PHARMACIST'S LETTER

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PRESCRIBER'S LETTER

Naloxone for Opioid Overdose (FAQs)

Chronic pain is often undertreated and can lead to disability, depression, and other problems.[1-3] In recent years, there has been increasing focus on ensuring that patients get their pain addressed. The U.S. Joint Commission considers pain assessment to be a patient right, and in 1996 the American Pain Society pioneered the concept of pain as the 5th vital sign.[3,4] Treating chronic pain may require the use of opioids. In Canada and the U.S., opioid prescribing doubled from the late 1990s to 2012.[5,6] With increased opioid usage has come increased misuse and diversion.[7,8] In fact, most prescription opioids used nonmedically are obtained from family and friends, who usually obtain them from a single prescriber.[9] Despite these concerning statistics, opioid prescribing seems to be plateauing in the U.S. or even decreasing based on data from 2011 to 2013.[10] This may be due to prescribing restrictions, education, prescription monitoring programs, and prescription of abuse-deterrent formulations.[10,11] However, heroin use is up; this may be an unintended consequence of one or more of these changes.[10] Heroin is relatively inexpensive and easier to get in some areas than prescription opioids.[10,12] Based on data from 28 states, from 2010 to 2012, the death rate from heroin overdose increased from 1 to 2.1 per 100,000 people.[13] During this same timeframe, the death rate due to prescription opioid overdose decreased slightly from 6 per 100,000 to 5.6 per 100,000.[13] In Canada, there has been a surge in illicit fentanyl-associated deaths.[33] Health Canada has removed naloxone from the Prescription Drug List to enable its move to nonprescription status in response to the growing number of opioid overdoses.[30] The FDA has approved two naloxone products for use by lay persons to treat someone known or suspected to have overdosed on opioids: *Evzio*, an auto-injector, and *Narcan* nasal spray. In Canada, *S.O.S. Naloxone Hydrochloride Injection* is labeled for administration by laypersons.[29] Even though these products are new, and in Canada will no longer require a prescription, administration of naloxone by laypersons is not new; it has been used across the U.S. and Canada through take-home naloxone kit programs and administration by first-responders with reported success.[27,28,30,35] The chart below provides information on naloxone for opioid overdose in an FAQ format.

Clinical question	**Pertinent information or suggested resources**
What naloxone formulations are available? *Continued…*	<u>*Evzio* (U.S.)</u>: Each *Evzio* carton contains two active auto-injectors, each containing naloxone 0.4 mg, and one trainer. The trainer is in a black and white outer case, while the active *Evzio* auto-injector is in a purple and yellow outer case.[14] • The trainer is exactly like *Evzio*, except that it does not contain a needle or naloxone, and has no expiration date. Unlike *Evzio*, the red safety guard on the trainer can be removed and replaced. Each trainer can be used over 1000 times.[14] <u>*Narcan* nasal spray (U.S.)</u>: Each *Narcan* nasal spray carton contains two blister-packed, single-use nasal sprays, each containing 4 mg of naloxone.[15] • Be careful of mix-ups between the new *Narcan* nasal spray and an older, no longer available *Narcan* brand injection. For some, "*Narcan*" has become synonymous with injectable naloxone.

More. . .

Clinical question	Pertinent information or suggested resources
What naloxone formulations are available? (continued)	Naloxone kits (U.S.): • Naloxone for intramuscular injection is supplied in vials. For **intramuscular** use, it is recommended that naloxone be provided as 0.4 mg/mL in two 1 mL single-dose vials or one 10 mL multidose vial.[16] For each injection, a 23 gauge, 3 cc syringe with a 1-inch needle will be needed.[16] • For **intranasal** administration using the injectable solution, you will need two naloxone 2 mg/2 mL Luer Lock prefilled syringes made by IMS/Amphastar (NDC# 76329-3369-1), along with two mucosal atomization devices (MAD 300), which pharmacists can order by calling 800-788-7999. This device fits into the Luer Lock of the IMS/Amphastar naloxone.[17] • Information on preparing and prescribing naloxone rescue kits is available at www.prescribetoprevent.org. • With permission from the Prescribe To Prevent group, prescription forms with tear-off patient instructions are being made available to subscribers of *Pharmacist's Letter/Prescriber's Letter*: *Naloxone for Overdose Prevention (Intramuscular)* and *Naloxone for Overdose Prevention (Intranasal).* Nonprescription Naloxone (Canada) (e.g., *S.O.S. Naloxone*): • Naloxone is available as 0.4 mg/mL in 1 mL single-dose ampoules or vials, and as 1 mg/mL in 2 mL multidose vials. • The College of Pharmacists of British Columbia recommend dispensing at least two doses of 0.4 mg/mL naloxone plus at least two retractable 3 mL *VanishPoint* syringes with 25 gauge, 1-inch needles.[34] • Other supplies that might be helpful include a one-way barrier mask for giving rescue breaths and an ampoule breaker. Gloves and alcohol swabs could be included but are not necessary, as the injection can be given through clothing.[32] • Patient instruction sheets from the College of Pharmacists of British Columbia are available at http://www.bcpharmacists.org/naloxone. Kits are also available from community-based programs (often called "take-home naloxone" programs in Canada). In Canada, these programs provide kits (usually by prescription) and naloxone training. The kits typically consist of two 1 mL single-dose ampoules, needles, syringes, alcohol swabs, one-way barrier mask, instructions, and case.[35] See http://www.prescribetoprevent.org for programs in the U.S., or http://www.ccsa.ca/Resource%20Library/CCSA-CCENDU-Take-Home-Naloxone-Canada-2016-en.pdf, for programs in Canada. A chart comparing the naloxone formulations available in the U.S. is available at http://prescribetoprevent.org/wp2015/wp-content/uploads/Naloxone-product-chart.16_01_21.pdf.

Clinical question	Pertinent information or suggested resources
When should naloxone be administered?	Respiratory and/or central nervous system depression in a situation where opioids may be present is an indication to use naloxone.[14,29] • Naloxone should be given if the patient is excessively sleepy and cannot be aroused with a loud voice or sternal rub.[14,15] • Other indications include slow, shallow, or no respirations, or pinpoint pupils in a patient who is difficult to arouse.[14,15] • Other signs of overdose include blue or purple fingernails or lips.[18] The patient may emit a death rattle.[18] • The patient may also have a slow heartbeat and/or low blood pressure.[18]
How is naloxone administered by laypersons?	<u>*Evzio* (U.S.)</u>: • Each *Evzio* carton contains a trainer. Patients and anyone who may need to help the patient in the event of an overdose should practice with the trainer. *Evzio* product labeling recommends that the patient and caregivers practice daily for the first week, then weekly.[14] • *Evzio* has a speaker that provides voice instructions. If the voice instructions don't work for some reason, *Evzio* will still work. Users should follow the written instructions on the label.[14] • To use, remove *Evzio* from its case. Remove the red safety guard and place the black end of the injector against the outer thigh. (*Evzio* can be injected through pants.) To administer the dose (0.4 mg), press the injector firmly and hold for five seconds. If the patient is an infant, the injection should be given into a pinched-up area of the middle of the outer thigh muscle. The injector makes a click and hiss noise during injection.[14] <u>*Narcan* nasal spray (U.S)</u>: • Keep the spray in the original packaging until it is ready to use. The person to receive the spray should be lying on their back. Remove the spray from its packaging and hold it with the thumb on the bottom of the plunger and the first and middle fingers on either side of the nozzle. The patient's head should be tilted back gently and the tip of the nozzle inserted into one nostril until the fingers holding the nozzle are on either side of the person's nose. The plunger is then pressed firmly, spraying the naloxone (4 mg) into the nostril. The nozzle is then removed from the nostril. The patient does not have to inhale during the spray for the medication to be delivered.[15] <u>Injectable naloxone solution for **intranasal** use</u>: • Attach the atomizer device to the naloxone. There are three parts: the atomizer device, a plastic tube, and the naloxone vial. First, remove the two yellow caps from the plastic tube and the red cap from the naloxone. Hold the atomizer device by its plastic wings and twist it onto the plastic tube. Screw the naloxone into the barrel of the tube. After inserting the atomizer into the patient's nostril, the naloxone is delivered by giving a short, vigorous push on the naloxone vial, delivering half of the naloxone into each nostril (total dose= 2 mg).[17]

Continued…

Clinical question	Pertinent information or suggested resources
How is naloxone administered by laypersons? (continued)	Injectable naloxone solution for **intramuscular** use: • Remove the cap from the naloxone (or break the ampoule neck) and uncover the needle. Insert the needle through the rubber plug with the bottle upside down (for vials), and pull back the plunger to draw 1 mL into the syringe (for the 0.4 mg/mL strength). Inject the naloxone into the muscle of the shoulder or thigh or upper outer buttocks at a 90 degree angle.[16,29,32,34] The injection can be given through clothing.[32] Patient instructions are included with *Evzio*, *Narcan* nasal spray, and *S.O.S. Naloxone*. Another source of patient instruction sheets is the College of Pharmacists of British Columbia (http://www.bcpharmacists.org/naloxone). With permission from the Prescribe To Prevent group, prescription forms with tear-off patient instructions are being made available to subscribers of *Pharmacist's Letter/Prescriber's Letter*: *Naloxone for Overdose Prevention (Intramuscular)* and *Naloxone for Overdose Prevention (Intranasal)*.

What happens after a dose is administered?
 	
Continued…
	• The duration of most opioids is longer than that of naloxone (30 to 90 minutes), so **emergency medical help must always be summoned immediately**, even if the patient wakes up.[18]
	• If a patient's symptoms return or if the patient doesn't respond or achieve the desired response (i.e., adequate spontaneous breathing), and emergency medical help has not yet arrived, naloxone can be given every two to five minutes.[14,15,18,29]
	  • When giving additional doses of *Narcan* nasal spray, alternating nostrils should be used.[15]
	• Rescue breathing may be required, and ideally, patients experiencing opioid overdose should be given oxygen.[18]
	• Patients who have overdosed on partial agonists and mixed agonist-antagonists (e.g., buprenorphine) may not respond well.[14]
	• Naloxone use may precipitate withdrawal in opioid-dependent patients.
	  • Opioid withdrawal symptoms include sweating, goose bumps, achiness, shivering, GI symptoms, tachycardia, irritability, and increased blood pressure.[14] Fever, runny nose, sneezing, and yawning are other signs and symptoms of opioid withdrawal. The patient may become agitated or combative.[18]
	  • Patients may vomit after naloxone administration. The patient should be positioned on their side after naloxone administration.[18] This "recovery position" is illustrated in the *Narcan* nasal spray and *S.O.S Naloxone* patient labeling, and in the patient instruction sheets available at http://www.bcpharmacists.org/naloxone.
	  • Fortunately, most patients respond to naloxone with a return to spontaneous breathing with only mild withdrawal symptoms.[18]
	  • Opioid withdrawal is not typically life-threatening in adults.[18]
	• If naloxone is given to a patient who is not opioid-dependent or is not opioid-intoxicated, it has no clinical effects.[18]

Clinical question	Pertinent information or suggested resources
What happens after a dose is administered? (continued)	• *Evzio* (U.S.): once the injector has been used, the needle will retract into the base, the base will lock, the voice instruction will state that the injector has been used, a red light will blink, and a red indicator will show in the viewing window. The used injector should be placed in its case and disposed of in a sharps container, following any state or local laws about disposal of auto-injectors or perchlorate-containing batteries (California).[14] • Naloxone needles used for intramuscular injection should also be disposed of in a sharps container.[19] Emergency medical personnel might do this.[29]

How should naloxone be stored?	• Naloxone should be stored at room temperature and protected from light.[21]
	• *Narcan* nasal spray (U.S.) and *Evzio* (U.S.) should be stored in the original packaging and provided case, respectively, at 59°F to 77°F, although excursions to 39°F and 104°F are allowed.[14,15]
	• It is a good idea for patients to carry naloxone products with them, and to tell family, friends, co-workers, and others who may need to administer naloxone where it is kept.[14,15]
	• While counseling patients about naloxone storage, consider reminding them to keep their prescription opioid secure; divulging opioid use to others might invite theft.
	• Patients should periodically check the appearance of their naloxone.[14]
	  • Visually inspect naloxone vials or pre-filled syringes. There is a window in the *Evzio* (U.S.) auto-injector.[14]
	  • If the solution is discolored, cloudy, or contains particulates it should be replaced.[14]
	• Naloxone products (and syringes, if applicable) should be replaced before the expiration date.[21]
	  • If stored properly, naloxone products should be effective at least until the manufacturer's expiration date. Typically, the shelf-life is 12 to 18 months.[21]
	  • It has been suggested that pharmacists dispense naloxone with at least a six-month shelf-life at time of sale, and ideally longer than one year.[34]

Does naloxone availability encourage opioid misuse?	• Surveys of heroin users in the late 1990s suggest they do not use more heroin if naloxone is available. This may be because they do not want to experience withdrawal precipitated by naloxone.[25] • In one naloxone program for heroin users, the frequency of heroin injection (p=0.003) and number of overdoses (p=0.83) actually decreased.[26] Furthermore, in communities where naloxone distribution programs exist, opioid overdose deaths decrease.[27,28] • Monitor patients for opioid dose escalation, and discuss the risks with patients.[25]

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Clinical question	Pertinent information or suggested resources

For whom should naloxone be provided?	Consider a naloxone prescription for people:
	• with a history of opioid intoxication or overdose[22]
	• with a suspected history of substance abuse or nonmedical opioid use[22]
	• patients taking methadone or buprenorphine for opioid use disorder[22,36]
	• taking >50 mg or more of oral morphine or its equivalent daily[22]
	• being rotated from one opioid to another (due to risk of incomplete cross-tolerance)[22]
	• taking an opioid who:[22]
	  • smoke, or have a respiratory illness (e.g., COPD, sleep apnea, asthma, etc)
	  • have renal, hepatic, or heart disease, or HIV
	  • use alcohol or a benzodiazepine, sedative, or antidepressant
	• who live in a remote location[22]
	• who request it[22]
	
	U.S.: Many states now allow third-party prescribing of naloxone, such as to a caregiver or family member as opposed to a patient. Consult http://lawatlas.org/query?dataset=laws-regulating-administration-of-naloxone or your state medical board to find out if third-party prescribing of naloxone is allowed in your state.

Is naloxone available without a prescription?	U.S.: In several states, naloxone can be purchased without a prescription. Consult http://lawatlas.org/query?dataset=laws-regulating-administration-of-naloxone or your state pharmacy board to find out if naloxone is available without a prescription in your state. Canada: Health Canada made naloxone nonprescription in March 2016.[30] The National Drug Scheduling Advisory Committee will consider Schedule II status for naloxone in June 2016.[31] British Columbia has already reclassified naloxone as nonprescription.[30] Naloxone resources from the College of Pharmacists of British Columbia are available at http://www.bcpharmacists.org/naloxone.
How much does naloxone cost? *Continued…*	*Evzio* (U.S.): • Cost is $3750 (WAC) for two auto-injectors and a trainer. • To find out if a patient's private or government insurance might cover *Evzio*, see http://www.evzio.com/hcp/resources/insurance-coverage.php. For specific information regarding their individual coverage, patients should contact their insurance provider directly by calling the number on the back of their insurance card. Prior authorization may be necessary. • Patients with private insurance may be eligible to have *Evzio* mailed directly to their home without a copay. • Information on the *Evzio* patient assistance program is available at http://www.evzio.com/hcp/patient-savings/kaleo-

Clinical question	Pertinent information or suggested resources
How much does naloxone cost? (continued)	cares-patient-assistance.php. *Narcan* nasal spray (U.S.): • Cost is $125 (WAC) for two nasal sprays. • For qualified public interest groups (e.g., first responders, community naloxone programs, etc) the cost is $37.50 per device through Adapt Pharma distributors. • Broad insurance coverage is expected for *Narcan* nasal spray.[20] Naloxone "kits" (U.S.): about $50 • Some insurance plans, including Medicaid and Medicare in some states, will cover the kits or some components therein.[23] Nonprescription Naloxone (Canada):[34] • naloxone 0.4 mg/mL vial or ampoule $1 to $15 • *VanishPoint* syringe: $0.50 to $1 • Naloxone (medication only) may be covered by extended healthcare plans. If cost is an issue, consider referring patients to a community-based program, which might provide a kit for free. See *"What naloxone formulations are available?"* section above for contact information.
How do I bill for naloxone-related counseling (U.S.)?	Prescribers (U.S.) • Use the codes for Screening, Brief Intervention, and Referral to Treatment (SBIRT) to bill for counseling a patient about how to recognize overdose and how to administer naloxone.[18] • Use billing codes for SBIRT are CPT 99408 (commercial insurance, 15 to 30 minutes), G0396 (Medicare, 15 to 30 minutes), and Medicaid H0050 (Medicaid, per 15 minutes).[18] • For counseling and instruction on the safe use of opioids, including the use of naloxone, outside of the context of SBIRT services, the prescriber should document the time spent and use the E&M code that accurately captures the time and complexity. For example, in new patients deemed appropriate for opioid pharmacotherapy, when a substantial and appropriate amount of additional time is used to provide a separate service such as behavioral counseling (e.g. opioid overdose risk assessment and naloxone administration training), consider using modifier –25 in addition to the E&M code.[18] • Complete the DAST-10 drug abuse questionnaire (available at http://www.bu.edu/bniart/files/2012/04/DAST-10_Institute.pdf) and refer to a substance abuse treatment program if applicable.[24] For pain patients, the Current Opioid Misuse Measure (COMM; for patients already on opioids) or the Screener and Opioid Assessment for Patients with Pain (SOAPP; for patients new to opioids) may be more appropriate.[24] These tools are available at http://www.painedu.org/soapp.asp. • When using an evidence-based opioid misuse/abuse screening tool, CPT Code 99420 (administration and interpretation of health risk assessment instrument) can be used for patients with commercial insurance.[18]

Clinical question	Pertinent information or suggested resources
Are there liability issues related to naloxone?	• The medico-legal risks of prescribing naloxone to opioid users appear low.[24,25] • In the U.S., laws are being drafted and passed to protect bystanders who administer naloxone and prescribers who prescribe it. This is a rapidly evolving area. See http://www.lawatlas.org or www.prescribetoprevent.org for information by state. • Most Canadian jurisdictions have "Good Samaritan" or equivalent voluntary emergency medical aid legislation.

Users of this PL Detail-Document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

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Evidence and Recommendations You Can Trust…

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