

Physician Assisted Dying in Washington State: A primer for participating physicians

Carol Parrot, M.D., Robert Wood, M.D.

Summary

Physician Assisted Dying or Physician Aid-in-Dying (PAD) is now legal in six states and the District of Columbia. Though patients have been using the Death with Dignity laws since 1998, very little information is published for physicians, pharmacists, and patients who are trying to learn more about actual requirements, protocols, or patient instructions. Past and present drug regimens and current practice recommendations are discussed.

Background

Physician Assisted Dying (PAD) was first approved by Oregon voters in 1997. Since that time, Death with Dignity (DWD) has become law in Washington, California, and Colorado, by popular vote; in Vermont, by legislative vote; in Montana, by State Supreme Court decision; and in Washington, D.C. by City Council vote. The idea that a dying person be allowed lethal medicines to expedite his or her own death is being embraced by more people throughout the United States and is now available to about one of five residents. By court and legislative action, terminally ill persons in Canada may now obtain PAD, even by injection.

In 2008 Washington State voters passed its Death with Dignity Act, and the law was implemented in March 2009. By the end of 2016, 1184 participants had qualified under the act. At that time, there were 843 documented deaths from taking the medications; the other 29 percent of the participants died without taking the prescribed medications, or their status is unknown.¹

Physicians and pharmacists are not required to participate in DWD; they often decline for personal or religious convictions, or because of employer-imposed restrictions. Patients who pursue DWD are usually reasonably well informed and determined. They or their families ask doctors or hospice personnel, or search the web, to find where to go for information and help. Patients get discouraged and become anxious when their doctors refuse to grant them this option and they have to find new doctors.

Very little has been written on how PAD has actually been accomplished,^{2 3 4} partly because of concern that technical information on PAD might arm opponents and might be used by persons seeking to commit suicide. However, in the interest of providing safe, consistent,

quality options to patients who qualify for DWD and choose to use that option, we are presenting this information to interested physicians.

The Process of Qualifying

The PAD laws in Oregon, Washington, California, Vermont, and Colorado are very similar, but physicians are advised to review their own jurisdictions' laws and rules. In all states, a patient who has a medical diagnosis that is expected to lead to death within six months is required to qualify in accord with the following criteria:

1. The patient must be a legal resident of the jurisdiction where PAD is available.
2. The patient must be of sound decision-making capacity. A psychiatric/ psychological consult is required for any patient whom the attending or consulting physician questions being of sound mind.
3. Two independent licensed participating physicians must confirm that the patient is terminal; i.e., that life expectancy is six months or less. (Most jurisdictions require both doctors to complete a Physician Compliance form, which the prescribing physician sends to the jurisdiction's department of health, DOH.)⁵
4. The patient must make two oral requests to a physician, at least 15 days apart, requesting the option to use PAD, and these requests must be documented in the patient's medical record. In Washington State, the second oral request must be made to the prescribing (attending) physician, but may be made by phone call.
5. After seeing both physicians, the patient must sign a Written Request for Medication, which is witnessed by two individuals, at least one of whom is not related or entitled to any portion of the patient's estate. In Washington, this form, together with the two compliance forms, are sent to the state DOH when life-ending prescriptions are written. Note: The California End of Life Option Act also requires that those wishing to take the medication prescribed in accordance with the act must complete the Final Attestation Form 48 hours prior to taking the medication.
6. The patient must be counseled about all end of life options and told that the request for PAD may be canceled at any time.

Once both oral requests have been made, and the written request has been signed, attending physicians may write a prescription for life-ending medication and send it to a participating pharmacy. Note: In Washington, the law requires that physicians wait until the second oral request is made or at least 48 hours after the written request for medication is signed, whichever comes last, before writing the prescription. This time restriction differs by jurisdiction.

In Oregon, the average time between a patient's first request and his death is 46 days.⁶ If time is of the essence, this process of qualifying and obtaining prescriptions can be completed in 15 days minimum.

Life-Ending Medication Options

Existing Death with Dignity laws do not specify what medicine(s) physicians must prescribe for patient self-administration to peacefully end life, and assume physicians will know best. The clear drug choices for the first DWD prescriptions were the short-acting barbiturates, since these drugs were rapidly absorbed, promptly resulted in sleep, and overdoses uniformly caused death. When these drugs were not readily available or were no longer affordable, combination drug regimens have been developed. Over the years, several drug regimens have been used:

Pentobarbital 10 grams powder (no longer available in the US): This was very commonly used for DWD until 2015, and cost about \$500. However, powdered pentobarbital is produced by the Danish *pharmaceutical company* Lundbeck, which stopped exporting it to the United States in 2013.⁷ *Note:* Liquid Nembutal (pentobarbital) is presently available in small medical vials for injection. It would be unwieldy to use for oral ingestion purposes and would cost about \$20,000.

Secobarbital 10 grams powder: Secobarbital is still a very dependable and frequently used life-ending medication. However, for patients in North America, secobarbital is now produced by only one pharmaceutical company [Valeant], and has undergone a 1500% rise in cost over the past eight years. It is available as 100 mg capsules. One hundred capsules must be emptied (which can be done by the pharmacist if requested by the prescribing physician), and the powder mixed well into 3 oz. of clear juice or water, or into a shot of vodka or other strong alcohol, prior to ingestion. Cost: \$3500-\$4000. *Note:* propranolol (200 mg) is often prescribed as an adjunct to the secobarbital, to be taken 15 minutes beforehand, as data suggest the addition of propranolol shortens the time to death. (See table 1)

Chloral hydrate 20 grams, **morphine sulfate** 3 grams, and **phenobarbital** 20 grams (NO LONGER RECOMMENDED): This protocol was developed in Washington in 2015, in response to the increasing cost of secobarbital. The cost is about \$500. This mixture of ingredients must be prepared by licensed compounding pharmacists, and is best dispensed as a powder, which is mixed with 3-4 oz. of clear juice or water. The chloral hydrate has caused some patients to complain of severe burning in the mouth, posterior pharynx, esophagus, and stomach. In addition, clumping and crystallization are problems with this mixture, both in liquid and in the powdered form, so this mixture should be obtained only once the patient is sure he will use it within a few days.

In Washington, **DDMP2 is a substitute for expensive secobarbital: digoxin 50 mg, diazepam 1 gram, morphine sulfate 15 grams, propranolol 2 grams.** In an attempt to find a good drug regimen that might take the place of the problematic chloral hydrate protocol, mixtures of these four drugs were developed in Washington in the last half of 2016. After analysis of data from the first 50 ‘DDMP1’ patients (now numbering over 70) with lower doses of digoxin, diazepam, and morphine sulfate⁸, the dosages were increased (DDMP2) to provide faster death for patients who are tolerant to large doses of narcotics and sedatives.⁹ The current **DDMP2 mixture is being recommended** to DWD participating physicians as a similar cost replacement for the chloral hydrate mixture and DDMP1.

For patients in Washington State, a compounding pharmacist must also prepare DDMP2. (Other states may have different pharmacy licensing designations.) It is best dispensed in powdered form, in an amber colored glass bottle¹⁰. Immediately before ingesting, it can easily be mixed with 3-4 oz. water or clear juice, a favorite drinking alcohol, or a suspending agent provided by the pharmacist. Cost is \$700-\$850.

All of these drug regimens require that the patient have the ability to drink about a half cup of volume within a minute or two, so that (s)he ingests the entire amount of drug before becoming unconscious.

For all of these drugs regimens, prophylactic antiemetics should be given an hour prior to the life-ending medication. For the secobarbital regimen, ondansetron 8 mg and metoclopramide 20 mg has been commonly used. However, we are now recommending that all patients prescribed any life-ending medication receive haloperidol¹¹ 2 mg and metoclopramide 20 mg for anti-emesis, as haloperidol is an excellent antiemetic and promotes additional relaxation.^{12 13}

General information for participating Physicians, regardless of drug regimen

If not already enrolled, patients should be encouraged to **enroll in hospice**, as soon as they bring up the option of physician assisted dying. Hospices will be able to provide additional medical, physical, emotional, and spiritual support to the patient and his family, in the last days, weeks, and months of the patient’s life.

If a patient has a functioning ICD (implantable cardioverter defibrillator), his or her cardiologist must contact the manufacturer prior to the chosen day of death, and request that they send a technician to turn off the defibrillator.

There is a limited ‘window’ of opportunity for many terminally ill patients to use the DWD laws. Some patients have, or develop, progressive weakness (e.g., those with neuromuscular diseases) making them unable to swallow a half-cup of medicine. Others (e.g., those with brain tumors) may suddenly lose competence and become ineligible to use the law. These

issues should be reviewed in advance with the patient and family, as they can make a difference in the timing of the patient's decision-making process.

Writing the prescription

The attending physician discusses the prescription options with the patient and family, and makes sure everyone agrees with the chosen protocol. Though most Washington patients are now choosing DDMP2, secobarbital is still available for those who have enough money (or the rare insurance coverage) to pay for it. Secobarbital remains the 'drug of choice' because it has a longer history than DDMP1 and DDMP2, and it results in faster death when coupled with propranolol (See table 1). At this point, the chloral hydrate drug regimen is not recommended, due to patient complaints.

The attending physician should provide instructions to the patients and families beforehand – on positioning, mixing the medication, and what to expect (see below).

This can be incorporated into the counseling visit, when patients are instructed about all the end of life options available, and that they may rescind their request for DWD at any time. EndofLifeWA.org has suitable materials available for patient/family instruction.

Physicians should advise patients to leave the prescription on file at the pharmacy until they decide that the time has come to use the medication.

When writing the prescription, the name of the person(s) who might be picking up the medication should be included on the prescription. Including this information allows the pharmacist to dispense the medications to family members or a designee, since it is rare that a dying patient is able to pick up his own medications.

In Washington State, the original prescription must be hand delivered to the pharmacist by the prescribing doctor or courier, or sent by U.S. mail before it can be filled. Other states may allow these prescriptions to be faxed to the pharmacy, as it is allowable by federal law.

Pharmacy issues

Some pharmacies or pharmacists will refuse to participate in PAD when they realize that life-ending medicines are being prescribed. Though not required, it is often helpful for the attending physician to call the pharmacist to introduce him or herself and to let the pharmacist know that the prescription is coming. Pharmacists often have specific questions or suggestions. In addition, the quantities of medications dispensed are not always on hand, so the pharmacist might have to order some. One or two days of lead time are often in order, when requesting that prescriptions be filled. Prescriptions are good for six months, as written. Some patients may survive longer than six months, in which case Washington prescribing physicians can simply reissue the expired prescription, without having to restart the qualifying process.

Secobarbital (capsules) can be dispensed by any licensed pharmacy, if it is available. Most pharmacists, if asked, are willing to empty the capsules and dispense secobarbital as 10 grams powder, which is much easier for the patient's family.

DDMP2 can only be prepared and dispensed by a compounding pharmacy in Washington. By compounding pharmacy standards, shelf life for powdered mixtures like DDMP2 is estimated at six months; DDMP2 that is dispensed already mixed with a suspending agent is considered to have a shelf life of twice weeks.

Hospice participation

Most hospices have policies defining whether their physicians are permitted to participate as either Attending or Consulting Physicians for PAD. When hospice allows physician participation, it is usually as Consulting Physician, though an occasional hospice physician will serve as Attending Physician for DWD patients. Though some hospice employees (e.g., social workers, nurses, and chaplains) are personally supportive of DWD, hospice organizations often prefer that their employees do not attend DWD deaths.

Patient/Family Information for the day of death

The life-ending medications should be taken on a fairly empty stomach. Routine medications should be discontinued 12 hours prior to taking the medication, with the exception of pain medications, which should be continued as needed (and potentially even be increased just before the life-ending medicine). A patient may have a light meal the night before, or up to five or six hours before the chosen time, and then just some clear juice or water. Carbonated beverages are not recommended. It is usually easiest for everyone if the patient plans to take the medications in mid-to-late morning, as the dying process may take a long time.

The antiemetics are given an hour prior to the life-ending medication, with sips of water or juice. A patient may choose to be surrounded by friends and family, or to be alone with just one person in attendance. It is recommended that at least one person be present, to empty the powder out of the capsules if secobarbital has been dispensed in capsule form, to mix the medications, to help position the patient, to reassure the family, and to gather the information needed by the Attending Physician.

When it is time to take the medications, a family member or friend mixes the powder into juice, water, or alcohol (or a suspending agent, in the rare event that it is ordered by the physician and has been dispensed unmixed). The patient should then sit comfortably in a bed or recliner, propped up with pillows. The medication may be sipped through a straw or swallowed from a small glass. If the suspension is thickened with a pharmaceutical

suspending agent, use a bigger caliber straw or none at all. For patients who have been eating through a feeding tube, the medication may be administered into the feeding tube by the patient, as the law requires the medication be self-administered. **The patient must either push the plunger on 1-2 syringe(s) containing the suspended medicine or turn a switch or valve to allow the medicine to flow into the feeding tube.** No matter which drug regimen the patient has been prescribed, or what juice or alcohol it is mixed in, the life-ending medication which the patient ingests has a distinctly BITTER taste. It is a good idea to warn the patient in advance, as a prepared patient does a much better job of getting the medication ingested in the suggested time frame.

The entire dose of medication should be swallowed within a minute or two; otherwise, there is a chance the patient will fall asleep before completely consuming the medicine. It is potentially helpful for the patient to drink a cup of juice or water, during or after ingesting the medication, as gastric volume is a major determinant in stimulating gastric emptying.¹⁴ Most patients fall asleep in about 5-10 minutes, and sleep very comfortably thereafter, peacefully and without pain, until they die. If a patient has been on oxygen for comfort, it is fine to discontinue it after falling asleep.

The times to death depend on the agent chosen, as can be seen in Table 1.

Table 1: Time to Death by Life-Ending Medicines

as of 9/19/17	# cases	Cost	Minutes to Sleep				Minutes to Death			
			Med	Avg	Min	Max	Med	Avg	Min	Max
Secobarbital 10g	200+	\$3,500	5	5			22	68	4	1620
Secobarbital 10g, propranolol 200 mg	41	\$3,500	5	5			23	41	4	420
Chloral Hydrate Mixture	77	\$500	7	7			51	205	8	4280
DDMP1 (diazepam 500 mg, digoxin 25 mg, morphine sulfate 10 g, propranolol 2 g)	70	\$600	8	9	2	30	71	187	9	1860
DDMP2 (diazepam 1 g, digoxin 50 mg, morphine sulfate 15 g, propranolol 2 g)	52	\$650-\$850	7	8	2	28	45	110	9	912

End of Life, Washington, a nonprofit organization (with which the authors are affiliated), provides free volunteer support services to most persons seeking DWD in Washington. One of the volunteer medical directors (RW) has been keeping track of the data on all EOLWA clients using various life-ending options, presented in this chart.

Note: Over the years there have been rare patients who have not died for 10 or more hours (31 hours is the max), sleeping comfortably the entire time. In the over 800 patients who have taken legal life-ending medications in Washington State over the past 7 years, we know of a handful who have regurgitated the medicine; all of these patients died within 9 hours post regurgitation.

Patient positioning

Patient positioning has been a long discussed issue. The patient should be sitting to take the medication for at least the next twenty minutes to reduce the risk of regurgitation as he falls asleep. Patients are often laid in a semi-recumbent position afterward. Some physicians believe that the patient should then be placed supine and turned to the right lateral decubitus position, to enhance gastric emptying. One San Francisco physician, who attends his patients' deaths, employs the right-lateral-decubitus (RLD) position and gastric massage, if he prescribes a thickened pharmacy-suspended mixture, or for patients in which he suspects that altered anatomy (from previous surgery) or disease pathology might impact gastric emptying or drug absorption.

Comparing the influence of different body positions (sitting, supine, right lateral decubitus, and left lateral decubitus) on gastric emptying in healthy volunteers, two studies have shown no statistically significant difference between positions,^{15 16} while others have found gastric emptying to occur faster in sitting position than supine.^{17 18} Sanka et al. found that 100 ml of plain water flowed passively (without peristalsis) into the small bowel faster when the patient was positioned in RLD,¹⁹ but no thicker liquids were studied. In their excellent review of the effect of postural influence on the physiology and pharmacokinetics of drug absorption, Quackenberg and Fuhr summarize "... because for most of the drugs total [exposure in the patient] is not affected by posture, the clinical impact for mobile patients would seem to be quite limited. **In terms of bedridden patients, particularly those with severe illness and/or those taking drugs with a narrow therapeutic range, the situation may be different: to position a patient in right lateral posture may accelerate the onset of therapeutic effects.**"²⁰ A study in children found that delayed gastric emptying shows significant improvement with change of position.²¹ Interestingly, it is not uncommon for us to get reports from friends or family witnessing a Death with Dignity that the patient died within a short time after position change.

Little drug absorption occurs in the stomach; most occurs in the duodenum and jejunum. There are a myriad of factors which affect intestinal absorption and hepatic first pass metabolism. In addition, the rate of drug absorption is influenced by the solution or suspension in which the drugs are administered, how far the drugs actually travel within stomach and numerous small intestine absorptive compartments, available surface area, blood flow, and the patient's specific disease processes.²²

As death ensues

After the patient has ceased breathing and no longer has a pulse, hospice is called. For patients not enrolled in hospice, the medical examiner or the funeral parlor should be called. For non-hospice patients, the prescribing physician should also be notified and may need to intercede with the local medical examiner to avoid emergency response protocols.

In Washington State the attending physician must submit the After Death Form to the Department of Health within 30 days after the death. Other U.S. jurisdictions in which PAD is legal may have different requirements for summary paperwork. Physicians treating patients in other states where PAD is now legal must check with the appropriate State or jurisdiction Department of Health concerning all PAD requirements and documentation.

¹ Summary of Death with Dignity Yearly Reports, Washington State Department of Health, 2009-2016; <http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/DeathwithDignityAct/DeathwithDignityData>.

² Death with Dignity Act: A Guidebook for Health Care Professionals [pdf]. The Center for Ethics in Health Care, Oregon Health & Science University, 2008; <https://www.ohsu.edu/xd/education/continuing-education/center-for-ethics/ethics-outreach/upload/Oregon-Death-with-Dignity-Act-Guidebook.pdf>.

³ Loggers, Elizabeth, Starks, Helene; Shannon-Dudley, Moreen et. al. Implementing a Death with Dignity Program. NEJM, 2013; 368(15):1417-1424, 22(2):631-633.

⁴ Wang. Leo; Elliott, Michael; Henson, Lily et al. Death with dignity in Washington patients with amyotrophic lateral sclerosis. Neurology, 2016, November 15; 87:2127-2122.

⁵ "Attending Physician" (AP) is the physician who agrees to write the prescriptions for DWDA. The AP also takes primary responsibility for counseling the patient, ensuring compliance with the law, and submitting physician documents to the DOH.

The "Consulting Physician" (CP) examines the patient and makes a written confirmation of the patient's diagnosis, prognosis, ability to make an informed decision, and voluntary decision making.

⁶ Oregon Death with Dignity Act: 2015 Data, Oregon Public Health Division, 2016, February 4; <https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/year18.pdf>.

⁷ <https://www.theguardian.com/commentisfree/cifamerica/2011/jul/01/pentobarbital-lundbeck-execution-drug>.

⁸ digoxin 25 mg, diazepam 500 mg, morphine sulfate 10 grams, propranolol 2 grams

⁹ After the data from the first 50 cases of ingestion of lower dosage DDMP was analyzed, 20% of deaths were found to be longer than 4 hours, and were primarily in cancer patients with significant narcotic/sedative/alcohol dependency or uncontrollable pain. **RED FLAGS FOR PATIENTS WHO MIGHT TAKE 4 OR MORE HOURS TO DIE:** 1) patients using **PAIN PUMPS**, using **EXTREMELY HIGH LEVELS OF PAIN MEDS**, or with **UNCONTROLLED PAIN**; 2) **PATIENTS ABLE TO DRINK A FIFTH OF LIQUOR OR CASE OF BEER**; 3) those with **MORBID OBESITY** or 4) **POORLY CONTROLLED NAUSEA AND VOMITING**; and 5) **IV DRUG USERS**.

¹⁰ Diazepam is absorbed into plastic and degraded in light, thus it should only be dispensed in amber glass bottles.

¹¹ Haloperidol is often used in hospice patients as an antiemetic for nausea and vomiting refractory to ondansetron.

¹² Vella-Brincat J, Macleod AD. Haloperidol in palliative care. *Palliative Medicine*, 2004; 18:195-201.

¹³ Critchley P et al. Efficacy of haloperidol in the treatment of nausea and vomiting in the palliative patient: a systematic review. *J Pain Symptom Management*, 2001, Aug; 22(2): 631-4.

¹⁴ Steingoetter, Andreas; Fox, Mark, Treier, Reto et al. Effects of posture on the physiology of gastric emptying: A magnetic resonance imaging study. *Scandinavian Journal of Gastroenterology*, 2006; 41(10):1155-1164.

¹⁵ Burn-Murdock R; Fisher, MA and Hunt JN. Does lying on the right side increase the rate of gastric emptying? *The Journal of Physiology*, 1980; 302(1):395-398.

16 Steingoetter, Andreas; Fox, Mark; Treier, Reto, et al. Effects of posture on the physiology of gastric emptying: A magnetic resonance imaging study. *Scandinavian Journal of Gastroenterology*, 2006; 41(10):1155-1164.

¹⁷ Asada T, et al.

Effect of body position on gastric emptying of solid food--a study using a sulfamethizole capsule food method

.Nihon Shokakibyō Gakkai Zasshi. 1989 Aug;86(8):1604-10. <https://www.ncbi.nlm.nih.gov/m/pubmed/2585786/>.

¹⁸ Ikeda T et al. Effects of body positions on gastric emptying with enteral nutrition: a crossover study using a continuous real time ¹³C breath test (BreathID system). *Hepatogastroenterology*. 2008 Sep-Oct;55(86-87):19057. <https://www.ncbi.nlm.nih.gov/m/pubmed/19102419/>.

¹⁹ Sanaka, Masaki; Urita, Yoshihisa; Shirai, Takatsugu et al. Recumbent position of gastric emptying of water evidenced by ¹³C breath testing. *World Journal of Gastroenterology*, 2013; 19(3):362-365.

²⁰ Christian Queckenberg, Uwe Fuhr. Influence of posture on pharmacokinetics. *European Journal of Clinical Pharmacology*, Springer Verlag, 2008, 65 (2), pp.109-119.

²¹ Villanueva-Meyer J¹, Swischuk LE, Cesani F, Ali SA, Briscoe E. Pediatric gastric emptying: value of right lateral and upright positioning. *J Nucl Med*. 1996 Aug;37(8):1356-8.<https://www.ncbi.nlm.nih.gov/m/pubmed/8708772/>.

²² K. Sandy Pang. Modeling Of Intestinal Drug Absorption: Roles Of Transporters And Metabolic Enzymes (For The Gillette Review Series). *Drug Metabolism and Disposition*, December 2003; 31(12):1507-1519.