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## Opioid Overdose Prevention Through Pharmacy-based Naloxone Prescription Program: Innovations in Healthcare Delivery

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### Abstract

**Background**—Given that opioid misuse/abuse and opioid overdose have reached epidemic proportions in the **U.S.**, expansion of naloxone access programs are desperately needed. The objective of this study was to describe emerging trends in Naloxone Rescue Kit (NRK) prescription patterns by pharmacists in New Mexico as an example of a unique healthcare delivery system.

**Methods**—The study presents cross-sectional analysis of the data on NRK prescriptions by pharmacists who received Naloxone Pharmacist Prescriptive Authority Certification since 2013. Data were obtained from the Prevention of Opioid Overdose by NM Pharmacists (POINT-Rx) Registry, maintained by the University of New Mexico and the New Mexico Pharmacists Association.

**Results**—Since 2013, 133 NRKs prescribed by pharmacists have been reported to the POINT-Rx Registry. The mean age of the patients was 41.5±12.0 years (range: 19–67 years) and there were 60.2% female participants. Only 11.3% of the prescriptions were from pharmacists practicing in rural/mixed urban-rural areas. The majority of NRKs (89.5%) were first-time prescriptions. The

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### AUTHOR CONTRIBUTIONS

All authors were involved in interpretation of the results, drafting or critical revision of the manuscript for important intellectual content, and approval of the final version. In addition, Dr. Bachyrycz and Mr. Tinker were responsible for the design of the project, acquisition of the data, obtaining funding, administrative and technical support. Mr. Shrestha was responsible for acquisition and statistical analysis of the data. Dr. Bleske was responsible for the interpretation of the data, statistical analysis, administrative and technical support for the project. Dr. Bakhireva was responsible for the design of the project, acquisition and analysis of the data, obtaining funding, supervision of research staff, and IRB approval.

most common reason for a NRK prescription was patient request (56.4%), followed by a pharmacist's prescription of NRK due to high-dose of prescription opioids (28.6%) and history of opioid misuse/abuse (15.0%). In addition to opioids, other frequently reported substances included alcohol (9.2%) and benzodiazepines (10.8%). More than a third of patients (38.5%) reported polysubstance use in the previous 72 hours.

**Conclusions**—These results indicate that patients at-risk of opioid overdose might feel comfortable soliciting NRKs from a pharmacist. Participation of pharmacists in rural areas in the naloxone prescriptive authority highlight the opportunity for this novel healthcare delivery model in underserved areas; however, the program is clearly underutilized in these areas. Such a model can provide expanded patient access in community practices, while systematic efforts for uptake of the program by policy makers, communities, and pharmacists continue to be needed nationwide.

### Keywords

Naloxone; opioids; community pharmacy; delivery of health care

## INTRODUCTION

Opioid dependence and misuse/abuse in the United States has reached epidemic proportions in recent decades. According to the 2014 National Survey on Drug Use and Health, 15 million people aged 12 or older used prescription drugs non-medically in the past year, and 6.5 million did so in the past month.<sup>1</sup> In 2013, there were 16,235 deaths from prescription opioid overdose.<sup>2</sup> Fatal overdoses involving prescription opioids increased from 4.5 per 100,000 in 2003 to 7.8 per 100,000 in 2013.<sup>3</sup> A 153% increase in emergency department visits for problems related to opioid misuse was observed for the period between 2004 and 2013.<sup>4</sup> These data indicate a startling and deadly trend in the United States, which requires urgent attention. Innovative healthcare delivery approaches<sup>5</sup> are desperately needed to curb the epidemic of opioid overdose.

An effective and life-saving approach to treating opioid overdose is the process of screening for the need for naloxone, increasing patient education on the availability of naloxone,<sup>6</sup> and increasing education on the administration of naloxone. Naloxone is an opioid-antagonist which blocks the mu, kappa, and sigma receptors. Naloxone reverses respiratory and central nervous system depression caused by activation of these receptors following an opioid overdose.<sup>7,8</sup> Previously, the available routes of naloxone administration included intravenous, intramuscular, and subcutaneous. In the hospital setting, naloxone is predominantly administered via the intramuscular or intravenous route.<sup>9</sup> In an outpatient setting, however, intranasal administration of naloxone is the safest mode of administration, since it eliminates the risks associated with using needles.<sup>10</sup> In addition, establishing vascular access can be challenging for many patients, while intranasal absorption allows for a fast systemic effect free of a needle-stick injury.<sup>11</sup> Several randomized clinical trials have demonstrated that administration of a naloxone rescue kit (NRK) was as efficient as intramuscular naloxone in reversing opioid induced respiratory depression.<sup>12,13</sup> Today, the intranasal route of administration is widely available and presents a unique opportunity to reduce opioid overdose mortality. Patients or caregivers can now easily, and without needles, administer naloxone in the case of emergency and often life-threatening opioid overdose

situations. The Massachusetts Overdose Education and Nasal Naloxone Distribution (OEND) program reported reduction in opioid overdose death rates in communities which implemented the program compared with no implementation.<sup>14</sup>

Despite the alarming prevalence of opioid misuse/abuse and related mortality, regulatory barriers in many countries result in naloxone being administered only in medical facilities.<sup>15</sup> The United States pioneered the administration of naloxone outside traditional medical facilities by implementing several naloxone access initiatives, including the distribution of NRKs by Emergency Medical Services and public health workers among high-risk patients, such as ones seen in homeless shelters, HIV prevention centers, methadone maintenance clinics, and substance abuse treatment centers.<sup>16</sup> In Massachusetts and North Carolina, the Legislature passed laws which allowed community and hospital pharmacists to furnish NRKs per prescriber-issued standing orders.<sup>16</sup> In 2013, New Mexico was the first state in the country to allow pharmacists to prescribe NRKs to patients at-risk of opioid overdose using their clinical and professional judgment and without a prescription order from the physician. While many states have recently passed laws intended to facilitate access to naloxone, most focus on increased access through prescription by physicians or standing order.<sup>17,18</sup> Compared to other states, New Mexico allows the pharmacist to serve as the prescriber, therefore increasing direct access of NRK for the patient.

We are not aware of any prior reports evaluating original data from a pharmacy-based NRK prescribing program. The primary purpose of this report is to describe and evaluate the emerging trends in NRK prescription patterns by pharmacists in New Mexico utilizing their own prescriptive authority. These data are intended to provide important information in regards to opportunities for improvement and expansion of the naloxone access program across the nation and to highlight emerging innovations in healthcare delivery to potentially curb the opioid overdose epidemic.

## METHODS

### POINT-Rx Data Registry and Analyses

Data reported in this manuscript were obtained from the Prevention of Opioid Overdose by New Mexico Pharmacists (POINT-Rx) Data Registry. The New Mexico Pharmacist Association (NMPhA) prepared the Naloxone Pharmacist Prescriptive Authority Protocol, which was approved in 2013 by the New Mexico Board of Pharmacy, Board of Nursing, and Board of Medical Examiners. This protocol now allows pharmacists, who complete a certification training program, to prescribe NRKs using their clinical and professional judgment. As part of the training administered by the NMPhA, each certified pharmacist in the Naloxone Pharmacist Prescriptive Authority Program is requested to send a brief summary form for each prescribed NRK to the POINT-Rx Registry, maintained by the University of New Mexico (UNM) College of Pharmacy. The POINT-Rx Registry has been approved by the UNM Human Research Review Committee (protocol: 15-058; PI: Bakhireva) and contains no personal identifiers to protect confidentiality of the patients. The Registry data are stored using the Research Electronic Data Capture (REDCap) data management tool, maintained by the NIH-funded Clinical and Translational Science Center at UNM. Unique features of the REDCap system include secure web connection with

authentication and data logging, multi-site access to authorized study personnel, ability to export data to common data analysis packages, customization of the data entry forms, cross-field and range validation, and security through an automatic log of any data-related activities.

Collected data include general patient characteristics (e.g., gender, race, age, ethnicity and insurance status), reasons for NRK prescription (e.g., polyopioid use, long-term opioid use, high dose, or patient's request), other substances used by the patient in the previous 72 hours, polysubstance use (use of two or more substances in the past 72 hours), and the National Provider Identification (NPI) Number for the participating pharmacy. Race and ethnicity information is self-reported by patients, and collected as a potential predictor of the program utilization. As of January, 2016, 133 forms have been received by the POINt-Rx Registry for NRK prescribed by pharmacists across the state. Descriptive statistics (means and frequencies) have been utilized to summarize the data. Open source R statistical software was used for all analyses.<sup>19</sup>

### **Pharmacist Training and Board of Pharmacy Requirements**

In order for pharmacists to prescribe NRK to a patient, they must complete the NMPHA certification training, consisting of a 4-hour Accreditation Council for Pharmacy Education (ACPE) class and understand the protocol details for NRK prescribing. To maintain this certification, pharmacists must then complete 2 hours of live (ACPE or equivalent) continuing medical education every two years on the topic of opioid misuse/abuse.

### **Naloxone Protocol – Patient Screening**

Although there are several variables when identifying a patient as high-risk for potential opioid misuse/abuse or overdose, the protocol also consists of several suggestive situations that may facilitate the patient screening process in the community pharmacy setting. These situations may also assist in determining whom would benefit from a NRK prescription, but clearly indicate that NRK prescribing should be determined by the pharmacists using their professional judgment for each individual patient. Patients that are prescribed long-acting opioids, such as oxycodone extended release, oxymorphone extended release, morphine extended release, transdermal fentanyl, methadone, or buprenorphine are considered “high-risk” for a potential opioid overdose. In addition, patients taking a high daily dose of opioids and/or using opioids for more than 30 days and those concurrently using prescription or over-the-counter medications that could potentiate CNS and respiratory depression properties of opioids (such as benzodiazepines, antipsychotics, and/or antihistamines) are also considered as good candidates for NRK. Finally, elderly patients (>65 years of age) receiving an opioid prescription, households with people at-risk of overdose (such as children or household members with a substance abuse disorder), those living in rural or underserved communities where emergency medical services may be difficult to access, and other ‘high-risk’ patients, as determined by the pharmacist under their professional judgment, can be prescribed NRK.

## RESULTS

Since 2013, 196 pharmacists received NMPHA certification to prescribe NRKs, and this report is limited to the first 133 reports obtained by the POINT-Rx registry by January, 2016. As shown in Table 1, the majority of patients were females (59.8%) and had either Medicaid (58.1%) or lacked health insurance (25.8%). The mean age of the patients was  $41.8 \pm 12.4$  years (range: 19–79). Almost half of the patients were Hispanic (45.9%), reflecting the racial/ethnic distribution in New Mexico. Most patients were from Bernalillo and Santa Fe counties (88.7%), while only 11.3% of forms were received from pharmacies in rural/mixed urban-rural areas in New Mexico (data not shown).

Most patients (89.5%) indicated that it was their first prescription for NRK (Table 2). The most common reason for NRK prescription was patient's request (56.4%). Other common reasons included prescription of NRK due to a high dose of opioids (28.6%), history of opioid abuse (15.0%), or long-term opioid use (12.0%).

While only a small proportion of NRK prescriptions were due to the use of opioids concurrently with benzodiazepines (6.0%) or alcohol (0.8%), polysubstance use was very prevalent in the study population (38.5%). As expected, opioids (opioid analgesics, heroin, methadone, and buprenorphine) were the most prevalent substances reported by the patients (Table 3). After opioids, alcohol (9.2%) and marijuana (7.7%) were the most commonly reported substances used in the previous 72 hours.

## DISCUSSION

### Emerging Trends from the New Mexico POINT-Rx Program and the Value of Pharmacy-Based Interventions

To our knowledge, this is the first original research report of a pharmacy-based NRK prescription program in the nation. Initial results indicate that patients at-risk might feel comfortable asking for NRKs from a pharmacist, given that 56.4% of the NRKs in our Registry were prescribed per patient's request. These data may also be interpreted as underutilization of the Prescriptive Authority for NRKs by the pharmacists. Our results also highlight that polysubstance use is very common among patients receiving opioids – a group of patients who might particularly benefit from having a NRK available to them. Prior research indicates that the risk of opioid overdose is substantially higher among polysubstance users, particularly when opioids are used concurrently with central nervous system-depressant drugs, such as benzodiazepines, alcohol, antidepressants, or antipsychotic drugs.<sup>20,21</sup> In addition, emerging evidence indicates that concurrent use of benzodiazepines might limit the effectiveness of naloxone to reverse opioid overdose.<sup>21</sup> Somewhat surprising was the gender distribution in the sample, as 60.2% of NRKs prescribed by pharmacists were to female patients. These data, however, might reflect the recent trends at the national level of higher prevalence of opioid analgesics use among women compared to men.<sup>22</sup>

Interestingly, 62% of NRKs were prescribed at the request of the patient, suggesting that patients might view pharmacists as an important resource for such programs. Community pharmacy-based interventions have been successfully implemented for annual influenza

immunization,<sup>23</sup> smoking cessation interventions,<sup>24</sup> screening for diabetes and risk factors of cardiovascular disease,<sup>25</sup> emergency hormonal contraception,<sup>26</sup> early cancer detection initiatives,<sup>27</sup> assessing for worsening heart failure,<sup>28</sup> and improving pneumococcal vaccination coverage for at-risk patients.<sup>29</sup> A recent systematic review about the feasibility and acceptability of community pharmacy-based screening for major diseases found high patient satisfaction rates with such services.<sup>30</sup>

Access to pharmacy-based opioid overdose prevention programs is particularly pertinent to rural and/or underserved areas, where pharmacists are much more readily available than other health professionals. While only 11.3% of the prescriptions were from pharmacists practicing in mostly rural areas of the state, the uptake of the program in these underserved areas is particularly important given the shortage of medical providers. Patients in rural counties have higher mortality rates due to drug poisoning, including opioid overdose,<sup>31</sup> after adjusting for population density.<sup>32</sup> New Mexico has the second highest drug overdose mortality rate in the country,<sup>33</sup> with some rural/non-metropolitan counties having opioid overdose mortality rates 5 times higher than the national average.<sup>34</sup> For example, Rio Arriba and Mora counties in northern New Mexico have 78.4 per 100,000 and 67.9 per 100,000 unintentional overdose death rates, respectively, compared to a national average of 13.8 per 100,000.<sup>34</sup> Approximately half of these deaths are due to prescription opioid overdose. Higher mortality rates in such rural counties might be due to lack of medical access, economic deprivation, inequality, structural discrimination, and other pervasive stressors contributing to health disparities in a broader sense.<sup>35</sup> Factors which contributed to underutilization of the Naloxone Prescriptive Authority in rural areas of New Mexico might include understaffed pharmacies, pharmacists' perceptions regarding their role in preventing opioid overdose, and NRK reimbursement rates. This underutilization highlights the need for additional research in this area and for the identification of innovative healthcare delivery approaches in rural/underserved areas to curb the epidemic of opioid overdose.<sup>5</sup>

Despite the promise of pharmacy-based prescribing of NRK, this is only one aspect to preventing opioid deaths. Declaration from the United Nations Office of Drugs and Crimes clearly states and outlines that a coordinated and integrated community effort from both professionals and non-professional services is needed to reduce opioid deaths.<sup>36</sup> In addition, it is essential that cultural aspects are taken into consideration. Cultural approaches are especially important in states like New Mexico where large percentages of the population are Hispanic or Native American.<sup>36</sup> One example of a coordinated community effort is Project Lazarus.<sup>37</sup> This is a community-based program that incorporates a number of stakeholders, including physicians and nurses, law enforcement officials, and policy-makers. However, pharmacy-based independent prescribing initiatives are not part of Project Lazarus, as this would require legislative changes. As comprehensive community-based programs evolve, pharmacy-based NRK prescribing and education will need to be a key part of these programs.

### **Potential Barriers to Pharmacy-Based Naloxone Prescription Programs**

Accessibility is the primary advantage of the pharmacy-based naloxone prescription/distribution programs. However, key barriers from the perspective of pharmacists might



include: 1) optional certification of pharmacists; 2) normative attitudes towards opioid-dependent patients; and 3) variability in the coverage for NRKs by health insurances. In New Mexico, about 10% of pharmacists pursued certification in the Naloxone Pharmacist Prescriptive Authority Program since its inception in 2013, which clearly highlights the need for expansion. A recent study assessing the feasibility of pharmacy-based intervention for injection drug users (IDUs) identified the following barriers: time, space, sufficient staff, pharmacist training, legal considerations, pharmacist attitudes towards IDUs, cost and reimbursement issues.<sup>38</sup> Another pilot study in Rhode Island also reported that the key barriers to pharmacy-based naloxone intervention programs for IDUs include misinformation about naloxone, attitudes towards IDUs, and cost.<sup>39</sup> Prior research indicates that pharmacists' normative attitudes towards highly stigmatized populations, such as IDUs, can be changed with concerted structural efforts.<sup>40</sup> It should be noted, however, that the New Mexico Naloxone Prescriptive Authority Program does not specifically target IDUs. The program focuses on all people who might be at risk of opioid overdose, including many patients living with cancer and non-cancer chronic pain.

Currently, New Mexico has required state Medicaid programs to cover NRKs; however, for many patients not covered by Medicaid, a NRK might be cost prohibitive. In addition, pharmacists participating in the prescriptive authority of naloxone spend additional time educating the patient on how to use the NRK, signs and symptoms of overdose, and other important counseling points. Early experience from our program demonstrates that it was difficult for pharmacists to obtain reimbursement for such services..<sup>41</sup>

### **Strengths, Limitations, and Future Directions**

Several important limitations of this report need to be acknowledged. First, this study is largely descriptive, aiming at presenting the feasibility, 'uniqueness', and potential of the Naloxone Pharmacist Prescriptive Authority Program as an example of innovative pharmacy practice. Second, information on concurrent substance use was self-reported by patients, and thus might under-estimate the true prevalence. Third, a small sample size did not allow for stratified analysis by the type of pharmacy setting. A recent Web-based survey study among pharmacists in Texas and Utah revealed that practicing in a chain pharmacy was a strong predictor of screening for opioid misuse, with much lower uptake among independent pharmacies.<sup>42</sup> Corporate policies within the chain pharmacies might be an important factor for success of the pharmacy-based interventions, including in the area of opioid overdose prevention. Fourth, this report does not include data on the opioid overdose reversals. Fifth, the POINT-Rx registry might not capture all NRK prescriptions by pharmacists, since the submission of the form to the Registry is requested as a part of the training but is not mandated by New Mexico Law. However, quality assurance and quality control efforts conducted by the NMPPhA indicate that a small sample size of a POINT-Rx Registry to date is, in fact, a function of underutilization of the Program by New Mexico pharmacists, rather than under-reporting. We are initiating an in-depth mixed-method study to systematically evaluate barriers and facilitators of active prescribing of NRK by pharmacists in the state.

Despite these limitations, this report describes the feasibility and emerging trends in pharmacy-based opioid overdose prevention programs. It is apparent that overdose

magnitude increments are product-related, given that opioids have a narrow therapeutic ratio, and are not easily counter-balanced by any available alternative other than product restriction. Naloxone is the first major decrement to the risk of overdose, which is non-restrictive in nature, and thus not altering to a valid prescription for proper analgesic management. Our report highlights a novel approach to naloxone prescribing and patient risk-based education.

While in some other states, legislatures have passed laws which now allow community and hospital pharmacists to furnish NRKs per prescriber-issued standing orders, New Mexico legislation recognizes pharmacists as the prescriber for NRK. Such an approach potentially can increase direct access to NRKs by the patients and caregivers; however, future studies need to compare effectiveness of prescriptive authority versus standing order-based pharmacy programs. Other states can also encourage state representatives to support legislation that allows pharmacists to prescribe naloxone. In New Mexico, regulatory barriers were overcome by the high opioid overdose mortality rate in the state. The lack of access to NRK among many patients was a significant factor in the successful addition of this Prescriptive Authority Program to the role of New Mexico pharmacists. In addition, this report also shows the pressing need to systematically examine barriers and facilitators to pharmacy-based opioid overdose prevention programs from a multi-stakeholder perspective.

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**Table 1**Demographic Characteristics of the Sample (N=133<sup>a</sup>)

Characteristics	Distribution
Age, Mean (SD), years	41.8 ± 12.4
Gender, No. (%)	
Male	53 (40.2%)
Female	79 (59.8%)
Ethnicity: Hispanic, No. (%)	56 (45.9%)
Health insurance, No. (%)	
No insurance	32 (25.8%)
Employer-based	4 (3.2%)
Medicare	10 (8.1%)
Medicaid	72 (58.1%)
Other	6 (4.8%)

<sup>a</sup>Sample size might vary due to pairwise deletion of the missing data

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**Table 2**

## Reason for Naloxone Prescription

Reasons for prescription	No. (%)
High dose opioid	38 (28.6)
Long-term opioid use	16 (12.0)
Opioid use with concurrent benzodiazepine use	8 (6.0)
Opioid use with known/suspected alcohol use	1 (0.8)
Current poly-opioid use	7 (5.3)
History of opioid abuse/misuse	20 (15.0)
Patient request for naloxone	75 (56.4)
Other <sup>a</sup>	21 (15.7)
First prescription	119 (89.5)

<sup>a</sup>Other: household risk, other substance use

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**Table 3**Self-reported Current Substance Use<sup>a</sup>

Substances	n (%) <sup>b</sup>
Alcohol	6 (9.2)
Opioid analgesics	16 (24.6)
Marijuana	5 (7.7)
Methadone	20 (30.8)
Subutex <sup>®</sup>	3 (4.6)
Suboxone <sup>®</sup>	7 (10.8)
Cocaine	1 (1.5)
Methamphetamines	2 (3.1)
Heroin	16 (24.6)
Benzodiazepines	7 (10.8)
Prescription sleep medicine	3 (4.6)
Polysubstance use <sup>c</sup>	25 (38.5)

<sup>a</sup> self-reported substance use in the previous 72 hours

<sup>b</sup> sample size is limited to 65 patients with complete information on current substance use

<sup>c</sup> use of 2 substances in the previous 72 hours