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Naloxone for Opioid Overdose Prevention: Pharmacists' Role in Community-Based Practice Settings

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Abstract

Background—Deaths related to opioid overdose have increased in the past decade. Community-based pharmacy practitioners have worked toward overcoming logistic and cultural barriers to make naloxone distribution for overdose prevention a standard and accepted practice.

Objective—To describe outpatient naloxone dispensing practices, including methods by which practitioners implement dispensing programs, prescribing patterns that include targeted patient populations, barriers to successful implementation, and methods for patient education.

Methods—Interviews were conducted with providers to obtain insight into the practice of dispensing naloxone. Practitioners were based in community pharmacies or clinics in large metropolitan cities across the country.

Results—It was found that 33% of participating pharmacists practice in a community-pharmacy setting, and 67% practice within an outpatient clinic-based location. Dispensing naloxone begins by identifying patient groups that would benefit from access to the antidote. These include licit users of high-dose prescription opioids (50%) or injection drug users and abusers of prescription medications (83%). Patients were identified through prescription records or provider screening tools. Dispensing naloxone required a provider's prescription in 5 of the 6 locations identified. Only 1 pharmacy was able to exercise pharmacist prescriptive authority within their practice.

Conclusion—Outpatient administration of intramuscular and intranasal naloxone represents a means of preventing opioid-related deaths. Pharmacists can play a vital role in contacting providers, provision of products, education of patients and providers, and dissemination of information throughout the community. Preventing opioid overdose-related deaths should become a major focus of the pharmacy profession.

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Keywords

opioids; antidote; naloxone; overdose; intranasal

Introduction

Prescription and illicit opioid abuse is prevalent and over-dose-related deaths are becoming an increasingly common occurrence. The increase in opioid abuse has led to more than 16 500 deaths annually in the United States.¹⁻⁴ Fatalities are often related to use of prescription methadone, hydrocodone, and oxycodone.^{3,5} What was once a crisis primarily seen in injection drug users in large metropolitan areas has become a leading national cause of death for all users of opioids, whether for medical or nonmedical use. However, what mortality data do not portray is the morbidity that is coupled with opioid abuse and overdose. Patients may experience multiple overdose events before a fatal occurrence, which can lead to frequent emergency department visits, inpatient admissions, or criminal arrests. In fact, there are substantial data from emergency department visits to illustrate the extent of this problem. This evaluation of data highlights the need for public health initiatives to not only curb nonmedical use of opioids, but curb overdose deaths.⁶

Naloxone is a potent and competitive antagonist of the μ -opioid receptor. It acts rapidly to reverse centrally mediated respiratory depression as a result of opioid overdose, whether intentional or unintentional.^{3,7} It has been an established antidote for opioid overdose for decades, with primary use among emergency department personnel and first responders such as paramedics.⁷⁻¹⁰ Naloxone is approved for intravenous (IV), intramuscular (IM), and subcutaneous administration. Alternative, off-label routes of administration, including endotracheal, sublingual, inhaled, and intranasal (IN) administration, have allowed health care providers to care for overdose patients in emergent scenarios without IV access.¹¹⁻¹³

Needle-free routes of administration have afforded several advantages to both patients and health care providers. In a prehospital setting, it may be lifesaving to avoid time obtaining IV access and spare the patient an intubation. From the provider standpoint, blood-borne virus transmission such as human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, is greatly reduced in the absence of a needle-stick injury.¹⁴⁻¹⁶ IN administration also represents a unique opportunity to expand the role of naloxone for use in outpatient overdose prevention strategies.

There already exist data supporting the use of IN naloxone in acute overdose settings.^{14,17-20} However, there is little in the way of primary literature documenting the use of naloxone by laypersons in emergent situations. Access to naloxone for outpatient distribution is limited by several barriers, including access to products, funding and reimbursement, legal barriers, and the need for education at the level of the patient, the caregiver(s) or family, and provider. The practice is also controversial and parallels some ethical, moral-hazard and medical-legal issues providers have faced with dispensing other prescription medications such as emergency contraceptives. Despite these hurdles, there have been initiatives to implement prevention strategies to reduce mortality associated with opioid overdose.

A multitude of states have started outpatient naloxone dispensing to curb opioid overdose-related deaths. For instance, Massachusetts has evaluated how overdose education and naloxone dispensing affected opioid-related overdose deaths. They found a reduction in the number of deaths related to opioid overdose over a 3-year period.^{21,22} Across the nation, there is limited exposure to this unique practice and limited appreciation for the role of a pharmacist within this clinical setting. Additional awareness is needed regarding how community-based practitioners have initiated dispensing programs and how barriers to establishing the practice have been overcome.

Objectives

This report aims to introduce and describe outpatient naloxone dispensing to further highlight the circumstances surrounding the practice. Specific aspects related to this practice that were felt pertinent to highlight included the methods by which practitioners initiated and implemented dispensing programs, prescribing patterns that include targeted patient populations, barriers to successful implementation, methods for patient education, and a brief discussion on ethical and medical-legal considerations.

Methods

This report describes the results of several interviews with community-based pharmacy providers who have collaborated with physician specialists in the area of opioid abuse and overdose prevention in order to initiate outpatient naloxone dispensing. The providers interviewed practice in community- and clinic-based settings in large metropolitan cities, including Boston, Seattle, and Pittsburgh. They were identified through their affiliations with collaborating providers. The 6 interviews were conducted over a 3-month period from September to November 2012. Every pharmacist was contacted in advance to confirm his or her interest in disclosing aspects related to their practice and experiences. A standard list of interview questions was developed prior to contacting those who participated. These questions were provided to each person in adequate time prior to the scheduled interview day. The same interviewer led all the discussions.

Results

The Products

Naloxone may be dispensed either as an IM injection or as a needle-less preparation for IN administration. The route of administration depends on which product is stocked for dispensing. For IM administration, providers typically select single-dose vials at a concentration of 0.4 mg/mL (Hospira, available as single dose, 1-mL vials).^{23,24} The product used for IN administration is a prefilled syringe at a concentration of 2 mg/2 mL (IMS/Amphastar, prefilled syringe).^{24,25} The IN mucosal atomization device (MAD-Nasal; LMA North America) fits onto the luer-lock of the prefilled naloxone syringes or a standard syringe for injection. During the course of the interviews, it was found that only 1 pharmacy dispensed the IM product, whereas all others stocked and dispensed products for IN administration. At the time of dispensing, pharmacies label the product with instructions

stating, “Use as directed.” Included in the kit is a detailed instructions sheet with verbal instructions and illustrations on proper use of the intended preparation.

The Philosophy of Naloxone Distribution

The principle of naloxone distribution stems from several different practice models. The first is representative of a more traditional medical model, wherein providers would be prescribing and dispensing pursuant to a prescription. This is how the majority of community or clinic-based pharmacies dispense naloxone because this provides an opportunity to bill prescription and seek third-party reimbursement. Of the 6 pharmacy locations interviewed, 5 required a provider’s prescription prior to dispensing naloxone. Only 1 pharmacy was able to exercise pharmacist prescriptive authority within their practice setting and proactively seek out patients to discuss dispensing naloxone.

The second practice model is the public health model in which naloxone distribution is done as part of a larger public health mission, such as health promotion, injury prevention, or harm reduction. This is similar to other public health–driven projects, such as needle-exchange programs or supervised injection facilities. The goal in this model would be prevention of morbidity, mortality, and disease transmission. In clinical practice, several pharmacies have adopted this philosophy and have taken on the charge of identifying patients and dispensing naloxone without reimbursement rather than seeking third-party payment.

Identifying the Need

Patients who may benefit from the use of naloxone in an emergent setting for reversal of respiratory depression secondary to opioids include high-risk patients (see Table 1).^{1,26,27} Currently, practitioners find motivation to start services from the patient populations that they serve on a day-to-day basis, generally in pain management or substance abuse treatment practices and needle-exchange programs.²⁸⁻³⁰ These providers found a need for an overdose prevention strategy that would directly benefit their patients and also work toward an over-arching goal of reducing deaths related to opioid overdose.

Identifying Patients

The process for identifying the targeted patient population depends on overall patient demographics at the practice site, but also includes high-risk patient groups (see Table 1). Most pharmacists found themselves targeting 1 of 2 patient populations: (1) patients on high-dose opioids for chronic pain management or (2) patients at high risk of overdose secondary to abusing opioids, whether prescription or illicit. Practitioners interviewed were predominantly based in clinic pharmacy settings. The greater part practiced within a hospital-based clinic, an HIV clinic, or a pain clinic or within close proximity to a hospital.

For those pharmacists who are pairing with a provider to target users of high-dose opioids for chronic pain management, identifying patients through prescription and medical records is simple and straightforward. This patient population is encountered by a much broader scope of providers than those who participate in high-risk behaviors of abuse. In fact, 50% of pharmacies targeted patients within this sub-group. This method allows providers to

propose the idea to patients in a nonconfrontational manner because it is from the standpoint of coprescribing and offering an antidote in the event of an emergency involving their routinely prescribed medication. This is also a simple way in which pharmacists with prescriptive authority can identify patients at the time of prescription processing. A collaborative care agreement allows them to initiate the discussion and prescribe naloxone to patients without the need to go through another provider.

Pharmacists and prescribers targeting high-risk patients such as those who currently abuse opioids or have a history of abuse are faced with a more challenging mission. This requires additional proactive screening efforts to recognize patients with high-risk behaviors or approaching a specialist who work in areas of alcohol and drug abuse to help identify patients known to be at risk. Of those interviewed, some targeted groups were patients treated in emergency departments for overdose events, patients in outpatient methadone maintenance programs, those who attended opioid addiction clinics, those who participated in clean needle-exchange programs, and patients of HIV clinics with a history of injection drug use. The bulk of pharmacies (83%) targeted these high-risk patient groups because the majority of pharmacies were located either within or in close proximity to hospitals, methadone clinics, or HIV clinics (67%). In this setting, pharmacists rely heavily on specialists to refer patients best suited for outpatient naloxone, and the education and training comes from not only the prescriber but also the pharmacy.

When approached by pharmacists, discussing implementation of services was met with a high rate of provider acceptance and support. Prescribers initially approached several pharmacists, and other pharmacists had to initiate the discussion with physician colleagues to build support for the practice. Enthusiasm for the practice has grown as data from first-responder experiences have become available. These data supporting IN naloxone for emergent clinical scenarios has allowed practitioners to feel comfortable transitioning it from use in ambulances, to the code cart in clinics and hospitals, and ultimately to the pharmacy counter as an outpatient prescription.^{14,17-20}

Education

In pharmacies that have started dispensing naloxone, all pharmacists and pharmacy staff were trained on administration of the products. Training was provided for staff to allow them to become acquainted with the IN atomizer or IM injection and the patient instructions.

Educating patients and their family members at the time of dispensing is paramount to successful use of the product. This is analogous to dispensing injectable epinephrine for treatment of an anaphylactic reaction, wherein the patient is not going to be able to self-administer the product but another person will be responsible for administration. Therefore, education of the third party is also essential to successful administration. Some providers have actually dispensed naloxone to those related to or acquainted with the patient because they would be using the product at the time of administration. However, this practice is not legal in all states, and only in Illinois, Massachusetts, New York, and Washington has this practice been applied.

Many pharmacies have either developed their own educational protocols and materials or used those available at www.prescribetoprevent.org. As with dispensing of any antidote, it is critical to convey the proper steps in emergency management of an overdose condition. Part of the educational competency would be to establish that the patient or third party is capable of calling 911, doing rescue breaths, checking for a pulse, preparing the product for administration, assessing for a response, and potentially repeating a dose if necessary. The educational materials are dispensed with naloxone, typically constructed as a kit complete with naloxone syringes and the luer-lock atomization device (for IN administration) or needle (for IM administration). Some physician providers have utilized video materials available online to help provide a multifaceted, visual, and verbal demonstration prior to the patient leaving the office. Determining whether a patient has demonstrated competency is at the pharmacist's discretion, just as with any other medication. However, documentation of providing education and counseling are still subject to previously established legal standards.

Reimbursement and Payment

Getting provider support is the first milestone to reach when dispensing naloxone for overdose prevention. However, most pharmacists have found that struggles with financial and reimbursement issues were more difficult to surmount than gaining support from prescribers.

Naloxone is approved for use as an injectable drug. Therefore, it has traditionally not been covered under most outpatient prescription plans, including many state Medicaid programs. The IN atomization device is considered a medical device and similarly has not been covered by prescription plans. Depending on the practice site and arrangements with affiliated providers, the solution to this dilemma may vary.

One established solution is for pharmacies or clinics to incur the cost of the drug and the devices, which can range anywhere from \$15 to \$30 per prescription. Those pharmacists or pharmacies affiliated with state health departments or state and federally funded HIV clinics have opted to incur the cost of dispensing the products and either supplement funds through grant support or actually bill the clinics to help recover some cost of the drug and supplies (33%). This option places the financial burden on providers and has the potential to deter interest in implementing programs.

As an alternative, pharmacists who work with a large Medicaid population have lobbied naloxone manufacturers to participate in state Medicaid rebate programs, so that carriers will include naloxone on their formularies (67%). They have also been successful in adding the atomization device onto Medicaid formularies as well, which has drastically reduced their financial burden.

Although naloxone is not a controlled substance, on interviewing pharmacists and providers, it was found that prescription processing was most successful when providers sent patients to a single pharmacy. There are several reasons this was found to be true. One reason was that pharmacists must work with third party payers to establish appropriate reimbursement. Lack of experience with this process reduces the success rate of prescription processing.

Second, some pharmacies had little experience with dispensing the products. Perhaps they were not familiar with the practice, felt uncomfortable with an off-labeled indication, were unaware of the educational and counseling materials available to them, or were unable to order the atomizer devices in a timely manner.

Ethical and Medical-Legal Considerations

Various providers have examined the legality of dispensing naloxone to laypersons for administration and why state regulations have impeded the ability of naloxone dispensing to ascend into mainstream practice. Some providers have viewed this as a hindrance to advocate for avidly prescribing naloxone. They have found that the biggest regulatory barrier is that naloxone is not included within the scope of all state Good Samaritan statutes. These statutes normally protect laypersons from criminal prosecution for responding to the aid of a person in an emergent scenario. Numerous states have drafted laws to include naloxone administration as part of the Good Samaritan statutes, which ensures that prescribers can write a naloxone prescription for a patient and authorize a third party to administer the antidote. In general, it is advisable to check with the state board of pharmacy to see which regulations are already in place. This is also a simple way to determine their stance on distribution programs and what support will be provided in establishing this practice.

There are other ethical considerations for pharmacists and prescribers. Many would question whether it should be the role of a pharmacist to identify patients for naloxone distribution. Proponents for the practice would equate this to identifying patients eligible for other routine health screenings, such as with medication therapy management and cholesterol or blood pressure screening. To them, identifying patients at risk of opioid-related overdose and death is almost as important as identifying those at risk of heart disease or stroke.

Second, some pharmacists ask whether involving themselves in the evaluation of clinical outcomes and follow-up is appropriate or whether the role of a pharmacist should be limited to education and counseling. The pharmacists who currently dispense naloxone find themselves actively engaged in both portions of the process. From the harm reduction and prevention perspective, counseling and education serve as the cornerstones of opioid overdose prevention and the best way to prevent an opioid-related death. There exists an infrastructure of educational and counseling materials to assist pharmacists and providers in conveying the crucial information at the time of dispensing. Actively engaging in clinical follow-up with the patients they treat regularly is seen as an integral part of their practice.

Given the clinical circumstances surrounding the topic, it may be asked whether pharmacists have a right to refuse to fill naloxone prescriptions based on moral or ethical considerations. As pharmacists, would you be subsidizing or serving as a proxy endorsing continued drug abuse? Those interviewed were asked whether pharmacists at their respective practice sites were permitted to refuse filling naloxone prescriptions. We found that even though all were given the choice to refuse, once they understood the motivation and philosophy behind the practice, none stated that they would. This, in part, stems from the fact that individual pharmacies and pharmacists work so closely with local physician specialists in the area of opioid abuse and overdose prevention to establish the practice that there is a vested interest

in making the project successful. In the end, both parties have found the process extremely rewarding and of clinical merit.

Conclusions

The number of deaths related to opioid overdose has steadily increased over the past decade as a result of multiple factors that work to create a greater overdose risk. It has become increasingly apparent that this risk is not just for those who abuse opioids but also for those who routinely take high-dose opioids for chronic pain management. Dispensing IM or IN naloxone for overdose prevention is an attractive option for decreasing overdose-related deaths. The alternative routes of administration can be used by laypersons during emergent situations, and the availability of prefilled syringes and needle-less administration devices has made distribution feasible and safe.

The risk of opioid overdose-related death is shared by several groups, including the patients, pharmacists, and prescribers. It seems obvious that the medical community needs to begin to simultaneously address pharmacological management of pain, addiction, and abuse to better understand wherein the solution to preventing overdoses and deaths may lie. A vast opportunity exists for pharmacists to rise to the forefront in preventing opioid-related deaths. Pharmacists can serve as invaluable instruments in identifying high-risk patients, particularly those with an established presence within primary care clinics and health departments because they have direct access to patients at the time of screening. All pharmacists, regardless of practice setting, can collaborate with prescribers to formulate policies and protocols for dispensing naloxone, help train providers and patients, and aid in circulating information throughout the community and the profession. As a profession, developing strategies to reduce overdose-related deaths should become a major focus because this represents a national leading cause of drug-related death and a major health risk to a vast number of patients.

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Table 1

Patient Populations at High Risk of Opioid Overdose-Related Death.

Recent hospitalization for opioid overdose or poisoning
History of injection drug use
Suspected or confirmed heroin abuse or nonmedical opioid abuse
Enrolled in buprenorphine or methadone maintenance or detoxification program
High-dose opioid prescription (>100 mg morphine equivalents per day) Use of extended-release or long-acting opioid preparations
Any opioid prescription and known: smoking, COPD, emphysema, asthma, sleep apnea, or other respiratory system disease; alcohol use; concurrent benzodiazepine use

Abbreviation: COPD, chronic obstructive pulmonary disease.

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