Naloxone prescribing by psychiatric clinical pharmacists for patients receiving opioid agonist treatment

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Abstract
Take-home naloxone is an important intervention for addressing opioid overdoses. Patients with a history of a substance use disorder are at an elevated risk of experiencing an overdose, and even in substance-abuse treatment, they may continue to witness peer overdoses. The purpose of this innovative practice was for psychiatric clinical pharmacists to improve access to intranasal naloxone and provide opioid overdose prevention training for patients receiving opioid agonist treatment (OAT). This program took place at a San Francisco Department of Public Health pharmacy that provides OAT (buprenorphine and methadone) to approximately 200 patients with opioid use disorders as part of an integrated treatment program. During the 17-month study period, 47 intranasal naloxone kits were prescribed. Patients reported 3 successful opioid overdose reversals using intranasal naloxone. Based on these findings, psychiatric clinical pharmacists can improve patient safety by increasing access to intranasal naloxone and opioid overdose prevention training for patients receiving OAT.

Keywords: naloxone, substance abuse, opioid-assisted treatment, clinical pharmacist

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Background
Drug overdose surpassed motor vehicle accidents as the leading cause of unintentional death in the United States in 2010. Of these overdoses, opioid analgesics were involved in more cases than any other drugs, including heroin and cocaine.¹ Opioid overdoses occur with both therapeutic and recreational use of opioid analgesics and heroin. Patients with comorbid psychiatric and substance use disorders are at a particularly high risk for opioid overdose, and even those in substance abuse treatment are at risk for witnessing or experiencing an opioid overdose themselves.² Prescribing take-home naloxone is one intervention that can reduce the number of opioid overdose deaths.

Naloxone is a µ opioid receptor antagonist that is indicated for complete or partial reversal of opioid-induced respiratory depression through intramuscular, intravenous, and subcutaneous injection. The injectable product can be used off-label by intranasal administration with the attachment of a mucosal atomizing device. Outside of the hospital, intranasal naloxone has demonstrated effectiveness for the treatment of opioid-induced respiratory depression by paramedics.³ Naloxone can also be used by lay people as a bystander-administered treatment, which is commonly referred to as take-home naloxone.

Take-home naloxone has traditionally been available from needle-exchange sites and harm reduction programs. A 2010 US survey reported 188 naloxone distribution...
programs that trained 53,032 people and reported 10,171 opioid overdose reversals. In San Francisco, the Drug Overdose Prevention and Education (DOPE) project has distributed take-home naloxone at needle-exchange sites to injection users since 2003. The DOPE project reported in a 6-year period they dispensed naloxone to 1942 patients, and it was used in 399 opioid overdoses with 89% of overdoses reversed. However, in San Francisco as well as other locations, patients who enter substance abuse treatment programs might no longer access needle-exchange services and therefore might not have ongoing access to take-home naloxone.

Psychiatric clinical pharmacists work closely with a population at high risk for opioid overdoses, including those with a history of mental illness and/or substance abuse. Therefore, these pharmacists are ideally positioned to identify patients at risk of experiencing or witnessing an overdose, provide overdose prevention training, and prescribe take-home naloxone. There has been little published data on pharmacy-based naloxone distribution in community-based practice settings. This is the first report of psychiatric clinical pharmacists prescribing take-home naloxone under a collaborative practice agreement in a substance abuse treatment program setting.

Legal Background
In the United States, as of July 2014, there are 24 states, including California, with laws that protect prescribers who are prescribing naloxone and/or lay people administering naloxone in the setting of an opioid overdose outside of the hospital. In general, prescription medications cannot legally be administered by nonmedically licensed individuals as it is considered practicing medicine. California Civil Code Section 1714.22 allows nonmedically licensed individuals to possess and administer naloxone to a person suspected of experiencing an opioid overdose. Under this law, naloxone may be prescribed to “a person at risk of an opioid-related overdose or a family member, friend, or other person in a position to assist a person at risk of an opioid-related overdose.”

Opioid Overdose Risk Assessment
Take-home naloxone should be considered for all patients exposed to opioids regardless of the source. The risk of an opioid overdose is a hazard of the drug and drug combinations that are used. This applies to recipients of prescription and nonprescription opioids, those who take opioids for pain and who abuse them alike. Additional risk factors for opioid overdose include concurrent use of benzodiazepines, history of opioid addiction or other substance use disorder, comorbid mental illness, receiving prescriptions from multiple pharmacies and multiple prescribers, and daily opioid doses exceeding 100 mg of morphine equivalents. Patients receiving maintenance treatment with buprenorphine or methadone are included both as opioid recipients and as individuals with a history of opioid addiction.

Purpose
The purpose of this project was to improve access to intranasal take-home naloxone and provide opioid overdose prevention training for patients receiving opioid agonist treatment (OAT) with an end goal of increasing patient safety.

Description of Innovative Service
This program took place at the Community Behavioral Health Services (CBHS) pharmacy, which is a specialty mental health pharmacy for the San Francisco Department of Public Health. The CBHS pharmacy provides OAT (buprenorphine and methadone) to approximately 200 patients with opioid use disorders as part of an integrated treatment program.

A collaborative practice agreement was developed with the medical director of substance use disorders for the 7 psychiatric clinical pharmacists to prescribe intranasal naloxone to patients receiving OAT at the CBHS pharmacy. Patients were notified of the program through pharmacy signage. In addition, pharmacists informally interviewed patients at the pharmacy window and reviewed complete medication regimens when available. They focused their efforts on patients at high risk for experiencing or witnessing an overdose. Risk factors included concurrent CNS depressant use (eg, benzodiazepines, muscle relaxants, alcohol, etc.), history of mental illness, and ongoing substance use in social network.

Naloxone kits were prepared at the CBHS pharmacy at the time of prescribing and included two prefilled naloxone syringes, two mucosal atomizing devices, and a brochure on opioid overdose prevention developed by the San Francisco Department of Public Health. At the time of prescribing, naloxone was billed to the patient’s third-party payer. Mucosal atomizing devices do not have a NDC code and therefore could not be billed to the patient’s third-party payer and were provided by the San Francisco Department of Public Health. All patients prescribed naloxone were counseled on how to prevent, recognize, and respond to an opioid overdose. In order to comply with documentation and reporting requirements of California Civil Code Section 1714.22 for an opioid overdose prevention and treatment training program, patients requesting refills were asked the following in a paper survey: Was the naloxone used for an overdose, did adverse events occur, and was the overdose successfully

reversed? This law was amended in October 2013 to no longer require this documentation and reporting; however, pharmacists continued to collect the data for internal program evaluation.

**Impact on Patient Care**

Beginning in October 2012, psychiatric clinical pharmacists offered intranasal naloxone kits and opioid overdose prevention training to all patients receiving OAT at the CBHS pharmacy. Between October 2012 and February 2014, 427 patients were eligible for receiving naloxone kits. Forty-seven intranasal naloxone kits were prescribed. Patient demographics are summarized in the Table. Patients were a mean age of 40 years and predominantly male (64%). Buprenorphine was the most common OAT (91%). The primary third-party payer was the San Francisco County Plan (72%). All naloxone prescriptions were successfully billed through the patients’ third-party payers with no copay. Concurrent CNS depressant use was identified in 20% of patients. Refills accounted for 7 of the intranasal naloxone kits prescribed. Patients returning for naloxone kit refills reported 3 successful opioid overdose reversals using intranasal naloxone. Other reasons for naloxone kit refills are summarized in the Figure. No unsuccessful reversals or serious adverse events were reported. A limitation of this program was pharmacists did not document the number of patients who were offered naloxone or the number of patients who declined naloxone in order to assess patient acceptability.

**Conclusions**

Psychiatric clinical pharmacists can improve patient safety by increasing access to intranasal naloxone and opioid overdose prevention training for patients on OAT. Anecdotally, OAT patients demonstrated that they were receptive to opioid overdose prevention training and intranasal naloxone. Patients on OAT are present during peer overdoses, can successfully reverse opioid overdoses with naloxone, and should be a priority for naloxone distribution programs. Psychiatric clinical pharmacists are uniquely trained to identify high-risk medication regimens, including concurrent CNS depressant use in OAT

**TABLE:** Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients prescribed naloxone (n = 47)</th>
<th>All OAT patients during time period (n = 427)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (range)</td>
<td>40 (26-58)</td>
<td>40 (15-76)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>30 (64%)</td>
<td>309 (72%)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (36%)</td>
<td>118 (28%)</td>
</tr>
<tr>
<td>Opioid agonist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>43 (91%)</td>
<td>419 (98%)</td>
</tr>
<tr>
<td>Methadone</td>
<td>4 (9%)</td>
<td>8 (2%)</td>
</tr>
<tr>
<td>Third-party coverage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>County plan</td>
<td>34 (72%)</td>
<td>323 (76%)</td>
</tr>
<tr>
<td>Medicaid</td>
<td>13 (28%)</td>
<td>81 (19%)</td>
</tr>
<tr>
<td>Medicare part D</td>
<td>0 (0%)</td>
<td>23 (5%)</td>
</tr>
</tbody>
</table>

**FIGURE:** Reasons for naloxone kit refill
patients. Given the success of this innovative practice, psychiatric clinical pharmacists should consider starting a naloxone distribution program at their practice sites. Pharmacists wishing to implement a similar program would have to consider their own state laws, formulary coverage, and access to mucosal atomizing devices.

References


