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Expanding Access to Naloxone in Maine: Opportunities and Barriers

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Table of Contents Page

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention have declared prescription drug abuse a national epidemic (Office of National Drug Control Policy, 2014). In addition to strategies designed to prevent opioid abuse and misuse, many public health officials, policy makers, healthcare providers and harm reduction task forces seek to increase access to naloxone, a prescription drug known to reverse the effects of an opioid overdose. This report provides an overview of the barriers and opportunities for the state of Maine to expand access to the opioid antagonist, naloxone, in an effort to reduce fatal opioid drug overdose rates.

Methods

A thorough review of the literature was conducted to identify national trends in expanded naloxone access, the perspectives of public health stakeholders, and the early outcomes of more aggressive naloxone distribution programs in other states. Research and brief interviews were conducted to determine the state of the opioid abuse issue in Maine, the current status of naloxone expansion efforts, and the unique challenges that different public health stakeholders in Maine may face. Stakeholders were identified as those who could be directly involved in the distribution of naloxone. These include healthcare providers, law enforcement, pharmacies, community health organizations, and the family and friends of overdose victims.

Results

Research shows that efforts are being made to increase access to naloxone in Maine but are largely piece-meal and are only made possible by the few who choose to champion the effort. Proponents of increased naloxone access in Maine are likely to discover common barriers that inhibit increased distribution, including access to intranasal naloxone supply, the increasing cost of naloxone, and a regulatory framework that inhibits buy-in.

Additional barriers were also identified that apply in a unique way to each of the stakeholders listed above, including:

- Perception of opioid users and scope of job responsibilities
- Fear of liability for prescribing or administering naloxone
- Lack of education about naloxone, its applications, and its benefits
- Cost of implementation, including drug cost, training, staff time, and outreach

Given the current challenges that public health stakeholders face in Maine, some “low-hanging fruit” stand out as Maine’s greatest opportunities to increase access to naloxone and, as a result, reduce fatal opioid overdoses. These opportunities are: legislative education and support, naloxone distribution via primary care practices with an integrated behavioral health model, and increased distribution to law enforcement officials in Maine.

Naloxone is very much a part of the public health conversation in Maine. None of the barriers presented are insurmountable but would be more easily overcome with a statewide, systematic public health approach rather than the current ad-hoc approach. To establish greater buy-in and rally the broad support of policy makers and public health stakeholders, it will be important to change the public perception of can benefit from increased naloxone access.

BACKGROUND

Need

The Centers for Disease Control and Prevention have declared prescription drug abuse a national epidemic (Office of National Drug Control Policy, 2014). Overdose deaths involving prescription drugs now outnumber deaths involving all illicit drugs combined, including heroin and cocaine (Trust for America's Health, 2013). In 2013 alone, 22,767 people died from pharmaceutical overdoses across the U.S. and 71% of these deaths involved the use of opioids for both medical and non-medical reasons (Centers for Disease Control and Prevention, 2014). Opioids are powerful, addictive medications prescribed to manage pain. Medications that fall within the opioid class are hydrocodone, oxycodone, morphine and codeine, among others.

Prescription drug and overdose death rates have doubled, tripled and, in some states, even quadrupled since 1999. According to a 2013 report by the *Trust for America's Health,* the number of drug overdose deaths in Maine increased by 96% between 1999 and 2013 (Trust for America's Health, 2013). In 2012 alone, Emergency Medical Services in Maine report responding to 1,953 calls related to drug and medication overdoses (Hornby Zeller Associates, 2013).

Prescription drug deaths have grabbed the attention of the nation and the world. The overdose deaths of high-profile actors like Philip Seymour Hoffman and Cory Monteith have shined a spotlight on the growing drug abuse epidemic in the U.S.

In recent years, a diverse group of public health stakeholders have begun to address the prescription drug issue by placing an emphasis on reduced access to prescription drugs and, as a result, reducing prescription drug diversion. Efforts include the development of statewide prescription drug monitoring programs, drug take-back programs, and the establishment of more stringent clinical guidelines for the prescription of opioids to treat non-cancer pain.

In addition to these preventive strategies some public health officials, policy makers, healthcare providers and harm reduction task forces seek to increase access to naloxone, a prescription drug known to reverse the effects of an opioid overdose.

What is naloxone?

Naloxone is a prescription drug known as an "opioid antagonist." When administered during an opioid overdose, naloxone can reverse opioids' lethal effects by preventing respiratory depression (Harm Reduction Coalition). Naloxone has been available since the 1970's and is most widely used in emergency departments and by paramedics (UW Alcohol and Drug Abuse Institute, 2013). Its brand name is Narcan. Naloxone can be administered intravenously, intraosseoussly (directly into a person's bone marrow), intramuscularly and intranasally. While reports show that when the drug is administered the individual may exhibit typical signs of withdrawal, there are no known side effects of the drug itself (Robinson & Wermeling, 2014). Naloxone has no effect on non-opioid related overdoses.

Since prescription drug abuse rates have reached epidemic proportions, many states have taken a progressive approach to increasing access to naloxone for even those without professional medical training. In 2012, the Centers for Disease Control and Prevention recommended that public health agencies consider implementing community-based opioid drug overdose prevention programs that include naloxone training and distribution as part of their overall prevention strategy. The CDC recommendation stemmed from research conducted by the Harm Reduction Coalition (HRC) in Oakland, California. The HRC surveyed 50 community-based overdose prevention programs known to distribute naloxone. Results of the survey showed that between 1996- 2010, 53,032 naloxone kits were distributed. During that time, 10,171 successful overdose reversals were reported using distributed naloxone kits (Wheeler, 2012).

In recent years, liberalized naloxone distribution has received the endorsement of the White House Office of Drug Control Policy, the American Medical Association, the American Public Health Association, and the Justice Department. States including California, North Carolina, Ohio, and Colorado are leading efforts to make naloxone distribution an essential piece of the overall drug abuse and overdose prevention strategy. In Maine, however, the efforts to make naloxone more widely accessible to date have been largely ad-hoc.

Many who stand to benefit from increased access to naloxone in Maine are potentially overshadowed by the stigma that exists of the drug-using population. According to the most recent report released by the National Institute of Drug Abuse on the number of drug-related emergency department visits in 2009, nearly 50% of these visits were attributed to adverse reactions to pharmaceuticals taken *as prescribed* (Health, National Institute of, 2011). This demonstrates that the risk of overdose or adverse drug reactions is not unique to drug-abusers.

Proponents who advocate to make naloxone available to communities in Maine are likely to discover common barriers. These barriers include: access to supply of intranasal naloxone, the price of the drug, legislation, public perception, fear of liability, lack of education, and cost of program implementation. None of these challenges are insurmountable. Each barrier would be more easily overcome with a statewide, systematic public health approach.

This paper explores the barriers to expanded naloxone access in Maine. First, the overarching issues of drug supply, cost, and legislation are discussed, followed by the unique barriers that exist for those most likely to serve on the "front lines" of distributing the drug. Those are: healthcare providers, law enforcement, pharmacies, and community health organizations. The perspectives of end-users of naloxone and bystanders are also explored. Finally, given the identified barriers, Maine's greatest opportunities for naloxone distribution are discussed.

Major Issues

Intranasal Naloxone Supply

Naloxone, in its injectable form, is approved by the U.S. Food & Drug Administration (FDA). A series of articles written between 2000-2012 references a shortage of available naloxone with a lack of manufacturing by pharmaceutical companies as the cited reason. However, naloxone is not currently on the list of FDA Drug Shortages, implying that availability of the drug, in its injectable form, may no longer be an issue. (U.S. Food & Drug Administration, 2014). This may be due to the widespread attention that the prescription drug issue has now received and the national movement to make naloxone more widely available.

The intranasal form of naloxone is not currently approved by the FDA. Intranasal naloxone (IN) may be legally prescribed by a physician, but access to the drug in this form may present a challenge due to its "off label" designation. Additionally, IN requires the use of a nasal atomizer to ensure the most effective administration of the drug. To date, the atomizer is not available for purchase through pharmaceutical wholesalers and is not covered by insurance companies. Atomizers are widely available for purchase online but would require a pharmacy to take steps outside of their normal ordering procedure to make these available for customers.

The FDA appears to be taking steps to increase access to naloxone. In February 2015 the FDA granted Fast-Track designation to Adapt Pharma's IN formula after a clinical study determined that the drug in this form can reach a patient's blood stream as quickly as the drug in its intramuscular form (Marotta, 2015). Similarly, in 2014 the FDA granted Fast-Track status and approved kaleo Pharma's naloxone auto-injector product, Evzio (Kroll, 2014). Evzio is an intramuscular form of naloxone that is designed to release the drug by simply pressing the injector against the overdose victim's thigh. The carton provides voice-directed instructions that walk the bystander through the administration of the drug. Though now available at pharmacies, most insurance companies will not cover Evzio without prior authorization or a coverage review deeming the patient to be at elevated risk of overdose.

Drugs can receive Fast-Track designation from the FDA if they are intended to treat a serious medical condition or have the potential to address an unmet medical need (U.S. Department of Health and Human Services Food and Drug Administration, 2014). The FDA's decision to fast-track Evzio and an intranasal form of naloxone indicates the time-sensitive, critical scale of the drug abuse epidemic in our country.

Cost

Providers, pharmacists, law enforcement, and public health organizations are finding that no matter what form of naloxone they plan to distribute, the cost of the drug is increasing steadily without solid explanations from pharmaceutical companies. There is speculation that pharmaceutical companies are capitalizing on a public health crisis. The dramatic increase in naloxone's price seems to correlate with the increased demand by states, municipalities, and community health organizations.

State Attorney's General are taking steps to stabilize the price of naloxone. The New York and Massachusetts Attorney's General have requested that Amphastar Pharmaceuticals justify recent price spikes for the company's naloxone kits in the past year. As a result, Attorney General Eric Schneiderman of New York has been able to negotiate a rebate for kits purchased by police departments and other agencies in the state who distribute the kits (Goodman, 2015). Discussions between Amphastar Pharmaceuticals and Attorney General Maura Healey still continue in Massachusetts (MacQuarrie, 2015).

In many instances, the most popular and user-friendly forms of naloxone carry a higher the price from manufacturers. The intramuscular form of naloxone has been available in emergency departments since the 1970's and has been, historically, as inexpensive at $3 per dose. In contrast, reports show that the intranasal form of naloxone, a form considered more palatable with the general public, currently range between $42-95 per kit (Rosenthal, 2014) (Tavernise, 2015).

Determining the cost of Evzio, the newly approved auto-injector, has proven difficult. Reports vary from $200 per dose to $500 per dose. In January, 2015, the Clinton Health Matters initiative announced a collaborative partnership with kaleo Pharma, the Evzio manufacturer, to negotiate a lower, more stable government price for the auto-injector. Although the new government-negotiated price for Evzio has not been made public, the goal is to make the drug more widely available and affordable to municipalities that have negotiated their own purchasing terms in the past with less purchasing power (Tavernise, 2015).

The additional costs of naloxone program implementation are discussed throughout the rest of this paper.

Prior and Current Legislation Regulating Naloxone

Current Status of Naloxone Laws in Maine

In 2013, Governor Paul LePage opposed the initial naloxone expansion bill. The Governor stated that increased access to naloxone will create a "false sense of security" for those who carry it.

The Maine House and Senate unanimously passed LD 1686 in April, 2014, giving licensed providers the right to prescribe naloxone to high-risk patients or their family members without the fear of civil or criminal liability. Governor LePage refused to sign the bill, but allowed the measure to become law. This bill grants providers the right to prescribe naloxone to high-risk patients and/or family members without fear of civil or criminal liability. The bill also protects the patient and/or family member from liability for the possession or administration of naloxone. Finally, this bill grants first responders and firefighters permission to carry and administer naloxone after receiving appropriate training. There are currently 28 states in the U.S. which have this law in place.

Current Bills Before the Maine Legislature:

LD 710, the Good Samaritan bill, would provide limited immunity for individuals from drug possession charges in the event that they assist an overdose victim by calling 911. This bill was previously vetoed by Governor LePage. Currently, 22 states in the U.S. have this law in place.

LD 140 and LD 812 have been merged to provide several key protections for those prescribing or administering naloxone. Access to naloxone requires a prescription from a licensed provider. In recent years, many harm reduction groups and public health organizations across the country have gained access to larger quantities of naloxone for distribution to their clients through a standing order prescription by a licensed medical provider. The passage of a standing order bill would grant the same rights to qualified organizations in Maine. This bill would also allow for standing order prescriptions to be written to individuals who are identified as at-risk of an opioid overdose. Like LD 710, this bill also includes Good Samaritan provisions, which provide legal immunity for prescribers and those who administer the drug during an overdose event.

Advocates for increased access to naloxone have made legislative progress. However, even if the newest bills before the legislature pass, many barriers still exist that will make access to naloxone an ongoing challenge for those who need it most and for those who wish to distribute it.

Key Stakeholders

Providers

Primary care providers (PCP) have the potential to serve as the first line of defense against opioid overdose. In 2012, the American Medical Association endorsed access to naloxone for laypeople and adopted new policies to support the implementation of programs that offer naloxone to those determined to be at-risk. These new policies encourage provider and patient education with regard to naloxone distribution and use.

Due to their long term relationships with patients, PCPs are well-positioned to prescribe naloxone as a form of preventative care for high-risk patients. PCPs typically have an established history with their patients and a greater foundation of trust to facilitate an open dialogue with high-risk patients. The technological advancements of electronic medical records and the prescription drug monitoring program further enable PCPs to detect opioid addiction or misuse among their patients and to prescribe naloxone.

PCPs can play an important role to reduce opioid-related deaths through naloxone prescribing, but the literature suggests that currently many PCPs lack awareness and education necessary to fulfill this role (Matheson, et al., 2014). Many providers, particularly those in primary care, remain unaware that prescribing naloxone is an option for those patients perceived to be at-risk of opioid overdose. Those who are aware of the option lack the confidence to prescribe it and have expressed differing

perspectives and concerns on the topic (Green, et al., 2013). These concerns have the potential to inhibit buy-in at the provider level.

Perception

Among providers, a commonly referenced concern is the "moral hazard" of prescribing naloxone to already-known drug abusers. Providers in this camp fear that access to naloxone will make a drug addict feel a false sense of security and encourage them to push their boundaries of opioid intake. This concern expressed by providers suggests that the stigmatized view of the drug using/abusing population is one that providers share. However, many studies have shown that moral hazard regarding naloxone is an unfounded concern (Green, et al., 2013).

Some PCPs feel that conversations related to substance use/abuse and overdose prevention are not their responsibility. PCPs often have limited time to address broad health goals and topics with individual patients. Time constraints during regular patient visits have been cited by PCPs to suggest that screening patients for high-risk opioid behaviors do not fall within the PCP's purview.

Liability

Many providers continue to fear legal liability for naloxone prescribing. As referenced above, the passage of LD 1686 granted licensed providers the right to prescribe naloxone to patients who are deemed at-risk of overdose and/or their family members. Many feel that the legal protections provided in the language of this bill do not provide assurances that providers will be immune from legal action should an adverse event take place as a result of the prescription. The newest bill before the legislature, LD 140, strengthens the legal protections afforded to prescribers.

Previous reports show that fear of liability is likely disproportionate to the actual risk. Assuming that a provider is prescribing naloxone to the actual end-user and following all protocol that would normally be expected with the prescription of any drug, the risk of liability is highly unlikely (Temple University Beasley School of Law, 2007).

Education

Provider

Many providers do not have experience or education in the area of addiction management and feel unprepared to advise their patients about potential overdose risks or the benefits of carrying naloxone.

To date, Maine lacks standardized naloxone training for providers but, a variety of national training resources exist.

- Prescribetoprevent.org, a website endorsed by the Office of National Drug Control Policy, provides a range of educational resources geared to healthcare providers. Provider resources include a list of criteria for identifying patients who could benefit from a naloxone prescription. The site also includes *Screening, Brief Intervention, and Referral to Treatment* (SBIRT) billing

codes for Medicaid, Medicare and commercial insurance companies to ensure that providers are reimbursed for the time spent screening a patient (Instructions for Healthcare Professionals: Prescribing Naloxone, 2012).

- The Substance Abuse and Mental Health Services Administration has also published an Opioid Overdose Toolkit which covers the prescriber-specific topics of treatment with opioids, reimbursement for SBIRT, and liability.

Cost

Providers remain concerned about unreimbursed costs to prescribe and distribute naloxone. While providers do not bear the cost of purchasing or distributing naloxone kits, some express concern that the time they take to screen their patients and educate them on naloxone use will not be reimbursed. As mentioned above, providers are eligible for reimbursement for SBIRT screening through many commercial and government health insurance providers.

Overcoming Challenges in Maine: MaineGeneral Prevention Center

In March, 2014 MaineGeneral Prevention Center worked in collaboration with the Harm Reduction Center, Department of Physiatry, Pharmacy Department, and Family Medicine Institute to implement a pilot program aimed at distributing naloxone to patients deemed at-risk of opioid overdose. Phase I of the program focused on identifying partners within MaineGeneral to dispense naloxone kits, educating those who received kits, making follow up calls to those who had received a kit, and building relationships with area pharmacies. Criteria for receiving a kit were adapted from the list of risk factors identified by Project Lazarus, an overdose prevention program based in western North Carolina. Patient education was provided on site by a health educator or nurse when possible or via a YouTube video link that was provided on a business card. Patients provided consent to receive follow-up calls from Prevention Center staff regarding the status of their kit (Harper, 2014).

As discussion of increased naloxone access in Maine continues, the experiences and lessons learned by MaineGeneral will continue to serve as an important resource for all in the public health sector.

Law Enforcement

Police officers are usually the first to arrive on-site during an emergency. Therefore, in the event of a drug overdose, law enforcement often have the opportunity to administer naloxone before Emergency Medical Services arrive. As a result there has been a national effort to put more naloxone kits in the hands of first responders.

LD 1686 granted permission to first responders in Maine to carry and administer naloxone. In March, 2015 the Kennebec County Sheriff's Department became the first law enforcement agency in Maine to train and distribute naloxone to its officers (US Law Enforcement Who Carry Naloxone, 2015).

Despite the backing of the state legislature, local law enforcement still have challenges to overcome that mirror those of providers.

Perception

Naturally, police officers feel a strong sense of duty to protect and serve the communities in which they work. But studies show that law enforcement have differing opinions on whether or not overdose prevention should fall within their scope of duties (Green, et al., 2013). Opinions seem to vary based on officers' experience with illicit drug users and/or family members of overdose victims, the perception of adequate or inadequate addiction management resources in their community, their level of empathy for those who are dealing with chronic pain issues, and a general concern over the work load for officers.

Liability

Fear of liability may deter local law enforcement from adopting a naloxone program. Carrying naloxone has been likened to carrying an automated external defibrillator (AED) to treat individuals whose heart has stopped beating (Green, et al., 2013). As with AED's, federal, state, and local laws may vary regarding officer accountability and liability. Addressing law enforcement's concerns about potential liabilities regarding naloxone training is important to establish state and local buy-in.

Education

A protocol was developed by the Maine Medical Direction and Practices board for all law enforcement and firefighters who carry naloxone in April 2014. Governor LePage allowed for passage of LD 1686 with the stipulation that all law enforcement and firefighters who carry naloxone participate in a standardized training protocol. The primary objectives of the training are to ensure that law enforcement and firefighters can recognize the signs of an overdose, properly administer intranasal naloxone, and be prepared for the potential physical reaction to naloxone.

The education barrier has been largely addressed as a result of the newly developed training protocol, leaving the execution of the training in the hands of individual law enforcement departments.

Cost

Currently, funding has not been made available for program implementation or to cover the cost of purchasing naloxone kits for law enforcement and firefighters. Individual departments are left to bear the cost of purchasing kits and budgeting for staff training time should they choose to prioritize a naloxone program.

Overcoming Challenges in Maine: York Police Department

Despite the challenges referenced above, York Police Chief, Douglas Bracy has developed plans to roll-out a naloxone program within his police force beginning in May 2015. Naloxone training for the York police force will be facilitated by a local emergency room doctor at which time all training participants will sign a memorandum of understanding. Chief Bracy has also negotiated a collaborative partnership with a local hospital to obtain naloxone kits at cost through the hospital pharmacy. The current "at-cost" price is just under $40 per kit. Once received from the hospital, the patrol lieutenant will be responsible for distributing kits to the team. Officers will be required to keep the kits in their duty bags and locked in lockers when not on patrol. Extra naloxone supply will be locked up at the station just like ammunition or anything else that is issued to officers (Bracy, 2015).

Pharmacy

Pharmacies are a key player in the effort to expand naloxone access. In recent years, New Mexico, North Carolina, and Rhode Island have made great strides in developing cooperative agreements between community pharmacies and public health stakeholders to make intranasal naloxone kits available through retail pharmacies, recognizing that many people would be more willing to administer the drug in this form (Yap, 2015). Partners in the efforts in these states have included major pharmacy chains like CVS and Walgreens.

Buy-in from local pharmacies will play a crucial role in executing a broader naloxone distribution program in Maine but some challenges will need to be overcome to succeed.

Perception

As with providers and law enforcement, pharmacists may feel that they are already over-tasked with daily responsibilities. Many community pharmacies are now moving towards providing more comprehensive services to the public, including vaccinations and basic health screenings, adding to the work load of their staff. As a result, pharmacy staff may not be eager to take on the added responsibility of training customers on the use of naloxone.

Liability

Liability is less of a concern for pharmacists as long as the customer provides a legitimate prescription written by a licensed provider.

Education

Staff

More robust naloxone access in the state would require broad training of pharmacy staff. Because naloxone has largely been used in emergency departments and by paramedics to date, pharmacists in a community setting have little experience with the drug.

Customer

Pharmacists are required to provide drug counseling, if needed or requested, to the customer upon delivery of a prescribed drug. With the FDA's approval, it is expected that intranasal naloxone will became more readily available to the general public. The time it may take for a pharmacist to meet with and educate a customer on the assembly and administration of an intranasal kit may serve as a barrier to buy-in for pharmacies to keep kits in stock.

Additionally, naloxone prescribing can be a very sensitive topic for those determined to be at risk. Community pharmacies are often not set up to provide adequate privacy for a customer and the pharmacist to discuss the specifics of a drug. This could serve as a deterrent for customers who are concerned about confidentiality.

Cost

Potential for unreimbursed costs could diminish pharmacy participation in naloxone programs. The time spent counseling a customer is not billable by the pharmacist. Training a customer on the proper administration of naloxone may take longer than drug counseling for a typical pill-based prescription.

Overcoming Challenges in Maine: Maine Medical Center Emergency Department Pharmacy

The Maine Medical Center (MMC) Emergency Department has developed a work group to work through the logistics of making take-home intranasal naloxone kits available to patients. Liability, perception, education, and cost are important considerations to address. Additional considerations include:

1) Criteria to assess patient need for a Naloxone prescription;

2) A cost/benefit analysis of making these prescriptions available to the uninsured;

3) Identifying the appropriate staff person to discuss naloxone with the patient; and

4) Conducting follow-up with patients once they are sent home with a kit.

MMC is able to make naloxone available in an in-patient setting and negotiate pricing for the drug through its membership with a national group purchasing organization. Because MMC's retail pharmacy is open to the public, it is not eligible for the same group wholesale pricing that applies to in-patient pharmaceuticals. However, MMC is a qualified 340B organization. The 340B Drug Pricing Program requires that drug manufacturers make outpatient pharmaceuticals available at discounts for qualified institutions which may be helpful if MMC moves forward with an out-patient naloxone program.

For the work group, understanding what happens to these kits once a patient is sent home with one is an important element of the program. To address the issue of patient follow-up, the work group is currently working through the Institutional Review Board process so that patients can be asked to provide consent for follow-up after being prescribed a take-home kit.

Recognizing that pharmacy specialists are not trained substance abuse specialists, the group is also working to identify the appropriate staff member to discuss naloxone with a patient. Once discussed, the pharmacy specialist would engage in the conversation to ensure that the patient is properly trained to administer the drug if needed (Marden, 2015) (Rolfe, 2015).

Community Health Organizations

Public health organizations and prevention programs are often at the front lines of working with a community's most vulnerable populations. A community health clinic may be a high-risk drug user's only resource for medical care and education. As a result, increasing naloxone access for community health organizations would be a logical and effective method to reach a large segment of the drug-abusing population in Maine.

There are a wide variety of community health organizations in Maine. The Maine Office of Substance Abuse and Mental Health Services offers a searchable database of state licensed agencies, including

both private and public entities. Most offer substance abuse treatment, prevention programs, and/or mental health services and therefore would be appropriate organizations to target for naloxone education and distribution.

Additionally, community health organizations that provide medication management, particularly methadone maintenance, would be strong candidates for a naloxone program given the heightened overdose risk associated with methadone patients.

Perception

The mission of substance abuse treatment and prevention and public health organizations would suggest that naloxone distribution programs would be a priority for these organizations.

Liability

Community health organizations and prevention programs stand to benefit greatly from the passage of a standing order bill. Standing orders allow a licensed medical provider with prescriptive authority to issue rights to a trained health care worker to distribute naloxone to clients who are identified as at-risk. This would eliminate the need for a physician/licensed provider to be physically present for a community health clinic to distribute naloxone to individuals. States like Massachusetts and cities like San Francisco have demonstrated success with preventing overdose deaths as a result of their standing order models (Case Studies: Standing Orders, 2013) (Straus, Ghitza, & Tai, 2013).

Education

Staff

A successful naloxone distribution model through a community health or prevention program requires education and training at both the staff and client level. While naloxone is not a new drug, it may be new to the staff members of a public health organization, thus requiring that the organization invest in the time and resources necessary to educate their team.

Client

Educating clients and/or family members to identify a person who is overdosing and appropriately administer naloxone is essential. Depending on the available resources of the organization and the specific needs of their clients, trainings can be tailored to be one-on-one with the client or offered as an on-going resource that community members have available through the organization. Trainings would also need to be tailored to the type of naloxone that is being distributed by the organization. Those receiving intramuscular naloxone will administer this differently than those who may need to administer intranasal naloxone.

Cost

Public health organizations and prevention programs are most often tasked with providing healthcare and mental health services on a limited budget. The recent spike in the cost of naloxone kits has threatened the ability of many public health organizations to provide kits to their community, or at a minimum, has reduced the number of kits available through their respective programs.

The price of the drug itself is not the only cost that community health organizations face in creating a naloxone distribution program. As mentioned throughout this paper, training and education with regard to naloxone use is an essential part of a successful program. The costs associated with properly educating the community may include staff time to develop educational materials, the cost of printing materials, and the time spent training the staff, end-user or family member on safely administering naloxone. Should the naloxone distribution program also include follow up with the patient/family member to track the status of the kit, this requires additional staff time and resources that may not fit into an organizations budget.

Other

Communicating the availability of naloxone kits to the broader community without creating further stigmatization of their client population in the eyes of the general public is an additional challenge for public health and community health organizations.

Overcoming Challenges in Maine: Portland Needle Exchange, India Street Public Health Center

The India Street Public Health Center in Portland faces many, if not all of the challenges outlined above. But with a commitment to serving their patients, they are in the early stages of a naloxone distribution and education program which is facilitated by their needle exchange program staff and on-site physicians. The naloxone program is not currently funded but has been made possible by a donation of 800 doses of intramuscular naloxone by an out-of-state harm reduction organization. Funding for the program will be necessary in the near future to cover the cost of developing a training protocol for staff and clients, developing educational materials, and to cover the staff time that will be necessary for a more comprehensive roll-out. The Portland Needle Exchange has an established relationship with the Portland Police Department, who are aware of the new naloxone distribution program. The public health center has made a conscious decision not to make a public announcement about the new naloxone program recognizing that this may draw negative attention to the already stigmatized population who use the services of the Portland Needle Exchange (Odlin-Platz, 2015).

End-Users & Bystanders

Studies show that the majority of fatal overdoses occur in a home setting and in the presence of others. Therefore, the family and friends of opioid users and/or abusers are likely in the greatest position to save lives with access to and training on the use of naloxone (Darke, 2000).

Perception

End-User

The distribution of naloxone can be a sensitive subject. The process of screening and prescribing or distributing naloxone can leave a patient feeling judged or as though they are accused of being a drug-addict. This perceived stigma may serve as a deterrent for high-risk individuals to engage in the naloxone conversation.

As stated earlier, 50% of emergency department visits related to adverse drug effects and overdoses are a result of the patient taking their prescription as instructed. Co-prescribing naloxone along with all opioid prescriptions as a standard of practice is a commonly referenced method of ensuring greater access to naloxone while eliminating the risk of a patient feeling singled out.

Bystanders

A bystander's perspective on administering naloxone to an overdose victim may depend on their relationship with the victim, their own experience with drug use, and the form of naloxone available.

It can be assumed that family members would be the most willing bystander to administer naloxone to a loved one when needed. A friend's willingness to administer the drug may depend on their fear of liability (to be discussed in the next section) and their own drug use habits. Research shows that those who have a history of injectable drug use, have overdosed in the past, or have witnessed a drug overdose in the past are more willing to administer naloxone if needed (Lagu, 2006).

The type of naloxone available to family and/or friends may have an impact on a bystander's comfort with taking action in an overdose situation. Greater access to intranasal naloxone would likely increase the comfort level of bystanders should they need to take action in an emergency. Use of intramuscular naloxone is not likely to be as appealing to the general public who have no experience with syringes or injectable drugs.

Liability

Research shows that only 10-60% of bystanders will dial 911 when witnessing an overdose due to fear of legal repercussions (Doyon, Aks, & Schaeffer, 2014). LD 1686 granted the rights of family members to receive a naloxone prescription on behalf of a drug-using patient. Should LD 140, the Good Samaritan Bill, pass during the 2015 legislative session, the friends of drug-users would also be granted this right. The Good Samaritan bill, offers even greater legal protection than LD 1686, granting immunity to bystanders rather than merely affirmative defense. This is an important distinction.

The University of Washington's Alcohol and Drug Abuse Institute conducted a study exploring the attitudes of law enforcement and illicit drug users after the passage of a Good Samaritan law. Results showed that 88% of drug users reported that they would be more likely to dial 911 after being made aware of the new legal protections afforded them (Straus, Ghitza, & Tai, 2013).

Education

Numerous studies have demonstrated that appropriate training for lay administrators of naloxone leads to increased knowledge of how to react in an overdose situation (Jones, Roux, Stancliff, Matthews, & Comer, 2014). The general consensus regarding lay administration of naloxone is that it is imperative that those who receive a prescription for naloxone also receive the appropriate training. This training includes but is not limited to CPR training, education to recognize the signs of an overdose, an understanding that 911 should still be dialed, and that once administered, naloxone is only in effect for a limited duration and may need to be administered twice to be successful.

Cost

The cost of naloxone may serve as one of the greatest barriers for bystanders or opioid users. For those who are insured, Mainecare, Medicare and some private insurance companies do cover naloxone but many have specific criteria that must be met to qualify a patient for coverage. For example, Anthem Blue Cross Blue Shield will provide coverage for naloxone if a patient is being prescribed the equivalent of 100mg or more of morphine per day or "other reason being at risk". Even with insurance coverage, the copayment for some forms of naloxone, like the Evzio auto-injector, can be as high as $100 out-of-pocket.

OPPORTUNITIES FOR EXPANDING ACCESS TO NALOXONE

For those in the greatest position to prescribe or administer naloxone, common barriers exist. Perception, fear of liability, lack of education, and cost of implementation all serve to delay or inhibit buy-in for key stakeholders. Given this current reality, it is important to recognize Maine's greatest opportunities to expand access and begin there.

First, legislative action to increase naloxone distribution and decrease potential liability is essential to develop a systematic approach to increasing naloxone access in Maine. Increased legislative support would serve as a catalyst for more widespread buy-in from those in the greatest position to save lives using naloxone.

By passing the Good Samaritan and Standing Order bills, the Maine legislature would provide greater legal protections for providers and bystanders and broaden the naloxone distribution network available through the community health organizations that serve Maine's most vulnerable populations. Needle exchange programs, substance abuse clinics, and methadone treatment programs are natural allies in the fight against drug overdoses. With the passage of a standing order bill, these organizations would be poised to educate and distribute naloxone to those who are at highest risk of overdose in Maine.

Second, primary care practices that have an integrated behavioral health model are an ideal starting point for a take-home naloxone distribution program at the provider level. Given the finite resources that PCPs possess, a practice that has the staffing to provide coordinated care for both physical and mental health has the greatest potential to identify those patients who could benefit most from a naloxone take-home kit or prescription.

Over 200 practices currently participate in Maine's Patient Centered Medical Home (PCMH) and MaineCare Health Homes (HH) initiatives (Maine Quality Counts, 2015). By participating in these initiatives, primary care practices demonstrate a commitment to comprehensive, coordinated care which includes behavioral health integration. Home Health practices are prime candidates to execute a naloxone distribution program because they are required to provide substance abuse screening for their patients. Educational resources, tools, and reimbursement codes are made available for those practices that choose to use the SBIRT method for screening within their practice.

At a minimum, it would be important to ensure that all PCMH/HH providers are educated in naloxone prescribing practices. Making naloxone take-home kits available at PCMH's and HH's would be even more logical and effective to fulfill the mission of the PCMH/HH model and ultimately save more lives.

Finally, ensuring that every police officer in the state carries naloxone is one of Maine's greatest opportunities. The legislative basis and training protocols are in place to make naloxone more accessible to law enforcement in Maine. The Kennebec County Sheriff's Department and York Police Department have proven that, with support from decision makers and the appropriate medical and pharmaceutical partners on board, a naloxone program is possible.

Funding for law enforcement remains a challenge, but steps are being taken at the federal level to provide more financial support to states. The 2016 federal budget includes $133 million in funding for organizations to treat opioid disorders and prevent overdose deaths. This includes funding for the Department of Health and Human Services to make grants available to up to 10 states to purchase and train staff to use naloxone, including law enforcement (Willard, 2015)**.**

Additionally, in April, 2015, the Federal Office of Rural Health Policy announced a new grant program specifically aimed at expanding access to naloxone for rural communities through law enforcement and local community organizations (Services, U.S. Department of Health and Human, 2015). Eleven of Maine's 16 counties are considered rural, making Maine a strong candidate for funding (Health Resources and Services Administration, 2013).

While prevention is the ideal aim of public health stakeholders in any community, there is a reality to the prescription drug issue that requires a focus not only on preventing abuse and addiction, but also on those who have already fallen victim to the prescription drug epidemic.

The issue of expanded naloxone access is a great example of the diffusion of innovation model. As with any new public health endeavors, there will be early adopters, those who lag behind in fully embracing the concept, and those who fall somewhere in the middle. To establish greater buy-in and rally the

broad support of policy makers and public health stakeholders, it will be important to change the public perception of who stands to benefit from increased naloxone access.

Nationally, progress is being made to increase access to naloxone to decrease fatal overdose rates. States that are taking a more aggressive approach to expand naloxone access advocate not only for distribution through community health organizations and law enforcement but also for availability of kits in schools, on college campuses, and for those who are being released from prison. In Maine, naloxone availability lags behind more progressive states but is very much a part of the current public health conversation. While it will likely be years before Maine's naloxone distribution program is as robust as those in other states, the proper legislative and other elements are being put in place to ensure wider availability in the future.

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