



The Oral MAiD Option in Canada Part 2: Processes for Providing Review and Recommendations

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Oral MAiD

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Executive Summary

Medical Assistance in Dying (MAiD) has been legal in Canada since Bill C-14 received royal assent in June 2016. Following approval against eligibility criteria, MAiD can be provided in the majority of Canadian provinces and territories, by either intravenous administration of medications by physicians or nurse practitioners, or self-administration of oral medications by the patient themselves. The main advantage of offering patients an oral option is the autonomy it provides for patients to take the medications themselves, and re-establish some control during a challenging time in their disease or illness.

The purpose of this paper is to outline best practices for the safe dispensing, administration, and evaluation of the plausibility of an oral MAiD provision. Guidance will be provided for both clinicians and pharmacists in the provision of oral MAiD. The medications recommended for oral MAiD are covered in Part 1 of this guideline.

The following are summary recommendations:

1. Clinician presence is currently recommended for all oral MAiD provisions in order to be able to evaluate success and effectiveness and, if needed, intervene with intravenous medications in the case of delay or failure.
2. With greater experience with oral medications in Canada and greater knowledge of the effectiveness of oral regimens, there may come a time when clinician presence need not be required for oral MAiD provisions.
3. Clinicians should write prescriptions for both oral and IV medications for patients requesting oral MAiD.
4. Regular communication with the patient should be maintained to confirm that the patient's preference and the ongoing appropriateness for an oral route has been preserved for the planned date/time.
5. To optimize absorption, patients should refrain from eating 6 hours prior to taking the coma-inducing medications. Clear, non-carbonated fluids can be continued.
6. The patient is recommended to take an anti-emetic regimen at least 1 hour before consumption of the coma-inducing agent.
7. Secure delivery of the medication is important to prevent harm to others from this lethal dose of medication. Secure delivery of the medication could be accomplished by dispensing the medication directly to the providing clinician, either on their way to the provision or by a participating pharmacy to a clinician already present at the site of provision.
8. In preparation for potential delay or failure of the oral medication, ease of vascular access should be assessed, as with all patients requesting MAiD. If vascular access may be difficult, clinicians, in consultation with the patient, may opt to start an IV prior to oral ingestion.

9. Clinicians should come to an agreement with patients prior to the MAiD procedure on an agreed upon time (for example, 1 hour) that if death has not occurred, there will be IV supplementation with standard IV MAiD medications to cause death.
10. Where applicable, instructions from pharmacies should be followed explicitly with respect to reconstitution of the oral MAiD regimen.
11. Immediately prior to the start of the procedure clinicians should obtain final consent for MAiD, which should include both the oral MAiD procedure as well as consent for potential IV MAiD supplementation.
12. Clinicians should witness the ingestion of the medication. The patient should assume a standard Fowler's position (60 degrees) when consuming the medication and remaining sitting for at least 20 minutes, even if unconscious, to optimize absorption and prevent regurgitation.
13. The patient should consume all of the medication within 4 minutes. Use of a straw should be avoided as its use can slow the rate of consumption. Clear fluids between swallows are allowed as long as it does not prolong duration of consumption.
14. After consuming all the medication, the aftertaste can be mitigated by consumption of a strong liquor (1/4 cup of vodka or whiskey), or a room temperature non-carbonated beverage (1/2 cup). Creamy and milky liquors or beverages should be avoided.
15. Any unused medications should be returned to the pharmacy for proper disposal.

Improving Access to Oral MAiD for Canadians

Providing options for Canadians

The provision of MAiD through the administration of intravenous (IV) medication by a provider, while safe and highly effective, for many patients may feel “institutionalized” and/or “proceduralized”. While providers always strive for a patient centred experience through provisions in the home, an intravenous MAiD can be perceived by some patients as very clinical. The clinical perception is somewhat unavoidable given the requirement for vascular access and the necessary bedside participation of a clinician with IV MAiD, which can extend the intimacy of the moment beyond a circle of friends and family. Some patients may want to feel empowered to control this final act of their life. The availability of oral medications for MAiD may facilitate a more intimate and empowered process for a patient by lessening some of the procedural aspects and a need for bedside clinician intervention through IV medications.

Improving access to MAiD across Canada

Currently there is no accurate or stable data for the number of clinicians providing MAiD services in Canada. In a pre-legislation survey by the Canadian Medical Association (CMA), only 29% of physicians surveyed said that they would consider providing MAiD, and as many as 63% said that they would refuse (Vogel, 2015). No differentiation was made between providing the prescription or IV medications and completing a consultation for MAiD. Increasing the complexity of accurate data is that some physicians opt to only be involved in the assessment portion of the process, and not be involved in the actual provision of MAiD. While this data may have shifted since Bill C-14 was legislated, it can be inferred that at the time there are far fewer physicians providing MAiD services than those who conscientiously object.

While an oral option has existed in most provinces and territories since Bill C-14 was legislated, almost all provisions in Canada to date have been through the administration of IV medications. The proportion of those clinicians willing to complete assessments and to physically provide MAiD versus those only willing to complete MAiD assessments is probably multifactorial and includes the psychological burden of being a more active participant in the death as well as a lack of comfort with vascular access and knowledge of the medications used. With an estimated 0.3-4.6% of all deaths provided by MAiD in countries with a longer history and greater experience (Health Canada, 2017), we can safely assume that there are currently not enough practitioners willing to provide MAiD in Canada. Recent polling has suggested that the introduction of reliable oral medications for the provision of MAiD may increase access by increasing the comfort for “assessor-only” practitioners to expand their practice to provisions by mitigating some of the concerns outlined above. This assumption may be incorrect, at least short term, as prescribing physicians should still need to be present to obtain final consent and ensure the lethal dose of medication is delivered securely and successfully. This will also mean that clinicians will still need to be prepared to obtain vascular access, or otherwise have an IV established before

the oral provision, and administer IV medications in the case of failure or excessive delay in death.

Geographically, Canada is the largest country where physician assisted death is legal. As a result, the population is widely distributed. While MAiD is a legislated right of all Canadians, access to it, from both an assessment and provision point of view, is very likely inequitable, with most service providers concentrated in the urban centres. Appropriate referral of any patient requesting MAiD has been mandated by medical regulatory authorities. Unfortunately, without consultant MAiD clinicians available in all communities, most referrals must be directed to the aforementioned urban centres. While we acknowledge that this can be similarly true of many medical and surgical services, a major goal of any MAiD service is to remain patient-centred. Due to the nature of the eligibility criteria many MAiD patients are unable to travel. Alternatives (ie. phone or e-consultation) to in person consultations, to mitigate inability to travel, vary depending on provincial regulation. However, the provision of MAiD will, at least in the short term, require travel by either clinician or the patient. With greater experience with the effectiveness and reliability of oral medications, as well as regulations to guide safe dispensing practice, there may come a time when the oral medications can be offered to patients for administration in the absence of clinicians and increase equitable access across Canada.

Key Collaborations in the Provision of Oral MAiD

The planning and provision of an assisted death with oral medication requires communication and collaboration with the patient, their family, the practitioner, the pharmacist and potentially other supportive healthcare professionals such as nursing and social work. Once a patient is assessed as eligible and the decision is made to choose the oral option, a date for the provision is made that is agreeable to patient, practitioner and pharmacist. This date should take into account the 10-day mandatory reflection period unless there is concern that the patient will either lose the capacity to provide informed consent within that time frame or the patient is at imminent risk of death before the end of the 10-day waiting period (House of Commons Canada, 2016). However, in the interval between confirmation of eligibility and selection of the method, the clinical condition may change, and should be regularly assessed. The patient may prefer the IV option if unable to ingest an oral dose on the planned date.

Practitioner and patient

Patients who choose oral MAiD often have the desire to plan their assisted death as more of an event. This may take some coordination among various people, and likely requires some flexibility on the part of the clinician, as this type of medically assisted death may require more time. Depending on the illness, disease or disability, the clinical status of the patient may change between the decision to have oral MAiD and the date set to ingest the medication. If the patient is unable to tolerate oral MAiD, but wants an assisted death, the practitioner should discuss the option of starting directly with the IV MAiD medications.

Clinicians should discuss pre-medication with an anti-emetic to help prevent or treat any nausea or potential regurgitation. Ideally, the patient should refrain from eating 6 hours prior to the provision. This optimizes the absorption of the coma-inducing medication.

Clinicians should discuss the approximate time to coma and death with the patient and family, and should explain to the patient that the oral route has a higher risk of failure. Clinicians should discuss the time frame for an intravenous (IV) intervention in the case of a delayed or failed oral provision. The pre-determined time frame should ideally be established prior to the day of the MAiD provision (for example, 1 hour or 2 hours as a time frame). An IV may be started prior to the oral procedure or only after the oral procedure has failed. This decision should be made taking into account the clinician's comfort in starting an IV, the predicted ease in establishing IV access, and the patient's desire or comfort in having an IV prior to the start of oral ingestion.

Emphasis should be placed on continuing usual medications right up to the time of the provision, especially pain and anti-emetic and pro-motility medications. While the continuation of some cardiac medications may not seem to be necessary, clinicians do not want the patient experiencing chest pain or shortness of breath prior to the provision as this will only contribute to their suffering. To prevent any prolonging of time to death, pacemakers and defibrillators should be deactivated if possible. If such access to cardiology services is not available, you should be able to

obtain a magnet from a local hospital for placement over the device to turn off the ICD function. Oxygen should be discontinued immediately after the person loses consciousness. The family should be prepared for signs and symptoms that the dying person may exhibit such as snoring, gurgling, changes in rate of breathing, and increased paleness or greying or duskieness of skin. As in all MAiD cases, the events for after the procedure, such as body disposition should also be clarified and confirmed with the family prior to start.

Practitioner and pharmacist

Prior to offering MAiD, and particularly oral MAiD, practitioners should identify pharmacies that are willing and competent to provide the service. The specific pharmacy standards around MAiD are governed by the provincial colleges of pharmacy and vary from province to province. Some pharmacies do not offer collaboration with practitioners providing MAiD, or with the MAiD coordinating service due to conscientious objection or the lack of facilities to properly compound products. Compounding pharmacies are undergoing more regulation as a result of cases of inaccurate potencies and contamination in compounded products (Riley, 2017). There are variations in multiple aspects of MAiD provision including drug protocols, preparations of medications, storage, dispensing, destruction, documentation and inclusion of regulated pharmacy technicians in preparation (Verweel L et al., 2018). Each practitioner must be familiar with individual provincial medical and pharmacy standards.

Early communication between the practitioner and the pharmacist about the anticipated date of the provision is key to success. This allows the pharmacy to have all the appropriate medications and ingredients available to compound the prescription and have the agreeable staff available to carry out the compounding. Formulations that are compounded into suspensions or solutions have a limited expiry date and should not be prepared until immediately before the scheduled assisted death. The practitioner and the pharmacist must discuss the appropriate antiemetic regimen, as well as the need and format of the IV back-up kit. This should be done prior to writing the MAiD prescription.

The security chain of these lethal medications should be clearly delineated and transfer of medications should be understood by physician and pharmacist. Ideally, the medication should be prepared and then picked up immediately prior to the scheduled provision so there is no need to secure it for extended periods of time after dispensing. Alternatively, arrangements could be made to have the medications delivered to the site of MAiD provision. In such circumstances the clinician would need to be present to receive the medications to maintain the chain of security.

Pharmacist and patient

Bill C-14 (House of Commons Canada, 2016) outlines the pharmacists' role in dispensing the medications and does not include direct participation in administering medications. However, pharmacists do have to provide the dispensing service and if they do not have the ability to compound the medication or are conscientious

objectors, they have the responsibility to help the physician and/or the patient find an alternative pharmacy that can provide this service.

Pharmacists do have the responsibility of providing patients and families with information around MAiD when enquiries are made including which drugs are used, maintaining security of the medications and correct administration procedures.

Safe Acquisition and Administration of Oral MAiD Medications

Safe compounding

The preparation of oral MAiD formulations requires adherence to strict compounding procedures to protect the safety of staff preparing the product and to ensure an accurate, stable and palatable product. In the absence of MAiD specific published literature, these recommendations rely on references such as the US Pharmacopeia Non-sterile Compounding Guidelines (US Pharmacopeia, 2016) and the Canadian Society of Hospital Pharmacists Guidelines on Non-sterile Compounding (Canadian Society of Hospital Pharmacists, 2014) These references recommend using compounding monographs from standardized pharmacopeia's or peer-reviewed journal articles. It is also recommended that a regulated health professional, either a pharmacist or a regulated pharmacy technician, are primarily involved in the compounding procedure. Some provinces do not allow the involvement of a regulated pharmacy technician in the MAiD preparation and dispensing.

Since the preparation of oral MAiD formulations often requires manipulation of powders with strong pharmacological actions, compounders should wear personal protective equipment (PPE) such as a clean gown, powder-free gloves, mask, beard guard (if necessary) and eye protection to avoid inhalation or absorption through the skin. An 'independent double check' of all measures is advisable to ensure accuracy to the weighted powders/doses.

Safe Dispensing

There are some general practices of safe dispensing that will be applicable to all oral preparations. Ideally, formulations should be dispensed in a ready-to-use format that can be easily consumed by a person in less than 4 minutes. The preferred format is a suspension or solution of less than 120 mL. This ensures a tight security chain and minimizes time that is required to store the medication at home. The disadvantage of this format is that the stability of the medication cannot be guaranteed beyond a certain period of time. If oral MAiD prescriptions are dispensed in powder format, there is a need for the person to mix the powder with water and juice prior to consumption, increasing the risk of complications such as decreased palatability, failure to consume total dose and failure of completion. In those situations, it is recommended the compounding of the product should not happen until immediately prior to the scheduled assisted death.

The phenobarbital, chloral hydrate and morphine combination must be compounded into a suspension as the phenobarbital has some solubility in water and alcohol, but the aqueous solution is not stable (Gerald, 2018). The chloral hydrate is quite soluble in water, but easily volatilizes when exposed to air, and decomposes when exposed to light. Therefore, it is recommended to dispense this formulation in an amber glass bottle with minimal air space at the top. Since this formulation is a suspension, it must be shaken well prior to administration. There is no standardized pharmacopeia formulation that guides us on an expiry date so the determination is

based on the US Pharmacopeia (2016) approach of aqueous preparations of moderate compounding complexity. It advises that water containing oral formulation could have a 'beyond use date' of 14 days from preparation if stored at controlled cold temperatures and 7 days if stored at room temperature. The British Columbia MAiD protocols have opted for a 72 hour expiry date to ensure the stability and potency of the preparation and discourage the dispensing of the preparation too far ahead of the scheduled date of the assisted death (MAiD BC Pharmacy, 2018) The formulation should include auxiliary labeling to "shake well prior to administration", "lethal Dose", and "protect from extreme temperature fluctuations".

Dispensing of secobarbital will differ from other agents and practices are largely based on Dutch experience. The Dutch protocol provides a compounding procedure for pentobarbital and secobarbital (KNMG/KNMP, 2012) It advises a beyond use date of 1 month for the unopened bottle if stored at room temperature. This formulation should NOT be stored in the fridge. Secobarbital solution should NOT be shaken as the high pH of the solution causes it to form bubbles in a soapy manner. Therefore, auxiliary labeling should include "lethal dose", do NOT shake, and do NOT store in fridge. Keep at room temperature.

The digoxin/Diazepam/Morphine/Propranolol (DDMP2) combination was developed in Washington state and has now been adopted by some Canadian provinces. There has been no formulation that guides the compounding of this into a suspension or solution. Therefore it is dispensed as a mixture of the four drug powders with directions to mix powder into 100-125 mL of water, clear juice, or alcoholic beverage. The mixture must be shaken or stirred well until smoothly mixed and milk-like. The entire contents should be consumed within 1-2 minutes. The requirement to mix it immediately prior to consumption makes this option less desirable in that the powders can be aerosolized and inhaled by providers or surrounding family and friends. The patient also may have trouble consuming the full amount in 1-2 minutes as it also has a bitter taste. This increases the risk of incomplete dosing, extended dying periods and/or failure to achieve death.

The antiemetic agents may be dispensed in tablet format anytime prior to the scheduled date and consumed as directed. There may be a need to dispense a solution format, depending on patient specific factors. This requirement can be discussed with the pharmacist during the planning phase.

IV backup kits can be provided in a ready-to-use format (medication drawn up in syringes), appropriately labelled to minimize the delay in administration when the decision is made to complete the provision with one or more IV medication. This eliminates possible mistakes on site and minimizes the time needed to draw-up the medications.

In order to maintain the security chain, oral MAiD medications should be passed from pharmacist to practitioner who provides it to the patient at time of MAiD provision. This will minimize any concern of the medication being used or administered by another person, and maximize the effective and timely use of the medication by the still competent person for whom it was intended. The practitioner

then should return any unused portions to the pharmacy for documentation and destruction. This will ensure no residual amounts are consumed by others at the patient's location, or by pets or animals.

Safe Administration

Safe administration of these medications will optimize absorption, which is crucial to maximizing the effectiveness of the regime. To optimize absorption, patients should refrain from eating 6 hours prior to taking the coma-inducing medication if possible. Clear non-carbonated fluids can be continued. Ensure the anti-emetic regimen is taken at least 1 hour before consumption of the coma-inducing agent. Usual medications should be continued right up to the time of the provision, especially pain and anti-emetic/pro-motility medications. In particular, while the continuation of some cardiac medications may not seem to be necessary, experiencing chest pain or shortness of breath prior to the provision will only contribute to suffering.

Read the directions on the bottle of the coma inducing medication: some formulations such as suspensions need to be shaken well before administration and some should NOT be shaken. Patients should remain in a Fowler's position (60 degrees) when consuming the medication and for at least 20 minutes after consumption, even if becoming unconscious, to optimize absorption of the medication and prevent regurgitation. After that time, they can be lowered to a semi-reclined position.

Patients should consume the medication as quickly as possible to ensure they have consumed the entire dose before becoming sedated or losing consciousness. Use of a straw may slow down the rate of consumption. Sips of water or clear juice may be taken in between swallows as long as it is done quickly and does not prolong the consumption of the coma inducing medication.

MAiD medication is often bitter tasting. To help rinse away the bitter aftertaste and enhance the effect of the medication, $\frac{1}{4}$ cup of strong liquor such as vodka or whiskey OR $\frac{1}{2}$ cup of room temperature, non-carbonated beverage can follow the consumption of the MAiD medication.

Optimizing the Patient and Family Experience for Oral MAiD

Preparations for a successful process

Individuals eligible for MAiD may indicate a preference for oral medication, however, their commitment to that route of administration may change at anytime up to the provision of MAiD. Furthermore, their preference may be altered by a change in their status which renders them incapable of either holding a container or swallowing effectively. In preparation for these potential changes, oral and IV medications should always be concurrently ordered and preparations taken so that both are options at the time of provision. As with any MAiD provision, regular and timely communication ensures capacity and consent to proceed with a planned date and time.

On the day of the oral MAiD provision, individuals often spend their final moments with family and friends. Events may include wishes to consume food, beverages, alcohol, and/or other substances. As with any MAiD provision (oral and IV routes), any consumption must be balanced against maintaining capacity for final written and/or verbal consent to proceed with the planned provision. If an oral route is preferred, individuals should be informed of enhanced efficacy of medications on an empty stomach, and as such, should ideally avoid solids and full fluids in the preceding 6 hours. Clear fluids can be continued up to the planned provision. Individuals should also be informed of the risks of nausea and vomiting associated with these bitter medications, and if applicable, burning associated with chloral hydrate. Antiemetic regime adherence is crucial to promoting a successful oral procedure.

Obtaining final consent prior to MAiD provision

In all provinces and territories in Canada, the MAiD process requires both a written request from an individual and 10 “clear” days between the written patient request and the date of the event. A final consent is obtained prior to the administrations of IV medications, and the same should be obtained prior to the ingestion of any oral medications. These requirements ensure that there is no coercion and full capacity of the individual to receive medications that will result in death. We suggest that a MAiD provider must be present at the time of an oral provision to confirm capacity and consent. Presence is also highly recommended to witness actual ingestion of the medication, as the provider is ultimately responsible for the prescription of the medication.

Preparing for a delayed or failed oral medication process

Examining the Canadian experience of using phenobarbital, chloral hydrate and morphine, coma typically occurs in 15 and 20 minutes, and death between 45 and 75 minutes (Trouton, 2018). The variability in the onset of death is well documented in the literature. Unarousable coma was followed in a stepwise fashion by slow and shallow breathing, agonal breathing, obstructed breathing, apneic spells, and death. These latter stages can take several minutes and can be very difficult for families to observe. Considering these factors, final MAiD consent prior to oral administration should include the insertion of an IV either prior to ingestion or within reasonable time frame post ingestion. Securing vascular access can ensure that all MAiD provisions in

Canada are successful, and that any potential failure in our system has been reduced to the lowest acceptable risk. This will also ensure the most compassionate provision of MAiD for patients and their families.

Oral MAiD Provider Experience in Canada

There have been 11 cases of oral MAiD provision in Canada - one in Ontario, 1 in Saskatchewan, 1 in the Yukon and 8 in British Columbia. The summary of the 8 cases in BC is as follows:

	Oral medication used	Time from drink to death	Pre medication	Diagnosis
1	Phenobarbital, morphine and chloral hydrate	60	Ondansetron	Glioblastoma
2	Phenobarbital, morphine and chloral hydrate	60	Ondansetron and lorazepam	Spinal stenosis, CAD
3	Phenobarbital, morphine only	45	Marijuana	End stage COPD
4	Phenobarbital, morphine and chloral hydrate	75 *	Marijuana	End stage COPD
5	Phenobarbital, morphine and chloral hydrate	n/a patient was too ill to hold or ingest	none	Metastatic breast cancer
6	Phenobarbital, morphine only	60*	none	Frailty, CAD and COPD
7	Phenobarbital, morphine only	83	Ondansetron	Progressive supranuclear palsy
8	Phenobarbital, morphine only	90*	none	Hepatocellular carcinoma

* IV was started and process completed with propofol and rocuronium

Case 5 included as on the day prior to MAiD, the patient still expressed strong desire to do oral, and clinician arrived with that medication, and IV back up kit. The 4 medications were administered, as for IV-MAiD.

Patients were contacted approximately one hour prior to clinician arrival. On arrival, the patient's consent was re-affirmed, and they were offered a chance to withdraw consent for the provision, and if they expressed a desire to continue, then to

reconfirm their desire for the oral versus the IV route. In all cases, they proceeded to take the drink directly from the medicine bottle, rather than a separate vessel.

A physician was present for all eight cases. All patients were strongly motivated to not have an IV but consented to having an IV inserted if prolonged death was observed. The first 3 cases presented did not have any IV intervention. An IV was used in case 4, 6 and 8, as agonal breathing persisted longer than 60 minutes. 6 of the 7 patients noted bitterness, and 6 of 7 patients successfully took the entire volume under 4 minutes. The one who was not able to take it in 4 minutes had pre-medicated with alcohol as part of the event, and continued to take alcohol between sips of the oral medication. Regurgitation or vomiting were not observed in any of the cases. In case 2, a trial of Benzocaine spray (Hurricane ©) was used, but did not seem to improve the bitterness significantly. There was no loss of bladder or bowel control at any time for any patient. In all cases, the coma inducing medication was brought by the attending physician and would not have been able to be picked up by any of the 7 patients themselves because of physical decline.

In this short case series, the patients and families gave positive feedback regarding the oral experience as a whole. Between the coma and death, the family discussed suffering, reflected on a life well spent, and shared condolences. The total time with the patient and family was not significantly longer than IV, but the time was organized differently.

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