

Barriers and Facilitators to Implementing a Naloxone Collaborative Drug Therapy
Agreement: A Qualitative Study of Washington State Pharmacists

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Abstract

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Background: Opioid-involved overdose deaths have increased dramatically over the past decade, both nationally and in Washington State. A naloxone collaborative drug therapy agreement (CDTA) is an emerging community pharmacy-based strategy to expand access to take-home naloxone, the opioid overdose antidote.

Methods: Semi-structured interviews were conducted with 13 community pharmacy managers and owners in Washington State's Puget Sound region to assess their knowledge, attitudes, and practices regarding a naloxone CDTA.

Results: Although many pharmacists regularly encounter patients at risk of opioid overdose, few address this risk directly when providing patient education. Low awareness of take-home naloxone, discomfort with approaching patients about overdose, cost issues, and regulatory implications present as significant barriers to implementing a naloxone CDTA.

Conclusions: Comprehensive implementation efforts are needed address a number of barriers to naloxone CDTA adoption and provide adequate education and support to pharmacists who may see a need for take-home naloxone in their patient populations.

Introduction

Fatal drug overdose has reached epidemic levels in the United States. Annual overdose deaths have tripled since 1990 and an estimated 100 Americans die from drug overdose every day.^{1,2} Accidental overdoses involving prescription opioid analgesics continue to drive these trends, accounting for more deaths than heroin and cocaine combined.^{3,4} Of the 38,329 overdose deaths that occurred in 2010, 43% involved prescription opioids.⁵

As of 2008, Washington State's age adjusted overdose fatality rate, 14.7 per 100,000 population, was the 14th highest in the nation and significantly greater than the national rate of 11.9 per 100,000.⁶ In 2006, overdose surpassed motor vehicle accidents becoming the leading cause of injury death in Washington.⁷ Much like national trends, prescription opioids play a predominant role in overdose fatalities occurring in Washington State. Between 1995 and 2011, the state's fatal prescription opioid overdose rate increased twelve-fold to 5.9 per 100,000 age adjusted population.⁸

Existing literature on prescription opioid overdose identifies the following demographic factors associated with fatal overdose: male gender, non-Hispanic White or American Indian/Alaska Native race, 20-64 years old, low income or Medicaid enrollee, and resident of a non-metro county.^{1,6,7,9,10} Clinical factors, such as chronic non-cancer pain, mental health issues, history of substance abuse, being opioid naïve or having lowered tolerance to opioids, and nonmedical use of prescription opioids are also associated with fatal overdose.¹⁰⁻¹⁴ Additional drug factors include regimens greater than 50 milligrams daily morphine equivalent dose, prescriptions for extended release or long acting opioids (especially methadone), using a nonmedical route of administration, concurrent benzodiazepine prescriptions, or having multiple opioid prescriptions or multiple providers.^{7,10,12-14}

Death from opioid overdose results from respiratory failure, typically one to three hours after exposure.¹⁵ Fatal opioid overdose is preventable with timely administration of naloxone, a highly safe and effective opioid antagonist that

reverses the pharmacologic effects of opioids and temporarily restores normal breathing. Naloxone itself has no potential for abuse or overdose and has no clinical effects on non-opioid substances.¹⁶

Bystanders, often friends and family of at-risk individuals, are uniquely situated to recognize overdose situations and intervene by calling emergency medical services and administering naloxone. Overdose prevention programs prescribing naloxone, commonly operated by syringe exchanges, have been efficacious in training individuals to respond to overdoses and prevent fatalities among heroin users.¹⁷⁻²⁵

Community based naloxone programs have enabled bystanders to reverse over 10,000 overdoses with naloxone over the past 15 years.²⁶ The implementation of overdose prevention and naloxone distribution programs in Massachusetts was associated with a reduction in opioid overdose mortality at the community level.²⁷ Coffin and Sullivan found distributing take-home naloxone to heroin users prevented overdose deaths and was highly cost effective, even under conservative assumptions. In simulated models, estimations suggest one death was prevented for every 227 naloxone kits distributed, with an overall incremental cost of \$438 per quality-adjusted life year gained.²⁸

Practitioners, researchers, policy makers, and community members are challenged to scale-up overdose prevention efforts and develop new naloxone distribution models targeting additional at-risk populations, such as those at risk of prescription opioid overdose. Several programs, such as Project Lazarus in North Carolina, have implemented naloxone co-prescription (concurrent naloxone prescription for high risk pain patients) to prevent fatal prescription opioid overdose.^{26,29,30}

A naloxone collaborative drug therapy agreement (CDTA) is an emerging community pharmacy-based naloxone distribution model in states with laws that allow such assignment of prescriptive authority. A naloxone CDTA between an authorizing prescriber and a community pharmacist allows a pharmacist to directly prescribe and dispense naloxone. The prescribing process is streamlined, involving only the authorizing prescriber(s) and pharmacists

specified in the agreement. In Washington State, a naloxone CDTA enables a community pharmacist to engage patients at risk of witnessing or experiencing an opioid overdose about overdose prevention and naloxone prescription in the pharmacy setting.

CDTAs were established in 1979 in Washington State under RCW 18.64.011. Pharmacists' scope of practice was expanded to include the "initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs."³¹ CDTAs are regulated under WAC 246-863-100, which requires agreements are filed with the Washington State Board of Pharmacy.³²

Passed in 2010, Washington State's "911 Good Samaritan Law" removes important legal barriers to implementing a naloxone CDTA. RCW 69.50.315 authorizes individuals at risk of witnessing or experiencing an overdose to receive, possess, and administer a naloxone prescription.³³ RCW 18.130.345 further states that good faith efforts related to the "administering, dispensing, prescribing, purchasing, acquisition, possession, or use of naloxone" will not constitute unprofessional conduct."³⁴

Little is known about provider support for take-home naloxone or a naloxone CDTA. What research exists has focused on non-pharmacist providers attitudes' toward take-home naloxone to prevent heroin fatalities. Prior surveys indicate there is limited awareness and support among prescribers for take-home naloxone.^{35,36} A majority of Baltimore area EMS providers did not think injection drug users could effectively manage overdose situations and administer naloxone.³⁷ In a qualitative study of general practitioners, substance abuse providers and pain specialists in New England, Green et al found that while providers generally supported take-home naloxone for pain patients and heroin users, they were concerned about moral hazard (patients using naloxone as a safety net) and felt they needed to have a certain level of trust with take-home naloxone candidates.³⁸

Community pharmacists play a key role in naloxone prescription, particularly the CDTA model. Yet, little is known about pharmacists' attitudes towards and willingness to support take-home naloxone distribution. The purpose of this paper is to describe the knowledge, attitudes, and practices (KAPs) of Puget Sound community pharmacy managers and owners regarding a naloxone CDTA. Additional research aims include: generating hypotheses about barriers and facilitators to implementing a naloxone CDTA in Washington State, assessing differences in KAPs by pharmacy type (independent compared to chain) and urban-rural status (pharmacists practicing in urban compared to those in suburban or rural settings).

Methods

Study Design and Setting

A qualitative research design, based in phenomenology, was used to assess pharmacists' KAPs regarding a naloxone CDTA in the context of their own lived experiences. An inductive approach guided research design and activities, due to the exploratory nature of research aims. Semi-structured interviews were conducted with community pharmacy managers and owners practicing Washington State's Puget Sound region. Three pharmacists with involved in implementation efforts helped develop the interview guide (Appendix Table 1). A fourth pharmacist, unfamiliar with take-home naloxone, was interviewed to pre-test the guide.

Several strategies were used to facilitate interviews with participants who lacked familiarity with take-home naloxone. The researcher provided clarifying information if participants misunderstood a fundamental aspect of take-home naloxone (it was mistaken for another medication, for example). Participants were asked to consider how naloxone might be used in a community setting prior to being questioned about their attitudes toward take-home naloxone. Additionally, questions directed toward the researcher about interview subject matter were answered throughout the interview.

Sampling Strategy

Typical cases, or pharmacists having the most influence over adopting CDTAs, were sampled to participate in this study. The sampling frame included senior chain pharmacy managers overseeing operations in the Puget Sound region, independent retail managers and owners, and managers of ambulatory health system pharmacies practicing in King and Snohomish counties.

Washington State Pharmacy Association (WSPA) staff identified senior managers of five major chains. Independent pharmacy managers and owners were randomly selected from a list of pharmacies located in King and Snohomish counties, also provided by the WSPA. Stratified random sampling ensured an equal number of urban (Seattle and Everett) and suburban or rural (outside of Seattle and Everett) independent pharmacists were represented in a relatively small sample. Participant recruitment stopped when thematic saturation was achieved and no new themes emerged from the data.

Data Collection

Participants were interviewed, in person or by phone, over a three week period in April and May of 2013. Interview data was audio recorded and loosely transcribed into expanded field notes. Prior to the interview, participants were asked to fill out a short demographic questionnaire covering the following items: gender, race, age, years of practice, position, and pharmacy setting.

Analysis Plan

One researcher carried out all phases of data collection and thematic analysis, utilizing methods described by Braun and Clarke.³⁹ ATLAS.ti version 7.0 (ATLAS.ti Scientific Software Development GmbH, Berlin) was used to for data management and analysis. Audio data was time marked, thematically coded, and then linked to the corresponding transcription segment. Preliminary themes and subthemes were refined and finalized and important quotes were transcribed verbatim. A thematic map was then constructed to illustrate theme relationships.

Results

Study Sample

A total of 32 pharmacists were contacted to participate in this study. With a 41% participation rate, 13 pharmacists were successfully recruited and agreed to be interviewed. Thematic saturation was achieved after the 13th interview. Eleven interviews occurred in person and two took place over phone. Twelve pharmacists were audio recorded. One pharmacist declined to be recorded but consented to have the researcher take notes during the interview.

The sample includes three chain pharmacy managers, five independent suburban or rural pharmacists (referred to as rural hereafter), and five independent urban pharmacists, including two ambulatory care pharmacy managers of major health care systems. Over half the study participants were female and most were Caucasian. The mean age was 47 years old and the mean duration of experience in pharmacy practice was 22 years (Appendix Table 2).

Patient Population and High Risk Groups

Pharmacists' perceptions of high risk patient groups varied by pharmacy setting and location. While all pharmacists felt that patients taking chronic high doses of opioids were at risk of overdose, two chain pharmacy managers were primarily concerned about a subset of these patients – the elderly with multiple prescriptions. This group was seen as highly vulnerable and likely to confuse a long acting opioid for a short acting opioid. Chain managers did not address risk behaviors involving the intentional misuse of opioids.

Unfortunately most commonly with the patients we actually see doing these errors, they're usually older and living by themselves. And that's why they made the mistake to begin with, because there's nobody else with them assisting.

- Chain Manager

Independent managers and owners identified a larger number of at risk patient groups. Four risk profiles (not mutually exclusive) were the focus of

concern: 1) chronic pain patients prescribed patch formulations and other extended release or long acting products, 2) chronic pain patients on escalating doses, 3) individuals perceived as misusing prescription opioids, and 4) those using heroin.

Pharmacists that discussed heroin and opioid misuse were directly exposed to drug use behavior in their patient populations and considered opioid addiction and overdose a public health problem in the larger community. Three independent owners knew of patients or family of patients who had overdosed on opioids, including one that occurred in the pharmacy setting. Respondents practicing in rural areas observed changing drug use patterns at the community level.

Well, there's a big heroin problem in [area]. Big. And, it's gotten bigger since they reformulated Oxycontin. And, you know, from my perspective, as a community member, that's bad. From my perspective as a pharmacy owner... You know, we used to be broken into, every year or two. And we haven't gotten broken into since they reformulated Oxycontin. So, I mean, it's a little bit of a... I mean, I grew up in this town. I've been here since I was two. Um, so there's a lot of heroin.

- Independent Owner, Rural

Current Practices

Current pharmacy practices to prevent opioid overdose fell broadly into two categories: 1) counseling patients on medication safety and 2) acting as a gatekeeper to influence prescribing practices.

Patient Counseling

Pharmacists primarily use an indirect strategy to educate patients about overdose, often emphasizing the correct use of opioids (adhering to the dosing schedule, not mixing with other medications or alcohol).

I try to explain to patients that, you can't... you can't lose these. You have to follow the directions. You cannot exceed. I try to make sure that they know about extra Tylenol, if they are taking a pain reliever with Tylenol already. I try to make sure that they

adhere to the schedule and do not exceed. It's tough though, because sometimes you know it's going to end bad.

- Independent Owner, Rural

Two rural pharmacy owners took a more direct approach, counseling patients on the risk of overdose. However, no pharmacist provided education about the signs and symptoms of respiratory depression and appropriate bystander response.

If I have patients that are not only on narcotics, but lots of benzos. I'll bring them in here [private space], even if for a long time, and talk to them about the fact that, you know, we don't know where the lethal dose is. Could be right almost where you are, or it could be a ways off. But we don't know. So, I just try to spend some extra time with them and just caution.

- Independent Owner, Rural

Pharmacist as Gatekeeper

Respondents described acting as a gatekeeper to prevent patients from receiving opioid therapy perceived as harmful or inappropriate. Two processes were central to this role: 1) coordinating with providers about dosing and 2) “catching” patients who exhibit drug seeking behavior.

Cultivating pharmacist-prescriber relationships was viewed as key to effective care coordination and improving outcomes among pain patients. Pharmacists regularly provide feedback to prescribers on dosing guidelines when initiating or increasing opioid therapy.

You see someone that might be taking too much. We're careful about how you might communicate that to the physician or to the patient. But we do, do that. You know, on the side. And we might say, you know um, “So and so, you know, they're having additional problems. We noticed there was an increase in their meds. Is everything okay? Is there anything we can do?” That's how we approach, say the doctor so that we're not trying to... you know.

- Independent Owner, Urban

Independent pharmacists described a number of “red flags” or “cautionary flags” they considered indicators of drug seeking behavior, nonmedical use, or diversion. When a patient exhibits one or more red flags, the pharmacist gathers

additional evidence to verify suspected misuse, usually through Washington State's Prescription Monitoring Program (PMP). Some described proactively tracking opioid refills, to monitor for nonmedical use and possible stockpiling.

As a gatekeeper, pharmacists coordinate with prescribers to verify a patient's treatment plan or limit access to opioids in these situations. Pharmacist intervention with nonmedical users often permanently severs the pharmacist-patient relationship. Some noted that because of their diligence, the number of nonmedical users coming into the pharmacy had decreased.

The more you check, the fewer times that happens in your practice. Because the people who do do that kind of thing, I swear to God there's a club or a network. Because if you allow that to happen, it will happen more and more often. If you don't allow it to happen, it dries up. So, I'm happy to say that it doesn't happen because I think we are trying to pay attention.

- Independent Owner, Rural

Experience with CDTAs

Eleven of the thirteen pharmacists had experience with CDTAs, primarily immunizations and emergency contraception. Respondents felt that patient demand or benefit and profit to the pharmacy were the most important factors to consider when initiating a CDTA. Additionally, if a therapy was perceived as low risk, with few side effects or low probability of patient harm, it was also more desirable for CDTA consideration.

We're a private company, so it has to be profitable. There has to be some group out there we are servicing that is going to result in a payment to us. Um, and then secondarily it has to have a benefit to our patients. We have to see some reason to offer this service to our particular patient group that is going to improve our standing with our patients and give them something they want.

- Chain Manager

One independent owner also discussed adopting CDTAs that were not profitable because of overwhelming patient demand.

But, I would have to say, most of it is driven by the community saying, "Hey we would really like you to do something here." And so, we do it.

- Independent Owner, Rural

Take-Home Naloxone

Awareness

Respondents had little experience with naloxone in community pharmacy practice and more than half the sample initially confused it with naltrexone or buprenorphine. Ten of the thirteen pharmacists interviewed had never heard of an individual at risk of experiencing or witnessing an opioid overdose being prescribed naloxone. Of the three independent pharmacists who were familiar with take-home naloxone, two owners were contacted to initiate naloxone CDTAs and one read about it in a pharmacy journal. Determining who would administer naloxone during an overdose was a common point of confusion.

You are expecting patients to know that they've overdosed or family to recognize they've overdosed?

- Chain Manager

I didn't know that people had naloxone at home, to administer to themselves or somebody else. I have never done it. I don't know.

- Independent Owner, Rural

Patient Benefit

Pharmacists were largely supportive of prescribing naloxone to chronic pain patients, especially those on very high or escalating doses. Some were eager to learn how they could better help chronic pain patients avoid the risks associated with dose escalation and saw take-home naloxone as a potentially useful tool.

I have a lot of concerns for a lot of these patients. We see some chronic pain patients that are on monstrous doses. And um, you know, it would give me a lot of peace of mind if I knew they had something at home. That could help if something were to go wrong.

- Independent Owner, Rural

However, several respondents indicated that benefit to patients would depend on the general competency of the at-risk individual or existence of an involved competent support system that could intervene during an overdose.

I start applying that scenario to people I know who are at risk of, and probably have overdosed on opiates. I can't think of anybody around them that I trust to accurately... to competently administer that medication at the right time. Yeah, I'd be a little worried. Again, case by case. I'd need to know lots.

- Independent Owner, Rural

As we know, most drug addicts are very responsible people [laughs]. Let's see. "You know, I'm going to carry my naloxone because my friend's going to be shooting up some, uh black tar heroin tonight, along with me, of course. And, uh, we gotta have that to save his life." I can't see that happening. People that are into drugs don't think very clearly.

- Independent Manager, Urban

Five pharmacists had a broader sense of the patients who might benefit from take-home naloxone, including users of illicit drugs and those in outlying areas, farther away from emergency medical services.

Certainly, there's kind of two groups of people out there that I think that this would appeal to. It would be the family members, the people that would really want these individuals to get off drugs, and they're clean and don't do anything. And then there's the other people who are, "This is my buddy, and we do drugs together and we're looking out for one another."

- Independent Owner, Urban

...because, you never know when something like that might be happening, when you're out camping or just not near emergency services. You can be emergency services.

- Independent Owner, Rural

Risks to Patient

Several pharmacists had misconceptions regarding the safety of naloxone, as they had never encountered intramuscular or intranasal naloxone in the community pharmacy setting. Three thought it may have harmful clinical effects to individuals not overdosing or those not on opioids. Two pharmacy

managers felt naloxone was inherently risky because of perceived abuse potential.

I think it's just the drug itself. I think it's a high risk drug. And with that, I mean, it can come in a kit. But, how do you know someone's not going to break up the kit? I mean, you know, it's not as safe. And if I were the provider, I would not just let anybody prescribe that under my name, because I'll be liable.

- Independent Manager, Urban

Three pharmacists cited moral hazard or safety net effect – that individuals misusing opioids would “test their limits” if they knew they could fall back upon naloxone, as a potential concern. However, this was seen as minor issue, something respondents thought they would need to look out for.

You know, we can get people to recover from narcotic abuse, but we can't get them to recover, once they're dead. So um, I would say, I would be more likely to be in favor of something like this than opposed to it. Even though there is that potential increased risk [of moral hazard]. Um, you know, the alternative is just not very acceptable.

- Independent Owner, Urban

Perceived Legal Barriers

Pharmacists had limited knowledge of Washington State's 911 Good Samaritan Law. Six of the thirteen pharmacists had heard of the law, but only three were aware of protections pertaining to possession charges. Although it was considered a potentially effective strategy, a majority thought providing overdose education and naloxone to likely bystanders violated HIPAA or Washington State laws. After learning about the provisions of the 911 Good Samaritan Law, third party naloxone prescriptions were perceived as legally plausible in Washington State.

"So anybody could have naloxone then. It makes sense. It makes good sense."

- Independent Manager, Urban

Patient Demand

Counseling

Pharmacists felt it would be difficult and uncomfortable to talk to at-risk patients about respiratory depression and naloxone, because of perceived stigma around drug abuse and overdose. Offending or upsetting patients by discussing overdose was a major concern.

Would they be upset that you would be thinking that about them? Even though you're caring about them? You know, sometimes you hurt the ones you love, type idea. They may feel like, you know, you're hurting them.

- Independent Owner, Urban

Overall, a pharmacist's comfort level with providing overdose counseling improved if they had an established rapport with a patient and the pharmacy had a private space. One owner reflected on providing overdose counseling in current pharmacy practice:

And so, having a separate room like this is really helpful, because you aren't having it publicly. And some of the... a lot of the women especially, get kind of teary about it. Um, and the fact they know that I'm on their side and we have that relationship. That makes it easier, also.

- Independent Owner, Rural

Others thought it would be easier to counsel motivated caregivers.

My initial reaction is, whoa. Um, for this high risk group you're saying, "Hey. You know what buddy? You're a high risk guy. You might overdose. Here I'm going to give you this, so that you don't kill yourself." It has a... the patient is going to look at you with a jaundiced eye. And so, I'm a little concerned about that. Um, if a family member came in and says, "Hey. I'm concerned about my daughter, my son, my friend, my cousin, my aunt, and um... I'm around them. I see them. I've sometimes come upon them when they've been out. Don't know if they're alive and called 911." I could see something along those lines. Where you have a caretaker... I call them a caretaker. It could be anybody, but it's a caretaker. I could see them coming in and getting that for an emergency, like having nitroglycerin or an Epipen. I totally could see that.

- Independent Owner, Urban

Cost

Pharmacists felt out of pocket costs to patients would be an important driver of demand for take-home naloxone. Three forms of out of pockets costs were identified, all resulting from gaps in insurance coverage:

- 1) The time spent by the pharmacist providing overdose counseling would be passed on to the patient in the form of an education fee.
- 2) As intranasal naloxone is considered an off-label use, patients would need to pay for the mucosal atomizing device (MAD).
- 3) A concerned bystander would need to pay for naloxone, MAD for intranasal naloxone, and education fee entirely out of pocket.

Overall Demand

All pharmacists felt coverage issues and out of pocket expenses significantly limited the reach of take-home naloxone, regardless of perceived potential candidates and at-risk populations. Additionally, a majority of respondents felt generally uncomfortable with the primary mode of marketing naloxone – approaching patients directly about overdose.

A naloxone CDTA was often referred to as “niche” or “small.” After considering the at-risk population, candidates for take-home naloxone, and out of pocket costs, some pharmacists felt demand would be so small that participation would not be worthwhile. Those who had either a narrow view of at-risk patients or felt eligibility should be restricted to high functioning patients and caregivers questioned the overall demand for take-home naloxone.

It's not big enough. I need it to be big enough.

- Independent Manager, Urban

Chain managers thought they could hypothetically maximize demand by implementing naloxone CDTAs in high dispensing stores, typically near pain specialists or hospitals in urban areas.

At least not until it became something that patients were requesting, it would be something that would be deployed everywhere. Like immunizations. Patients ask for that everywhere. Until it was something that patients were looking for, it would be a hard thing to go everywhere. I could certainly see it ending up around some of our stores in Seattle by, um, pain clinics, where some of the patients are going from the pain clinics to the pharmacies and we have a higher population base there that may need something like that.

- Chain Manager

Respondents who had more inclusive criteria for at-risk patients and naloxone eligibility discussed demand in more optimistic terms. One independent owner felt it was possible to market naloxone to groups outside of the immediate patient population, such as the families of at-risk individuals, through social media forums. However, this prospect was accompanied by minor apprehension about how community members would respond.

The interesting thing would be, you know, marketing something like that. And um, the community's response to something like that. Everyone has their own ideas to how you should handle things like that. Whether it gets swept under the rug, ignored, um actively try to prevent, yeah. So, um, that's one of the tricky things.

- Pharmacy Owner, Rural

Risk to Pharmacy

Heroin Users

Recognizing the draw of illicit drug users, two respondents mentioned the possibility of disruptive behavior or theft in the pharmacy. A pharmacy owner noted that because naloxone is not an ongoing therapy, contact with heroin users would likely be limited to one-time encounters. Having heroin users in the pharmacy was characterized as a minor concern.

And um, then again, you know, these people probably aren't going to be coming in a whole bunch of times, like they would with insulin syringes. It's probably a one-time visit. So, that crosses my mind but I don't think it's a huge major concern or a drawback.

- Pharmacy Owner, Urban

Another pharmacy owner was actively pursuing a naloxone CDTA through a partnership with a syringe exchange program and local health department. The pharmacist's role in this particular model involved verifying the patient received education at the exchange and dispensing naloxone to syringe exchange personnel, who would then deliver it to the patient. A pharmacist taking on the role of an outreach worker, providing direct naloxone services to much of a syringe exchange program's clientele, was viewed as neither feasible nor appropriate.

[The needle exchange coordinator's] comment was, "We know our clients. We would identify them. Either my partner or her would come and pick [the naloxone] up, because I don't want my clients in your store." And I said, "That would probably be good. Because I probably don't want your clients in my store either, but I do want them to have the naloxone."

- Independent Owner, Urban

Federal Regulatory Agencies

Two pharmacists felt adopting a naloxone CDTA could pose a serious risk to pharmacists, particularly if Washington's 911 Good Samaritan Law was not recognized by federal regulatory agencies. They worried the DEA specifically, would consider prescribing and dispensing naloxone unprofessional conduct. Respondents reporting this concern discussed two hypothetical scenarios that could provoke or complicate a DEA investigation:

- 1) If pharmacists were able to effectively create demand for naloxone among chronic pain patients, the amount of controlled substances dispensed by the pharmacy would rise to "unacceptable" or "suspicious" levels.
- 2) During an ongoing or new DEA investigation, naloxone co-prescriptions would be interpreted as evidence of inappropriate prescribing and dispensing practices.

In that case, if you're having to take big doses. I guess, you know, [naloxone] could apply to someone that is using [opioids] completely for legitimate purposes. And you know, it's just, again,

kind of a questionable sort of area. Can you do that without it being a risk? Do you have any backup? To say, “Hey, we’re giving potentially dangerous dose and dangerous in terms of, they could overdose or get confused and overdose.”

- Independent Owner, Urban

One pharmacy owner felt that prescribing naloxone to heroin or nonmedical opioid users (in cases where the opioid prescription is not filled) would be less risky for the pharmacist, as the sale of the controlled substance would not be connected to the pharmacy.

The one thing is... if it’s a patient I’ve never seen before and I don’t take care of, but I can go on the PMP and see that this person is, you know, does indeed look like they might be at risk. Um, then that is a little bit different situation. Or if they’re not getting things from me and they’re a heroin abuser or something that’s certainly not a, you know, C2 that’s involved. It’s a schedule one that’s involved.

- Independent Owner, Urban

The pharmacy community at large was described as fearful of interacting with the DEA or practicing in any way that could be interpreted as a “red flag” for unprofessional conduct. Despite supporting take-home naloxone and observing need in the patient population, respondents citing this concern felt it was the primary barrier to adopting a naloxone CDTA.

Willingness to Consider Adoption

When reflecting on past experience, pharmacists indicated patient benefit or demand, profit, and risks to pharmacy influenced their decision to adopt CDTAs. These factors are largely consistent with how respondents described their willingness to consider adopting a naloxone CDTA, which fell into four categories: early adopter, possible support, limited support, and not interested (see Appendix Table 3 for full description).

Discussion

Although many pharmacists regularly encounter patients at risk of opioid overdose, few address this risk directly when providing patient education. Critical

opportunities exist to approach patients about overdose, especially when coordinating care for chronic pain patients or intervening with those suspected of opioid misuse. However, the pharmacist's gatekeeper role largely revolves around restricting or modifying supply in these situations.

When it was passed in 2010, the legislation for Washington's 911 Good Samaritan Law lacked dedicated funding or a comprehensive plan for widespread implementation. Given that pharmacy managers and owners are unfamiliar with take-home naloxone and the Good Samaritan Law itself, coordinated implementation efforts are essential to promoting naloxone CDTA adoption (See Thematic Map and Table 4 in Appendix for illustration and summary of hypothesized barriers, facilitators, and implementation strategies).

Many pharmacists confused naloxone for other therapies or assumed it was "high risk." Others felt the efficacy of naloxone would depend on general competency of patients and caregivers. Disseminating basic information about take-home naloxone and the efficacy of syringe-exchange based models may remedy concerns about safety and the perceived "responsibility" needed to administer naloxone.

Pharmacists would benefit from receiving additional tools to identify and approach at-risk individuals, especially suspected nonmedical users or unfamiliar clients. Chain managers likely underestimate the pool of patients who are at higher risk of overdose and dissemination of epidemiologic evidence about known risk factors may be useful. Incorporating unambiguous information about opioid overdose into existing medication safety discussions and interventions with nonmedical users could be the nearest low hanging fruit.

Some respondents indicated patient request for naloxone could influence the decision for adoption. Sustained education and outreach efforts are vital to informing the public about the risks of overdose and appropriate bystander response, including the option for naloxone prescription. Patient advocacy may be critical to implementing naloxone CDTAs in chain settings.

The out of pocket costs of take-home naloxone remain a significant barrier to generating patient demand. Unfortunately, patients viewed as being the most

motivated and easiest to approach, concerned friends and family, bear the largest burden of out of pocket costs. Development of instructional aids may help reduce counseling time and associated education fee. Local and state health departments should consider fostering partnerships with pharmacists to directly finance take-home naloxone efforts, to incentivize both pharmacists and patients. As evidence suggests take-home naloxone is a cost effective way to prevent heroin fatalities, this is likely a worthwhile investment.²⁸

Additional coordination is needed between state and federal agencies, particularly the DEA. The “culture of fear” described by pharmacists may partially explain the low recruitment rate for this study and present as a barrier to future coordination efforts with pharmacists. Pharmacists concerned about DEA involvement suggested that a formal recognition of Washington’s 911 Good Samaritan Law may lessen the risks they associated with naloxone CDTAs. Perhaps state and local support for naloxone CDTAs can also be communicated to federal agencies by registering participating pharmacies with local health departments.

Independent owners and managers practicing in suburban and rural communities with high or growing rates of heroin use may be more supportive of naloxone CDTAs. Early implementation efforts may be more successful in these settings, as there may be a greater perceived need among pharmacists for interventions that address opioid misuse and overdose.

This study adds to the growing body of literature on provider support for take-home naloxone. Similar to past research findings about the support of non-pharmacist providers,^{35,36} pharmacists in this sample had a low level of awareness for take-home naloxone. However, this analysis provides a detailed account of pharmacists’ experiences with take-home naloxone (or lack thereof) and the assumptions about the safety of naloxone that result. Study results show the importance of pharmacy context and shed light on some of the unique challenges pharmacists face when treating pain patients or those experiencing addiction. Findings support several conclusions presented by Green et al,

specifically provider need to trust take-home naloxone candidates and concern for moral hazard.³⁸

Perceived risk to pharmacists posed by federal regulatory agencies is, perhaps, the most interesting finding. Although pharmacists citing this concern were philosophically aligned with harm reduction and felt positively about take-home naloxone, implementing a naloxone CDTA was perceived as being too risky. This finding is likely relevant to overdose prevention efforts in other states with 911 Good Samaritan Laws, as providers who prescribe or dispense controlled substances may feel these laws do not adequately protect them against investigation from federal agencies.

Study findings call for additional research on how federal regulatory agencies will respond to the implementation of 911 Good Samaritan Laws. Future research should also examine the attitudes and perceptions of individuals at risk of witnessing or experiencing an opioid overdose toward purchasing take-home naloxone and receiving overdose education in the pharmacy setting. Such research could inform pharmacist efforts to approach patients about overdose and take-home naloxone and help providers assess and grow patient demand for take-home naloxone.

Limitations

Results from this project may not be generalizable beyond senior chain and independent pharmacy managers and owners in the Puget Sound region. However, generating hypotheses is a primary goal of this project and external validity is less of a concern. Qualitative research can often benefit from multiple perspectives in the coding process. Multiple coding was not possible for this project as coding and analysis was conducted by one researcher. It was also not possible to perform triangulation by way of additional data sources (survey or focus groups) or respondent validation.

Additionally, a significant number of pharmacists declined to participate in this study. Although independent pharmacists were randomly sampled, the final sample likely over represents pharmacists with an interest in this topic. In person

interviewing may also be subject to a greater degree of social desirability bias compared to other modes of questioning.⁴⁰

Conclusion

Comprehensive implementation efforts are needed to promote naloxone CDTA participation in Washington State. Outreach to pharmacists should include education on naloxone safety, efficacy of syringe exchange-based naloxone programs, Washington's 911 Good Samaritan Law, and known risk factors for opioid overdose. Many pharmacists interviewed were supportive of take-home naloxone and voiced interest in receiving additional overdose prevention education and tools to assist chronic pain patients. Ongoing coordination between pharmacies and county, state, and federal agencies may help address other barriers discussed in this paper and provide adequate support to pharmacists who see a need for take-home naloxone in their patient populations.

Appendix

Table 1: Interview Guide Topic Areas

Interview Guide
• Current practices to help patients avoid opioid overdose • Awareness and perceived efficacy of prescribing take-home naloxone to individuals at risk of opioid overdose to prevent overdose deaths • Awareness and perceived efficacy of prescribing take-home naloxone to individuals at risk of witnessing opioid overdose to prevent overdose deaths • Perceived legal issues associated with prescribing take-home naloxone to individuals at risk of experiencing or witnessing opioid overdoses in Washington State • Prior experiences and attitudes toward implementing CDTAs • Attitudes towards implementing a naloxone CDTA in current pharmacy practice

Table 2: Participant Characteristics

Participant Characteristic	N= 13
Gender	
Female	54% (7)
Male	46% (6)
Age	
Mean Age	46.8 years
Years of Practice	
Mean Years of Practice	22.5 years
Race	
Caucasian	92% (12)
Asian	7% (1)
Pharmacy Setting	
Chain Managers	23% (3)
Independent	77% (10)
Characteristics of Independent Pharmacists	
Manager	40% (4)
Owner	60% (6)
Urban	50% (5)
Rural	50% (5)

Table 3: Participant Willingness to Consider Adoption

Degree of Willingness (n)	Pharmacist Characteristics	Description
Early Adopters (2)	Two rural pharmacy owners	• Actively pursuing a naloxone CDTA • Recognized opioid misuse and heroin use as a public health issue in the community • Confident take-home naloxone would benefit patient population • One was willing to market naloxone to individuals outside of the immediate patient population
Possible Support (4)	Three rural and one urban independent pharmacist	• Supportive of take-home naloxone and thought it could benefit their patient population • Recognized opioid misuse or heroin use in patient population • Some concern about approaching patients or cost issues • Interest in taking continuing education on take-home naloxone and acquiring new skills to assist chronic pain patients
Limited Support (2)	Two chain managers	• Perceived limited demand for take-home naloxone • A naloxone CDTA would be feasible in a few settings, such as high dispensing stores or those near pain clinics and hospitals in urban areas
Not Interested (5)	One chain manager and four urban independent pharmacists	• Proportion of at-risk patients seen as small, with limited demand • Take-home naloxone seen as “high risk” • Two were otherwise supportive of a naloxone CDTA, but potential response from DEA was the primary barrier.

Thematic Map: Theme Relationships and Implementation Barriers

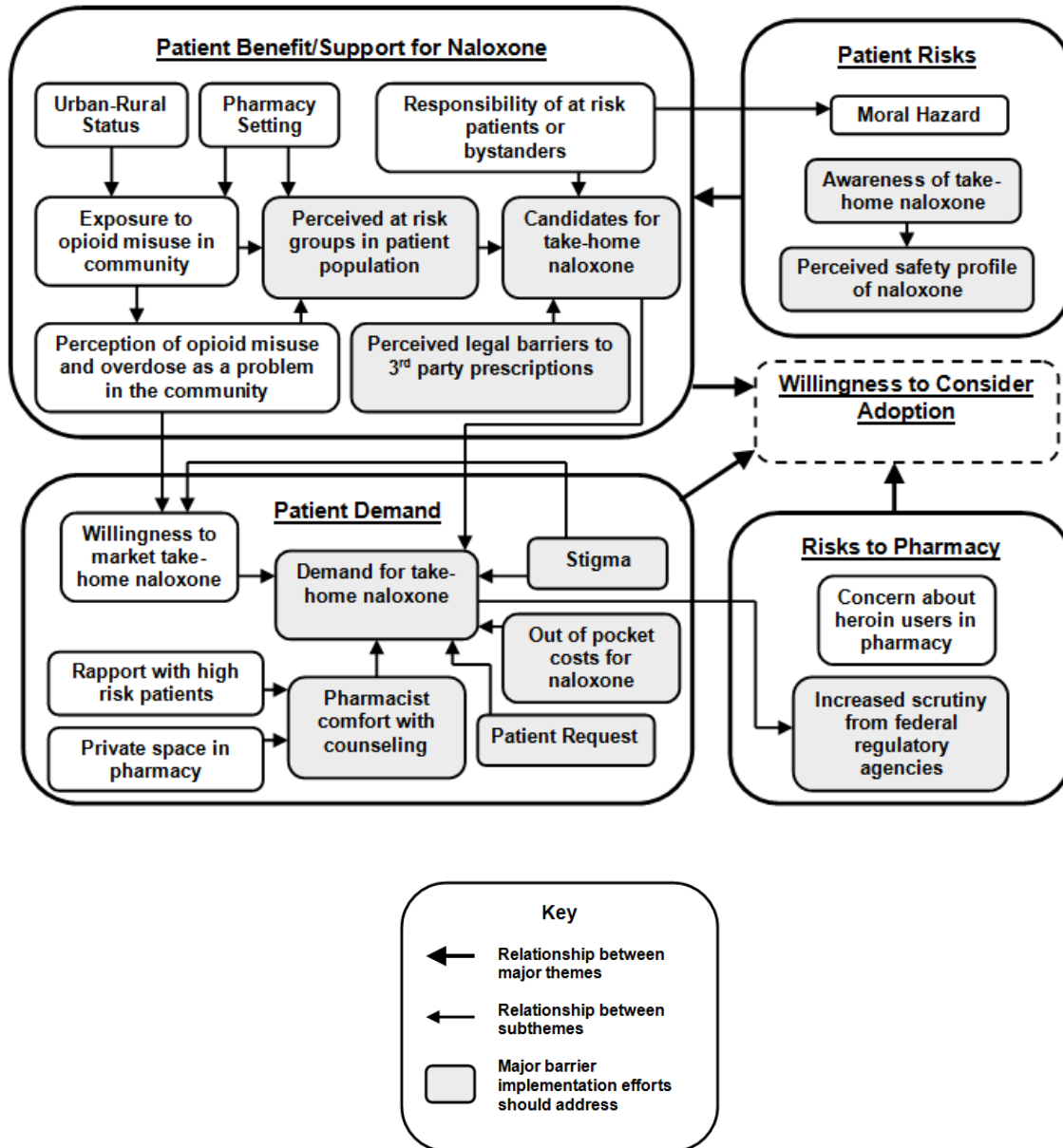


Table 4: Summary of Barriers, Facilitators, Implementation Strategies

Barriers • Lack of familiarity with naloxone • Perception of naloxone as “high risk” in the community setting • Lack of awareness of 911 Good Sam Law • Narrow view of at-risk patient groups • Narrow view of candidates for take-home naloxone • Discomfort and time involved in providing overdose counseling • Out of pocket costs to patients, especially third parties • Perception that a naloxone CDTA could provoke or complicate a DEA investigation • Concern about having heroin users in the practice
Facilitators • Exposure to substance abuse in the community • Perception that opioid misuse and overdose are public health problems in the community • Belief that take-home naloxone will benefit patients • Broader view of at-risk groups in patient population • Broader view of candidates for take-home naloxone • Willingness to market take-home naloxone • Desire for additional tools to assist chronic pain patients • Private space in the pharmacy to discuss overdose and naloxone • Rapport with at-risk patients
Possible Implementation Strategies • Public outreach and education regarding overdose prevention and take-home naloxone • Pharmacist education on known risk factors, 911 Good Samaritan Law, basic naloxone information, and efficacy of other naloxone models • Local health department-pharmacy partnerships to finance take-home naloxone and demonstrate support for naloxone CDTA • Additional strategies to help pharmacists identify and approach patients at risk of opioid overdose • Formal DEA recognition of 911 Good Samaritan Law and coordination between state and federal agencies.

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