III College (MSPPM)

2.0 OVERVIEW OF OPIOID EPIDEMIC

The Opioid epidemic is a multifaceted widespread issue in the United States (U.S.). Pennsylvania (PA) has been hit particularly hard by opioid substance abuse and overdose deaths. As of 2016 PA is ranked above the national average in fatal overdoses with Allegheny County ranked 8th in the state for drug related deaths per 100,000 people.¹ In 2014, overdose death surpassed motor vehicle death as the most common injury-related cause of mortality in Allegheny County. Among other factors overprescribing of opioid drugs, addiction has increased in recent years and consequently so has a market for a cheaper illegal drug option, heroin. The appearance of black tar heroin in the West Coast of the U.S. has law enforcement and public health officials concerned on implementing successful intervention plans and decreasing addiction cases. However, in Pennsylvania individuals are seeing heroin mixed with Fentanyl, a very potent substance that increases the strength of heroin, attributing even more to the overdose death toll.

The high risk of death associated with opioid and heroin use is a significant public health concern and has evolved into a public health emergency, especially in PA. The overdose death rate in Allegheny County has risen from 109 deaths in 2000 to 329 in 2015.² Heroin presence has increased rapidly in the county, measured by examining death certificates. In 2010, heroin was the third most-present drug represented on death certificates but now it constitutes more than 58% of drug related deaths.³ This high rise in mortality has emphasized an immediate need for harm reduction. Emotional and financial burden on families, friends and the whole community has motivated research initiatives to aid in developing harm reduction strategies. Throughout this document, information and recommendations are laid out to increase knowledge on the subject and promote a call to action in Allegheny County.

In regards to terminology, the term “opioid” will be used to describe both the derivative drugs and traditional “opiates”, which is the term used to describe drugs such as morphine and heroin.

3.0 ECONOMIC IMPACT OF OPIOID ABUSE

3.1 BACKGROUND

Opioid misuse refers to use of prescription opioids outside of medical direction and illegal opioid substance abuse (refers to use of illicit opioids, such as heroin) are straining public health resources due to widespread health impacts and financial burden on the economy. The opioid epidemic is multifaceted and therefore a cost analysis of opioid abuse is complicated. Economic analysts have broken down the problem into three principal areas: crime, health and productivity.⁴

3.2 METHODOLOGY

Our methodology is based primarily on broad national statistics found in previously published reports on the economic impact of opioid misuse and abuse. From there we compiled available data in order to illustrate the approximate cost of the opioid epidemic based on historical data. Using data from national reports, primary literature, and non-profit organizations we are able to illustrate the scope of the economic costs at the national, state, and county levels. We then used data provided from the Allegheny County Health Department to provide an impact analysis from lost days of productivity due to opioid related hospitalization. The breakdown of the costs to crime and healthcare were limited by the data publicly available at the county and state levels.

3.3 RESULTS

3.3.1 National

Cost estimates of opioid misuse and abuse in the United States have been tabulated by an array of government and scholarly sources. The White House and DEA both cited opioid misuse costs the nation over \$50 billion U.S. dollars annually in direct costs based on a 2007 estimate.⁵ The CDC also released findings estimating that opioid related abuse costs the nation over \$72 billion U.S. dollars annually.⁶ Table 1 below breaks down the costs for nonmedical use of prescription opioids using estimates from the study broken down into three categories: Crime costs (total over \$8.2 billion), Health costs (total over \$2.2 billion), and Productivity costs (total over \$42 billion).⁶ This manner of estimating the

costs of the opioid epidemic is consistent across both the literature and reports analyzed and provide a way to identify costs at the national, state, and local levels.

Table 1. Economic Cost of Nonmedical use of Prescription Opioids

<i>Estimated Total Cost in US of Nonmedical Use of Prescription Opioids Cost Breakdown</i>	
Crime Subtotal	\$8.2 billion (15%)
Health Costs:	
§ Drug Abuse Treatment	\$2.2 billion (4%)
§ Medical Complications	\$944 million (2%)
Productivity Subtotal	\$42 billion (79%)
Total Cost:	\$72 billion

Source: *Economic Impact of Illicit Drug Use of American Society*⁴

The breakdown of estimated costs of nonmedical prescription opioid use is based on methodology that identifies multiple sources of costs that result from opioid misuse. It is challenging to identify large national cost associated with prescription opioid abuse due to the difficulty in estimating cost to the overall economy of illicit drug use. Based on a report from the U.S. Department of Justice National Drug Intelligence Center Report, *The Economic Impact of Illicit Drug Use on American Society 2011*, the cost to the U.S. economy of illicit drug use is broken down into these same subcategories of crime, health, and productivity on the scale of hundreds of billions of U.S. dollars.⁴

To illustrate the scope of the financial burden to society, data has been incorporated from the report to include other illicit drug and misused Schedule II-IV drugs. Crime is broken down into criminal justice system costs and crime victims and their property. Health is sub-grouped by drug related specialty treatment, hospital costs, and insurance costs. Productivity is subcategorized by labor participation costs. The U.S. Department of Justice Report totals \$61 billion spent in Crime costs in 2007 alone, \$11 billion in healthcare costs, and \$120 billion in productivity losses.⁷ This equates to a total economic cost of over \$193 billion dollars in 2007 from illicit drug use.

Table 2. Total Cost of Drug Use to Society in 2007

Crime Subtotal	\$61,376,694,000
Health Costs Subtotal	\$11,416,232,000
Productivity Subtotal	\$120,304,004,000
Total Cost to Society:	\$193,096,930,000

Source: *The Economic Impact of Illicit Drug Use of American Society 2011*⁴

These national estimates serve to illustrate the economic losses that are a result of opioid misuse. From here we narrow our data to examine the economic data from the state of Pennsylvania.

3.3.2 State

Based on opioid abuse costs from CDC data in 2007, a report issued by the Partnership for Drug-Free Kids further breaks down the \$25 billion national economic cost.⁶ According to the report by Matrix Global Advisors LLC prepared for A Partnership for Drug-Free Kids, \$873 million was spent on health care costs for opioid abuse in the state of Pennsylvania alone.⁸ The methodology used to calculate Pennsylvania's State health care costs uses three factors: population, cost of health care, and rates of opioid abuse for each state.⁸ Hospital adjusted expenses per inpatient day collectively came from the US Census data, Substance Abuse and Mental Health Services Administration (SAMHSA), and the Kaiser Family Foundation. Using these estimates, analysts modeled and identified the costs per state credited to opioid abuse for all 50 states.

Limitations to the Matrix analysis include the use of conservative numbers due to the health costs attributable to opioid abuse being inherently conservative. This was found across our analysis of the primary literature. Additionally, healthcare costs are difficult to concretely determine due to inconsistency between classifying specific costs to opioid use. For these reasons, cost can be assumed to be greater due to underlying financial burdens, misclassification of patients being treated, and incomplete data collection.

3.3.3 Allegheny County

Primary literature and government reports were unavailable for county level analysis; therefore, data acquired directly from the county health department was utilized. The total economic loss from days spent in the hospital in Allegheny County serves as a way to quantify the cost of opioid misuse and abuse to the economy of the county. Two different sources of economic analysis were used to identify the cost to the community from lost days of productivity; patient cases with estimated wage losses, and patient days spent hospitalized.

Based on International Classification of Diseases 9th revision (ICD-9 codes) data provided by the ACHD along with wage estimates from the bureau of labor statistics, estimated loss of wage from hospitalization due to opioid overdose was determined.

Code descriptions:

965.01 (POISONING BY HEROIN)

965.09 (POISONING BY OPIATES AND RELATED NARCOTICS OTHER), 965.00 (POISONING BY OPIUM, UNSPECIFIED)

Total patient days were **1,107 days for 253 discharges**.

Table 3. Overdose Data 2014-2015: Q2 2013-Q2 2015

Overdose Data 2014-2015: Q2 2014-Q2 2015		
Diagnosis	Discharges	Patient Days
965.01 POISONING BY HEROIN	138	529
965.09 POISONING BY OPIATES AND RELATED NARCOTICS OTHER	65	319
965.00 POISONING BY OPIUM , UNSPECIFIED	50	259
~ALL	253	1,107

Source: Allegheny County Health Department

Using patient days as a source of analysis, two different numbers are associated with the costs of these lost days in productivity. First, assuming an average weekly wage of \$825.00 provided from Bureau of Labor Statistics (BLS), lost wages from patient days in the hospital is **\$130,000**.⁹ This is a conservative estimate in lost wages from opioid related hospitalizations in Allegheny County.

Next, using the Value of Statistical Life (VSL) estimates, lost productivity was calculated from the total number of hospital days provided by the ACHD. The VSL estimates are based upon how much an economy values a human life. A human life value is based on risk estimates calculated from tradeoffs that people make between money and an increase in risk of death. These trade-offs are calculated using Hedonic wage studies that identifies the amount an individual is willing to pay for a reduction in risk in the workplace. Because of the nature of a VSL calculation there is a vast range of values placed on a statistical life.¹⁰ Then, comparing the lost wages from patient days to the estimated loss in productivity between Q2 2014 and Q2 2015 from hospitalizations and using the VSL estimate, we can calculate the economic loss from the total days spent in the hospital (1,107) due to opioid overdose.

The VSL estimate used in this analysis is based on the ranges provided in Cropper et al. and the Environmental Protection Agency's recommended estimate of \$7.4 million dollars in 2006.¹⁰ Adjusting for inflation, the number is approximately \$8.7 million. Other assumptions used in this calculation include the average person's lifespan of 80 years, based on the Pittsburgh Health Care Cost Containment Council data. The resulting estimate of \$330,000 represents the total loss to society in productivity due to total days spent in the hospital from Q2-2014 to Q2-2015 in Allegheny County. Based on our conservative estimates related to productivity loss, days spent in the hospital cost Allegheny County \$330,000 between 2014-2015 from opioid related hospital days

3.4 COST-EFFECTIVENESS ANALYSIS

In order to help guide effective use of limited resources, provide justification to stakeholders, and give evidence and compare to similar interventions, a cost-effectiveness analysis (CEA) was performed. This analysis included hospital care costs for overdose cases with and without use of Naloxone, cost of providing naloxone kits to all public schools, and amount of deaths prevented in the state and local communities per 100 kits distributed. A CEA calculation to support wide distribution of Naloxone in as many facilities as possible (schools, prisons, pharmacies/hospitals) was performed.

To justify distribution programs and mitigate concerns of financial costs to the state and taxpayers, a summary of a national report titled “Giving Naloxone to Heroin Users Reduces Overdose Death and is Highly Cost-Effective” retrieved from Naloxoneinfo.org.¹¹ The report analyzed over 188 naloxone distribution programs in the country, and compared the amount of lives saved to cost of Quality Adjusted Life Years (QALY) gained. The same analysis can be duplicated using state level facts and figures.

The methodology included:

- Published data to form a mathematical model of heroin use, overdose, and naloxone distribution
- Techniques accepted in health economics such as Markov decision analytic modeling with deterministic and probabilistic analyses.
- Local death rates and average ages of heroin use, as well as other information specific to the US (i.e. risk of overdose, roles of witnesses and emergency medical services, rates of abstinence from and relapse to heroin use, and costs)
- Outcomes of studies where deaths were prevented and cost of gaining one quality-adjusted life year.

In the U.S., a reach of 20% of opioid/heroin users with this program, it could prevent approximately 10% of deaths due to opioid/heroin abuse within the first 5 years.¹² The cost of naloxone distribution would be approximately \$421 per one QALY gained. However, this cost does not include criminal justice, healthcare, or other expenditures. Adjusting estimates for these additional factors, the study concludes that roughly \$2,429 would be spent on naloxone distribution per one QALY gained. At most, if naloxone was minimally used or effective during the 5-year program, distribution cost would be \$14,000 per QALY gained. All of these values are within the national cut off of \$50,000 for cost-effectiveness strategies and is less than the standard threshold for cost-effective health care interventions.¹²

Though the report shows cost-effectiveness on the national level, it is still important for Pennsylvania to conduct its own analysis. The cost per one QALY gained is based on the number of naloxone kits distributed and effectively used. Therefore, it is crucial to know how many kits are currently being distributed within the state and what gains have been made in deaths prevented.

3.5 CONCLUSIONS

Limitations to both economic and CEA analyses

Data collection became an obstacle when making calculations. This was either due to data on cost savings surrounding Naloxone distribution and use not yet being collected at the state level or that it has yet to be made public. Hospital costs were variable and difficult to gather within one region with multiple hospital systems. Many naloxone users may or may not seek treatment at a hospital or may be diagnosed under a different category than for overdose. When reaching out to the state to understand costs spent on providing schools with Naloxone kits, there was no indication that a cost-effectiveness analysis had been conducted by officials beforehand or that data was currently being collected for retrospective study. Both the economic and CEA analyses are national and cannot be compared to Pennsylvania directly until statewide data collection is complete. Assumptions include that national averages are consistent with PA averages on Naloxone distribution and use.

Recommendations

In order to combat limitations in data collection, it is recommended that Pennsylvania's state department of health designate a task force for compiling current data statistics on cost of naloxone distribution, amount of kits accessed and used, and deaths prevented. The state and local governments need to know if this intervention is successful within its first year to three years of implementation.

4.0 CASE STUDY REVIEW

4.1 OVERVIEW

There are established harm reduction programs for opioid users in many jurisdictions across the United States, including Western Pennsylvania. Harm reduction is an evidence-based approach that seeks to minimize the negative effects of drug abuse, recognizing that abstinence is usually not a realistic goal and interventions are most successful when they meet the user “where they’re at”.¹³

Naloxone education and distribution is a key component of many of these programs. However, the length of time that they have been able to provide it to participants depends on state-by-state Good Samaritan laws and Naloxone Access. Many programs have also been successfully operating needle exchanges, hosting support groups, and connecting at-risk members of the community with social services for years. Each individual program is a case study in intervention techniques and a valuable source of information when considering possible programmatic interventions. Successful components of local programs may hold promise in other cities and states, or even at the national level. The following selection of successful harm reduction programs should be viewed as a guide to intervention efforts in the future.

4.2 CASES STUDIED

Chicago Recovery Alliance¹⁴ is a harm reduction organization that was founded in 1992. Their earliest work focused on establishing a safe and accessible syringe exchange, and they successfully worked to exempt their group from laws in Illinois that banned possessing/distributing syringes without a prescription. The Alliance began providing free naloxone trainings in 1996, and started distributing it to program participants in 2001, making them the first take-home naloxone program in the United States. They developed the SCARE ME model for overdose intervention (Stimulation, Call 911, Airway, Rescue Breathing, Evaluate the situation, Muscular injection, Evaluate again), which has since been adopted by many other overdose intervention education programs across the country.

The Chicago Recovery Alliance’s approach has been primarily based on creating positive relationships with participants and remaining attuned to their needs, interests, and feedback. The Alliance continues to work as legal advocates, and helped enact a Good Samaritan law in Illinois in 2010 (20 ILCS 301/5-23) which exempts both prescribers of naloxone and laypersons who try to revive a person with naloxone from prosecution.

Clean Works¹⁵, based in Grand Rapids, Michigan, began in 2008 as a partnership with local healthcare providers to distribute naloxone and training information. This program derived from the Red Project, Grand Rapids's syringe exchange program that has been serving the community since 1998. Clean Works has adopted the Chicago Recovery Alliance's SCARE ME model for their educational programs, and maintains a similar focus on participant empowerment.

The DOPE Project¹⁶, based in the San Francisco Bay Area, began in 1993 as an initiative by youth outreach workers distributing educational overdose prevention flyers made by the Santa Cruz Needle Exchange. Monthly overdose prevention trainings began in 1998, and with additional funding in 2001 they were able to expand their trainings to syringe exchange workers, homeless shelters, pretrial diversion programs and drug treatment programs.

The DOPE Project curriculum was adapted from the Chicago Recovery Alliance, the Santa Cruz Needle Exchange, and the San Francisco Needle Exchange. In 2003, after the San Francisco Department of Public Health made the decision to support a take-home naloxone program, the DOPE Project began incorporating naloxone into their trainings, and with the passage of a citywide policy in 2010, trainers were allowed to distribute naloxone directly to participants under a standing order.

The success of the DOPE Project has been closely tied with their ability to engage a wide body of stakeholders to build a diverse institutional buy-in. They continue to work with local health departments and community organizations, and have been instrumental in advocating for more evidence-based addiction treatment policies.

Learn To COPE Parents Group¹⁷ was founded in Randolph, Massachusetts in 2004 by Joanne Peterson as a support group for the families and loved ones of opiate addicts. Joanne's own son had been struggling with opiate addiction, and she quickly identified the need for an accepting community that could harness the pain and helplessness felt by parents and other family members of opiate addicts into a positive force for change. The Learn to COPE group partnered with a needle exchange program in 2005, and shortly thereafter began to work together with Healthy Streets/Not One More Anonymous Death, an overdose prevention and naloxone distribution program.

The Learn to COPE group trains parents to become Opioid Overdose Trainers, many of whom have gone on to create their own naloxone education/harm reduction groups in different cities. Learn to COPE promotes the idea that trainers should meet parents where they feel comfortable. For example, trainers can meet parents in their homes or support groups, instead of asking them to come to needle exchanges or other areas that are traditionally the domain of the "addict." They have piggybacked off the idea of meeting opiate addicts where they're at, and expanded to parents and family members. This approach has been extremely successful, and the Learn to COPE Parents Group continues to expand throughout Massachusetts and other states.

Massachusetts Overdose Education and Naloxone Distribution Program (OEND)¹⁸ is a statewide naloxone distribution program. It is the product of a joint public health system and community advocate effort that began through collaboration with a needle exchange program. In 2006, the board of the Boston Public Health Commission (the city of Boston's health department) approved a pilot program to train active injectors on how to avoid/respond to overdose, and began distributing nasal naloxone to enrollees. With promising results, the program was approved for continued funding. Regulations named the staff of the program "special employees" for whom the city assumed legal liability for activities related to the overdose prevention pilot program, including naloxone distribution conducted at the local needle exchange.¹⁸ By 2007, the program had expanded statewide and leadership moved to the Massachusetts Department of Public Health. Massachusetts' OEND Medical Director issued a standing order for naloxone, allowing public health workers to train and distribute nasal naloxone. Potential overdose bystanders were anonymously enrolled using a code formula and are able to refill naloxone kits at agency locations.

By 2011, eight agencies operating in 12 communities provided overdose training to more than 10,000 drug users, friends and families of drug users, and service providers. By 2012, they had received 1,200 reports of naloxone being used to reverse an overdose. Services continue to be delivered at needle exchange programs, HIV prevention drop-in centers, homeless shelters, methadone clinics, detox centers, office-based medical care, emergency departments, residential drug treatment programs, community meetings and street outreach, as well as home delivery. Support from the Massachusetts Department of Public Health was critical in the success and expansion of this project.

Project Lazarus¹⁹, a statewide community-based overdose prevention program in North Carolina, focused on encouraging physicians to prescribe naloxone to prescription opioid users. The physicians, through training provided by Project Lazarus, were encouraged to combat drug use stigma not by dwelling on the differences between "legitimate" and "illicit" users of opioids. Instead, they combat by presenting straightforward, unbiased information. Patients who opt to receive naloxone watch a DVD about overdose prevention and naloxone use in the clinic, and then retrieve it at a pharmacy. Those entering drug treatment and anyone voluntarily requesting naloxone are also able to receive the drug for free. From 2009 to 2010, Project Lazarus saw the overdose death rate drop by 42%. Additionally, from 2008-2010 substance abuse-related emergency department admissions in the area fell by 15.3%.

Prevention Point Pittsburgh (PPP)²⁰ has built upon the successful Project Lazarus model with the Overdose Prevention Project (ODP), aiming to make naloxone and opioid safety education accessible to pain patients of Allegheny County since 2002. The ODP Project provides training on overdose prevention, recognition, and response to individuals at risk of drug overdose in addition to their family and friends. Trainings are offered at their needle exchange site, at methadone and other drug treatment programs, and at community settings as requested. All participants in the Naloxone Prescription Program learn how to perform rescue breathing as well as how to administer naloxone. When a

county-wide standing order for naloxone was issued in 2015, access began to expand, although many larger chain pharmacies in the area have been slow to offer their support.

OPD and a community pharmacy run by the Duquesne University School of Pharmacy, the Center for Pharmacy Services (CPS), partnered in with PPP in 2011 to develop an additional model for opioid overdose prevention. Patients presenting at CPS with a prescription for an opioid analgesic are offered education materials and counseling on opioid safety. The patient or caregiver also receives instruction on how to identify and effectively respond to an overdose, and how to administer naloxone.

Since its start, over 5,000 injection drug users have been enrolled in PPP's programs. As of the end of December 2015, over 1,400 overdoses have been reversed with naloxone obtained from PPP. In addition to needle exchange services, PPP has grown to include comprehensive case management services, drug treatment assistance, individualized risk-reduction counseling, health education, condom and bleach distribution, overdose prevention through naloxone prescription, and free HIV, Hepatitis C and syphilis screening in collaboration with the ACHD.

In 2000, Allegheny County established the Jail Collaborative, a cooperative effort between the Allegheny County Jail, DHS, state and local Health Departments, Court of Common Pleas, and community partners with the purpose of reducing recidivism and increasing successful reintegration for inmates post-incarceration. This was done by focusing on treatment and services in jail, as well as intensive support for inmates and ex-offenders. As PPP was developing the ODP, the jail warden made the decision to allow all inmates to receive the PPP naloxone and harm reduction trainings while incarcerated. Inmates who did not wish to participate were allowed to opt out by remaining in their cells. The inmate population gradually warmed up to instructors throughout the course of the project, with trainings being conducted 2-3 times per month.

During the course of the initiative, the Jail Collaborative reached over 6,700 inmates. The program was more successful than anticipated, and many people at the Pittsburgh needle exchange say they learned about PPP from the "jail trainings." A pre/post test evaluation indicated a 250% increase in knowledge among training participants in the first year of the program. However, this program has since ended despite its positive results.

4.3 CONCLUSION

The success of these programs shows the value of effective partnerships with a variety of stakeholders. Local health departments have tremendous power to promote the harm reduction approach, and partnerships can successfully be expanded to include family support groups, mental health providers, primary care physicians, religious organizations, law enforcement and local government. Harm reduction is an evidence-based approach that has tangible results^{21,22}, and the failure of punitive strategies to alleviate the burden

of opiate-related overdose and death in the United States must be a wake-up call to policymakers.

5.0 LEGAL ANALYSIS

5.1 OVERVIEW

A public health law is “the legal powers and duties of the state and its partners to assure the conditions for people to be healthy and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary or other legally protected interests of individuals for protection or promotion of community health.”²³ The authority to intercede in public health matters is generally left to the states. There is no express authority under the United States Constitution for the federal government to enact public health laws; therefore, under the 10th Amendment, this authority vests with the states. Many states have provisions in state constitutions for public health powers. Also, the United States Supreme Court has confirmed that states, pursuant to their police powers, have the authority to enact laws to protect the safety, health and morals of its citizenry.²⁴ Some state public health laws have notably reduced the opioid epidemic burden, acting as legal facilitators to prevent and treat overdose.^{25,26,27} More specifically, there are laws, regulations, and policies governing naloxone access and bystander immunity (or Good Samaritan law). In Pennsylvania, PA Act 139 is the naloxone access and Good Samaritan law.

Definitions

There are several key legal and public health terms that will be used throughout this section. Please refer to the Glossary for definitions.

5.1.1 Act 139 and Standing Orders

There are several key legal and public health terms that will be used throughout this section. Please refer to the Glossary for definitions.

PA Act 139

Pennsylvania Act 139 ([Appendix D: Act 139](#)) was signed into law in September 2014.²⁸ The law itself is fairly broad and open to interpretation, but it does specify protections surrounding naloxone access and distribution as well as a Good Samaritan provision. The statute offers civil and criminal immunity for prescribers and dispensers who distribute naloxone to individuals as well as “third parties”, or individuals who may administer naloxone to someone. In general, PA Act 139 protects:

- Third party-prescribing for physicians
- Dispensers/pharmacists
- Individuals (the general public or emergency personnel) who may administer naloxone

PA Act 139 also has a Good Samaritan provision, which offers immunity for individuals who act in good faith to report an overdose.^{29,30} This is important since often times bystanders are also using drugs themselves. This part of the law limits those circumstances in which individuals are immune. For example, individuals who report an overdose must give their name when calling 911, be cooperative with law enforcement, and remain with the victim in order to be granted immunity.²⁷ In general, this provision protects someone who witnesses an overdose from:

- Charge
- Prosecution
- Parole or probation violations

Act 139 also addresses naloxone training. The law creates a rebuttable presumption that, if an individual receives training and instructional materials, they have acted in good faith and with reasonable care when administering naloxone. Law enforcement and first responders are provided a certification portal that allows for training,³¹ while options for the general public are less clear. There are educational materials posted on the PADOH website, and information is always included with dispensing of naloxone kits.³⁰

State and County Standing Orders

Both the state of Pennsylvania and Allegheny County have standing orders ([Appendix E: Pennsylvania Department Of Health Standing Order](#), [Appendix F: Allegheny County Health Department Standing Order](#)) to increase access to naloxone. Under the ACHD standing order, pharmacies must register with the health department to participate. The PADOH standing order does not have this requirement. As of 2016, 23 pharmacies in Allegheny County have registered to carry naloxone.³² It is important to note that Medicaid and Medicare will reimburse for naloxone under the standing order, but other insurers may not.^{30,33}

Purpose

The purpose of the legal analysis was to examine the heroin/opioid epidemic from the lens of the law. Understanding the legal aspect of the opioid epidemic is important for decision-making and implementation of public health programs. The overall objective was to examine PA Act 139 and identify its strengths and weaknesses in terms of protections for bystanders and identify possible recommended areas of improvement. The aim is to 1) summarize the laws across the United States, 2) review Act 139 and compare Act 139 to other state Good Samaritan Laws, and 3) make general recommendations pertaining to Act 139 and the legal aspects of the epidemic.

5.2 METHODOLOGY

General Legal Analysis

State Good Samaritan Laws components were aggregated and summarized using data from the Network for Public Health Law,²⁹ LawAtlas³⁴ and the public health law literature. Pennsylvania Act 139 was then reviewed to identify these specific components of the Good Samaritan Law, such as provisions for immunity, protections, and trainings. Two other state statutes (CA and MN) were reviewed and compared to PA Act 139 and strengths and weaknesses of Act 139 were identified. California was selected since it has had a detailed law in place, while Minnesota was chosen for having a similar law.

Ecological Exploratory Analysis

As part of an exploratory analysis to generate hypotheses regarding the relationship of Good Samaritan laws, their components, and drug overdose deaths, age-adjusted state overdose death rates were compiled using data from the Centers for Disease Control and Prevention for the most recent data year available (2014).³⁵ LawAtlas data on state Good Samaritan laws and their respective protections was used for all 50 states and the District of Columbia.³⁴ In order to be included as a state with a law in place in 2014, the law had to be in place for at least 6 months in 2014.

Rates of drug overdose deaths by state were compared to postulate potential relationships between Good Samaritan Laws and drug overdose deaths. Univariate poisson regression was used to compare rates by types of bystander immunity since we had access to death counts and death rates. Results were reported as model coefficients (β) and as incident rate ratios. All deaths were resident deaths for each state. All rates were per 100,000 resident population. All analyses were conducted in SAS 9.4.³⁶

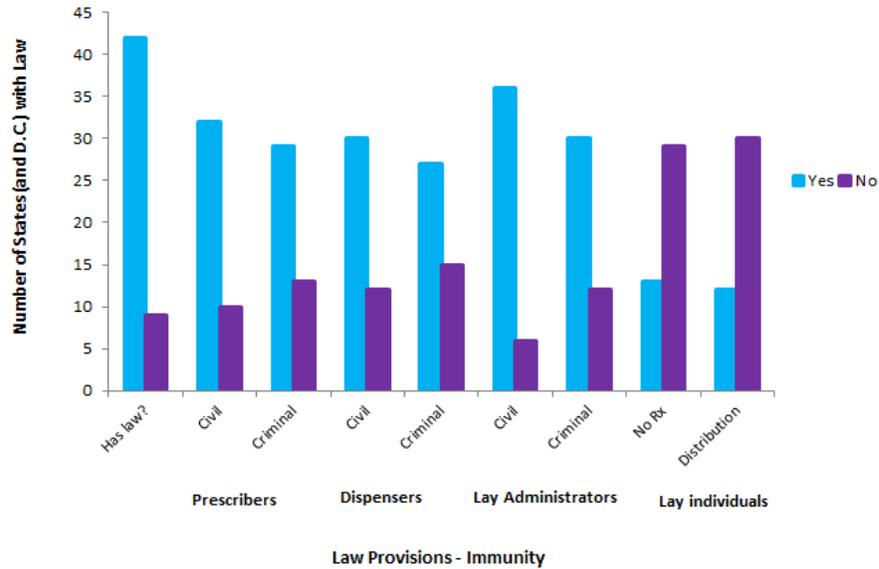
ArcMap 10.3 was used to map drug overdose rates and Good Samaritan laws by state with the LawAtlas data from above.³⁷ The TIGERLINE shapefiles for the United States were downloaded from the U.S. Census website.³⁸

5.3 RESULTS

General Legal Analysis: Naloxone Access

Eighty-four percent of states (and D.C.) have enacted a Good Samaritan law as of 2015 (Figure 1). Most states that do have laws offer immunity for prescribers, both civil (76%) and criminal (69%). There are similar protections for dispensers (71% and 64%, respectively), which are typically pharmacists.

Figure 1: Naloxone Access and Good Samaritan Provisions by State: U.S., 2015 (n=51)



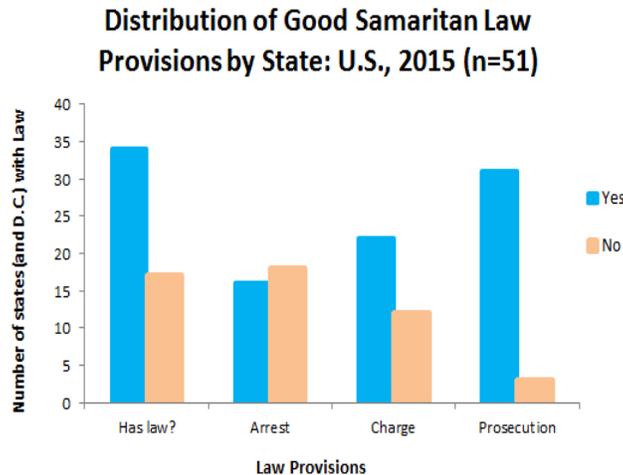
*Data obtained from Network for Public Health Law: LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND OVERDOSE GOOD SAMARITAN LAWS

Figure 1. Naloxone Access and Good Samaritan Provisions by State: U.S., 2015

Eighty-six percent of the laws offer civil immunity for lay individuals who administer naloxone to someone else, and 71% provide criminal immunity. However, far fewer laws have specific provisions for lay distribution of naloxone (31%).

General Legal Analysis: Possession

Some states offer varying levels of Good Samaritan immunity for possession of drugs (including opioids). Thirty-four states (67%) have such a law in place (Figure 2). Most states offer immunity from prosecution for possession (91%). However, only 22 laws (65%) provide immunity from being charged for possession and about half (47%) provide immunity from arrest. PA Act 139, which encompasses third party prescribing, bystander immunity, and possession immunity provisions, does not offer immunity from arrest ([Appendix D: Act 139](#)).



*Data obtained from Network for Public Health Law: LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND OVERDOSE GOOD SAMARITAN LAWS

Figure 2. Distribution of Good Samaritan Law Provisions by State: U.S., 2015

General Legal Analysis: State Law Comparison

As mentioned before, PA Act 139 (See [Appendix D: Act 139](#))²⁸ has fairly broad language and is open to interpretation, but also contains very precise components that essentially define what constitutes civil and criminal immunity. Unlike Act 139, California code for naloxone access and Good Samaritan is broken down into three statutes: CA Health & Safety Code 11376.5 (2012), CA Bus. & Prof. Code § 4052.01, and CA Civ. Code § 1714.22 (West 2014).^{39,40,41} In general, the CA codes fairly straightforward in their language. California protections are more comprehensive than Pennsylvania protections with respect to naloxone access, while their Good Samaritan law is fairly similar. Though California offers immunity for arrest, it does not offer protection from parole or probation violations.

Minnesota law is more similar to PA Act 139.⁴² Much like Act 139, Minnesota law does not offer protection from arrest but will provide immunity for parole or probation violations. Both Pennsylvania and Minnesota allude to the use of a standing order where individuals can access naloxone via prescription or dispenser, but the Minnesota statute does not mention anything about immunity specifically for prescribing to a third party. Minnesota law is more limited than Pennsylvania law (See [Appendix G: Legal Analysis](#), Table 1 for language comparison).

Overall, the PA Act 139 provides comprehensive protections for multiple parties that have a role in overdose prevention and reversal. It is exact in its wording about Good Samaritan protection and is similar to other state statutes. However, there are some areas of the statute that could be improved. First, the law does not provide immunity from arrest. While this may serve a role unbeknownst to us, it makes sense to provide more protections. Second, the statute should more clearly define the training component for those individuals who receive naloxone. It is unclear how training is to be implemented or enforced, suggesting the need for a regulation.²⁸

Ecological Exploratory Modeling of Good Samaritan Laws

For detailed results of the exploratory analysis, please see [Appendix G: Legal Analysis](#). Overall, states with the highest drug overdose death rates in 2014 were mostly in the Appalachian region and the Southwest United States (Figure 1, [Appendix G: Legal Analysis](#)). 22 states (43%) had Good Samaritan laws enacted as of 2014 for at least 6 months (Figure 2, [Appendix G: Legal Analysis](#)). Of the twelve states with the highest overdose rates, eight (67%) did not have Good Samaritan laws.

The results of the regression model indicated an association between the presence of a Good Samaritan Law and drug overdose mortality rates. Not having a Good Samaritan law significantly increased the IRR by 18% ($p < 0.0001$). When examining the components of the law and their respective associations with overdose mortality, there was a strong significant trend. Protection from arrest, charge and prosecution were all associated with declines in the IRR for mortality ($p < 0.0001$). See Table 2 in [Appendix G: Legal Analysis](#) for further modeling results.

5.4 CONCLUSIONS

Limitations

Analyses were limited by several key factors and Pennsylvania was unable to be included as an enacted-law state in our modeling. However, the analyses were a broad first step to examine how this public health law affects the epidemic using both legal and health components.

The legal analysis was very broad and only included data from one source.³⁴ While the laws were broken down into separate segments, each law was not accessed to compare specific language and interpretability.

The exploratory analysis was ecologic, meaning that any conclusions drawn from the results cannot be applied at the individual level (i.e. one cannot state whether or not the laws actually changed individual behaviors). Additionally, the analysis and data cannot determine how the laws are actually enforced in each state. Finally, the analysis was limited to a single year and the duration of the law over time may be an important factor that was not accounted for. While many more states have laws in place as of 2016, the lag in obtaining death data prevented us from looking at 2015.

The regression models were unadjusted univariate models, meaning that the results are confounded by other variables that we did not account for but are important with respect to overdose deaths. These results are overestimates of the true association between the law and overdose mortality rates because laws were included that were in place for at least six months. This time frame is probably not sufficient to see any real impact on mortality. However, the drug overdose data may have included drugs beyond opioids (though this is unlikely to have affected the results since the majority of drug overdose deaths are opioid-related).³⁵

5.5 RECOMMENDATIONS

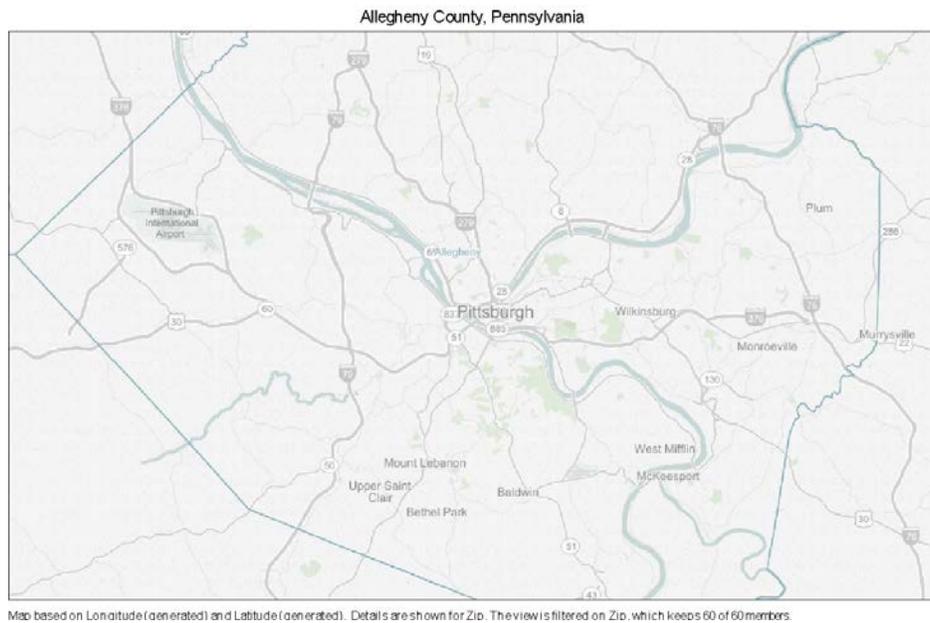
Act 139 offers immunity from charge and prosecution for bystanders under certain circumstances, as well as other protections. Though conclusive individual-level evidence to suggest that protection from arrest is associated with improved health outcomes is unavailable, it is recommended that Pennsylvania revisit Act 139 and consider amending the statute to offer protection for bystanders from arrest. Given that the standing orders do not promise reimbursement by all insurers, it is suggested the county revisit the standing order and consider ways for insurers to reimburse under the order.

PA Act 139 requires training that is designed for and certifies emergency personnel around administration of naloxone; however, there is no specification of how training is provided or enforced for lay individuals.³¹ In conjunction with evidence from the case study section, ACHD should consider implementing a large-scale training for the public and first responders on Act 139 and naloxone administration.

Finally, other states that have not yet enacted a naloxone access and Good Samaritan laws should consider doing so as part of their efforts to combat the opioid epidemic. It is further recommended that they offer protection for arrest, charge and prosecution to ensure full immunity is provided for bystanders.

6.0 GIS MAPPING

The impacts of naloxone distribution are far reaching. Allegheny County (Figure 3) is a mix of urban, suburban, and rural areas. Some communities are close to corporate pharmacies, and others have family-owned operations where people can purchase medications. As a result of this variation, it stands important that there be equal availability of naloxone across Allegheny County.



Map based on Longitude (generated) and Latitude (generated). Details are shown for Zip. The view is filtered on Zip, which keeps 60 of 60 members.

Figure 3. Allegheny County, Pennsylvania

Providing naloxone to incarcerated individuals being released from Allegheny County custody is a good step to decrease the frequency of opioid overdose deaths. However, as is demonstrated throughout the body of this research, opioid addiction does not follow the typical path of adherence to specific social determinants of health. Age, race, income, and education are all indicators that have been able to help epidemiologists and policy makers identify disease precursors so that health departments could implement targeted health improvement campaigns. But, as asserted, social classifiers are not reliable determinants in the case of this epidemic. **Appendix H: GIS Overlay, Overdose Deaths by Household Income** includes a map overlaying opioid overdoses and economic status is used to put into perspective that this epidemic transcends any single demographic.

It is necessary to note that common sense suggests that making naloxone more available, in general, will decrease the tragedy of the heroin and opioid epidemic across the Commonwealth of Pennsylvania. As shown above (Figure 3), there are few pharmacies

participating in Pennsylvania Act 139, at least few registered under the law.¹ Granted, of course, there are other pharmacies distributing naloxone under Dr. Hacker's standing order, which does not require registration. Nevertheless, there are many opportunities for improving the availability of naloxone across the county.

The map below (Figure 4) illustrates the number of pharmacies in each jurisdiction registered with Act 139, cross-tabbed with the number of overdose deaths in aggregate from 2005-2013. Interestingly, the pharmacies registered under the state regulation are concentrated to the eastern side of Allegheny County and, even though Moon Township has the fourth highest mean overdose death frequency over the observation period (an average of 56 overdose deaths per year over eight years) there are not any distributing pharmacies registered in the county. As shown, there are many zip codes across Allegheny County that have experienced overdose deaths, but do not have Act 139 registered naloxone distributors in the zip code.

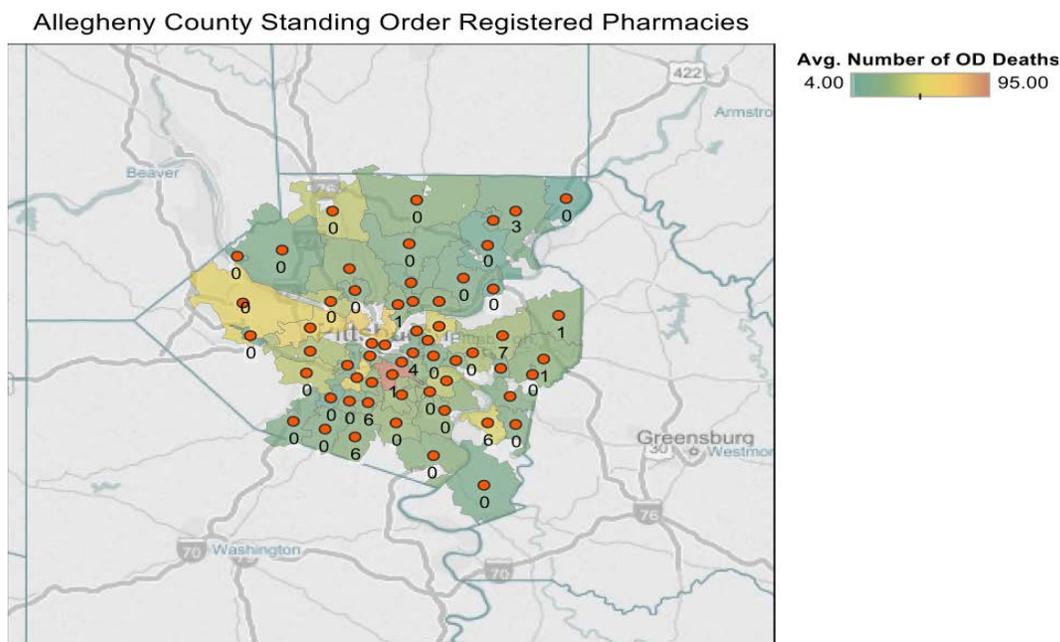


Figure 4. Pennsylvania Act 139 Registered Pharmacies

One of the issues surrounding the Act 139 implementation is that the legislation does not provide for any substantial oversight, nor does the standing order *mandate* that pharmacies exceeding a threshold of capital availability adhere to the standing order to reduce overdose deaths across the Commonwealth.

Many corporate pharmacies have committed to stocking naloxone under the standing order, however many of the corporate pharmacies are not stocking the antidote despite

¹ There are other pharmacies—independent, corporate, and hospital system owned—distributing naloxone under the Allegheny County Standing Order. These facilities are not required to register with the Allegheny County Health Department or any other entity.

publically discussing intentions to provide naloxone. The reality is that, the distribution and availability of naloxone should be standardized across the commonwealth. The map below (Figure 5) shows the number of pharmacies in the area that could reasonably distribute naloxone based on the best available data by color, cross-tabbed against the mean overdose deaths in Allegheny County from 2005-2013.

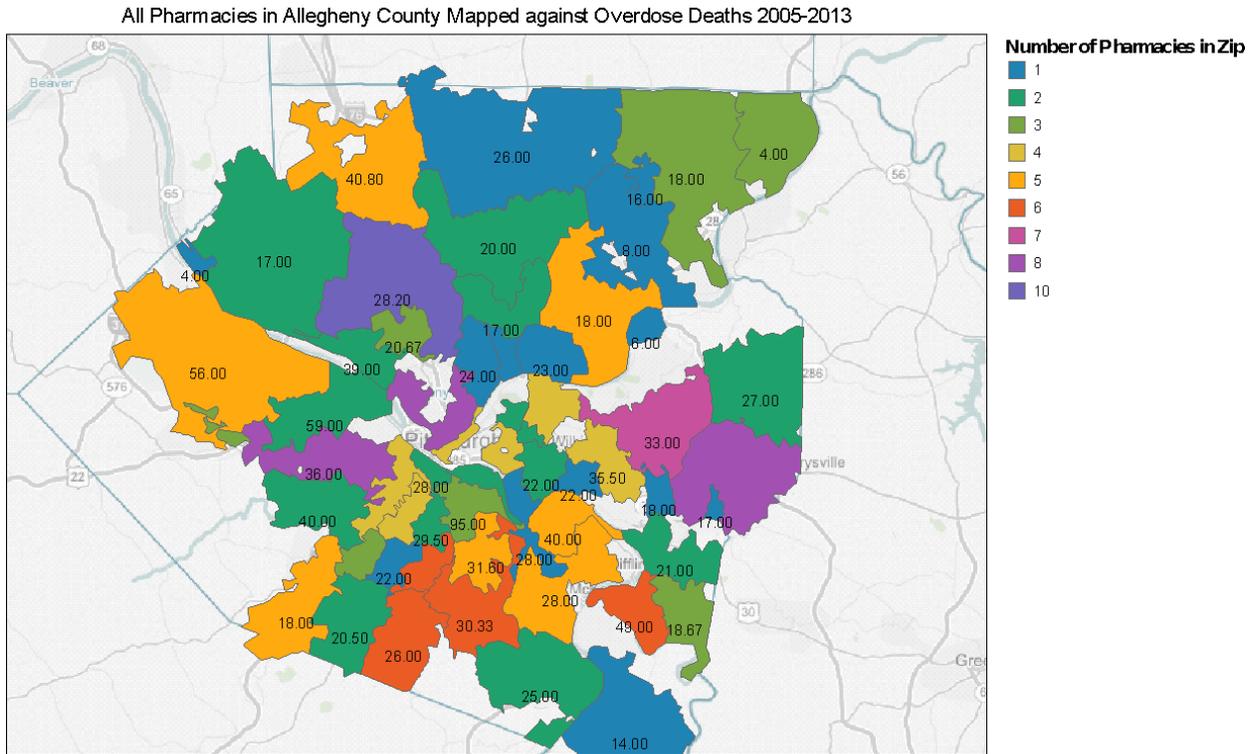


Figure 5. All Pharmacies in Allegheny County Mapped Against Overdose Deaths 2005-2013

As demonstrated by the map, by standardizing naloxone distribution through standing order participation across Allegheny County, the availability of the life-saving compound would increase and, presumably, public health professionals would see an overall decrease in the number of overdose deaths across the county.

Note that this assertion is made with the following caveat: there is not enough available data to reliably link naloxone availability with naloxone use and subsequent overdose death reversals. In addition, the counterfactuals are abundant and altogether untested, since there are a number of ethical questions involved in this evaluation. In other words, since we know that naloxone reverses opiate/opioid overdose symptoms (thereby avoiding overdose death), it is unreasonable to propose a study that provides the antidote to some and not to others in the study target population with the assumption that those not receiving naloxone would die from an overdose incident.

Most importantly though, few localities have implemented similar interventions to allow a research team to perform a longitudinal least-squares regression (LSR) synthetic population pre-post intervention comparison. As such, long-term policy studies are required to substantiate the claims suggested by these data, and to evaluate the

relevance of the claims set forth in this paper. In the end, if credence is given to the primary recommendation within this document, the Health Department will be able to realize the perpetual value that an ongoing, collaborative data portal will have in terms of public and population health benefit. That data can be used to solve similar issues with drug and disease epidemics across the globe through the development of complex LSR models using demographic, geographic, and public health data to predict the evolution of public health issues across communities, countries, and continents so that professionals are better prepared to proactively eliminate risks.

7.0 CORRECTIONAL FACILITIES

7.1 OVERVIEW

Formerly incarcerated individuals have a higher rate of mortality than the general population, especially in the time period immediately following release.⁴³ One source of this excess mortality is drug overdose. While incarcerated, many drug users experience withdrawal, which increases their vulnerability to overdose upon release. As the rates of opioid overdose have increased across the U.S. in the last decade, fatal opioid overdose in former prisoners has become a growing public health concern.

Specifically, an estimated one in 200 incarcerated individuals will die of heroin overdose within one month of release.⁴⁴ Moreover, the risk of death due to overdose is three to eight times higher in the two weeks following release compared to the weeks that follow.⁴⁵ One cohort study following 76,208 individuals released from Washington State Department of Corrections between 1999 and 2009 found that overdose was the leading cause of death in the cohort and opioids were responsible for 14.8% of all deaths.⁴⁶

Currently the Allegheny County Jail has several drug therapy options available to individuals who are incarcerated; however, none of these programs are specifically designed to reduce opioid use and overdose upon release. A literature review was conducted in order to identify effective interventions aimed at reducing opioid use and overdose upon release that could be adopted by the Allegheny County Jail.

7.2 LITERATURE REVIEW

7.2.1 Methods

A search of the PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) database was conducted on February 8th, 2016 using the phrase “((Prison OR Jail OR Parole OR Halfway House OR Criminal Justice) AND (Heroin OR Opioid) AND (Reduce OR Prevent)) OR ((Prison OR Jail OR Parole OR Halfway House) AND (Heroin OR Opioid) AND (Overdose))”. The search was limited to articles written in English, and resulted in 175 titles for review. 109 articles were excluded based on titles that were not relevant to the present review, leaving 66 abstracts. All 66 abstracts were read, and 43 were excluded due to content that was not relevant to the review or the fact that they were commentary or opinion pieces. Of the remaining 23 manuscripts, three could not be found via University of Pittsburgh Libraries, and two were excluded since they were only descriptive studies of incarcerated drug users. This process is outlined in Figure 6. All included articles can be found in. All

included articles can be found in [Appendix I: Literature Review Matrix, Correctional Facilities](#).

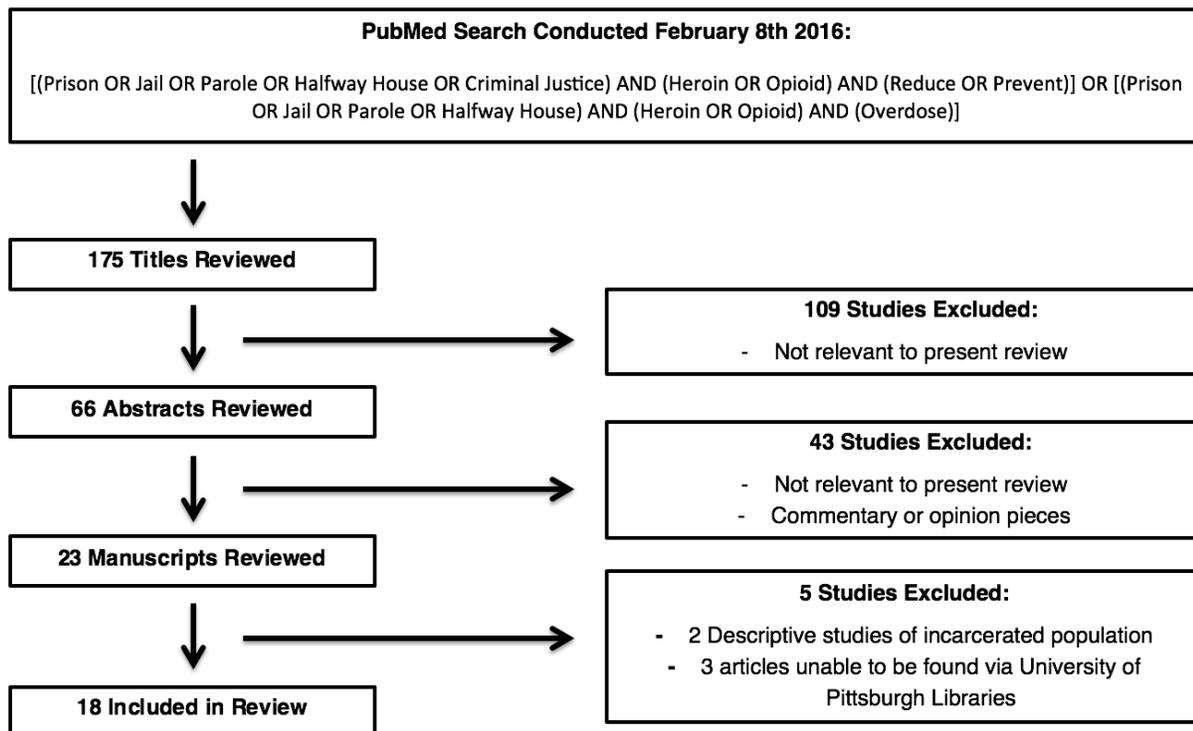


Figure 6. Flow Diagram Illustrating the Search Strategy for the Literature Review Regarding Interventions Aimed at Reducing Opioid Use and Mortality in Individuals Recently Released from Jail or Prison

7.2.2 Results

Overall, the studies included in the review investigated a wide variety of interventions and health outcomes in individuals who were incarcerated or recently incarcerated. Studies investigating similar interventions had remarkably consistent results. The majority of studies were of good quality; however, some of the randomized controlled trials (RCTs) lacked generalizability. Details regarding the design, results, and limitations of each of the studies reviewed can be found [Appendix I: Literature Review Matrix, Correctional Facilities](#). There were a total of 18 studies included in this review: seven randomized controlled trials (*Lee et al.*, *Rich et al.*, *Perry et al.*, *Perry et al.*, *Cropsey et al.*, and *Lobmaier et al.*), six retrospective cohort studies (*Bird et al.*, *Winter et al.*, *Degenhardt et al.*, *Larney et al.*, *DeBeck et al.*, and *Oser et al.*), three prospective cohort studies (*Jones et al.*, *Roshanfekar et al.*, and *Kinner et al.*) and two feasibility and acceptability studies (*Gordon et al.* and *Cropsey et al.*).

Four studies investigated medication-assisted treatments (MAT), and each found that MAT initiated during incarceration reduces the long-term drug-related and all-cause mortality. In addition to reducing mortality, individual studies found that MAT initiated

during incarceration reduced drug-use and criminality, and increased the likelihood of adherence to community-based MAT upon release. However, it is important to note that none of these studies found that MAT initiated during incarceration reduced the short-term overdose mortality risk seen in the two weeks following release. Three additional studies examined a combination of MAT and naloxone distribution and education. These studies again found that MAT and naloxone distribution reduced mortality upon release, though none specifically looked at short-term mortality risk. However, one study that examined MAT only versus MAT and naloxone found that the treatment group that was supplied with MAT and naloxone had a lower risk of re-incarceration in the year following release. One of these studies was a pilot study examining the feasibility and acceptability of naloxone education and distribution, and the results suggested that this intervention is both feasible and acceptable in this population. Additionally, there were two studies investigating the effects of incarceration and MAT which found that while incarceration alone increases the risk of injection drug use, MAT reduces that risk.

Two RCTs examining the efficacy of naltrexone injection compared to standard care found that this intervention reduces drug use, relapse, and re-arrest. An acceptability study also found that naltrexone injection is a well-accepted intervention for individuals who are incarcerated. However, while these results of these RCTs are in agreement, the study samples were very small and not necessarily representative of the general incarcerated population (e.g. young, white females).

One study investigating the effects of jail-based cognitive behavioral therapy (CBT) found that CBT reduces the risk of re-incarceration but not re-arrest in individuals originally arrested for a drug offense. Another study examining post-release risk factors for non-fatal overdose found that unemployment and psychological stress increase one's risk of non-fatal overdose upon release from incarcerations. Finally, the remaining studies all examined non-specific drug therapy treatments offered by jails and prisons. The majority of these studies found that any drug therapy initiated in jail or prison improves health behaviors and healthy decision-making upon release. However, the interventions and outcomes utilized in these studies were poorly defined, and several of these studies were limited by lack of generalizability.

7.2.3 Conclusions

Correctional facilities are in a unique position to have a tremendous impact on the burgeoning U.S. opioid epidemic. Jail or prison-based MAT, especially when continued in the community, is an effective method of reducing long-term overdose mortality upon release. Additionally, this intervention has been shown to reduce criminality and drug use. However, this strategy does not reduce mortality risk in the weeks immediately following release. Naloxone distribution and education is a feasible and acceptable intervention aimed at reducing overdose mortality immediately following release. However, clinical trials are necessary in order to determine the efficacy of this intervention.

7.3 RECOMMENDATIONS

The literature suggests that a combination of two interventions, (1) jail-based MAT and community MAT referral and (2) naloxone distribution and education upon release, would likely reduce short- and long-term drug use, criminality, overdose, and mortality in individuals released from the Allegheny County Jail.

8.0 EDUCATIONAL FACILITIES

8.1 OVERVIEW

According to a report from Trust for America's Health, Pennsylvania fared particularly poorly in terms of overdoses among youth. The overall rate among youth ages 12 to 25 was 11.8 per 100,000, while the national rate is 7.3.⁴⁷ In an attempt to combat this issue, Pennsylvania Governor Tom Wolf signed an Executive Order to support the storage and use of naloxone within all 500 schools across the state.⁴⁸ Under this order, school personnel have the ability to stock and use naloxone on school grounds without fear of liability under PA Act 139.⁴⁹ However, data from CDC WISQARS2 and the Allegheny County medical examiner show that the majority of youth overdose deaths were among older youth rather than all school-aged students, and this Executive Order does not apply to universities.⁵⁰

There is no evidence suggesting that youth are more likely to overdose in schools as opposed to other locations, although the Order also does not include provisions for a take-home program. In fact, overdoses in schools are not frequent events.⁵¹ Overdosing at home is much more common; a study in New York showed that 75% of nearly 3,000 individuals who overdosed did so at home.⁵²

As of 2005, roughly 10% of schools across the U.S. offered evidence-based programs to everyone.⁵³ However, prior studies of smoking cessation and alcohol-related curricula suggest that these in-school programs often fall short of expectations.⁵⁴ A literature review was conducted in order to identify effective interventions aimed at reducing opioid use and overdose among school-aged youth of Allegheny County.

8.2 LITERATURE REVIEW

8.2.1 Methods

A search of the PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>) database was conducted on February 9th, 2016 using the phrase “((School [Title/Abstract]) OR (Adolescent [Title/Abstract]) OR (Teen [Title/Abstract])) AND ((Naloxone OR Narcan OR Heroin))”. The search was limited to article written in English, and resulted in 388 titles for review. 353 articles were excluded from this literature review based on their title not being relevant to the present literature review, leaving 35 abstracts for review. After each of the 35 abstracts were read, 20 were excluded due to content that was not relevant to the review or due to the fact that there were commentary or opinion pieces. Of the 15

remaining studies, four were excluded for irrelevance to this review. The 11 remaining articles were included in this literature review. This process is outlined in Figure 7. All included articles can be found in [Appendix J: Literature Review Matrix, Educational Facilities](#).

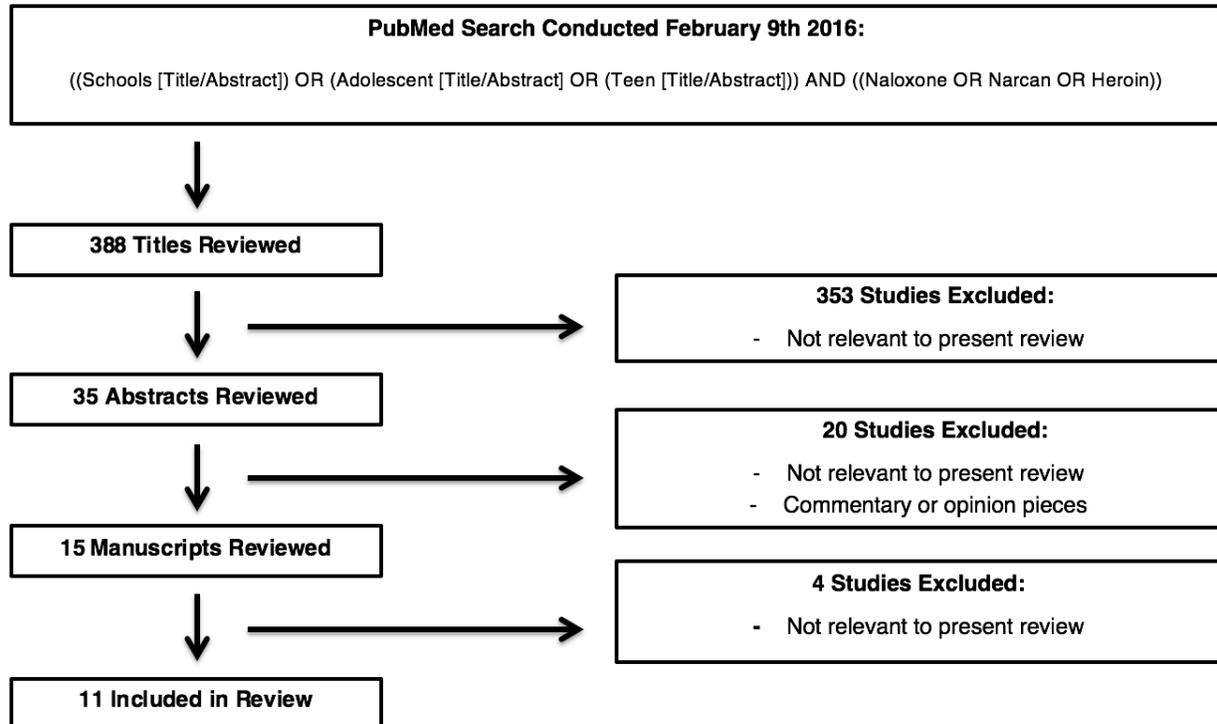


Figure 7. Flow Diagram Illustrating the Search Strategy for the Literature Review Regarding Interventions Aimed at Reducing Opioid Use and Mortality in Schools

8.2.2 Results

The studies included in the review investigated a wide variety of interventions and health outcomes among school-aged youth, although not necessarily in the school setting due to limited research. Studies investigated a wide variety of interventions and revealed the immediate need for additional studies to compare intervention options. The majority of studies had small samples sizes and low follow-up rates, lacked generalizability, and were often dated. Details regarding the design, results, and limitations of each of the studies reviewed can be found in [Appendix J: Literature Review Matrix, Educational Facilities](#). There were a total of 11 studies included in this review: one randomized controlled trial (*Woody et al.*), two retrospective studies (*Bell et al.* and *Hulse & Tait*), two prospective studies (*Pagano et al.*, and *Smyth et al.*), one observational study (*Millman and Khruj*), one case-series study (*Fishman et al.*), one modeling study (*Caulkins et al.*), and three reviews (*Minozzi et al.*, *Rowan et al.*, and *Schwartz et al.*).

Four studies focused on medication-assisted therapy for school-aged youth. Two of these studies weighed the use of methadone versus buprenorphine. Both studies had low- or

no- follow-up rates, but suggested that methadone had significantly longer retention than subjects treated with buprenorphine with this population. Additionally, they provided evidence that buprenorphine-naloxone may provide higher rates of treatment success in youths compared to simple detoxification in the first eight weeks, yet failed to justify this with long-term benefits. Extended release naltrexone, studied by the other two groups, suggested successful or “good” treatment results. Both of these studies had extremely small sample sizes, but provide some evidence that extended release or implantable naltrexone can serve as a feasible, yet costly treatment option for youth.

Three studies revealed the importance that the environment of treatment plays within the school-aged population. These studies supported the importance of fostering a positive environment during youth addiction treatment and one specifically focused upon peer helping as a tool to facilitate this. Another study stressed psychologically supported opiate substitution treatment. This aspect of treatment unique to the youth population is important to address.

Four studies concluded that despite the significant increase in heroin use by American teenagers, there is a lack of evidence-based research on a pharmacotherapeutic agent for this population and a lack of clinical experience in treating this population. These studies suggested there is an urgent need for further research to be conducted in this field, specifically additional randomized controlled trials comparing maintenance treatment with detoxification treatment or psychosocial treatment. However, a lack of evidence could be the result of difficulty in conducting trials with youth for practical and ethical reasons. The permanence of prevention efforts is undetermined and concrete evidence in school based drug treatment is not an activity whose primary benefits are associated with reduction in illicit drug use, but aimed in reduction towards tobacco and alcohol use. Overall, while these studies investigated multiple forms of treatment to reduce the burden of opiate overdose in school-aged youths, they were unique studies and not strongly supported. The interventions and outcomes utilized in this literature were often poorly defined and lacked generalizability.

8.2.3 Conclusions

The evidence base for in-school substance abuse programs is severely lacking. The existing literature has not revealed evidence that stockpiling naloxone in schools across the state will reduce youth mortality and the impact of such a program remains unclear. Rather the literature suggests that further studies must be done to weigh various treatment options, as this wide variety of exploratory studies suggest preliminary, but encouraging results.

The current Executive Order is unlikely to have a significant impact on youth mortality from drug overdose. Policymakers should work with school administration to consider the impact of distributing naloxone for use outside of school and support getting naloxone to those at high-risk. Officials should focus resources on other vulnerable populations that might benefit from such an order.

8.3 RECOMMENDATIONS

No formal recommendations are suggested for overdose prevention in schools. The literature suggests that there is no evidence base that stockpiling naloxone or naloxone use in school settings is a superior public health intervention. School and government officials should consider additional policies for alternative naloxone use, such as take-home programs.

9.0 VETERAN'S ADMINISTRATION MEDICAL SYSTEM

9.1 OVERVIEW

Patients receiving treatment in the Veteran's Administration (VA) medical system are identified as a high-risk, vulnerable population in regards to opioid misuse, abuse and overdose.⁵⁵ One study revealed that "the absolute number of [VA] patients on chronic opioids quadrupled from 2003 to 2008".⁵⁶

VA patients are at a high risk of overdosing due to the large number of opioid prescriptions, the lack of awareness of dangers associated with long-term opioid use, and the prevalence of comorbid conditions. The perception of risk of overdosing among veterans is small, with one study finding that 70% of the participants identify their risk as lower than average even when having an average of six risk factors.⁵⁷ Many veterans treated for chronic, non-cancer pain also possess an average of eight comorbidities, of which most are related to mental health.⁵⁸ Patients with mental health diagnoses that were prescribed opioids have been found to be at an increased risk of long-term opioid use and drug and alcohol use disorders, and to be more likely to obtain early refills.^{59,60}

Although the VA medical system operates under federal regulation, limiting the potential for local initiatives, a literature review was conducted in order to identify effective interventions aimed at reducing opioid use and overdose that could be implemented by the Allegheny County Health Department.

9.2 LITERATURE REVIEW

9.2.1 Methods

A search of published literature was conducted using the PubMed database on February 9, 2016 using the following phrases: (("veteran*" OR "veterans affairs" OR "veterans affairs medical center" OR "VA") AND (opioid* OR "opioid overdose" OR "opioid epidemic")), (("veteran*" OR "veterans affairs" OR "veterans affairs medical center") AND ("opioid*" OR "opioid overdose" OR "opioid epidemic") AND (reduce OR prevent)), and (("veteran*" OR "veterans affairs" OR "veterans affairs medical center") AND (opioid* OR heroin) AND (reduce OR prevent)). The search was limited to articles written in English. 1,451 articles appeared in our initial search results and 661 articles were excluded after a title review as they were not considered relevant to this project. Of the 790 articles that underwent an abstract review, 29 were considered relevant and included for a full text review (FTR). The FTR resulted in 22 articles being included in the final literature review,

with seven articles being excluded due to irrelevancy. This process is outlined in Figure 8. All included articles can be found in [Appendix K: Literature Review Matrix, Veteran's Administration Medical System](#).

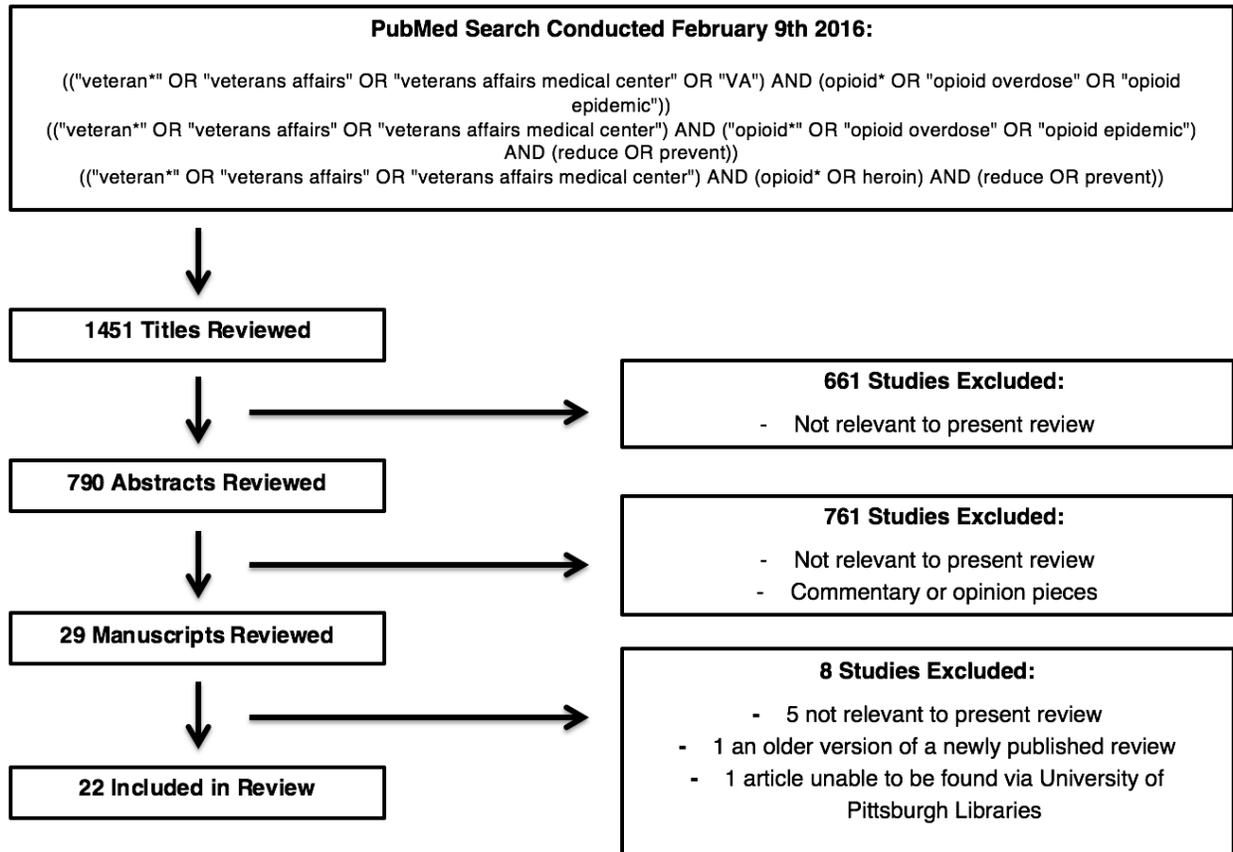


Figure 8. Flow Diagram Illustrating the Search Strategy for the Literature Review Regarding Interventions Aimed at Reducing Opioid Use and Mortality in Individuals Receiving Care at the Veteran's Affairs Medical Centers

9.2.2 Results

The studies included in this literature review investigated trends in prescribing patterns and overdoses due to opioids in the Veteran's Administration medical system. The majority were observational studies that were likely affected by bias. Details regarding the design results and limitations of each of the studies included in the review can be found in [Appendix K: Literature Review Matrix, Veteran's Administration Medical System](#). There were a total of 22 studies included in this review: one cross-sectional (*Dobscha et al.*), one multi-level, mixed effects regression analysis (*Timko et al.*), one repeat cohort (*Bohnert et al.*), one pre-/post-treatment multi-site clinical trial (*Worley et al.*), two case studies (*Hinrichs et al.* and *Westanmo et al.*), two prospective cohorts (*Wilder et al.* and *Ashrafioun et al.*), three observational studies (*Manhapra et al.*, *Barry et al.*, and *Mosher et al.*), and 11 retrospective cohort studies (*Edlund et al.*, *Sekhon et al.*, *Wu et al.*, *Gordon et al.*, *Miller et al.*, *Baser et al.*, *Seal et al.*, *Woody et al.*, *Ilgen et al.*, *Bachhubber et al.*,

and *Berger et al.*).

Six retrospective studies analyzed prescribing patterns and the prevalence of opioid prescriptions in the VA population. All concurred that patients within the VA medical system receive opioid prescriptions more frequently than the general population, with an increasing average day's supply. There is regional variation in high-dose prescribing patterns, as well as variations in prescribing patterns based on facilities. One study found that opioid abuse prevalence among patients prescribed an opioid was 3.04%.⁶¹ Additionally, due in part to the wars in Afghanistan and Iraq, the prevalence of young veterans with chronic opioid prescriptions increased four-fold between 2003-2008.⁵⁶ It was also found that there was a high prevalence of co-occurring psychotropic medication prescriptions in individuals who also received opioid prescriptions, with one study finding that opioid prescriptions were associated with an increased risk of suicide. The six studies all pertained to large sample studies, but did not address prescriptions for opioids that patients may have received outside of the VA system.

An additional four studies investigated the prevalence of unintentional opioid overdoses in the veteran population, and each found that there was a higher risk of unintentional overdoses in patients receiving long-acting opioids as opposed to short-acting opioids. Additionally, they found that the overdose trends found in the general population are also found in the VA population, with a good deal of regional variation. It is important to note that none of these studies accounted for potential access to non-prescription opioids or prescription opioids from a non-VA clinician, and did not track adherence to opioid prescriptions by patients. Other limitations include that the participants of many studies were mostly homogenous with respect to age, gender, and race, and that most results were based off of claims data, which may not always be complete.

Four studies examined MAT, such as methadone or buprenorphine, with mixed results in terms of effectiveness, patterns of use in the VA medical system and adherence to treatment. Three additional studies reviewed the perception of risk of opioid abuse, dependence and overdose in the VA population, as well as a patient's confidence in recognizing and responding correctly to an overdose in regards to naloxone administration. Both studies, though hampered by small sample sizes, found that perception of risk and overall knowledge pertaining to opioids and naloxone was low; however, with education, knowledge and confidence increase significantly. Two studies examined staff and clinician perceptions of chronic pain treatment and management, as well as potential interventions (including improved community partnerships and education for clinicians) that could result in improved efficiency in treating pain in the VA population. However, results are limited by the small sample size of both studies. One other study evaluated physician prescribing practices in regards to the VA guidelines, and found very low compliance to chronic, non-cancer pain prescribing guidelines.

Finally, the remaining studies investigated available services in regards to detoxification and addiction treatment, specifically with homeless veterans. One suggested that programs addressing homeless veterans should engage with those seeking addiction treatment to improve outcomes, while the other indicated the need to improve availability

of detoxification treatments as there currently exists high regional variability across the national VA medical system. Both studies were limited by homogenous patient populations, affecting generalizability.

9.2.3 Conclusions

Results from the literature review support the identification of veterans as a vulnerable population in the opioid epidemic, as most patients have multiple risk factors.^{55,57} Increased education for both providers and patients is needed to improve prescribing patterns, adherence to medication regimens, and awareness of the risks associated with long-term opioid use for chronic, non-cancer pain. Additionally, studies support the benefits of education pertaining to naloxone use for patients, caregivers and family members. A sub-population that could result in improved health outcomes, if effectively targeted, is homeless veterans, through improved access to detoxification and addiction treatments.

9.3 COMMUNITY PERSPECTIVES

In order to fully comprehend the issues faced by the VA, it was critical that we gain an internal perspective, both at a national and local level. In this vein, we reached out to a clinical pharmacy specialist (CPS), Dr. Stephanie Soddors, and a primary care physician (PCP), Dr. Benjamin Kisslinger at the Pittsburgh Veteran Affairs (VA) Healthcare System. We also sought the expertise of Dr. Elizabeth Oliva, the VA's national director of the Opioid and Overdose Education and Naloxone Distribution Program (OEND).

At the national level, the need for addressing the opiate epidemic in veteran populations and implementing harm reduction strategies is well recognized and supported. The VA launched its OEND program in May 2015 which has since been implemented at every VA site. This is an overarching harm reduction program that, among other things, has dispensed over 190,000 naloxone kits and recorded upwards of 170 reversals. This program has been largely modeled off successful community-based programs and adapted to the medical setting. Dr. Oliva summed up nicely the value in partnering with community programs with the statement, "We are standing on the shoulders of giants." This appreciation is undoubtedly mirrored at ACHD in their partnering with Prevention Point Pittsburgh (PPP). Strong ties with PPP and other community programs may serve as the ACHD's greatest resource in addressing the opiate epidemic in all vulnerable populations within the county.

At both the local and the national level, opioid prescribing has shifted to a last line of defense for pain management. This is not unique to the VA. When other strategies have been exhausted and opioids are still indicated, the VA has also become stricter with its prescription caps. This can be a double edged sword from the PCP's perspective. Even

in the urban setting of Pittsburgh there are still patients who will have difficulty in scheduling and obtaining transportation to their appointments. These caps may lower the likelihood of diversion and misuse, but they also create further burden for patients who depend on pain medication for everyday functioning. As the medical community begins to limit the supply of prescription pain medication there is also a justifiable fear that people will begin to transition to heroin to continue their habit. As with many issues in dealing with the opiate epidemic, this presents a delicate balancing act and highlights the importance of anticipating the consequences of even the most well-intended policies.

For those patients with chronic pain who require long-term opioid regimens, there are certain expectations of the patient that are outlined in a VA opioid agreement. These may include urine drug screens, participation in other therapies such as acupuncture and chiropractic therapy, psychiatric care, and other requirements the provider may see as clinically relevant. At the VA Pittsburgh Healthcare System, all patients treated with opioids for chronic pain are also co-prescribed naloxone. This prescription is supplemented with education that may consist of small group, one-on-one, or video sessions provided by either the PCP or CPS on proper utilization. Dr. Kisslinger sees the compulsory prescribing of naloxone as possibly overreaching and noted that his physician colleagues typically prefer to prescribe at their discretion rather than under blanket policies. This is a valid concern; however, given the Pharmacy Benefits Management division of the VA agreement to cover up to 28,000 kits and the efforts in place to work with the company producing naloxone (EVZIO) to reduce copays, it may be better in this case to overreach than under reach.

The issues presented above are again not unique to the VA, but they reveal a theme that is prevalent at the VA and medicine as a whole. Patient providers, especially physicians, place a high value on their freedom to exercise individual clinical judgment. A top-down approach that larger provider networks are prone to take may run the risk of alienating the people on the front lines. Dr. Kisslinger noted that one major issue that arises when trying to incorporate new practice policies is constraint on time. The medical home model of care employed at the VA can help lower this burden with a multidisciplinary team of clinicians for each patient. Clearly defined roles for each team member and effective communication can help ease the implementation of programs such as OEND. The impetus to act quickly in curbing opiate overdose rates needs to be balanced with thorough education and recognition for the concerns of individual prescribers. This fact is not lost on the VA. They have provided short educational videos for prescribers and patients and are continuing efforts to refine their approach in making it easier for providers to initiate conversations with their patients about opioid risk.

This process will, nonetheless, still have its hurdles moving forward. While the sentiment we gathered from our informants was overall quite optimistic, there will always be providers who find harm reduction strategies to be a form of enabling, and there will always be patients who feel entitled to their opioid prescriptions no matter the risk. The above findings barely skim the surface of the difficulties faced at the bedside in treating our veterans. These patients have provided a great service to their fellow citizens, and thus it is imperative that they receive top-notch, compassionate care. While these

discussions did not provide specific examples of how the ACHD can help serve the veteran population, given the inherent overlap in the goals of the VA and the ACHD, a close association on the issue of naloxone distribution and access could be of benefit. If the ACHD were to reach out to the Pittsburgh VA, Dr. Sodders affirmed that an active partnership, “is an opportunity [they] would consider.”

9.4 RECOMMENDATIONS

Based on review of the relevant literature, it is recommended that there is collaboration between VA and ACHD to ensure connection to community support systems as well as physician support to address prescription opioid risks.⁶² In addition, this collaboration must extend to connecting family members of veterans to opioid overdose prevention education and services.

10.0 POLICY RECOMMENDATION

The following recommendations were devised specifically to address the burden of opioid overdose in Allegheny County, PA and for potential implementation by the Allegheny County Health Department (ACHD). Recommendations were developed for each of the three vulnerable populations with respect to actionable items and policy proposals. Both short term and long term recommendations were developed. General recommendations for ACHD were also developed to address more broad actionable items.

10.1 RECOMMENDATIONS FOR INCARCERATED INDIVIDUALS

Based on evidence presented in the literature review, incarcerated individuals are at high risk of death from opioid overdose in the weeks and months following release. MAT has been shown to be most effective for overdose death prevention during the first year post-incarceration; however, MAT was not effective in preventing overdose death in the first two weeks post-incarceration when overdoses greatly increase among this population. It is therefore necessary to offer naloxone to incarcerated individuals upon release from the correctional facility to prevent overdose death in the weeks following release.

Short-term Recommendation

Naloxone should be offered in combination with appropriate in-person training to opiate addicted inmates upon release from the Allegheny County Jail. A model regulation was developed ([Appendix A: Model Regulation](#)) for ACHD to regulate naloxone distribution to all opiate-addicted inmates of the Allegheny County Jail upon re-entry to the community. The justification for this regulation stems from PA Act 315.²⁸ ACHD has the duty to 'prevent or remove conditions which constitute a menace to public health.' A considerable proportion of overdose deaths in Allegheny County occur in individuals who had been previously incarcerated in the Allegheny County Jail. Providing naloxone to Allegheny County Jail inmates upon release would prevent overdose deaths which should be considered a 'menace to public health.'

Long-term Recommendation

We recommend the Allegheny County Jail offer opiate-specific MAT (such as methadone or Suboxone) to incarcerated individuals who were addicted to opioids pre-incarceration. Community MAT referral should also be offered upon community re-entry.

Funding Sources

Funding sources for these types of interventions for incarcerated populations were considered. The most probable source of funding for an inmate community re-entry pilot naloxone distribution program would be a federal grant through the Substance Abuse and

Mental Health Services Administration (SAMSHA) or the Bureau of Justice. Currently, there are several calls for funding around overdose:

Residential Substance Abuse Treatment (RSAT) for State Prisoners Program
<https://www.bja.gov/Funding/RSAT16.pdf>

Second Chance Act Reentry Program for Adults with Co-Occurring Substance Abuse and Mental Disorders
<https://www.bja.gov/Funding/SCACoOccurring16.pdf>

10.2 RECOMMENDATIONS FOR SCHOOLS

No formal recommendations were developed for overdose prevention in schools. There was insufficient evidence to support stockpiling naloxone in schools for overdose prevention.

10.3 RECOMMENDATIONS FOR THE ALLEGHENY COUNTY VETERAN POPULATION

The VA Pittsburgh Health System (VAPHS) is following comprehensive national VA policies for opioid overdose prevention. Nevertheless, it is recommended the Allegheny County Health Department work to ensure opioid overdose prevention for Allegheny County veterans by collaborating with VAPHS on third-party naloxone distribution. VAPHS cannot provide naloxone to non-VA clients; however, family and friends of opiate-addicted VA clients should have access to naloxone should they witness an overdose. The VA and ACHD should work together to connect family and friends of opiate-addicted VA clients to Allegheny County community organizations that provide naloxone free of charge to third-parties in need.

10.4 GENERAL RECOMMENDATIONS FOR THE ALLEGHENY COUNTY HEALTH DEPARTMENT

Based on our findings from case studies of other states, we recommend that ACHD in conjunction with the Allegheny County Department of Human Services should conduct a large-scale in-person naloxone training program for first responders and Allegheny County bystanders. This program would also include naloxone distribution to bystanders to prevent personal overdose or overdose of friends and/or family members.

One of the chief assertions developed out of researching the prevalence of heroin and opioid-related deaths in Allegheny County is that more data must be collected and released to arm researchers and policy makers with the tools necessary to make strides in reducing the public and population health impacts of this epidemic. Thus, ACHD should expand data-sharing initiatives with the Veterans Health Administration across the Pittsburgh region, as well as improve the transfer of more complete and accurate information between the Department of Human Services (DHS), Allegheny County Jail, and the Health Department. Doing so would facilitate accurate research into the issue of heroin and opioid related overdose deaths en route to developing sound, data-driven policy recommendations that will improve the overall health of the Allegheny County population.

Academic institutions, such as the Public Health Dynamics Lab at the University of Pittsburgh or Carnegie Mellon University, should be consulted in order to provide low or no-cost research and modeling, and to provide ACHD access to information systems, public policy, and public health professionals. Engaging with local institution would expand the resources base of ACHD, and ensure that impactful improvements are made to the data landscape surrounding this particular issue while preserving funding for other needs within the agency. Moreover, this type of partnership between the ACHD and local academic institutions would signal an ongoing commitment to the community, and serve as a model for other local health departments experiencing the same public health tragedy.

APPENDIX A: MODEL REGULATION

OPIOID OVERDOSE PREVENTION FOR ALLEGHENY COUNTY JAIL RELEASEES: A NALOXONE DISTRIBUTION PROGRAM

PURPOSES

Incarcerated individuals have an increased risk of opioid overdose mortality upon release from a correctional facility. This increased risk of opioid overdose death can be attributed to forced drug withdrawal and decreased drug tolerance during incarceration, in addition to a return to pre-incarceration usage patterns upon release. The risk of overdose death in this incarcerated population poses a threat to public health and should be addressed by the Allegheny County Health Department. A significant proportion of opioid overdose-related deaths in Allegheny County occur in individuals who have been recently incarcerated in the Allegheny County Jail. Medication-assisted treatment has been shown to be most effective for overdose death prevention during the first year post-incarceration; however, naloxone (Narcan) is required for overdose prevention in the first two weeks post-incarceration when overdose death risk is highest in this population. Providing naloxone upon release from incarceration is a recommended, cost-effective approach for acute overdose mortality prevention in recently released inmates.

STATEMENT OF POLICY

The regulation of naloxone distribution upon release from the Allegheny County Jail is necessary to prevent a significant proportion of overdose related deaths. This regulation will ensure consistent implementation of naloxone distribution in the Allegheny County Jail as the single correctional facility in the county.

EFFECTIVE DATE

This regulation will be effective starting [insert date].

DEFINITIONS

The following terms when used in this Article have the following meanings:

“Board of Health” shall mean the Allegheny County Health Department Board of Health

“Department” shall mean the Allegheny County Health Department

“DHS” shall mean the Allegheny County Department of Human Services

“Jail” shall mean the Allegheny County Jail

“Naloxone Distribution Program” shall mean the Allegheny County Jail Naloxone Distribution Program

“Program Participant” shall mean an inmate of the Allegheny County Jail eligible for the Naloxone Distribution Program

“Program Administrator” shall mean Allegheny County Jail staff member involved in the Naloxone Distribution Program

ALLEGHENY COUNTY JAIL NALOXONE DISTRIBUTION PROGRAM REQUIREMENTS

A. The Department in collaboration with the DHS shall, subject to the approval of the Board of Health, devise operating procedures of the Naloxone Distribution Program to be executed by the Jail. The Board of Health shall not approve or alter any operating procedure without providing written notice of the new procedure(s) to the Allegheny County Council and Chief Executive at least thirty days prior to the Board of Health’s vote.

B. The Board of Health shall review the proposal for the Naloxone Distribution Program, and upon approval, shall forward written copies of all materials pertaining to the approved proposal to the County Chief Executive and Council, and to the Mayor and Council as well as the DHS and Jail Administration at least 90 days before the Naloxone Distribution Program proposes to begin operations.

C. The Jail will modify its intake procedures to include questions related to opiate addiction to identify eligible inmates for the Naloxone Distribution Program.

D. The Naloxone Distribution Program should enroll participants upon entry to the Jail by assigning each Program Participant with a unique identifier and record the Program Participant’s age, gender, self-reported race, zip code, and disease status (HIV, Hepatitis B or C). Participants may choose the option to report their past drug use (including substance, frequency, and dosage).

E. During the standard procedure for community reentry, every Program Participant should be offered training on proper use of naloxone in addition to a naloxone kit. Resource materials should be provided to educate the Program Participant about the risk of opioid overdose. Every Naloxone kit distributed should be assigned a unique identifier and recorded for the Program Participant in a centralized database. Unique kit identifier for individual encounter, type of naloxone, dosage, Program Administrator identifier, Program Participant identifier, and date of distribution should be recorded. The person documenting the encounter and all individuals providing materials or services to any Program Participant shall provide his or her initials. Documentation shall be retained by the Jail for at least three years.

F. The Naloxone Distribution Program should be used primarily for Allegheny County residents, but non-residents may participate if there are available resources.

REPORTING

The Department in collaboration with the Jail shall submit annual reports of progress of the Naloxone Distribution Program. Naloxone Distribution Program statistics and opioid overdose mortality and morbidity statistics for the Jail incarcerated population within one year of release should be included in this report.

APPEALS

Any person aggrieved by any action of the Department and the Jail may file an appeal in accordance with the Allegheny County Health Department Rules and Regulations, Article XI, entitled "Hearings and Appeals."

SEVERABILITY

Should any section, paragraph, sentence, clause or phrase of this Article be declared unconstitutional, null or otherwise invalid for any reason, the remainder of this Article shall not be affected thereby

APPENDIX B: COURSE SYLLABUS

Graduate School of Public Health
Department of Health Policy and Management
HPM 2033: Law in Public Health Practice
2 credits: Thursdays (3:30-5:20 p.m.), Room G46 BARCO

Professor: Elizabeth Van Nostrand, JD
Office: A734 Crabtree Hall
schmidte@pitt.edu
412.383.2231
Office Hours: Please email me to schedule a mutually convenient appointment.

Teaching Philosophy

The most meaningful measure of effective teaching is student learning. If my students grow and are challenged, especially through practice based professional learning, my teaching is successful. I take a personal interest in every student I teach. Students respond to high expectations, both in terms of what they must accomplish and in terms of their capabilities. I believe that students learn best when they think, do, write, speak, collaborate, and reflect.

Course Description

Local health departments play increasingly pivotal roles in the provision of community public health services; however, they also are experiencing diminished funding and reduced workforces. This course is the first of its kind: a practice-based, interdisciplinary, collaborative learning experience. Together, students will develop legal and public health interventions to address an issue identified by a practice partner as requiring the expertise of both cohorts.

This semester, the course topic will focus on public health and legal interventions to address the opiate epidemic. Our practice partner is the Allegheny County Health Department (ACHD).

Effective communication, project management, and work plan development skills are critical for success. Students in this course will benefit by applying both theoretical knowledge and research skills to analyze a “real life” problem and formulate meaningful outputs. Throughout the course, communication skills will be refined and networking opportunities in the practice communities will be provided. It is our goal to improve community health by providing the ACHD and others with effective intervention strategies.

Learning Objectives

By the end of this course, students will be able to:

- 1) Describe the federal, Pennsylvania and Allegheny County public health structure
- 2) Articulate the source, scope, and limitations of public health law and policy
- 3) Describe the legal rights and duties of the governmental public health system and its stakeholders
- 4) Understand the role that law and lawyers play in preserving, protecting and promoting the health of populations
- 5) Define the legal and policy implications of the opiate epidemic
- 6) Develop a vocabulary of legal and public health terms and to use it to effectively communicate
- 7) Draft model regulations, policies, and/or community outreach materials
- 8) Apply theoretical knowledge and research skills to address the opiate overdose issue
- 9) Demonstrate proficiency in project management and workplan development
- 10) Develop a translation and dissemination strategy
- 11) Conduct an informational presentation to stakeholders

Course Policies

Academic Integrity Policy:

All students are expected to adhere to the school's standards of academic honesty. Any work submitted by a student for evaluation must represent his/her own intellectual contribution and efforts. The GSPH policy on academic integrity, which is based on the University policy, is available online at <http://www.publichealth.pitt.edu/interior.php?pageID=126>. The policy includes obligations for faculty and students, procedures for adjudicating violations, and other critical information. Please take the time to read this policy.

Students committing acts of academic dishonesty, including plagiarism, unauthorized collaboration on assignments, cheating on exams, misrepresentation of data, and facilitating dishonesty by others, will receive sanctions appropriate to the violation(s) committed. Sanctions include, but are not limited to, reduction of a grade for an assignment or a course, failure of a course, and dismissal from GSPH.

All student violations of academic integrity must be documented by the appropriate faculty member: this documentation will be kept in a confidential student file maintained by the GSPH Office of Student Affairs. If a sanction for a violation is agreed upon by the student and instructor, the record of this agreement will be expunged from the student file upon the student's graduation. If the case is referred to the GSPH Academic Integrity Hearing Board, a record will remain in the student's permanent file.

Attendance Policy:

The American Bar Association and the School of Law require regular and punctual class attendance (see <http://www.law.pitt.edu/students/policies/attendance>). At the beginning of class, I will circulate an attendance sheet. It is your responsibility to ensure that you have signed the attendance sheet before leaving class. **Under the attendance policy, if you do not sign the attendance sheet before leaving class, you will be marked absent even if you were actually present in class.**

In terms of punctuality, if, for whatever reason, you arrive at class more than 10 minutes late or leave class more than 10 minutes early, you cannot sign the attendance sheet (or, if you have signed the attendance sheet, will nonetheless be marked absent). Regular attendance is defined as attendance and preparation at not less than 80% of the classes for the semester. **To be clear, if you are unprepared for class, you will be marked absent even if you are physically present in class.** Failure to satisfy these attendance requirements will result in your being certified out of the course with a grade of "U" (Unsatisfactory).

Computer and Cell Phone Policy:

Computers may be used for note taking, but not for purposes outside of the lecture (i.e., no use of Facebook, Twitter, or any other social media unconnected to the class). Students who use laptops, phones, other devices for purposes other than class-related tasks, as determined by the instructor, will reduce your grade.

Special Accommodations:

If you have a disability for which you are or may be requesting accommodation, please notify the instructor and the Disability Resources and Services no later than the second week of the term. You may be asked to provide documentation of your disability to determine the appropriateness of accommodations. To notify Disability Resources and Services, please call 412.648.7890 (Voice or TDD) to schedule an appointment. The Office is located in 216 William Pitt Union.

Required Materials

Dreamland: The True Tale of America's Opiate Epidemic
Sam Quinones

Additional materials can be found on CourseWeb.

Grading

The final grade will be determined as follows:

- Professionalism – 20%. Please see Professionalism Rubric on CourseWeb
- Peer Assessment – 20 %. Please see Professionalism Rubric on CourseWeb

- Public Health Policy Brief – 20%. Please see Public Health Policy Brief Rubric on CourseWeb
- Final Deliverable – 40%. Rubric will be provided prior to April 21, 2016.

The following scale will be used for letter grades. **THERE WILL BE NO ROUNDING.**

A+ 100% - 97%	A 96.9% - 93%	A- 92.9% - 90%
B+ 89.9% - 87%	B 86.9% - 83%	B- 82.9% - 80%
C+ 79.9% - 77%	C 76.9% - 73%	C- 72.9% - 70%
D+ 69.9% - 67%	D 66.9%-63%	D- 62.9% - 60%
F <60%		

Course Outline

The students are responsible for much of the decision-making in this course; therefore, the course outline must remain flexible. In addition, a number of professionals have graciously agreed to impart their expertise to the class. Their work schedules may precipitate changes in this outline.

Week	Date	Topics	Assignments
1	01.07.2016	<ul style="list-style-type: none"> • Course Introduction • Introduction to Public Health and Public Health Law 	
2	01.14.2016	<ul style="list-style-type: none"> • Guest Lecturer: LuAnn Brink, PhD, MPH, Chief Epidemiologist, ACHD • Pennsylvania's Public Health System and Infrastructure 	<ul style="list-style-type: none"> • Dreamland: Pages 1-55 • Research: Current issues surrounding the opiate epidemic
3	01.21.2016	<ul style="list-style-type: none"> • Practical Skills: Conducting a Meeting and Project Management • Deliverables: Policy briefs 	<ul style="list-style-type: none"> • Dreamland: Pages 56-123 • Research: Current issues surrounding the opiate epidemic • NPR Here and Now Podcast – Surviving Opioid Overdose
4	01.28.16	<ul style="list-style-type: none"> • Guest Lecturer: Abby Wilson, JD, LLM, Deputy Director, ACHD (4:30-5:30 p.m) • Deliverables: White Paper and Presentation 	<ul style="list-style-type: none"> • Dreamland: Pages 124-168 • Recommendations Regarding the Tattoo Industry in Allegheny County • Research: Current issues surrounding the opiate epidemic
5	02.04.16	<ul style="list-style-type: none"> • Guest Lecturer: Jonathan Han, MD, UPMC • Review of Recommendations Regarding the Tattoo Industry in Allegheny County 	<ul style="list-style-type: none"> • Dreamland: Pages 169-221 • Research: Current issues surrounding the opiate epidemic
6	02.11.16	<ul style="list-style-type: none"> • Guest Lecturer: Alice Bell, L.C.S.W., Overdose Prevention Project Coordinator, Prevention Point Pittsburgh • Using Models to Examine Public Health Law Issues 	<ul style="list-style-type: none"> • Dreamland: Pages 222-263 • Research: Current issues surrounding the opiate epidemic
7	02.18.16	<ul style="list-style-type: none"> • Guest Lecturer: Brian Demsey, DEA • Legislative and Regulatory Law 	<ul style="list-style-type: none"> • Dreamland: Pages 264-315

Week	Date	Topics	Assignments
			<ul style="list-style-type: none"> • LawAtlas • Research: Current issues surrounding the opiate epidemic
8	02.25.16	<ul style="list-style-type: none"> • Guest Lecturer: Jeanine M. Buchanich, MEd, PhD, Assistant Professor, Pitt Public Health • Preparing deliverables and presentation for the ACHD 	<ul style="list-style-type: none"> • Dreamland: Pages 316-356 • Research: Current issues surrounding the opiate epidemic
9	03.03.16	<ul style="list-style-type: none"> • Preparing deliverables and presentation for the ACHD 	<ul style="list-style-type: none"> • Research: Current issues surrounding the opiate epidemic
10	03.10.16	<ul style="list-style-type: none"> • SPRING BREAK 	<ul style="list-style-type: none"> • Have fun!
11	03.17.16	<ul style="list-style-type: none"> • Preparing deliverables and presentation for the ACHD 	<ul style="list-style-type: none"> • Public Health Policy Brief Due • Research: Current issues surrounding the opiate epidemic • Pitt Public Health Movie Night: OxyContin Express. 7 p.m. at the Pitt Public Health Auditorium
12	03.24.16	<ul style="list-style-type: none"> • Guest Lecturer: Sam Quinones, author of <i>Dreamland</i> • Preparing deliverables and presentation for the ACHD 	
13	03.31.16	<ul style="list-style-type: none"> • Preparing deliverables and presentation for the ACHD 	
14	04.07.16	<ul style="list-style-type: none"> • Preparing deliverables and presentation for the ACHD 	
15	04.14.16	<ul style="list-style-type: none"> • Rehearsal for the ACHD presentation 	
16	04.21.16	<ul style="list-style-type: none"> • 4:00 p.m. – 5:00 p.m. Presentation to the ACHD leadership 	

Faculty Course Competency Mapping Exercise

Pitt Healthcare Management Competency Model	Will this Competency be Emphasized in this Course?	Teaching Methods (e.g., Reading, Lectures, Guest Speakers, Class Discussions, Presentations, Field Experiences, Simulation, Consulting Project)	How Will You Assess? (e.g. weekly participation score, debate, policy memo, business plan, term paper, multiple choice exam, short-answer exam)
Cross Cutting			
Analytical Thinking	Yes	Lectures; Class discussion; Presentations	Public Health Policy Brief; Presentation; Deliverables
Communication	Yes	Class Discussion; Presentations; Drafting model regulations and policies	Presentation; Professionalism; Public Health Policy Brief; Deliverables
Systems Thinking	Yes	Presentations	Public Health Policy Brief; Deliverables
Self-Actualization			
Accountability	Yes	Deliverables; Public Health Policy Brief; Presentation	Public Health Policy Brief Rubric; Professionalism Rubric;

			Deliverables Rubric; Peer Assessment Rubric
Professionalism	Yes	Finishing deliverables timely; Interacting with the Allegheny County Health Department and guest lecturers	Professionalism Rubric; Deliverables Rubric; Peer Assessment Rubric
Self-Development	Yes	Class discussions; Formal and informal discussion on legal and ethical issues	Professionalism Rubric
Management			
Financial Skills	Yes	Working within a budget	Deliverables
Human Resources Management	No	N/A	N/A
Information Technology (IT) Management	No	N/A	N/A
Leadership	Yes	Working in groups on work product; presenting to the Allegheny County Health Department; Incorporating feedback	Professionalism Rubric;
Performance Measurement and Process Improvement	No	N/A	N/A
Contextual-Environmental Understanding			
Community Orientation	Yes	Working with the Allegheny County Health Department	Deliverables; Professionalism Rubric
Organizational Awareness	Yes	Lecture by the Allegheny County Health Department	N/A
Strategic Orientation	No	N/A	N/A

	Lower-Level Methods	Higher-Level Methods	Total
Specify which particular methods you will employ to <u>teach</u> students:	Readings; Lectures; Guest Lectures	Interactive development of project	n/a
Estimated % of Course Time Relying on these Teaching Methods:	____30____%	____70____%	100%
Specify which particular methods you will employ to <u>assess</u> students:	Health Policy Brief Rubric	Professionalism Rubric; Peer Assessment Rubric; Deliverables Rubric	n/a
Estimated % of Course Time Relying on these Assessment Methods	____20____%	____80____%	

APPENDIX C: BIOSKETCHES

Alexandria Ashraf is a second year MPH candidate, in the Department of Human Genetics at the University of Pittsburgh GSPH. Before entering her current degree program, she earned her B.S. in Biology from West Virginia University. Her research focuses on examining the availability of healthcare providers and support groups in rural Appalachia for patients and families afflicted with adult-onset genetic neurological disorders. Upon graduating, Alexandria would like to pursue a medical doctorate, concentrating in ophthalmology. Alexandria has a vested interest in reducing the stigma associated with addiction therapy, including distribution of naloxone.

Sara Brooks is a second year MPH candidate at the University of Pittsburgh GSPH. She is in the Department of Environmental and Occupational Health, and is also pursuing a certificate in Environmental Health Risk Assessment. She earned a B.A. in Spanish from Carnegie Mellon University, and has worked as a Certified Pharmacy Technician in a hospital setting for the last four years. She is also currently interning at United Steelworkers in the Health, Safety, and Environment Department, participating in a research project on hazard identification and control in over 100 metal and nonmetal mines in the United States. Sara's interest in harm reduction techniques and their application to the opioid epidemic in the United States stems from losing a friend to addiction.

Andrew Cobb is a second year MPPM student at the H. John Heinz III College at Carnegie Mellon University, focusing in health policy, particularly in the Veterans Health Administration and Department of Defense Health Care System. Andrew holds a B.A. in history from the Dietrich College of Humanities and Social Sciences at Carnegie Mellon University. Prior to returning to Carnegie Mellon University in 2013, Andrew served in the United States Marine Corps from 2006 to 2013. Three of his years with the Marine Corps were spent serving in a special billet with the Wounded Warrior Regiment in Landstuhl, Germany, working with Marine and Navy wounded, ill, and injured patients and their families.

Michael Coutinho is a third year undergraduate student studying Economics in the Dietrich School of Arts and Sciences at the University of Pittsburgh. Michael is also minoring in Chemistry and currently involved in biochemical research in the Department of Chemistry at the University of Pittsburgh. Michael is interesting in pursuing an MPH upon completion of his undergraduate work. His interest in opioid abuse and overdose stems from his studies in health economics.

Kathleen Creppage is a second year DrPH student in Epidemiology and is currently working on her dissertation around heroin-related overdose in Pennsylvania. Kathleen has an MPH from the University of Pittsburgh in Epidemiology and two B.S. degrees in Immunology, and Infectious Diseases and Toxicology from Penn State University. Prior to enrolling as a doctoral student at the University of Pittsburgh, Kathleen was stationed for two years in Raleigh, North Carolina while she completed the Centers for Disease Control/Council of State and Territorial Epidemiologists Applied Epidemiology Fellowship in substance abuse. Kathleen currently works on a project around traumatic brain injury and is particularly interested in drug overdose and injury epidemiology with an emphasis on application and translation.

Alex Dulin is a second year MPH candidate in the Department of Health Policy and Management at the University of Pittsburgh Graduate School of Public Health. She is also completing the Global Health certificate program within the school. Alex earned her B.S. in Biology, with a minor in Global Public Health, from The Ohio State University. Her research focuses include global health, comparative healthcare systems, and access to healthcare services, and she currently works with the Center for Public Health Practice at the University of Pittsburgh. Alex's passion for health policy and advocacy, specifically in regards to vulnerable and international populations, led her interest in addressing the opioid epidemic.

Spencer Keil is a first year MD candidate at the University of Pittsburgh School of Medicine. He has a B.S. from the University of Miami where he graduated with departmental honors in neuroscience. His clinical interests are in psychiatric services provided at correctional institutions. His research interests lie at the intersection of mental illness, public health, and law. Spencer is currently working on a research project within the Law & Psychiatry Program at UPSOM examining how factors such as substance abuse may mediate the progression from gun access to gun carrying in serious youth offenders.

Julie Murphy is a second year MPH student studying Behavioral and Community Health Sciences at the University of Pittsburgh GSPH. She graduated from the University of Central Florida with a B.S. in biology. Julie then worked as a microbiologist before she recognized her desire to directly improve patient health and quality of life, thus bringing her to the University of Pittsburgh's GSPH. Julie worked for UPMC on quality improvement for maternal and child health in addition to working for the Pennsylvania Department of Health, Bureau of Epidemiology on a program to promote judicious prescribing practices and antimicrobial resistance stewardship. Following graduation, she plans to attend dental school with the ultimate goal of delivering dental services to low-income populations. Julie's interest in this subject comes from a close friendship with a former addict.

John Ries is a second year MPH candidate at the University of Pittsburgh GSPH. He is studying in the department of Behavioral and Community Health Sciences with a focus on maternal and child health. With a particular interest in infant mortality, John is gearing his thesis research toward the health inequity facing African American women in Allegheny County. John earned his B.S. at the University of Pittsburgh, and is working as a research assistant in the department of Pulmonary, Allergy, and Critical Care medicine at the University of Pittsburgh School of Medicine while completing his MPH. John is particularly interested in the opioid epidemic due to personal connection to those affected by opiate abuse.

Natalie Suder is a second year DrPH student studying Epidemiology at the University of Pittsburgh GSPH. Natalie studied Biology and Spanish at Penn State University, and then completed her MPH in Infectious Diseases and Microbiology at the University of Pittsburgh while working as a clinical virology research specialist. Natalie is currently a trainee in the Department of Epidemiology Cardiovascular Training Program and is working toward her dissertation focused on subclinical atherosclerosis. Natalie's interest in opioid abuse and overdose stems from her interest in improving the health of vulnerable and underserved populations.

Abby Talbert is a first year MPH student studying Behavioral and Community Health Sciences at the University of Pittsburgh GSPH. She also plans to complete a certificate in public health program evaluation. Abby recently graduated from the Penn State University with a B.S. in immunology and infectious diseases and minors in global health and biochemistry. After completing a fieldwork study on the South African health care system during her undergraduate studies, her interest in analyzing cultural determinants of community health to form sustainable health practices emerged. As an intern at the Allegheny County Health Department, she aided the organization's efforts to become nationally public health accredited. In addition, she worked on The Plan for a Healthier Allegheny, developing interest in using both quality improvement and policy to drive public health action. Abby's passion to create policy and programmatic recommendations led to her interest in addressing the opioid epidemic.

Lauren Torso is a second year DrPH student in the Epidemiology Department of the University of Pittsburgh, GSPH. She is also a Graduate Student Researcher with the Bureau of Assessment, Statistics, and Epidemiology at the Allegheny County Health Department. Her focus is infectious disease epidemiology. In 2011, she earned her MPH from the Colorado School of Public Health. Lauren's DrPH dissertation research focuses on the epidemiology of community-acquired Legionnaires' disease in Allegheny County. Lauren is also the Chairperson of Pitt Public Health's Student Public Health Epidemic Response Effort. Her involvement with this organization provided an introduction to overdose prevention projects and research

Elizabeth Van Nostrand, JD created "Law in Public Health Practice" as an interdisciplinary, practice-based course in which students at Pitt partner with a public health organization to address an issue requiring the expertise of multiple cohorts. This course was developed during a Robert Wood Johnson Public Health Law Education fellowship. She is an Assistant Professor in the Department of Health Policy and Management at Pitt Public Health, an Adjunct Professor in the School of Law, and the Director of Pitt Public Health's JD/MPH program. Professor Van Nostrand is also the PI of a CDC-funded grant developing a legal tool for the nation's Medical Reserve Corps, and PI of the HRSA funded Mid-Atlantic Regional Public Health Training Center. Previously, she practiced litigation law with the United States Department of Agriculture in Washington, DC, with Thompson & Knight in Dallas, and with several small law firms in New Orleans.

APPENDIX D: ACT 139

**CONTROLLED SUBSTANCE, DRUG, DEVICE AND COSMETIC ACT – DRUG
OVERDOSE RESPONSE IMMUNITY**

ACT of SEPT. 30, 2014, P.L. 2487, No. 139
Session of 2014
No. 2014-139

SB 1164

AN ACT

Amending the act of April 14, 1972 (P.L.233, No.64), entitled "An act relating to the manufacture, sale and possession of controlled substances, other drugs, devices and cosmetics; conferring powers on the courts and the secretary and Department of Health, and a newly created Pennsylvania Drug, Device and Cosmetic Board; establishing schedules of controlled substances; providing penalties; requiring registration of persons engaged in the drug trade and for the revocation or suspension of certain licenses and registrations; and repealing an act," providing for drug overdose response immunity.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. The act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, is amended by adding sections to read:

Section 13.7. Drug Overdose Response Immunity.--(a) A person may not be charged and shall be immune from prosecution for any offense listed in subsection (b) and for a violation of probation or parole if the person can establish the following:

(1) law enforcement officers only became aware of the person's commission of an offense listed in subsection (b) because the person transported a person experiencing a drug overdose event to a law enforcement agency, a campus security office or a health care facility; or

(2) all of the following apply:

(i) the person reported, in good faith, a drug overdose event to a law enforcement officer, the 911 system, a campus security officer or emergency services personnel and the report was made on the reasonable belief that another person was in need of immediate medical attention and was necessary to prevent death or serious bodily injury due to a drug overdose;

(ii) the person provided his own name and location and cooperated with the law enforcement officer, 911 system, campus security officer or emergency services personnel; and

(iii) the person remained with the person needing immediate medical attention until a law enforcement officer, a campus security officer or emergency services personnel arrived.

(b) The prohibition on charging or prosecuting a person as described in subsection (a) bars charging or prosecuting a person for probation and parole violations and for violations of section 13(a)(5), (16), (19), (31), (32), (33) and (37).

(c) Persons experiencing drug overdose events may not be charged and shall be immune from prosecution as provided in subsection (b) if a person who transported or reported and remained with them may not be charged and is entitled to immunity under this section.

(d) The prohibition on charging or prosecuting a person as described in this section is limited in the following respects:

(1) This section may not bar charging or prosecuting a person for offenses enumerated in subsection (b) if a law enforcement officer obtains information prior to or independent of the action of seeking or obtaining emergency assistance as described in subsection (a).

(2) This section may not interfere with or prevent the investigation, arrest, charging or prosecution of a person for the delivery or distribution of a controlled substance, drug-induced homicide or any other crime not set forth in subsection (b).

(3) This section may not bar the admissibility of any evidence in connection with the investigation and prosecution for any other prosecution not barred by this section.

(4) This section may not bar the admissibility of any evidence in connection with the investigation and prosecution of a crime with regard to another defendant who does not independently qualify for the prohibition on charging or prosecuting a person as provided for by this section.

(e) In addition to any other applicable immunity or limitation on civil liability, a law enforcement officer or prosecuting attorney who, acting in good faith, charges a person who is thereafter determined to be entitled to immunity under this section shall not be subject to civil liability for the filing of the charges.

(f) As used in this section, the following words and phrases shall have the meanings given to them in this subsection unless the context clearly indicates otherwise:

"911 system." A system, including enhanced 911 service and a wireless E-911 system, that permits a person dialing 911 by telephone to be connected to a public safety answering point, via normal telephone facilities, for the reporting of police, fire, medical or other emergency situations.

"Campus security officer." An employee of an institution of higher education charged with maintaining the safety and security of the property of the institution and the persons on the property.

"Drug overdose event." An acute medical condition, including, but not limited to, severe physical illness, coma, mania, hysteria or death, which is the result of consumption or use of one or more controlled substances causing an adverse reaction. A patient's condition shall be deemed to be a drug overdose if a prudent layperson, possessing an average knowledge of medicine and health, would

reasonably believe that the condition is in fact a drug overdose and requires immediate medical attention.

"Emergency services personnel." Individuals, including a trained volunteer or a member of the armed forces of the United States or the National Guard, whose official or assigned responsibilities include performing or directly supporting the performance of emergency medical and rescue services or firefighting.

"Law enforcement officer." A person who by virtue of the person's office or public employment is vested by law with a duty to maintain public order or to make arrests for offenses, whether that duty extends to all offenses or is limited to specific offenses, or a person on active State duty under 51 Pa.C.S. § 508 (relating to active duty for emergency).

Section 13.8. Drug Overdose Medication.--(a) The department, in carrying out its duties under 28 Pa. Code Ch. 1023 (relating to personnel), shall have the following duties:

(1) By December 31, 2014, amend the prehospital practitioner scope of practice of emergency medical services providers to include the administration of naloxone.

(2) In consultation with the Pennsylvania Emergency Health Services Council, implement training, treatment protocols, equipment lists and other policies and procedures for all types of emergency medical services providers.

(3) In consultation with the Department of Drug and Alcohol Programs, develop or approve training and instructional materials about recognizing opioid-related overdoses, administering naloxone and promptly seeking medical attention. The training and instruction materials shall be provided free of charge on the Internet.

(b) A law enforcement agency, fire department or fire company may enter into written agreements with emergency medical services agencies, with the consent of that agency's medical director or a physician, to do the following:

(1) Obtain a supply of naloxone.

(2) Authorize a law enforcement officer or firefighter who has completed training under subsection (a)(2), or who has received the training and instructional materials under subsection (a)(3), to administer naloxone to an individual undergoing or believed to be undergoing an opioid-related drug overdose.

(c) Notwithstanding any other law to the contrary, a health care professional otherwise authorized to prescribe naloxone may dispense, prescribe or distribute naloxone directly or by a standing order to an authorized law enforcement officer or firefighter in accordance with an agreement under subsection (b) or to a person at risk of experiencing an opioid-related overdose or family member, friend or other person in a position to assist a person at risk of experiencing an opioid-related overdose.

(d) The provisions of the act of September 27, 1961 (P.L.1700, No.699), known as the "Pharmacy Act," shall not apply to a law enforcement officer or firefighter who stores naloxone pursuant to an agreement under subsection (b), and in accordance with directions from the health care professional that prescribed,

dispensed or distributed the naloxone, or to a person or organization acting at the direction of a health care professional authorized to prescribe naloxone so long as such activities are undertaken without charge or compensation.

(e) (1) A licensed health care professional who, acting in good faith, prescribes or dispenses naloxone shall not be subject to any criminal or civil liability or any professional disciplinary action for:

- (i) such prescribing or dispensing; or
- (ii) any outcomes resulting from the eventual administration of naloxone.

(2) The immunity under paragraph (1) shall not apply to a health professional who acts with intent to harm or with reckless indifference to a substantial risk of harm.

(f) (1) A person, law enforcement agency, fire department or fire company under subsection (b)(2) or (c) who, acting in good faith and with reasonable care, administers naloxone to another person whom the person believes to be suffering an opioid-related drug overdose:

- (i) Shall be immune from criminal prosecution, sanction under any professional licensing statute and civil liability for such act.
- (ii) Shall not be subject to professional review for such act.
- (iii) Shall not be liable for any civil damages for acts or omissions resulting from such act.

(2) Receipt of training and instructional materials that meet the criteria of subsection (a) and the prompt seeking of additional medical assistance shall create a rebuttable presumption that the person acted with reasonable care in administering naloxone.

(g) Nothing in this section shall be interpreted to limit any existing immunities for emergency response providers and others provided for under 42 Pa.C.S. § 8332 (relating to emergency response provider and bystander good Samaritan civil immunity).

Section 2. This act shall take effect in 60 days.

APPROVED--The 30th day of September, A.D. 2014.

TOM CORBETT

APPENDIX E: PENNSYLVANIA DEPARTMENT OF HEALTH STANDING ORDER



STANDING ORDER DOH-002-2016

Naloxone Prescription for Overdose Prevention

Naloxone Hydrochloride (Naloxone) is a medication indicated for reversal of opioid overdose in the event of a drug overdose that is the result of consumption or use of one or more opioid-related drugs causing a drug overdose event.

I. PURPOSE

This standing order is intended to ensure that residents of the Commonwealth of Pennsylvania who are at risk of experiencing an opioid-related overdose, or who are family members, friends or other persons who are in a position to assist a person at risk of experiencing an opioid-related overdose (Eligible Persons), are able to obtain Naloxone. This order is not intended to be used by organizations who employ or contract with medical staff who are authorized to write prescriptions. Such organizations should utilize the medical professionals with whom they have a relationship to write prescriptions specific to personnel who would be expected to administer Naloxone, and would be wise to ensure that all such personnel are appropriately trained in the administration of Naloxone.

II. AUTHORITY

This standing order is issued pursuant to Act 139 of 2014 (Act 139) (amending The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101 et seq.)), which permits health care professionals otherwise authorized to prescribe Naloxone to prescribe it via standing order to Eligible Persons.

III. AUTHORIZATION

This standing order may be used by Eligible Persons as a prescription or third-party prescription to obtain Naloxone from a pharmacy in the event that they are unable to obtain Naloxone or a prescription for Naloxone from their regular health care providers or another source. This order is authorization for pharmacists to dispense Naloxone and devices for its administration SOLELY in the forms prescribed herein.

IV. TRAINING AND INSTRUCTIONAL MATERIALS

Prior to obtaining Naloxone under this standing order, Eligible Persons are strongly advised to complete a training program approved by the Pennsylvania Department of Health (DOH) in consultation with the Pennsylvania Department of Drug and Alcohol Programs (DDAP), such as the one found on line at http://www.getnaloxonenow.org/online_training.html or at the DOH

website at <http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/A-D/Pages/Act-139-of-2014.aspx#.VTtP2WTD-Uk> and obtain a certificate of completion. Act 139 does not require training; however, training is necessary in order to ensure that Eligible Persons are protected from legal liability to the extent that Act 139 provides that the receipt of DOH/DDAP-approved training and instructional materials and prompt seeking of additional medical assistance creates a rebuttable presumption that an Eligible Person acted with reasonable care in administering Naloxone.

V. SIGNS AND SYMPTOMS OF OPIOID OVERDOSE

1. A history of current narcotic or opioid use or fentanyl patches on skin or needle in the body.
2. Unresponsive or unconscious individuals.
3. Not breathing or slow/shallow respirations
4. Snoring or gurgling sounds (due to partial upper airway obstruction).
5. Blue lips and/or nail beds.
6. Pinpoint pupils.
7. Clammy skin.
8. Note that individuals in cardiac arrest from all causes share many symptoms with someone with a narcotic overdose (unresponsiveness, not breathing, snoring/gurgling sounds, and blue skin/nail beds). If no pulse, these individuals are in cardiac arrest and require CPR.

VI. APPROPRIATE USE AND DIRECTIONS

Eligible Persons should be aware of the following information when dealing with a person who it is suspected is experiencing an opioid overdose event:

- 1. Call 911 for EMS to be dispatched.**
2. In cardiac arrest or pulseless patients: Call 911 for EMS and start CPR if able and trained to do so. In cardiac arrest, CPR is the most important treatment, and any attempt to administer Naloxone should not interrupt chest compressions and rescue breathing.
3. Naloxone should only be given to someone suspected of opioid overdose as noted in the signs and symptoms listed in Section V above.
4. In respiratory arrest or a non-breathing patient: If able to do rescue breathing, rescue breathing takes priority over Naloxone administration. Administer Naloxone if possible while doing rescue breathing.
5. Administration of Naloxone (only give to someone with suspected opioid overdose based on signs and symptoms listed in Section V above).

A. INTRA-NASAL NALOXONE

Eligible Persons should be provided with the following:

1. Luer-lock syringes and mucosal atomization devices (MAD)

- a. Two 2 mL Luer-Jet luer-lock syringes prefilled with naloxone (concentration 1 mg/mL);
- b. Two mucosal atomization devices
- c. Patient information pamphlet containing dosage and administration instructions.

2. NARCAN Nasal Spray

- a. Carton containing two blister packages each with single 4 mg dose of naloxone in a 0.1 mL intranasal spray
- b. Package insert containing dosage and administration instructions.

Instructions for use:

1. Luer-lock syringes and mucosal atomization devices (MAD)

- a. Pop off two yellow caps from the delivery syringe and one red cap from the naloxone vial.
- b. Screw the Naloxone vial gently into the delivery syringe.
- c. Screw the mucosal atomizer device onto the top of the syringe.
- d. Spray half (1ml) of the Naloxone in one nostril and the other half (1ml) in the other nostril.
- e. Note: Administer the Naloxone in a quick burst to ensure that it is atomized. A slow administration will cause liquid to trickle in without being atomized properly, which will slow delivery to the bloodstream.
- f. Continue to monitor breathing and pulse. **IF NOT BREATHING, give rescue breathing. IF NO PULSE, start CPR, if able and trained to do so.**
- g. If patient does not awaken after 4 minutes, administer second dose of Naloxone (if available) (1mL) briskly in one nostril and the other half (1mL) briskly in the other nostril.

- h. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.

2. NARCAN Nasal Spray

- a. Lay person on their back to receive a dose of NARCAN Nasal Spray.
- b. Remove NARCAN from the box. Peel back the tab with the circle to open the NARCAN Nasal Spray.
- c. Hold the NARCAN Nasal Spray with your thumb on the bottom of the plunger and first and middle fingers on either side of the nozzle.
- d. Tilt the person's head back and provide support under the neck with your hand. Gently insert tip of nozzle into one nostril until fingers on either side of the nozzle are against the bottom of the person's nose.
- e. Press the plunger firmly to give the dose of NARCAN Nasal Spray.
- f. Remove the NARCAN Nasal Spray from the nostril after giving the dose.
- g. Move the person onto their side after giving NARCAN Nasal Spray.
- h. Remain with the person, monitor breathing/pulse. **IF NOT BREATHING, give rescue breathing. IF NO PULSE, start CPR, if able and trained to do so.**
- i. Remain with the person, monitor breathing/pulse, and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional, such as a physician, nurse, or EMS.
- j. Watch the person closely. If the person does not respond by waking up, to voice or touch, or breathing normally another dose may be given. NARCAN Nasal Spray may be dosed every 2 to 3 minutes, if available, until the person responds or emergency medical help is received.

B. INTRA-MUSCULAR NALOXONE, BY WAY OF AUTO-INJECTOR

Eligible Persons should be provided with the following:

- 1. Two EVZIO (naloxone hydrochloride injection, USP) 0.4 mg auto-injectors
- 2. A single Trainer for EVZIO
- 3. Patient instructions

Instructions for use:

1. Currently the only available auto injector comes with automated voice instructions (EVZIO®) and has a speaker that provides voice instructions to help guide you through each step of the injection.
 - a. Follow automated voice instructions.
2. If the auto-injection device does not come with automated voice instruction or the automated voice instruction is otherwise disabled, follow below. The auto-injection device should still work even if the automated voice instructions do not.
 - a. Prepare device
 - i. For EVZIO®
 1. Pull off the Red safety guard. Note: The Red safety guard is made to fit tightly. Pull firmly to remove. To reduce the chance of an accidental injection, do not touch the Black base of the auto-injector, which is where the needle comes out.
 - b. Hold injector with a fist if possible and press firmly against outer thigh, until you hear a click or hiss. EVZIO® can be used through clothing. One auto injector delivers 0.4 mg naloxone.
 - c. Continue to hold pressure for a full 10 seconds to ensure full delivery of medication. Note: The needle will inject and then retract back up into the EVZIO® auto-injector and is not visible after use. Do not look for the needle as this will put you at risk for needle stick injury.
 - d. Continue to monitor breathing and pulse. If not breathing, give rescue breathing. If no pulse, start CPR.
 - e. If no response in 3-5 minutes, repeat the above instruction with a new auto-injection device.
 - f. Remain with the person, monitor and support breathing until he or she is under the care of a medical professional, such as a physician, nurse, or EMS.

C. REFILLS

Refills may be obtained as needed under this standing order.

VII. CONTRADICTIONS

Do not administer Naloxone to a person with known hypersensitivity to Naloxone or to any of the other ingredients contained in the packaging insert for Naloxone.

VIII. PRECAUTIONS

A. DRUG DEPENDENCE

Those who may be chronically taking opioids are more likely to experience adverse reactions from Naloxone. (See adverse reactions under section X below).

Additionally, after administration, they may awaken disoriented. Being disoriented can sometimes lead to combative behavior, especially if Naloxone is given by someone unfamiliar.

B. RESPIRATORY DEPRESSION DUE TO OTHER DRUGS

Naloxone is not effective against respiratory depression due to non-opioid drugs. Initiate rescue breathing or CPR as indicated and contact 911.

C. PAIN CRISIS

In patients taking an opioid medication for a painful illness such as cancer, administration of Naloxone can cause a pain crisis, which is an intense increase in the experience of pain as the Naloxone neutralizes the pain-relieving effect of the opioid medication. Comfort the patient as much as possible and contact 911 as the patient may need advanced medical treatment to ease the pain crisis.

IX. USE IN PREGNANCY (Teratogenic Effects: Pregnancy Category C)

Based on animal studies, no definitive evidence of birth defects in pregnant or nursing women exists to date. There also have not been adequate studies in humans to make a determination.

X. ADVERSE REACTIONS

A. OPIOID DEPRESSION

Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, abnormal heart beats, fluid development in the lungs and opioid acute withdrawal syndrome (see part B below), increased blood pressure, shaking, shivering, seizures and hot flashes.

B. OPIOID DEPENDENCE

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may cause an acute withdrawal syndrome.

Acute withdrawal syndrome may include, but not be limited to, the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, yawning, weakness, shivering or trembling, nervousness, or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and fast heart beats.

Most often the symptoms of opioid depression and acute withdrawal syndrome are uncomfortable, but sometimes can be severe enough to require advanced medical attention.

APPENDIX F: ALLEGHENY COUNTY HEALTH DEPARTMENT STANDING ORDER



AMENDED 1/4/16

STANDING ORDER FOR DISPENSING NALOXONE RESCUE KITS TO INDIVIDUALS AT RISK OF EXPERIENCING OR WITNESSING AN OPIOID-RELATED OVERDOSE

Naloxone is a medication indicated for the reversal of opioid-induced respiratory depression. It is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

I. COVERAGE AND EXCLUSIONS

This standing order applies to pharmacies in Allegheny County which choose to make naloxone available via standing order. This order does not require pharmacies in Allegheny County to carry naloxone.

II. WRITTEN AGREEMENT REQUIRED

If dispensing naloxone under this standing order, pharmacies shall keep a signed copy of this order on the premises. Pharmacists at participating pharmacies are strongly recommended to complete a Department-approved online training program. See Section V.

III. WHO SHOULD GET NALOXONE

Take-home naloxone rescue kits may be dispensed by a pharmacist under this standing order to patients at risk of experiencing or witnessing an opioid overdose. Consider offering a naloxone kit to:

- All patients prescribed long-term or high-dose opioids
- Anyone otherwise at risk of experiencing or witnessing an opioid overdose

Some indications for dispensing naloxone are:

1. Previous opioid intoxication or overdose
2. History of nonmedical opioid use

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3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment
4. Higher-dose (>50 mg morphine equivalent/day) opioid prescription
5. Receiving any opioid prescription for pain plus:
 - a. Rotated from one opioid to another because of possible incomplete cross-tolerance
 - b. Smoking, COPD, emphysema, asthma, sleep apnea, respiratory infection, other respiratory illness
 - c. Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS
 - d. Known or suspected concurrent alcohol use
 - e. Concurrent benzodiazepine or other sedative prescription
 - f. Concurrent antidepressant prescription
6. Voluntary request from patient or caregiver

IV. SIGNS AND SYMPTOMS OF OPIOID OVERDOSE

The signs and symptoms of an opioid overdose include:

1. A history of current narcotic or opioid use or fentanyl patches on skin or needle in the body.
2. Unresponsiveness or unconsciousness
3. Not breathing or slow/shallow respirations
4. Snoring or gurgling sound (due to partial upper airway obstruction)
5. Blue lips and/or nail beds
6. Pinpoint pupils
7. Clammy skin

Note that individuals in cardiac arrest from all causes share many symptoms with someone with a narcotic overdose (unresponsiveness, not breathing, snoring/gurgling sounds, and blue skin/nail beds). If no pulse, these individuals are in cardiac arrest and require CPR.



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V. ORDER TO DISPENSE

This standing order applies only to participating pharmacies in Allegheny County.

1. This standing order authorizes Registered Pharmacist(s) at _____ to maintain supplies of naloxone rescue kits for the purpose of dispensing to a person at risk of experiencing an opiate-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose.
2. This standing order authorizes Registered Pharmacist(s) at _____ to dispense naloxone rescue kits to a person at risk of experiencing an opiate-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose.
3. The Pharmacist Manager of Record must maintain a copy of this signed standing order and the "Naloxone Pamphlet" on file and both must be readily retrievable at the pharmacy location.
4. The pharmacy that assembles naloxone rescue kits will label kits as 'naloxone rescue kit' and note the expiration date based on the expiration date of the included naloxone hydrochloride unit.
5. The Registered Pharmacist dispensing naloxone rescue kits must be familiar with the "Naloxone Pamphlet," and further, distribute a copy of the pamphlet to the recipient of the rescue kit.
6. The Registered Pharmacist should recommend to individuals purchasing naloxone that they take free online training at www.prescribetoprevent.org. This link is provided on the "Naloxone Pamphlet." Other valuable resources can be found online at: <http://www.getnaloxonenow.org/>, and via the Pennsylvania Department of Drug and Alcohol Programs, which offers a Friends and Family Guidance Toolkit at: <http://www.ddap.pa.gov/portal/server.pt?open=514&objID=1938383&mode=2>.

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7. The Registered Pharmacist dispensing naloxone rescue kits should be familiar with the use of naloxone rescue kits, demonstrated by completion of free online training. A free comprehensive module is available at Prescribe to Prevent at the following link:

http://www.opioidprescribing.com/naloxone_module_1-landing

This training module confers continuing education credits.

8. The Registered Pharmacists may dispense **either intra-nasal naloxone or auto-injector naloxone (intramuscular)** to individuals at risk of experiencing or witnessing an opioid-related overdose with the following instructions and information:
 - a. Call 911 for EMS to be dispatched immediately.
 - b. In cardiac arrest or pulseless patients: Start CPR. Any attempt to administer naloxone should not interrupt chest compressions and rescue breathing.
 - c. Naloxone should only be given to someone suspected of opioid overdose as noted in the signs and symptoms listed in Section III above.
 - d. In respiratory arrest or a non-breathing patient: Start rescue breathing. Rescue breathing takes priority over naloxone administration. Administer naloxone if possible while doing rescue breathing.
 - e. **Note:** Individuals should become familiar with assembly and administration of naloxone prior to the need to use it.

DIRECTIONS FOR ADMINISTRATION OF INTRA-NASAL NALOXONE, BY WAY OF A MUCOSAL ATOMIZER DEVICE (MAD)

1. A naloxone intranasal kit will contain two naloxone 2mg/2ml vials, two delivery syringes, two mucosal atomizer devices, and one instructional pamphlet.
2. Pop off two yellow caps from the delivery syringe and one purple cap from the naloxone vial.
3. Screw the naloxone vial gently into the delivery syringe.
4. Screw the mucosal atomizer device onto the top of the delivery syringe.

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5. Spray half (1ml) of a naloxone vial in one nostril and the other half (1ml) of the naloxone vial in the other nostril. This will deliver 1mg of naloxone in each nostril for a total dose equal to 2mg of naloxone.
Note: Administer the medication in a quick burst to ensure that it is atomized. A slow administration will cause liquid to trickle in without being atomized properly, which will slow delivery to the bloodstream.
6. If patient does not awaken after 3-5 minutes, administer a second dose of naloxone. To administer the second dose of naloxone, spray half (1ml) of a naloxone vial in one nostril and the other half (1ml) of the naloxone vial in the other nostril. This will deliver 1mg of naloxone in each nostril for a total dose equal to 2mg of naloxone.
7. Continue to monitor breathing and pulse. If not breathing, **give rescue breathing**. If no pulse, **start CPR**.
8. Remain with the person, monitor breathing/pulse and provide rescue breathing or provide CPR if needed, until he or she is under care of a medical professional.

DIRECTIONS FOR ADMINISTRATION OF INTRA-NASAL NALOXONE, BY WAY OF NARCAN NASAL SPRAY 4mg/0.1ml

1. Currently, the only FDA-approved nasal spray kits contain two blister packages each with a single Narcan Nasal Spray (single 4mg dose of naloxone per 0.1ml).
2. To administer Narcan Nasal Spray, lay the person on their back to receive a dose of Narcan Nasal Spray.
3. Remove Narcan Nasal Spray from the box. Peel back the tab with the circle to open the Narcan Nasal Spray.
4. Hold the Narcan Nasal Spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.
5. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person's nose.
6. Press the plunger firmly to give the dose of Narcan Nasal Spray (4mg/0.1ml).
7. Remove the Narcan Nasal Spray from the nostril after giving the dose.

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8. If the person does not respond by waking up, to voice or touch, or breathing normally another dose (4mg/0.1ml) may be given. Narcan Nasal Spray may be dosed every 2-3 minutes, if available.
9. Repeat steps 3-7 using a new Narcan Nasal Spray to give another dose (4mg/0.1ml) in the other nostril. If additional Narcan Nasal Sprays are available, Steps 3-7 may be repeated every 2 to 3 minutes until the person responds or emergency medical help is received.
10. Put the used Narcan Nasal Spray back into its box.
11. Throw away (dispose of) the used Narcan Nasal Spray in a place that is away from children.
12. Important notes:
 - a. Narcan Nasal Spray is for use in the nose only.
 - b. Do not remove or test the Narcan Nasal Spray until ready to use.
 - c. Each Narcan Nasal Spray has 1 dose and cannot be reused.
 - d. You do not need to prime Narcan Nasal Spray.

DIRECTIONS FOR ADMINISTRATION OF INTRA-MUSCULAR NALOXONE, BY WAY OF AUTO-INJECTOR

1. Currently, the only available FDA-approved auto injector comes with automatic voice instructions (EVZIO) and has a speaker that provides voice instructions to help guide you through each step of the injection.
 - a. Follow automated voice instructions.
2. If the automated voice instruction is disabled, follow below. The auto-injection device should still work, even if the automated voice instructions do not.



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- a. Prepare device
 1. Pull off the **red** safety guard. Note: the **red** safety guard is made to fit tightly. **Pull firmly to remove.** To reduce the chance of an accidental injection, do not touch the **Black** base of the auto-injector, which is where the needle comes out.
- b. Hold injector with a fist hand if possible and press firmly against outer thigh, until you hear a click or hiss. EVZIO can be used through clothing.
- c. Continue to hold pressure for a full 10 seconds to ensure full delivery of medication. Note: the needle will inject and then retract back up into the EVZIO auto-injector and is not visible after use. Do not look for the needle as this will put you at risk for needle stick injury.
- d. Continue to monitor breathing and pulse. If not breathing, give rescue breathing. If no pulse, start CPR.
- e. If no response in 3-5 minutes, repeat the above instruction with a new auto-injection device.
- f. Remain with the person, monitor and support breathing until he or she is under the care of a medical professional.

REFILLS

Refills may be obtained as needed under this standing order pursuant to Section II.

VI. CONTRAINDICATIONS

Do not administer naloxone to a person with known hypersensitivity to naloxone or to any other ingredients contained in the packaging insert for naloxone.

VII. PRECAUTIONS

A. RESPIRATORY DEPRESSION DUE TO OTHER DRUGS

Naloxone is not effective against respiratory depression due to non-opioid drugs. Initiate rescue breathing or CPR as indicated and contact 911.

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B. PAIN CRISIS

In patients taking an opioid medication for a painful illness such as cancer, administration of naloxone can cause a pain crisis, which is an intense increase in the experience of pain as the naloxone neutralizes the pain-relieving effect of the opioid medication. Comfort the patient as much as possible and contact 911, as the patient may need advanced medical treatment to ease the pain crisis.

VIII. USE IN PREGNANCY (Teratogenic Effects: Pregnancy Category C)

Based on animal studies, no definitive evidence of birth defects in pregnant or nursing women exists to date. There also have not been adequate studies in humans to make a determination.

IX. ADVERSE REACTIONS

A. OPIOID DEPRESSION

Abrupt reversal of opioid depression may result in nausea, vomiting, sweating, abnormal heartbeats, fluid development in the lungs and opioid acute withdrawal syndrome (see part B below), increased blood pressure, shaking, shivering, seizures, and hot flashes.

B. OPIOID DEPENDENCE

Abrupt reversal of opioid effects in persons who are physically dependent on opioids may cause an acute withdrawal syndrome.

Acute withdrawal syndrome may include, but not be limited to, the following signs and symptoms: body aches, fever, sweating, runny nose, sneezing, yawning, weakness, shivering or trembling, nervousness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, and fast heartbeats.

Most often, the symptoms of opioid depression and acute withdrawal syndrome are uncomfortable, but sometimes can be severe enough to require advanced medical attention.

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X. REVIEW

This standing order is issued by authority vested with the Director of the Allegheny County Health Department by virtue of the Local Health Administration Law, 1951, Aug. 24, P.L. 1304, § 1., the Disease Prevention and Control Law of 1955, 1956, April 23, P.L. (1955) 1510, § 1., and the Controlled Substance, Drug, Device and Cosmetic Act, April, 14, 1972 (P.L. 233, No. 64).

This standing order will automatically expire 30 days after the licensed physician whose signature appears below has ceased being the Director of the Allegheny County Health Department, or until a health care professional otherwise authorized to prescribe Naloxone to the eligible persons does so as authorized under Act 139-2014, whichever comes first. This standing order will be reviewed, and may be updated, if there is relevant new science about naloxone administration, or at least every 4 years.

PRINT NAME, Pharmacist Manager of Record

Pharmacy Name, Location

SIGNATURE, Pharmacist Manager of Record

Karen Hacker
PRINT NAME Licensed Physician &
Director, Allegheny County Health Department

MD 449543
PA License #

[Signature]
SIGNATURE Licensed Physician &
Director, Allegheny County Health Department

Effective Date

APPENDIX G: LEGAL ANALYSIS

Results from the Multi-State Comparison

Table 1: Language Comparison for Statute Provisions: Immunity from Arrest, Charge or Prosecution

State	Language	Differences Noted
<p>Pennsylvania (PA Act 139)</p>	<p>Persons <u>experiencing drug overdose</u> events may not be charged and shall be immune from prosecution as provided in subsection (b) <u>if a person who transported or reported and remained with them</u> may not be charged and is entitled to immunity under this section</p>	<p>Person must remain with the victim for immunity or both parties.</p>
<p>California (CA Health & Safety Code 11376.5)</p>	<p>Notwithstanding any other law, it shall not be a crime for a person <u>who experiences a drug-related overdose and who is in need of medical assistance</u> to be under the influence of, or to possess for personal use, a controlled substance, controlled substance analog, or drug paraphernalia, <u>if the person or one or more other persons at the scene of the overdose, in good faith, seek medical assistance for the person experiencing the overdose.</u></p>	<p>Must seek medical attention (broad) - language states that it “shall not be a crime.”</p>
<p>Minnesota (Minn. Stat. § 604A.05)</p>	<p>The person seeks medical assistance for another person who is in need of medical assistance for an immediate health or safety concern, <u>provided that the person who seeks the medical assistance is the first person to seek the assistance, provides a name and contact information, remains on the scene until assistance arrives or is provided,</u> and cooperates with the authorities....</p> <p>... A person [who overdoses] qualifies for the immunities provided in this subdivision <u>only if the evidence for the charge or prosecution was obtained as a result of the drug-related overdose and the need for medical assistance.</u></p>	<p>The victim and bystander immunities are separate; the bystander is still dependent on their behavior while the victim is somewhat independent of the bystander.</p>

Results from the Ecologic Exploratory Legal Analysis

Figure 1: Drug Overdose Mortality Rates by State: 2014, United States

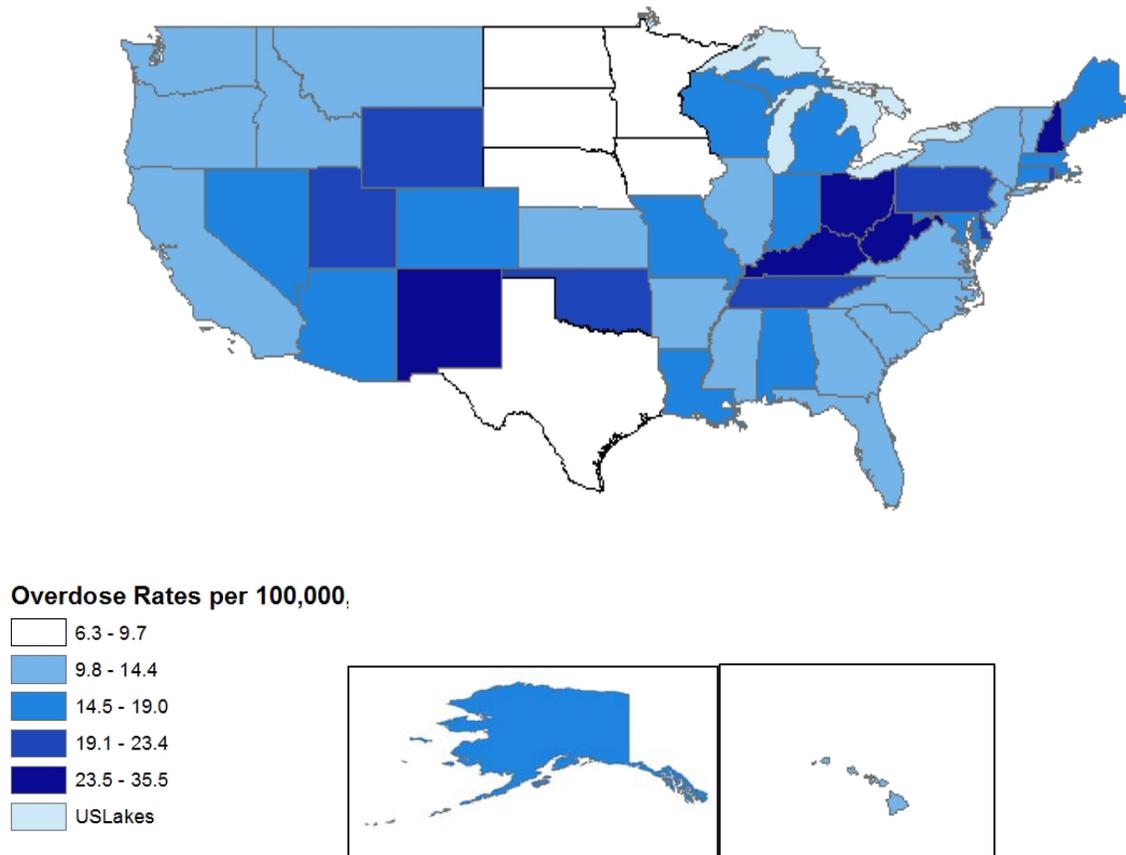


Figure 1 illustrates the drug overdose mortality rate per 100,000 population by state in 2014. States with the highest overdose rates (in order) are: West Virginia (35.5), New Mexico (27.3), New Hampshire (26.2), Kentucky (24.7), Ohio (24.6), Rhode Island (23.4), Utah (22.4), Pennsylvania (21.9), Delaware (20.9), Oklahoma (20.3), Tennessee (19.5), and Wyoming (19.4).

The trend highlights the magnitude of the problem in the Appalachian region and certain parts of the Southwestern United States.

*Adjusted mortality rates were downloaded from www.cdc.gov.
Data also presented at Pitt GSPH Dean's Day, 2016.*

Figure 2: Good Samaritan Laws by State: 2014, United States

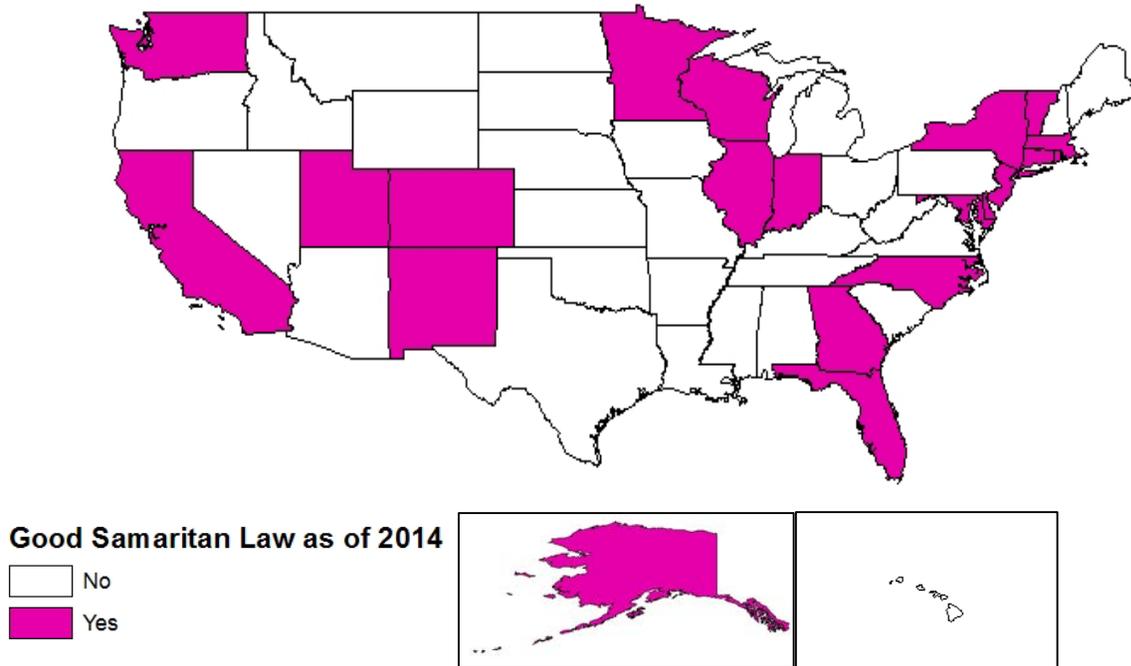


Figure 2 illustrates the presence of a Good Samaritan Law by state for at least 6 months or more in 2014. Pennsylvania is not included since its law was enacted after November 2014 (LawAtlas). When comparing Figure 1 to Figure 2, eight of the states with the highest overdose rates in 2014 also do not have Good Samaritan laws as of 2014. These include: New Hampshire, Kentucky, Ohio, Oklahoma, Pennsylvania, Tennessee, West Virginia and Wyoming. Four states (Delaware, New Mexico, Rhode Island and Utah) do have Good Samaritan Laws in 2014 and also have high overdose rates.

*Binary law data were downloaded from www.lawatlas.org.
Data also presented at Pitt GSPH Dean's Day, 2016.*

Table 2: Univariate Poisson Regression Results* by Components of the Good Samaritan Laws: 2014, United States (n=51)

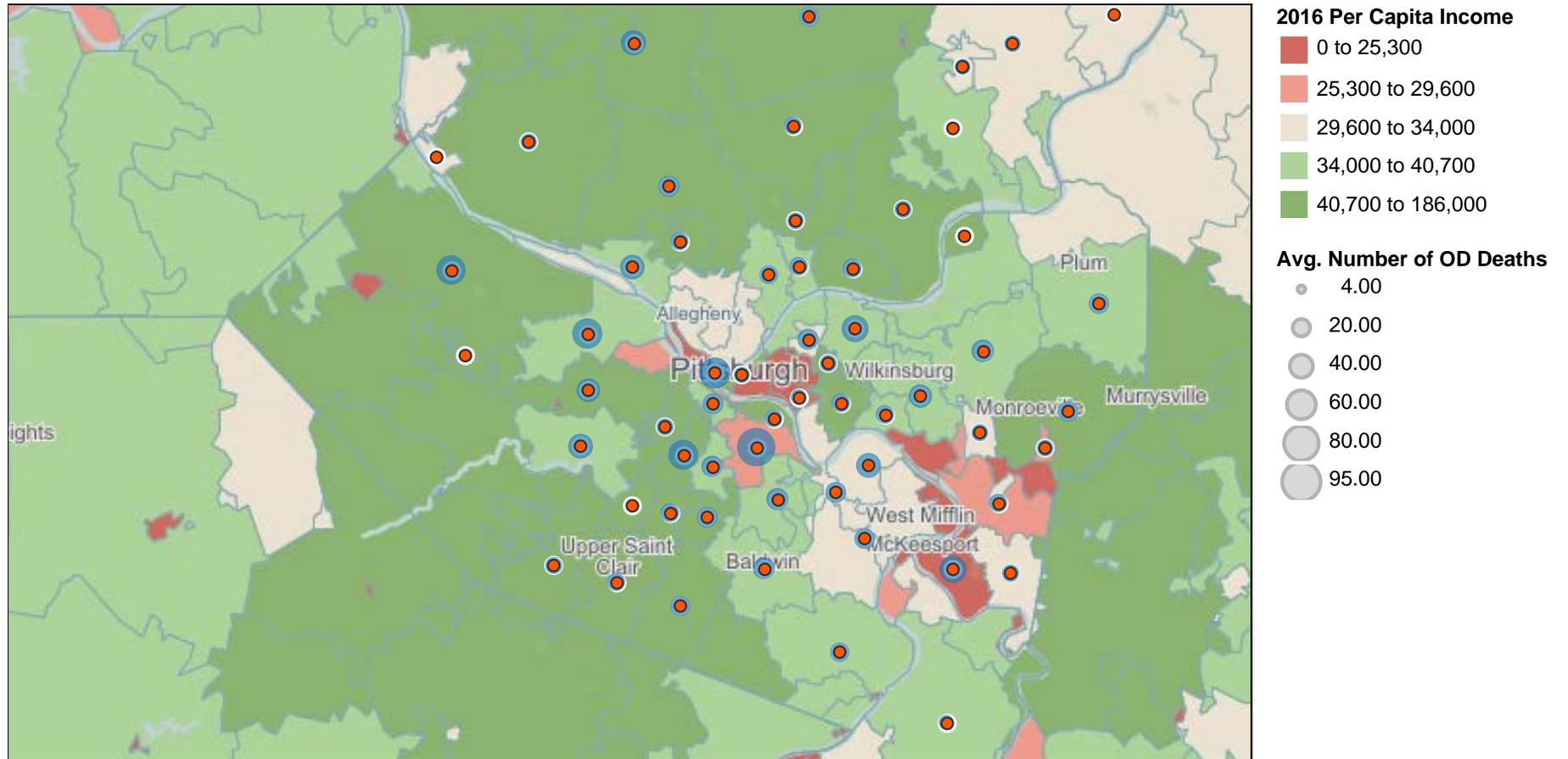
Good Samaritan Law Components	Estimate (β)	Incidence Rate Ratio (IRR)	P value
No Good Samaritan Law (n=29)	0.17	1.18	<0.0001
Any protection from Controlled Substances Possession Laws (n=22)	-0.28	0.75	<0.0001
No protection from Arrest	0.18	1.2	<0.0001
No protection from Charge	0.24	1.27	<0.0001
No protection from Prosecution	0.29	1.34	<0.0001
Any Protection from Drug Paraphernalia Laws	-0.17	0.84	<0.0001
Any Protection from Probation or Parole Violation	-0.09	0.91	<0.0001
Overdose Reporting is a not a Mitigating Factor in Sentencing	-0.11	0.89	<0.0001

*All results are unadjusted

Data also presented at Pitt GSPH Dean's Day, 2016.

APPENDIX H: GIS OVERLAY, OVERDOSE DEATHS BY HOUSEHOLD INCOME

Overdose Deaths by Average Household Income



Van Nostrand, et al. Addressing the Opioid Epidemic: Naloxone Availability as a Public Health Intervention in Allegheny County. 2016.

APPENDIX I: LITERATURE REVIEW MATRIX, CORRECTIONAL FACILITIES

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Jones et al, 2016 ⁶³	Multi-site prospective cohort	1,267 adult opioid or crack cocaine users	England (multi-site)	Drug treatment, and effect modification of criminal justice system referral	Short-term change in health-behaviors (i.e. drug use, overdose)	Drug treatment was associated with significant improvements in health behaviors (heroin use 87% vs. 51%); however, referral route was not associated with variation in outcome measures.	Lacked a control group
Bird et al, 2015 ⁶⁴	Retrospective cohort	150,517 individuals released from prison between 1996-2007 following imprisonment ≥ 14 days	All Scottish prisons	Prison-based OST (national policy implemented in 2003)	1) Risk of DRD within 12 weeks post-release 2) Proportion of DRD that occurred within 14 days	Risk of DRD in the 12 weeks following release decreased by 40%; however, policy implementation had no effect on the proportion of deaths occurring in the first 14 days following release.	This study is unlikely to have been affected by bias. If anything, it is unlikely to be generalizable given the population
Gordon et al, 2015 ⁶⁵	Phase 4, open label feasibility study	27 inmates with opioid disorders in the year prior to incarceration	Baltimore, Maryland (initiated in prisons then continued within community)	380 mg extended release (XR) injectable Naltrexone (NTX) monthly for seven months	1) Urine drug test for opioids and cocaine 2) Re-arrest and re-incarceration 3) Adherence to Naltrexone injections in community	Individuals who adhered to at all Naltrexone injections were significantly (0% vs. 62.5%) less likely to test positive for drugs in the community. Individuals who failed to complete the treatment course were more likely to be re-arrested (31.3% vs. 0%) however this difference was not statistically significant.	Non-randomized trial with no control group, lacked clarity in methods, and missing data

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Lee et al. 2015 ⁶⁶	Pilot RCT	34 adult male inmates released from NYC Jails who were previously opioid dependent and not interested in agonist treatments	New York City Jails	Extended-release Naltrexone injection	1) Opioid relapse within 4-weeks of release 2) Rates of opioid abstinence 3) Rates of cocaine use, HIV risk behaviors, re-arrest, re-incarceration, participation in community treatment programs and overdose.	Exposure to Naltrexone injection significantly reduced risk of opioid relapse (OR = 0.08). Percent of urine tests indicating opioid abstinence was significantly higher in the treatment group (59% vs. 29%). No difference in secondary outcomes.	Trial was not blinded and did not include women
Rich et al. 2015 ⁶⁷	RCT	223 Rhode Island inmates who were enrolled in a methadone OST at time of arrest with sentences between 1-6 months in length.	Rhode Island Department of Corrections	Methadone treatment throughout incarceration vs. forced tapered withdrawal	1) Engagement in community methadone clinic post-release 2) Adverse events	Participants assigned to methadone treatment were more than twice as likely to continue methadone treatment in the community post-release (HR = 2.04). There was no difference in adverse events between groups.	Lacks generalizability due to short sentences, small predominantly white sample, only one prison studied

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Winter et al. 2015 ⁶⁸	Retrospective cohort study	1,051 Australian adult inmates discharged between August 2008 - July 2010	Selected prisons in Queensland, Australia	Risk factors for non-fatal overdose such as age, sex, unstable housing, etc.	Non-fatal overdose	Risk of post-release overdose was higher in those who had been unemployed for longer than 6 months prior to imprisonment, had been removed from family as a child, reporting current psychological distress, had a diagnosed mental disorder, weekly use of benzodiazepines and/or pharmaceutical opioids in the 3 months prior to imprisonment, and ever having been on OST.	Incidence of overdose was likely underestimated due to bias resulting from differences in those who completed vs. did not complete surveys post-release
Degenhardt et al, 2014 ⁶⁹	Retrospective cohort	16,453 inmates released from prison who were previously in OST	New South Wales, Australia	Retention in OST during incarceration and following release	Crude mortality rates	The lowest mortality rate was seen for those who remained on OST after release (6.4 per 1000) compared to those without any OST (36.7 per 1000). Consistent with other studies, the protective effect of OST waned over time (best in acute time frame).	No information on individual dose of OST, meaning that results are simply "an average of the effective dose across all individuals"

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Larney et al., 2014 ⁷⁰	Retrospective cohort	16,715 opioid dependent adults (defined as having visited OST at least once) and had been incarcerated at least once from 2000 to 2012	Adult prisons, New South Wales Australia	OST	Natural and unnatural (suicide, injury, violence, overdose) deaths in prison	The hazard rate of death in prison was nearly 75% lower for prisoners enrolled in OST. The overall number of prison deaths was low, but the most significant reductions were seen in unnatural deaths.	Proxy measure for opioid dependence (first OST visit) is unlikely to be representative of true opioid dependence for that person. Unmeasured confounders (i.e. outside support, injury).
Perry et al. 2014 ⁷¹	Review of RCTs	7 trials examining 1,236 female drug-using offenders	Community and prison settings	Cognitive behavioral therapy, medication, cognitive skill education	Re-arrest and re-incarceration	All treatments had a positive effect on self-reported drug use and re-incarceration but not re-arrest	Only 7 studies analyzed. Results may differ by setting.
Cropsey et al, 2013 ⁷²	Pilot study	30 individuals from community corrections facility	Birmingham, AL	4 mg Buprenorphine during withdrawal, followed by 8 mg one week later, then 12 weeks or open label buprenorphine/naloxone therapy	Feasibility, acceptability, and effect size for reducing opioid use and HIV-related risk behaviors	Good feasibility. Recruited and enrolled 79% of eligible participants and 86.7% were retained over one month.	Small sample which limits ability to detect meaningful differences on several variables; non-generalizable. Insufficient to draw any major conclusions regarding treatment.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Perry et al. 2013 ⁷³	Review of RCTs	11 trials examining 2,678 drug-using offenders	Community and prison settings	Pharmaceutical therapy	Subsequent drug use	Overall, pharmaceutical therapies reduce subsequent drug use, but settings were examined individually there was no effect. Methadone did not significantly reduce incarceration but naloxone did.	No subsequent drug use data specifically for naloxone users. Small number of studies and sometimes low retention rate. Publication bias.
Roshanfekar et al. 2013 ⁷⁴	Prospective cohort	2,200 inmates in 7 large Iranian prisons	7 large prisons in 7 Iranian provinces	Exposure to harm reduction interventions in prison: detox, therapy, needle exchange, HIV testing etc.	Drug use while in prison	Exposure to harm reduction interventions was associated with reduction in prison drug use from 57% to 10%.	High prison inmate turnover resulting in missing data and sensitive nature of interviews may result in bias.
Kinner et al, 2012 ⁷⁵	Prospective cohort	2,515 illicit drug-users recruited from the community	Vancouver, Canada	Incarceration	Non-fatal overdose incidence	The odds of a recent NFOD were twice as high for recently jailed individuals compared to those who were not. OST was protective for both groups.	Outcome is an underestimate of true incidence of NFOD. NFOD may have occurred before incarceration rather than after, suggesting that the association we see could actually be attenuated.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Cropsey et al, 2011 ⁷⁶	Pilot RCT	36 women under criminal justice supervision and in inpatient drug treatment	Birmingham, AL	First nine received open-label buprenorphine; 27 randomized to buprenorphine/naloxone or placebo.	Efficacy of relapse prevention (abstinence) in short and longer term	This population was primarily young white females with history of mental illness, abuse, and drug use. At 12 weeks, only 33% of the treatment group tested positive for opioids in their urinalysis. However, by 3 months this effect dissipated. Risky drug behaviors were shown to decline overall during the study period.	Sample size is small. Limited generalizability. Their primary outcome was urine tests results, but these tests were taken sporadically and would be less likely to capture true day to day use of opioids.
Lobmaier et al. 2010 ⁷⁷	RCT	46 adult prison releasees	Norwegian prisons	Naltrexone implant vs. methadone treatment	Opioid and benzodiazepine use post release and criminality	Reductions in drug use and criminality seen in both naltrexone group and methadone group	Small sample size, lacks generalizability to women (only 3 included)
DeBeck et al, 2009 ⁷⁸	Retrospective cohort	1,603 injection drug users followed in the VIDUS study	Vancouver, Canada	Recent incarceration	Injection cessation	Recent incarceration was significantly negatively associated with cessation (OR = .43), while use of methadone was significantly positively associated with injection cessation (OR = 1.38)	Possible differential reporting of drug use according to incarceration, which would overestimate associations seen here. Several confounders were unmeasured.
Oser et al. 2009 ⁷⁹	Retrospective cohort	198 US nationally representative sample of jails and prisons	US jails and prisons	Organizational context, resources, culture, practices and system integration	Availability of detoxification services and medications for substance abuse treatment	US jails had more detoxification and medical services than US prisons	Survey administered to only warden who could have limited knowledge of inmate experiences.

APPENDIX J: LITERATURE REVIEW MATRIX, EDUCATIONAL FACILITIES

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Pagano et al., 2015 ⁸⁰	Prospective study	195 Adolescents (52% female, 30% Black), aged 14-18	Large treatment facility in the Northeastern US 2007-2009	Peer-helping during treatment	Assessment at treatment admission, treatment discharge, and 6 months for treatment discharge; influence of SAD on peer-helping and outcomes was examined	SAD onset preceded initial use for 2/3 youths; evidence of an association between SAD and earlier age of first use, greater lifetime use of heroin, incarceration history, and lifetime trauma. Peer helping is associated with reduced risk of relapse.	Causation of factors associated with SAD is inconclusive given study design. Tested models were not exhaustive and other variables may account for observed relationships.
Smyth et al., 2015 ⁸¹	Prospective study	32 heroin-dependent patients <18 commencing OST at either site from 2006-2013	Two treatment centers in Dublin 2010	Outpatient psychologically supported OST; methadone or buprenorphine	Beck Youth Inventory used to measure psychological well-being at treatment entry and repeated after 4 months of treatment	Psychosocially assisted OST appears to be associated with improved psychological well-being in heroin-dependent adolescent (in the areas of depressive and anxiety symptoms).	Small sample size and recruitment within a single city
Minozzi et al., 2014 ⁸²	Review					There is very little evidence in this field. The Cochrane Collaboration suggests that there is an urgent need for more randomized trials comparing treatment options in adolescents.	Only two trials and two studies included in this review.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Fishman et al., 2010 ⁸³	Case-series	16 adolescent and young adult cases (mean age 18.5 years)	Mountain Manor Treatment Center in Baltimore MD 2008	Treated for opioid dependence with Extended-release naltrexone	Substantial reduction in opioid use, no new drug-related problems, improvement in major domains of psychosocial functioning	10/16 were retained in treatment for at least 4 months and 9/16 saw "good" outcomes. XR-NTX is well tolerated and feasible in a community-based treatment setting.	Convenient, small sample
Woody et al., 2008 ⁸⁴	Randomized Clinical Trial	152 opioid-dependent patients aged 15-21	6 community programs from July 2003 to December 2006 across the United States	12 weeks of buprenorphine-naloxone (prescribed up to 24 mg/day) or a 14-day taper (detox).	Opioid-positive urine test results at weeks 4, 8, and 12.	Patients in the detox group had higher proportions of opioid-positive urine tests results at 4 and 8 but no difference was detected at 12 weeks. High levels of opioid use occurred in both groups at follow-up.	Short-term study; small proportion of patients younger than 18; low follow-up rate
Bell et al., 2006 ⁸⁵	Retrospective file review	61 adolescents (age 14-17 years, 61% female) with opioid dependence	Langton Centre, Sydney, Australia	Methadone, buprenorphine, symptomatic maintenance	Compare retention and re-entry to treatment between adolescent subjects treated with methadone, those treated with buprenorphine, and those treated with symptomatic (non-opioid) medication only	Subjects treated with methadone had significantly longer retention than buprenorphine treatment (mean days 254 vs. 58, p<0.01), and missed fewer days in the first months (mean 3 vs. 8 days, p<0.05), subsequent re-entry for further treatment occurred in 25% of subjects treated with methadone, 60% buprenorphine and 60% symptomatic medications.	Observational findings making it harder to attribute observed differences in retention to different drugs administered as treatment. No patient follow-up

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Caulkins et al., 2004 ⁵⁴	Models and extrapolation	United States Population	United States	School-based drug prevention program	Three estimates: amount of drug use, percentage reduction in use, and social value per unit of drug not used	The majority of benefits stem from reductions in use of tobacco and alcohol, and school-based drug prevention should be used primarily for these measures.	Models and extrapolation are inexact and depend on various assumptions
Hulse and Tait, 2003 ⁸⁶	Retrospective review of pilot study	8 "High-risk" adolescent (aged 15-19 years) heroin users	Four public hospitals in Perth, Western Australia, September 1999-October 2002	Pre- and post-Implantable naltrexone treatment	Compared the frequency of accidental opiate overdose and other morbidity resulting in hospitalizations	Dramatic reduction in opiate overdose post-implantable naltrexone treatment, with a smaller reduction in opiate overdose during oral naltrexone treatment compared to the pre-oral/implant period.	Findings require validation using a larger cohort over an extended period; expensive intervention
Rowan et al., 2000 ⁸⁷	Review					This is a review that outlines different treatment options and their pros/cons. It discusses the difficulties in treating adolescents, and that the epidemic in this population is the worst it has been in years.	
Schwartz, 1998 ⁸⁸	Review					This is a review that expresses that heroin use in adolescents is increasing and a major public health issue. It discusses methods that can be used to reduce heroin use in this population and the pros/cons of each	
Millman and Khruai, 1978 ⁸⁹	Observational	153 patients <18 with two+ years of daily intravenous heroin use and one year of treatment failure in a recognized program	Manhattan, 1968-1977	Detoxification process: methadone maintenance, live-in treatment facility	Methadone maintenance, therapeutic detoxification maintenance, discharge classification	Importance of fostering an environment where adolescents feel like they are always in treatment/recovery and don't have feelings of failure if they make a mistake and use drugs again.	Old study, possible changes in social implications

APPENDIX K: LITERATURE REVIEW MATRIX, VETERAN'S ADMINISTRATION MEDICAL SYSTEM

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Ilgen, M.A. et al, 2016 ⁹⁰	Retrospective Data Analysis	n=123,946 VA patients with chronic pain receiving opioids in FY2004-FY2005	VA Health System	opioid pain management retroactive data on dosage, length of treatment, and suicide rates	Higher doses of opioids are associated with an increase in suicide risk	"Controlling for demographic and clinical characteristics, higher prescribed opioid doses were associated with elevated suicide risk"	This paper makes controversial assertions that could affect the credibility of the study overall; bias towards eliminating the use of opioid therapy for chronic pain management (page 3).
Timko, C et al, 2016 ⁹¹	Multi-level, mixed effects regression analysis	n=266,908 VA patients in FY13	VA Health System Behavioral Health	Patient uptake of detoxification-related service utilization	Detoxification-related service utilization was highly variable across the VHA. Interventions are needed to optimize use	"...8.0% of VHA patients with alcohol or opiate dependence received detoxification in FY13...[Also] treatment was more likely in facilities with fewer vacancies for addiction therapists." "Follow up and specialty treatments were more likely among younger, healthier homeless patients with previous addiction treatment and a documented alcohol use disorder."	observational study; causal relationships cannot be concluded. Also, since the VHA patient population is not a good proxy for private sector healthcare setting, these findings may not be generalizable.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Wilder et al, 2016 ⁵⁷	Prospective cohort	90 veterans on chronic opioid medication; recruited through flier distribution	Two outpatient clinics (the Opioid Treatment Clinic, OTC, and the Pain Management Clinic, PMC) at the Cincinnati, OH VA hospital.	Taking opioid medication for at least 3 months; MAT/BAT control group, opioid pain management group	Patient perception of risk of opioid abuse/dependence/overdose in the VA population. Exemplifies the optimistic bias in health risk perception, which could be addressed through improved education of risks and resources available when veterans are prescribed opioids.	<p>1. 25% of OTC and 29% of PMC participants reported opioid-related aberrant behaviors, defined as taking more than the prescribed amount of opioids, using opioids obtained from non-VA prescribers, or using illicit opioids, at least once in the previous 3 months.</p> <p>2. There were misconceptions of risk factors of opioid misuse/dependence. 40% OTC participants thought being overweight was a risk factor, 70% of participants thought their risk of overdosing on opioids as lower than the average American adult.</p> <p>3. Every study participant had at least two opioid overdose risk factors, and the majority 6+.</p>	<p>1. All individuals had to conduct a survey in person, which limits the number of individuals able to participate.</p> <p>2. Small sample size</p>

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Ashrafioun et al. 2015 ⁹²	Prospective cohort	428 participants recruited through TV, radio, newspaper ads, word of mouth, and snowball sampling	New York	Naloxone/overdose prevention trainings, separated by participant type (healthcare provider, family/friend of user, user, or other) and naloxone administration type (intramuscular vs intranasal naloxone)	Knowledge about opiate overdose and confidence in their ability to recognize and respond correctly to an overdose in terms of naloxone administration	<p>1. Overall participant knowledge and confidence increased significantly from pre to post training among all participant groups.</p> <p>2. There was no significant association between participant knowledge and route of administration or participant type.</p> <p>3. Although confidence improved significantly from pre to post training across both routes of administration, confidence was higher among those who were trained using the intranasal naloxone compared to intramuscular.</p>	<p>1. The study was administered in one area by the same trainers, limiting generalizability.</p> <p>2. Used convenience sampling. Some participant groups (patients, for example) were much smaller than others (providers).</p> <p>3. No long-term follow-up.</p> <p>4. People were not randomized to intramuscular vs intranasal groups, and there was no "control" group.</p>
Bachhubber, M.A et al, 2015 ⁹³	Retrospective	n=2,699 Veterans initiating treatment in FY14 identified by VA's national homelessness screener	Addiction treatment programs operated by the VA	Opioid treatment	Programs to address veteran homelessness should engage with veterans seeking addiction treatment	"Integration of homelessness services into addiction treatment may...improve outcomes"	

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Barry, D. et al, 2015 ⁵⁹	Observational	328,398 veterans receiving healthcare services in the VA system in 2012, mostly men (93%) with an average age of 59	United States	Receipt of healthcare services for pain or mental health disorders in the VA system	Concurrent opioid and psychotropic medication prescriptions	<p>1. Among VA patients who filled at least 10 opioid prescriptions during FY 2012, 77% also received psychotropic medication, the most common being antidepressants (74%), anxiolytics/sedatives/hypnotics (55%), and anticonvulsants/mood stabilizers (45%).</p> <p>2. 55% of veterans who received psychotropic medications in conjunction with extensive opioid use were also prescribed anxiolytics/sedatives/hypnotics, which is cause for concern because opioids and benzodiazepines are the two drug classes most frequently found in pharmaceutical overdose deaths in the US.</p>	Pain-related variables such as duration, severity, and functioning were not available.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Hinrichs et al. 2015 ⁹⁴	Case study	Staff of a VA subacute rehab center ("Community Living Center" or CLC)	Boston, MA	Four newly developed working groups composed of staff and external leadership, called "interdisciplinary task forces".	The creation of a standardized curriculum for healthcare providers in the sub-acute rehab setting on how to "enhance an environment that supports and promotes motivation for veterans with substance use disorders while in CLC"	The groups were: 1. enhancement of unit safety 2. ID of at-risk veterans and staff education 3. facilitation of improved referral and access to addictions treatment 4. utilization of available resources. Improved staff buy-in, motivation, and confidence in caring for this specific patient population was found as a result of the staffing groups and standardized curriculum.	There was no discussion of how they measured the increased staff buy-in, confidence, or motivation that they reported after the creation of the interdisciplinary task force.
Manhapra et al. 2015 ⁹⁵	Observational	Approximately 14,000 VA patients with opiate use disorders using VA healthcare services in FY2012	United States	Receipt of methadone, receipt of buprenorphine, or receipt of both methadone and buprenorphine	Differences in clinical outcomes between study groups	1. There was no difference identified between the 3 groups in regards to psychiatric and medical comorbidities. 2. Veterans receiving only buprenorphine treatment tended to be younger, non-black, and from rural areas. 3. Veterans receiving buprenorphine and methadone treatments were comparable in all respects to the group receiving buprenorphine only treatment.	No information was provided on participants' years of addiction or IV drug use rates.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Miller et al. 2015 ⁹⁶	Retrospective cohort	840,606 VA patients filling new opiate prescriptions for chronic non-cancer pain between Jan 1, 2000 and Dec 31, 2009. Mostly male and over age 50.	United States	Long-acting vs short-acting opiate formulations	Rate of unintentional overdose	There was a 2.5-fold higher risk of unintentional overdose in patients receiving long-acting opioids as opposed to patients receiving short-acting opioids	<ol style="list-style-type: none"> 1. The results were based on claims databases, which are not always complete or accurate. 2. Opioid use was measured by the patient filling a prescription and not the patient's actual adherence to their prescription. 3. The analysis did not factor in other types of opiate use, for example, heroin or pills obtained on the black market. 4. The study population is homogenous in terms of sex and age, and cannot be generalized or used as a representation of the population of the US.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Westanmo et al. 2015 ⁹⁷	Case study	All patients receiving any prescriptions from the outpatient pharmacy, or from PCPs or other healthcare providers, in the Minneapolis VA healthcare system	Minneapolis, MN	A new program including planning, pain management education and training for healthcare providers	Opioid prescribing practices	The training/education program was associated with a substantial reduction in high-dose opioid prescribing, a reduction in overall dispensed opioid doses, and overall rates of opioid receipt.	1. Changes in prescribing could be related to other factors, like patient demographics/characteristics. 2. Lack of patient-reported outcomes.
Berger, R et al, 2014 ⁹⁸	Non-randomized retrospective data review	n=32 patients prescribed Buprenorphine/Naloxone between 01 Jan 10 and 31 Dec 12	VA San Diego Health System	group vs. individual prescribing formats	"Veterans prescribed buprenorphine/naloxone in a group setting as part of a drug and alcohol treatment program were retained in treatment longer than veterans prescribed individually."	At year 1 end, 69% of patients in the group prescription group were retained, compared to 27% of patients in the individual prescription group. In addition, of those patients in the group rx group, 46% were retained in treatment after year 1, with 94% opioid negative urine samples.	Data collection was limited to what was included in the charts surveyed; a small sample size was used in the study; unequal access to Buprenorphine/naloxone across the VA health system makes these findings difficult to generalize to the population in whole

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Edlund M.J. et al, 2014 ⁹⁹	Retrospective	CNCP diagnosis between 2009-2011; over 18	National VHA	CHCP diagnosis or opioid use between 2009-2011	<p>The aim of this study was to investigate "the percentage of VHA patients with CNCP who were prescribed any opioids in the past year," and prescribing patterns among those who were prescribed opioids. 50% of the VHA patients with CNCP diagnosis received at least one opioid prescription, with back pain (52%) and arthritis (65%) being the most common CNCP diagnoses; depression (32%), PTSD (21%) and substance use disorders (15%) were common. Those who received opioids were less likely to be Veterans of recent conflicts and more likely to have psychiatric disorders than those who did not. At least 57% of those receiving opioids had at least 90 days of opioid use; about 10% had at least 350 days with opioid use in the year. The median dose is 20 mg morphine.</p>	<p>The results suggest that high does opioid prescribing occurs less frequently among VHA patients when compared to other populations in Arkansas (where the study was based). A small percentage of patients require large percentage of opioids prescribed. The top 1% accounted for 18% of total opioid use, and the top 5% accounted for 45% of total opioid use.</p>	<p>Reliance on administrative data for diagnoses, no clinical assessments; not all CNCP diagnoses included, only most common; national data does not have regional/geographic variability</p>

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Mosher et al. 2014 ¹⁰⁰	Observational cohort	All patients receiving primary care within 137 VA healthcare systems during a given study year and receiving medication from VA providers one year before and during the given study year (span of 2004-2012)	United States	time period	Prevalent and incident opioid prescriptions	<p>1. Among patients prescribed opioids, the average days supply appeared to be increasing during the study period.</p> <p>2. The percentage of veterans with prevalent opioid prescriptions increased substantially during the study period.</p> <p>3. The only group that experienced increased incident rates of opioid prescription during the study period was the 65-79 age group.</p> <p>4. There are wide variations in prescribing practices between providers in a given facility, as well as between facilities.</p>	<p>1. Only prescriptions given by VA providers were accounted for.</p> <p>2. The study did not examine provider-level prescribing or indication for opioid use.</p>
Worley, M.J. et al, 2015 ¹⁰¹	Pre-treat/Post treat Multi-site clinical trial	n=353	Multi-site outpatient drug treatment facilities	12 weeks of Buprenorphine/Naloxone counseling	Those who spent more on drugs prior to treatment (i.e. those obtaining opioids from dealers/patients rather than physician prescribed) were more likely to use drugs during	Those who placed a higher economic value on drugs and drug use before treatment are more likely to continue using substances while in treatment, among patients with opioid addictions, with a variance between the minimum and maximum sample segments of approximately 24%.	The study did not control for quantity of opioid use; this study also only examined Phase II of the Prescription Opioid Addiction Treatment Study (POATS).

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Baser et al, 2014 ⁶¹	Retrospective cohort	All veterans in the VA medical/pharmacy claims system from 10-2006 to 9-2010	United States	use of VA healthcare services	1. Prevalence of diagnosed opioid abuse. 2. Healthcare utilization and costs.	<p>1. The 5-year prevalence of diagnosed opioid abuse in the general VA patient population was 1.11%.</p> <p>2. Among patients prescribed an opioid, opioid abuse prevalence was substantially higher at 3.04%.</p> <p>3. Average direct healthcare costs for inpatient services was nearly four times more expensive among patients with diagnosed opioid abuse, when compared with non-abusers.</p> <p>4. Diagnosed opioid abuse prevalence in the VA patient population is almost 7 times higher than estimates from commercial data of the general population.</p>	<p>1. ICD-9 codes for drug abuse disorders are not specific to prescribed opioid users vs illicit opioid users.</p> <p>2. Opioids could have been obtained illegally.</p>

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Bohnert, A. et al, 2014 ⁵⁵	Repeated cohort design	5% VHA patients from 2001-2009	United States	opioid prescriptions and fatalities	Increases in prescription opioid overdoses in general population are also found in VA population; supports trend in opioid prescribing and opioid overdose death. Regional variation is seen.	"The present results indicate that prescription opioid overdose was a significant and growing problem between 2001 and 2009...and that the estimated proportion of patients prescribed opioids increased across all types of opioids...There were statistically significant increases in the rate of [opioids] and methadone overdoses between FY01 and FY09...While some of the methadone overdose cases may include patients whose methadone use was related to opioid substitution treatment rather than pain care, supplementary analysis indicated that only 7% of methadone overdose decedents had received opiate substitution treatment from the VHA in the 3 months before death."	Causation is beyond scope of data; trends to specific opioids other than methadone were not able to be examined; lag in trend data availability; did not have changes in patient characteristics

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Sekhon R et al, 2013 ⁵⁸	Retrospective	Patients with CNCP between 18-87 (n=797)	Primary care setting in VA medical center	Received opioid prescription for 3+ months during 2009-2010	<p>The aim of this retrospective study was to measure compliance when prescribing opioids in regards to the VA/DoD guidelines with chronic non-cancer pain (CNCP). The study population was isolated from the W.G. Hefner Veterans Affairs Medical Center that were between 18 and 87 and had received a level II opioid for 3+ months during the one year of review (n=797). Compliance with guidelines for CNCP is low, with more education needed.</p>	<p>The median age was 58 and 94% of patients were male. 83.1% were being treated for chronic back/neck pain, with the median number of medical comorbidities being 8. Patients reported having depression (48.4%) and PTSD (26.4%), amongst other psychiatric comorbidities. 17.2% of patients had had a non-opioid substance abuse problem in the past, 13.7% having a current abuse problem, and 22.9% having aberrant drug-related behaviors. A signed opioid pain care agreement (OPCA) was found for 51% of patients, with 52.3% of patients having at least one urine drug screening (UDT) during the 1-year study period. Even though the guidelines call for a signed OPCA and random UDT for all patients with chronic opioid therapy, results varied drastically.</p>	<p>Predominantly male; results can't be translated to other settings; only schedule II opioids were included in the sample</p>

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Seal et al. 2012 ⁶⁰	Retrospective cohort	Veterans of the Iraq and Afghanistan conflicts who used VA healthcare services between Oct 1, 2005 and Dec 31st, 2008, who also received a non-cancer pain diagnosis within 1 year of VA healthcare system entry.	United States	At least 1 opioid prescription for at least 20 consecutive days in the first year of pain diagnosis, as well as the presence of PTSD or other mental health disorders.	Adverse clinical outcomes, defined as accidents with wounds or injuries, opioid-related accidents or overdoses, alcohol and non-opioid drug-related accidents or overdoses, self-inflicted injuries, or violence-related injuries.	<p>1. Veterans with mental health diagnoses prescribed opioids, especially those with PTSD, were more likely to have comorbid drug and alcohol use disorders, receive higher-dose opioid regimens, continue taking opioids longer, receive concurrent prescriptions for opioids, sedative hypnotics, or both, and obtain early refills (the study's proxy for high-risk opioid-related behavior).</p> <p>2. The receipt of prescription opioids was associated with an increased risk of adverse clinical outcomes for all veterans, but especially for veterans with PTSD, who were at the highest risk of alcohol and drug and opioid-related accidents and overdoses, as well as self-inflicted injuries.</p>	Researchers could not verify patient adherence to opioid prescriptions or illicit opioid use.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Wu P.C. et al, 2010 ⁵⁶	Retrospective	Veterans age 18-30 (n=4,270)	Veterans Integrated Service Network (VISN 21) data warehouse	Chronic opioid therapy from 2003-2008	The aim of this retrospective study was to evaluate the prevalence of chronic opioid use in young veterans and patterns in prescribing and monitoring opioids in the Veterans Affairs (VA) system. This population was identified as being vulnerable to misuse due to having multiple risk factors. Information was found in regards to high risk patients and prescribing patterns.	While the percent of young veterans with chronic opioid use increased from 2003 to 2008, it was not statistically significant (3% to 4.5%). "[T]he absolute number of patients on chronic opioids quadrupled from 2003 to 2008." Of the identified individuals, none were using opioids for malignant pain or methadone treatment. 91% were male, with 58.4% having received care for at least one mental illness during the study period. Each patient was, on average, prescribed two different opioids, which were prescribed by an average of three prescribers. The majority of prescribers were PCPs (79.5%), and less than 1% were prescribed by a pain specialist. The study did not show an improvement in pain scales by the patients	Patients may have received care outside of VA so data may not be comprehensive in regards to opioid exposure; pain scores were inconsistent and absent in some cases

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Dobscha S.K. et al, 2007 ⁶²	Cross sectional	45 VA clinicians	5 PCC of one VA medical center	Survey on pain-related attitudes and behaviors	The aim of this cross-sectional study utilizing clinician surveys and pharmacy data was to identify VA PCP attitudes regarding chronic pain treatment. Physicians reported being influenced by previous experiences with patients addicted to drugs, fear of contributing to physical dependence of opioids, and high addiction rates. Physicians may benefit from additional support to help them be more effective in treating pain.	Of 45 physicians, 71% felt moderately or strong confident in their ability to treat pain, 77% felt moderately or strongly in agreement that skilled pain management was a high priority, 73% moderately or strongly agreed that patients with chronic pain are a major source of frustration.	Small sample size
Gordon A.J. et al, 2007 ¹⁰²	Retrospective	Physicians and veterans	VHA integrated service networks from 2003-2005	Buprenorphine prescription	The aim of this retrospective study was to "describe the introduction of buprenorphine in the first 3 years after establishment of national non-formulary guidance by examining the number of buprenorphine physicians prescribers (BPP) and the number of patients who have received buprenorphine within [Veterans Health Administration] (VHA) regional networks" from 2003 to 2005. The study showed increase in opioid dependent diagnoses and increased buprenorphine prescriptions.	During the study period, the number of veterans with opioid-dependent diagnoses increased more than 7% (25031 to 26859). The number of veterans prescribed buprenorphine increased from 53 to 739 during this time, with the number of prescriptions increasing from 212 to 7076. Adoption of this opioid antagonist treatment was uneven and gradual, but it did increase.	Two veterans integrated service networks (VISNs) accounted for 31% of veterans on buprenorphine.

Author, Year	Study Design	Population	Setting	Exposure	Relevant Outcomes	Results	Limitations
Woody et al. 2007 ¹⁰³	Retrospective cohort	636 opioid-dependent veterans in methadone maintenance therapy between Jan 1, 2000 and Aug 31, 2002	Philadelphia, PA	Retention in methadone maintenance therapy vs. discharge from therapy	Rate of death, including rate of death from overdoses	<p>1. Mortality (both all-cause and specifically from overdose) is significantly increased among patients discharged from methadone maintenance therapy as opposed to patients retained in the program.</p> <p>2. Negative outcomes (continued drug use, joblessness, psychiatric problems) were associated with being discharged from methadone maintenance therapy.</p>	<p>1. Participants are mostly male and over 50, and are mostly hepatitis C positive.</p> <p>2. It is not known how many discharged patients were referred to other treatment programs.</p>

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