Impact of pharmacist provision of naloxone at an independent community pharmacy operating under state naloxone protocol

Authors:
Kathryn N. Anderson, PharmD
University of South Carolina
Medicine Mart Pharmacy
Patricia Fabel, PharmD
University of South Carolina
Kennedy Pharmacy Innovation Center
William J. Stevens, PharmD
Medicine Mart Pharmacy
Lynn E. Connelly
Medicine Mart Pharmacy

Previous Presentations:

Financial support:
An APhA Foundation Incentive Grant was awarded by the APhA Foundation and Community Pharmacy Foundation to support this project.

Conflicts of interest:
Lynn Connelly is the owner of Medicine Mart Pharmacy. Medicine Mart Pharmacy is an active participant in the Flip the Pharmacy grant initiative.
The remaining authors have no relevant financial conflicts of interest to report.

Corresponding author:
Kathryn N. Anderson, PharmD.
1300 Sunset Blvd
West Columbia, SC 29169
E-mail address: katieanderson.pharmd@gmail.com

Word count: (last updated 6/2/2020)
Abstract: 288/300
Total: 1,891/2,500
ABSTRACT:
Objectives: The primary objective of this study was to determine if a universal offer to provide naloxone to all patients dispensed an opioid, accompanied by patient counseling, increases naloxone possession rates among patients of an independent community pharmacy.

Methods: This study was conducted at an independent community pharmacy over a 4-month period. Patients 18 years of age or older who presented a prescription for an opioid medication were included in the study. Any patient with a known allergy to naloxone was excluded from the study. The pharmacist provided counseling and dispensed naloxone pursuant to state protocol upon patient request. Deidentified data from the study period was matched to data from the previous year, prior to the initiation of the naloxone service, to determine if community pharmacy-based naloxone dispensing by protocol improved the naloxone medication possession ratio (MPR). Factors associated with increased risk of opioid-related overdose were collected to identify the most common risk factors among patients dispensed naloxone. Descriptive statistics were used to report data regarding factors associated with increased risk of opioid-related overdose for patients dispensed naloxone.

Results: Following the introduction of a pharmacist driven naloxone dispensing service at an independent community pharmacy, the naloxone MPR doubled from 1.6% to 3.2%. Of the nine patients dispensed naloxone during the study period, 87.5% presented with ≥2 risk factors for increased risk for opioid related overdose. The most common risk factors identified were high opioid dose (>50 MME) and concomitant benzodiazepine use.

Conclusions: Community pharmacy-based naloxone dispensing provides access to naloxone. Upon implementation of a naloxone dispensing service, there was an increase in MPR and total number of naloxone doses dispensed. A similar service could potentially be implemented in other states as scope of practice and state law allows.

Introduction (318)
Reducing the number of opioid associated deaths remains a public health priority. In 2017, prescription opioids alone accounted for more than 47,000 deaths in the United States.1 The Surgeon General of the United States cites a surge in illicitly manufactured synthetic opioids as a contributing factor in the rapid increase in number of overdose deaths between 2010 and 2016.2 The CDC recommends that naloxone be considered for all patients receiving more than 50 morphine milliequivalents (MME) per day.1

While all 50 states have laws that expand access to the reversal agent through pharmacy dispensing, in 2018 naloxone was provided to only 1 in 69 patients dispensed a high dose opioid. Pharmacists are uniquely positioned to provide the public with access to naloxone...
and promote education for safe use of opioid analgesics. As an increasing number of patients receive high dose opioids for management of chronic pain, pharmacists can play an important role in addressing the opioid epidemic by utilizing the prescription drug monitoring program (PDMP), identifying patients who are at a higher risk for overdose, and dispensing naloxone.

Various strategies have been implemented to improve the availability and use of naloxone. One study conducted at the state level demonstrated a significant increase in the rate of naloxone dispensing per 100,000 people following the enactment of co-prescription mandates in Virginia and Vermont. Naloxone co-prescription does not account for patient diagnoses or additional risk factors, nor does it expand access to patients at risk of experiencing an opioid overdose related to illicitly manufactured opioids. While naloxone may be prescribed to a patient, it may not be accessible. A survey of pharmacies in a metropolitan area demonstrated that intranasal naloxone was available in 34% of pharmacies, and more likely to be available from a chain pharmacy than an independent pharmacy. The purpose of this study is to evaluate the potential impact of a naloxone dispensing service at an independent community pharmacy.

Objectives (67)

The primary objective of this study was to determine if a universal offer to provide naloxone to all patients dispensed an opioid accompanied by patient counseling improves naloxone possession rates among patients of an independent community pharmacy.

The secondary objective of this study was to identify factors associated with increased risk of opioid-related overdose that may be common among patients dispensed naloxone at an independent community pharmacy.

Methods (340)

This study was a single-site data review at an independent community pharmacy granted exemption by the University of South Carolina Institutional Review Board Committee. Any patient 18 years of age or older who presented a prescription for an opioid medication between November 1, 2019 and February 28, 2020 was included in the study. Any patient with a known allergy to naloxone was excluded from the study. When a new prescription for an opioid medication was presented, pharmacists offered to provide information about the benefits of naloxone to the patient. Upon pharmacist counseling and subsequent offer to provide naloxone, pharmacists dispensed naloxone to patients pursuant to The South Carolina Board of Medical Examiners and The South Carolina Board of Pharmacy’s Joint Protocol to Initiate the Dispensing of Naloxone HCl Without a Prescription, hereafter referred to as the joint protocol. Interventions resulting in the dispensation of naloxone were documented utilizing an electronic care (eCare) plan.
Deidentified data from the study period was matched to a control period from the previous year (November 1, 2018 to February 28, 2019) prior to the initiation of the naloxone service to determine if community pharmacy-based naloxone dispensing under the joint protocol improved the naloxone possession rate among patients dispensed opioid medications. The naloxone medication possession rate (MPR) was expressed as the percentage of patients dispensed an opioid prescription who also received naloxone. The study period MPR was compared to the MPR from the control period to determine if targeted intervention by community pharmacists impacted medication possession rates. Prescriber designation (MD, DO, NP, PA, RPh) was evaluated for each naloxone prescription dispensed. For patients dispensed naloxone, the number of daily morphine milliequivalents (MME) dispensed to the patient and identified factors associated with increased risk of opioid-related respiratory depression were recorded. Risk factors recorded included concomitant use of benzodiazepine, sedative/hypnotic, muscle relaxant, short acting bronchodilator, long acting bronchodilator, montelukast, roflumilast, or anti-retroviral therapy.

Descriptive statistics were used to report data regarding factors associated with increased risk of opioid-related overdose for patients dispensed naloxone by an independent community pharmacy.

Results (216)

During the study period, 251 unique patients were dispensed an opioid prescription. Eight of these patients were dispensed naloxone. The average age of the patients was 49.4 ± 4.8 years old (mean ± SEM; median=54); 87.5% were male. Patients were dispensed an average of 115.8 ± 38 MME per day (median=60).

Following the introduction of a pharmacist driven naloxone dispensing service at an independent community pharmacy, the naloxone MPR doubled. During the study period, 3.2% of patients dispensed an opioid prescription received naloxone compared to 1.6% of patients during the control period (Table 1). All patients dispensed naloxone under the state’s joint protocol were dispensed the naloxone prefilled nasal spray (4 mg/0.1 mL).

Most patients (87.5%) had two or more risk factors for opioid related overdose. The most common risk factors identified were high dose opioid prescription and concomitant prescription benzodiazepine use (Figure 1). Risk factors with zero patients presenting are not shown.

During the study period, nine total doses of naloxone were dispensed to eight unique patients. Pharmacists dispensed 44% of doses under the joint protocol without a prescription order; the remaining 56% of doses were written by a medical doctor (MD) or doctor of osteopathy (DO). During the control period, three doses of naloxone were dispensed, and all doses were co-prescribed by an MD.
During this study, there was an increase in both the total number of doses of naloxone dispensed and naloxone MPR. Half of the patients who received naloxone during the study period were provided naloxone by a pharmacist. Of note, one patient was dispensed 2 prescriptions for naloxone during the study period, both originating from a physician. An increased awareness and focus on safe use of opioids by the pharmacy staff following the initiation of the naloxone service may have had a positive impact on the number prescriptions written by a physician that were ultimately filled for the patient. Differences in naloxone prescribing rates from physicians and mid-level providers between the intervention and control periods were not assessed as part of this study. Prescriptions for naloxone that were profiled (prescribed but never dispensed) were not accounted for as part of this study and may have differed between the control and study period.

Four naloxone products are available to patients under the joint protocol—prefilled naloxone nasal spray (4 mg/0.1 mL), intramuscular naloxone (1 mg/mL) with mucosal atomizing device (MAD), naloxone for intramuscular injection (0.4 mg/mL), and naloxone auto-injector (2 mg/0.4 mL). Three of the four possible formulations of naloxone were available to patients during the study period; the naloxone auto-injector was not available through the pharmacy’s naloxone dispensing service. All patients included in the study received intranasal naloxone as a prefilled device. Factors that may contribute to product selection include availability, cost, manual dexterity, and patient preference.

Because all patients with an opioid prescription are eligible candidates for naloxone under the state’s joint protocol, patients prescribed fewer than 50 MME per day were not excluded from this study. In this study, 3.2% of patients dispensed an opioid prescription received naloxone. This is higher than the last known national rate for naloxone dispensing, 1 in 69 patients or 1.4%. This figure included only patients prescribed a high dose opioid (>50 MME per day) and is not directly comparable to the MPR determined in this study.3

Most patients dispensed naloxone had more than 1 risk factor for opioid related overdose, with the most common risk factors being high dose opioid prescriptions and benzodiazepine use. The risk factors evaluated as part of this study are not all inclusive. Concomitant use of prescription medications was utilized as a marker for a subset of risk factors that may predispose patients to an unintentional opioid related overdose cited in other reports or mentioned in the state’s joint protocol.5,6

This study supports conclusions of other studies evaluating pharmacy-based naloxone dispensing. While no such study is available for South Carolina patients, a large-scale study assessing naloxone dispensing rates for Ohio Medicaid patients demonstrated the significant impact of pharmacists dispensing naloxone under Ohio’s state naloxone dispensing protocol. Statewide naloxone dispensing rates were 24 times greater (a 2328% increase) following the
passage of expanded naloxone access laws. Among the Ohio Medicaid population, the mean number of naloxone orders increased from 0.025% pre-protocol to 6.09% post-protocol.\(^8\)

Increasing awareness of naloxone availability with sensitivity to patient perception provides a challenge. Many states, including South Carolina, have a public list of pharmacies that carry naloxone. Unfortunately, inclusion on such lists is not indicative of naloxone availability. In a survey of pharmacies listed in one such directory in North Carolina, 39.1% of listed pharmacies did not have naloxone in stock. Independent pharmacies were less likely to stock naloxone than chain pharmacies (OR=0.12, 95% CI 0.06-0.25).\(^9\) Patients who may benefit from naloxone may be unaware that naloxone is an available resource and that it may be purchased without a prescription in many states. Although the total number of doses of naloxone dispensed is low, provision of naloxone at the independent community pharmacy did increase availability.

Misconceptions surrounding the availability and utility of naloxone must be addressed to expand naloxone provision.\(^10,11\) Patient and pharmacy employee perceptions were not objectively assessed as part of the study. Additional research is warranted to assess patient and pharmacist perceptions of pharmacy driven naloxone dispensing services. Misinformation regarding naloxone availability could potentially impact access. A lack of formal training may limit the effectiveness of a pharmacy-based naloxone dispensing service.

At the time this study was completed, the pharmacy was also a participant in the Flip the Pharmacy initiative, which focuses on sustainable, scalable innovation in pharmacy practice. This study was completed ahead of the Flip the Pharmacy opioid progression which focuses on safe utilization of opioid analgesics. As part of this progression, pharmacy staff are provided formal training to integrate opioid safety interventions, including the offer to provide naloxone, into the pharmacy’s workflow. Completion of the opioid change package progression provides an opportunity for application and amplification of the service evaluated in this study.

Limitations (104)

The study is limited by its small sample size. More robust data regarding naloxone possession rates would be valuable in assessing the impact of independent community pharmacy-based naloxone services.

The results of this study may not be generalizable to a broader population. All patients who received naloxone during the study period were white and carried third-party insurance that covered naloxone. Anecdotally, cost was not cited by any patient as the reason for declining discussion about or provision of naloxone. While a similar service could be implemented at other independent community pharmacies, patient eligibility may differ as expanded access laws vary from state to state.

Conclusions (64)
Community pharmacy-based naloxone dispensing provides access to naloxone. Upon implementation of a naloxone dispensing service, there was a modest increase in total number of naloxone doses dispensed and MPR. A similar service could potentially be implemented in other states as scope of practice and state law allows. Additional research is needed to determine the best method for increasing the number of naloxone doses dispensed.

Citations (References)