

A Pharmacist Telephonic Intervention: Saving Lives, One Naloxone at a Time

Tina M. Menedjian^{1*}, Patricia L. Gray², Ryan Chaput³, Jason Shan⁴¹Post-Graduate Year 1 Pharmacy Resident²Pharm.D., FCSHP, Riverside Pharmacy Clinical Operations Manager, Post-Graduate Year 1 Pharmacy Residency Coordinator³Pharm.D., Drug Education Coordinator⁴Pharm.D., Pain Management PharmacyDOI: [10.36347/sajp.2020.v09i12.006](https://doi.org/10.36347/sajp.2020.v09i12.006)

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*Corresponding author: Tina M. Menedjian

Abstract

Original Research Article

Purpose: As of January 1st 2019, the California Assembly Bill (AB) 2760 (amended January 2020 to AB 714) requires physicians to offer a naloxone prescription and education to high-risk patients about overdose prevention and naloxone use [1, 2]. In 2019, Kaiser Permanente Riverside Service Area Local Controlled Substances Safety Committee developed a plan for an ambulatory care pharmacist (ACP) second naloxone outreach for high-risk patients. **Methods:** This is a single-center, retrospective, data-only study. Naloxone prescription pick-up rate was analyzed for patients who received an ACP second naloxone offer call in March 2020. The primary outcome was to increase naloxone prescription pick-up rates. Patients were included if they were ≥ 18 years old, on concurrent opioid(s) plus a benzodiazepine, had no history of naloxone sold at index date, and either previously declined a naloxone offer or failed to pick up a naloxone prescription ordered by their primary care provider (PCP). Index date was the first documented ACP outreach call. A secondary outcome was to identify patient reasons for declining naloxone. **Results:** 79 patients were included in the study. Nine (11.4%) patients successfully picked up their prescription. The top two patient reported reasons for declining naloxone were “I don’t need it” 53% and “too expensive” 20%. Descriptive statistics were used. **Conclusion:** Nine patients picked up their prescription. The study had several limitations and challenges, including the timing of outreach during the COVID-19 outbreak. Future studies using a larger sample size and initiatives involving pharmacists to improve naloxone prescription pick-up rates should be considered.

Keywords: ambulatory care pharmacist (ACP), California Assembly Bill (AB), COVID-19 outbreak.

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INTRODUCTION

According to the CDC report in 2018, every day 41 people died from prescription opioid overdose [3]. In 2019, the National Institute on Drug Abuse (NIDA) added that 30% of opioid-related overdoses involve benzodiazepines (BZDs) [4]. Use of naloxone is one of the key recommended mitigation strategies to reduce the incidence of death due to opioid-induced respiratory depression [5].

As of January 1st, 2019, the new California AB 2760 Naloxone law (which was amended and updated in January of 2020 to AB 714) requires physicians and other providers to offer a prescription of naloxone for the complete/partial reversal of opioid depression and to provide education to a patient and his/her designee on overdose prevention and the use of naloxone [1, 2].

Naloxone, a short-acting opioid antagonist, is used to reverse the effects of opioid-induced overdose and has proven to be widely successful in a population-level reduction in overdose mortality [6]. Thus, expanding naloxone availability through diverse mechanisms is considered an important component of opioid-induced overdose prevention. Despite the federal endorsement through the Centers for Disease Control and Prevention (CDC), in addition to the California AB 2760/714 naloxone law, naloxone prescribing and naloxone prescription acceptance rates are still relatively nascent [6]. It is crucial that gaps in care be identified to increase naloxone provider and patient education, prescribing, and patient prescription acceptance.

In lieu of the new law and with concern for patient safety, it was important to KP Riverside to study the impact of a pharmacist telephonic intervention in this high-risk patient population.

In 2019, the Kaiser Permanente Riverside Service Area (SA) Local Controlled Substances Safety Committee (LCSSC) identified 666 high-risk patients on concurrent opioid(s) plus a BZD. Naloxone was ordered for 81% of these patients and 38% of these patients did not pick up their naloxone prescription up to four months later, and thus remained at a high-risk for opioid-induced respiratory depression (OIRD). In November 2019, LCSSC developed a plan for an ACP second naloxone outreach for these high-risk patients that would be performed by an ambulatory care pharmacist (ACP) to increase naloxone prescription pick-up rates.

The ACP second naloxone outreach workflow consisted of the ACP first obtaining primary care provider (PCP) permission to contact their eligible high-risk patients (who had either initially declined their PCP first naloxone offer or failed to pick up their first naloxone prescription ordered by their PCP). The ACP then performed a pre-assessment electronic chart review through accessing patient record via HealthConnect[®], and prescription pick-up history via Permanente Online Interactive Network of Tools (POINT). Next, the ACP called the patient to provide the second naloxone outreach (Appendix 1). The ACP educated the patient about the risks, prevention, and detection of OIRD and naloxone use. The ACP also addressed patient barriers they had in previously picking up their first naloxone prescription ordered by their PCP, in addition to assessing barriers to declining ACP naloxone second offer at the end of telephone encounter (if patient declined second offer). If the patient agreed to pick up the naloxone prescription, the patient was informed of their prescription cost based on their pharmacy benefit and arranged for it to be filled at their preferred KP pharmacy. The ACP then documented the telephone encounter, patient reported barriers, outcomes of the call, and “time spent” (includes pre-assessment, ACP call, naloxone cost retrieval via POINT, documentation, KP Electronic Pharmacy Information Management System (ePIMS) order entry, etc.) in the electronic chart and pharmacist-managed Microsoft Excel[®] sheet.

The primary outcome of the study was to evaluate the impact of ACP naloxone outreach in increasing naloxone prescription pick-up rates. A secondary outcome was to identify patient barriers/reasons for declining naloxone prescription offered by their PCP. If the ACP outreach could prove to make a significant impact, the results could be used to potentially define care gaps and areas for improvement within KP and serve as a model for pharmacists as a safety net filling gaps in opioid safety at other KP Southern California facilities.

METHODS

This is a single-center, retrospective, data-only study, where the subjects served as their own control.

Data was collected from electronic medical records (EMRs) for patients managed within the KP Riverside SA. The study population included adult patients > 18 years, with active prescriptions for concurrent opioid(s) plus a BZD, and with no history of naloxone sold prior to ACP naloxone call. The primary outcome of the study was to increase patient naloxone prescription pick-up rates through ACP second naloxone outreach calls. The index date was the first documented outreach call from the ACP to the patient. Patients were included in this study if they were > 18 years old, on concurrent opioid(s) plus a BZD at index date, had no prior history of naloxone sold on patient EMR prior to index date, and received an ACP telephonic outreach call between March 9, 2020 to March 20, 2020. Patients were excluded if there was any loss of KP membership, if they were enrolled in hospice/palliative care or on active chemotherapy, within 1 month pre- and post-ACP outreach.

The principal investigator identified patients through pharmacist-managed Microsoft Excel[®] sheets that were used to document and track ACP outreach calls and follow-up of prescription pick-up within 15-days post-index date. A data analyst abstracted the data for each identified patient using HealthConnect[®], POINT, Pharmacy Management Data System, and International Classification of Diseases Codes (ICD-9 and ICD-10). The primary investigator performed medical record reviews of patients through HealthConnect[®] and POINT to confirm patient had not picked up their naloxone prescription prior to ACP second naloxone call. The number of risk factors for medications and comorbidities that may increase the risk of OIRD was collected for each patient, as defined by AB2760/714 naloxone prescribing criteria.^{1,2} The risk factors were identified through ICD-9 and ICD-10 codes and prescription history from their electronic medical records (Table-1). The primary investigator then analyzed data through Microsoft Excel[®].

The primary outcome was the naloxone prescription pick-up rate: the rate of prescriptions successfully picked up after ACP outreach. With authorization from qualified patients' PCPs, the ACP outreach calls targeted patients who declined their PCP first offer for a naloxone prescription or did not pick up their first naloxone prescription ordered by their PCP. An “index date” was defined as the date and time of the completion of the ACP first documented contact with the patient. Patient prescription pick-up was tracked up to 15 days post-index date. Naloxone prescription pick-up was considered successful if the naloxone prescription was picked up within 15 days post-index date.

One of the secondary outcomes included was to determine the patient reported barriers/reasons for declining their naloxone prescription. This was determined by ACP interviewing the patient at the

beginning of the telephone encounter about their barriers to picking up their first naloxone prescription. Additionally, if the patient declined the ACP second naloxone offer, the ACP would assess the patient reported reason(s) for declining the second naloxone prescription offered.

Another secondary outcome was to determine the average recorded time for the ACP telephonic outreach process as a work-process measure.

Descriptive statistics were used to analyze the prescription pick-up rate, patient reported barriers/reasons for declining first and second naloxone prescription, and ACP telephonic outreach average recorded time.

RESULTS

As shown in Figure-1, 516 patients were on concurrent opioid(s) plus a BZD from October 2019 through December 2019. After applying inclusion criteria, 84 patients remained in the study with no history of naloxone sold. 5 patients were then excluded from the study due to loss of KP membership (2), enrollment in hospice/palliative care (2), and initiation of active chemotherapy (1). After applying inclusion and exclusion criteria, this study had a total sample size of 79 patients. Of the 79 patients that met the inclusion criteria, there were a total of 49 patients successfully reached by ACP from March 9, 2020 to March 20, 2020.

Baseline characteristics of the 79 patients included in the study were identified (Table-2). The mean age was 60.6 years old, with 30 (37%) patients greater than or equal to 65 years old. 55 (69%) patients were female. Patients were prescribed an average morphine equivalents (MME) of 33.5, combined with a BZD. The number of risk factors (RFs) for OIRD was abstracted (excluding concurrent use of BZD from RF count as every patient had this RF from baseline). (Table 1) RFs for OIRD included disease comorbidities and concurrent medications. 31 (39%) patients had at least five to six RFs for OIRD and 26 (33%) patients had greater than or equal to seven RFs for OIRD. 34 (43%) patients were prescribed an opioid + BZD + Non-Benzodiazepine Z Drug (NBZD) combination, 26 (33%) patients were prescribed an opioid + BZD +

Skeletal Muscle Relaxant (SMR) drug combination, and 10 (12%) patients were prescribed an opioid + BZD + NBZD + SMR drug combination.

Figure-2 the primary outcome was the prescription pick-up rate 15 days post-ACP outreach. 9 (11.4%) patients of the 79 patients that met the study criteria successfully picked up their naloxone prescription 15 days after the outreach call. However, using a sub-analysis of the 49 out of 79 patients that were reached by phone, the naloxone prescription pick-up rate was 9 (18.4%). Although it was not a primary outcome, of the 49 patients reached, 19 (38.8%) patients accepted the ACP second offer for naloxone. Of these 19 patients, the successful naloxone prescription pick-up rate was 9 (47.4%).

Figure-3 one of the secondary outcomes was to determine the patient reported barriers/reasons for declining their naloxone prescription. The patient reported barriers for not picking up their first naloxone prescription offered by their PCP were the following: "I don't need it" 53%, "Too expensive" 20%, "What is naloxone?" 18%, "I live alone" 4%, and "My spouse/family member has it" 4%. The third column in Figure 3 displays patient reported barriers/reasons for declining second naloxone offered by ACP. 30 (61.2%) out of 49 patients reached declined the naloxone second offer and reported the top two reasons for decline: "I don't need it" 17%, and "Too expensive" 18%. The percent of patients that reported they did not "need" the naloxone and the percent of patients that reported "what is naloxone" after the ACP naloxone outreach, both decreased by 18% compared to when the PCP made the first offer for naloxone.

Figure-4 another secondary outcome was to determine the average recorded time for the ACP telephonic outreach process as a work-process measure. The average time for the ACP workflow was 28 minutes for patients reached and 11 minutes for those not reached. The total time for the ACP outreach project for the 79 patients was 38 hours. Additionally, after analysis of this secondary outcome, tasks were determined that could be performed by ancillary support staff to assist the ACP in the telephone outreach process, which could help to alleviate pharmacist time spent and lower future expenses to provide this service.

Table-1: Comorbidities and Medication Risk Factors for OIRD^a

Comorbidities	Concurrent Medications
Psychiatric: MDD, schizophrenia, schizoaffective disorder, BPD	Benzodiazepine class
Respiratory: Asthma, COPD, OSA	Non-Benzodiazepine Z Drug class
History of dependence or abuse: Opioid, alcohol, cannabis	Skeletal muscle relaxant class
Others: Advanced age, kidney or liver dysfunction	CNS depressant drugs

^aOIRD = opioid-induced respiratory depression, MDD = major depressive disorder, BPD = bipolar disorder, COPD = chronic obstructive pulmonary disorder, OSA = obstructive sleep apnea, CNS = central nervous system

Table-2: Demographic and Clinical Variables in Study Populations^b

Variable	Patients (n = 79)
Mean + S.D. age, yr	60.6 + 14.2
Female, no. (%)	55 (69%)
Age > 65 years, no. (%)	30 (37%)
Age > 60 years, no. (%)	50 (63%)
Avg MME, no.	33.5
OIRD risk factors (RF)	
1-2 RF, no. (%)	18 (22%)
3-4 RF, no. (%)	27 (34%)
5-6 RF, no. (%)	31 (39%)
> 7 RF, no. (%)	3 (4%)
On concurrent BZD + NBZD drug, no. (%)	34 (43%)
On concurrent BZD+ SMR drug, no. (%)	26 (33%)
On concurrent BZD + NBZD + SMR, no. (%)	10 (12%)

^bMME = morphine equivalents, OIRD = opioid-induced respiratory depression, BZD = benzodiazepine, NBZD = non-benzodiazepine, SMR = skeletal muscle relaxant

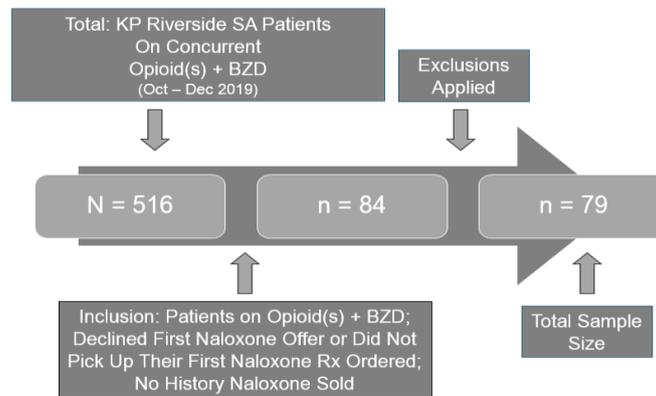


Fig-1: Study Population

Fig-2: Primary Outcome: Naloxone Prescription Pick-Up Rate

	Overall Naloxone Prescription Pick-Up (n = 79)	Naloxone Prescription Pick-Up After Outreach (n = 49)
Successful naloxone prescription pick-up, no. (%)	9 (11.4%)	9 (18.4%)

Fig-3: Secondary Outcome: Patient Reported Barriers*

Reasons for Declining Naloxone	Declined First Naloxone Offered by PCP (n = 49), no. (%)	Declined Second Naloxone Offered by ACP (n = 30), no. (%)
“I don’t need it”	26 (53%)	17 (35%)
“Too expensive”	10 (20%)	9 (18%)
“What is naloxone?”	9 (18%)	0 (0%)
“I live alone”	2 (4%)	3 (6%)
“My spouse has it”	2 (4%)	1 (2%)

Fig-4: Secondary Outcome: Time for ACP Workflow

	Patients Reached (n = 49)	Patients not reached (n = 30)
ACP outreach Tasks	Pre-assessment Rx review* ACP outreach call Documentation on electronic chart Rx benefit cost* and Rx fill Post-assessment Rx review* PCP follow-up, if applicable*	Pre-assessment Rx review* ACP voicemail, if available
ACP outreach, avg time, min.	28.2	11.1

*Tasks that could be performed by ancillary support staff in the future

DISCUSSION

The study demonstrated the impact of an ambulatory care pharmacist-led naloxone outreach for patients that either previously refused their PCPs offer for naloxone or failed to pick up their naloxone prescription (Rx) prescribed by their PCP. Figure-2 for the 79 patients included in the study, the overall naloxone prescription pick-up rate was 11.4% and 18.4% if reached by phone. Moreover, of the 49 patients reached, 19 patients accepted the ACP second offer for naloxone and of these 19 patients, the successful naloxone prescription pick-up rate was 47.4%.

Figure-3 the three most common patient reported barriers for picking up naloxone were “I don’t need it,” “too expensive,” and “what is naloxone?” The most concerning response was the 18% of patients that replied, “what is naloxone?” as these patients were outreached with the impression that they had declined their PCP first offer for a naloxone prescription after the PCP provided education to them on the risks of OIRD and the use of naloxone to help prevent unpredictable death due to OIRD. It appears either the patients did not understand their PCP, or the physicians may not have had time to do the required patient naloxone education and prescribed it for the patient without adequate education. The study revealed that while some physicians are doing their best effort to provide this education, there is room for improvement. The percent of patients that reported they did not “need” the naloxone and the percent of patients that reported “what is naloxone” after the ACP naloxone outreach, both decreased by 18 percent compared to when the PCP made the first offer for naloxone. Both of the stated reasons for declining naloxone may have improved as a result of more thorough naloxone education provided by the ACP.

During an ACP telephone encounter, one patient shared, “I was unaware of the risks of the combination of drugs. I was not familiar with naloxone. I am very interested in learning more and thankful KP cares about my safety.” PCP feedback for the ACP outreach was unanimously positive. Every PCP that was contacted by the ACP, authorized the ACP naloxone outreach. PCP feedback included, “Thank you for this. I really appreciate the great care being spent with this patient” and “This was a tough patient. I am so happy to hear they finally picked up their naloxone!”.

The average time for the ACP telephone outreach as a work-process measure was also evaluated. The average time for the ACP workflow for patients reached and not reached was 28 minutes and 11 minutes, respectively. For the 79 patients that met the inclusion criteria and a telephone outreach attempt was made, the total time for the ACP outreach project was 38 hours. After data analysis, outreach tasks that could be performed by ancillary support staff to assist the

ACP in the telephone outreach process, was determined. Use of ancillary support staff could help to decrease the pharmacist time spent and lower future labor expenses to provide this service.

Limitations of the study included that it was retrospective, had a small sample size, and patients served as their own control. One of the main challenges of this study was the timing of the ACP outreach during the COVID-19 pandemic outbreak, that deterred patients from visiting the pharmacy to pick up their naloxone. Because a mandatory in-person patient consultation was required, the naloxone prescription could not be mailed to the patient, however, this is under future consideration.

A next step for increasing naloxone prescription pick-up rate, especially for high-risk patients, would include expanding and emphasizing the importance of the outpatient pharmacist role in naloxone education when dispensing opioid prescriptions. Additionally, further feasible and effective initiatives should be considered to increase naloxone education and naloxone prescription pick-up using a more robust multidisciplinary approach, involving pharmacists, ancillary staff support, and PCPs.

Through ACP telephonic outreach, this study focused on a high-risk population who did not have access to naloxone in the case of emergent, life-threatening OIRD. This study also evaluated patient reasons for refusing initial provider education/naloxone prescription and barriers to picking up the medication when prescribed. While there are several articles that have discussed mitigation strategies to improve opioid safety, reduce/taper patients off opioid medications or opioid plus BZD combinations, and improve provider prescribing education, many do not include or focus specifically on improving patient naloxone acceptance rates.^{7,8,9} Moreover, they do not focus on a pharmacist-directed role to improve patient naloxone acceptance rates in a patient population at a higher risk for OIRD that either refused the physician previous offer or did not pick up their prescription of naloxone for various reasons. Three studies focused on a patient questionnaire or survey that identified experiences and/or perceptions of patients that had either received a naloxone prescription or were identified as high risk for an opioid-induced overdose [7-9]. These studies characterized the patients’ prior education about the risks of overdose from their medications or measured naloxone prescriptions rates, however, none of these studies included an explicit pharmacist role in the intervention [7-9]. Moreover, one study excluded patients who refused naloxone in their questionnaire [7], whereas this study focused primarily on patients at high risk for OIRD who refused a naloxone prescription from their provider or failed to pick up their prescription. Lastly, a 2017 study conducted in eighty

primary practices in three large facilities, (including Kaiser Permanente Colorado), strongly recommended future qualitative studies to explore the perceptions of

patients who decline naloxone prescriptions [8], which was a secondary outcome of this study.

Appendix 1: ACP Naloxone Second Outreach Education

Hi is this _____? My name is _____. I am a clinical pharmacist calling from Kaiser Permanente Riverside. I am calling on behalf of Dr. _____ to discuss with you your pain medication use and offer you some information about opioid safety. Do you have a about 10-15 minutes for this call?

1. Verify if taking meds:

- a. Our records show you are currently taking _____ (opioid). Is that correct? How do you take that medication? Frequency?
- b. Our records show you are currently taking _____ (BZD). Is that correct? How do you take that medication? Frequency?
- c. *Verify if taking other meds that increase risk for OIRD*
- d. *If Problem List includes: Asthma/COPD/obstructive sleep apnea... verify w/ patient*

2. Has your doctor explained to you the risks associated with the combination of your _____ (opioid) and _____ (BZD) medications? (+ if they have skeletal muscle relaxant or Z drug AND/OR other risk factors: age, psychiatric comorbidity, COPD/asthma/sleep apnea)

Mainly, we are calling all of our patients on these medications because we know now more about the increased risk for opioid overdose and want to provide another outreach call for your safety. All opioids can cause breathing to slow or even stop. It can happen by accident at any dose at any time and can cause death within a few minutes. Some studies have reported that the risk of overdose (including accidental overdose) can be 10 times higher with the combination of opioid + _____ (BZD) than taking an opioid alone. Taking alcohol or benzodiazepines such as your _____ (BZD) and other medicines that can make you sleepy could change your ability to tolerate the dose of opioid medication.

3. Has your doctor previously offered you naloxone education (also known as Narcan)? I see they have written you a prescription for the rescue medication, but it was never picked up...

Counsel points:

- a. It is an emergency rescue medication that, when given right away, temporarily works to reverse the effects of opioids, including slowed or stopped breathing. It may prevent possible death.
 - b. Naloxone is given to you by someone else (a bystander, family member, or someone trained to use it) when your breathing is slowed, or you cannot breathe, and you become unresponsive or unconscious
 - c. Naloxone only works if opioids are the cause of the overdose. It has no effect on alcohol or other drugs.
 - d. Takes 2-5 minutes to start working and may require more than one dose. The effects only last for 30-90 minutes, so someone MUST call 911 before giving you naloxone. If only one other person is present, have them give naloxone first and then immediately call 911.
 - e. If they ask: May result in withdrawal symptoms (NV, agitation, cramps). If these symptoms occur, they will go away as the naloxone wears off.
 - f. It is VERY important to share the info with family and friends and make a plan so others are prepared to respond to an emergency
4. According to our records, you did NOT pick up the naloxone medication prescribed to you by your provider. May I ask what barriers you had to picking up the medication?

May offer them options: (1=financial, 2=forgot, 3= Denial of need i.e. tapering already or does not exceed quantity prescribed, 4=Belief system i.e. believe they are labeled as a drug abuser, 5=misunderstanding importance of drug or how to use, 6=perception that provider will take med away, 7= report they live alone, 8=was not familiar with drug/unknown they were prescribed)

5. **Are you familiar with how to detect an overdose?** Teach your family, friends, and caregivers who may be around you when using an opioid how to respond to respiratory depression due to opioid overdose and how to use naloxone. When you pick up your medication, a pharmacist must go over these instructions with you in more detail.
- **Recognize respiratory depression, slow or no breaths, due to opioid overdose. Signs:**
 - Heavy nodding, deep sleep
 - Snoring, gurgling, choking
 - Unresponsive, unconscious (won't wake even if you shake the person or say his or her name loudly)
 - Slow breathing (less than one breath every five seconds)
 - When breathing stops, even for short periods
 - Blue or gray lips and fingernails
 - Pale, sticky, or damp skin
 - **Check for a response.**
 - Lightly shake the person and yell his or her name.
 - If the person does not respond, give naloxone first and then call 911.
 - **Give naloxone and call 911.**
 - If you have naloxone nasal spray, **DO NOT PRIME OR TEST** the spray device.
 - Gently insert the tip of the nozzle into one nostril and press the plunger firmly to give the entire dose.
 - When calling 911, give the address of your location and say that the person is not breathing.
 - Stay with the person until emergency personnel arrive.
 - **Check whether the airway is open.**
 - Give rescue breathing if you witness an overdose and the person is not breathing.
 - Give chest compressions if you did not see the person collapse and there is no pulse.
 - **Consider giving a second dose.** If the person is not responsive and breathing in three to five minutes give a second dose of naloxone. If using naloxone nasal spray, spray the second dose in the other nostril when possible.
 - **Recovery position.** If the person is breathing but unresponsive, put the person on his or her side to prevent choking with vomiting. Stay with the person until emergency personnel arrive for transport to a hospital.
 - If you have questions about opioid medications or naloxone, speak with any pharmacist.

CONCLUSION

Through ACP outreach, nine patients picked up their naloxone prescription which may possibly prevent nine future OIRD-associated events and/or possible deaths. Through ACP patient interviews during telephone outreach, it was learned that 18% of patients, (that were previously offered and declined a naloxone prescription from their provider), reported they did not know what naloxone was. It appears either they did not understand their PCP, or the physicians may not have had time to do the required patient naloxone education. This helped to identify areas for improvement in naloxone patient education. The study had several limitations and challenges, including the timing of outreach during the peak of the COVID-19 outbreak, that deterred patients from visiting the pharmacy to pick up their naloxone. In conclusion, working as a team with pharmacist, ancillary staff support, and providers, continuation of and consideration of new, feasible initiatives to increase naloxone prescription pick-up rates should be considered.

Disclosure: The authors have no conflicts of interests to disclose.

Additional Information

Dr. Tina Menedjian's data collection, analysis, and research write-up were used to fulfill requirements for the ASHP PGY1 residency at Kaiser Permanente Riverside.

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