Complications with Medical Assistance in Dying (MAID) in the Community in Canada

Review and Recommendations

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Contents

Executive Summary

Total MAiD deaths in Canada between December 10, 2015 and October 31, 2018 is reported as 6749 deaths as per the most recent report by Health Canada (1). Between January 1st, 2018 and October 31, 2018, an estimated 55% of those deaths have taken place outside of the hospital setting, in the patient's home, a long-term care facility, or a hospice. This most recently available reporting of MAiD in Canada is still an estimate, as it pre-dates mandatory federal monitoring and reporting and data is incomplete or approximate from several provinces and territories. The vast majority have taken place with parenteral medications, with only a very small number using self-administered oral preparations.

The purpose of this paper is to outline some of the potential complications that may be associated with the administration of MAID, both in intravenous (IV) or oral form, and to provide recommendations to both prevent and deal with any complications that do arise.

The following are summary recommendations:

1. All patients undergoing MAID in the community should have documentation outlining their request and consent for the provision available at the time of the provision. Patients should also have an up-to-date provincial Do Not Resuscitate form available, or equivalent order signed by them and their physician or nurse practitioner, to prevent attempts at resuscitation should attendance or transport by emergency medical services (EMS) be required.

2. Discussion of potential complications should be a routine part of the consent process when discussing the MAID provision with patients.

3. Clinicians should obtain consent from patients prior to the initiation of MAID for any therapies that may be required should a complication occur (e.g. conversion from oral self-administration to IV in the setting of delay, or the need for an unexpected transfer to hospital).

4. For MAID provisions in the community, physicians and nurse practitioners who do not insert IVs as part of their regular practice should be accompanied by another clinician experienced in inserting IVs, in the absence of a peripherally inserted central catheter (PICC). The need for a functional PICC should be considered based on physical examination prior to the provision. Port-a-cath devices can be considered for access by experienced clinicians. Midline catheters are less secure than PICC's, and their function should be confirmed before use. Intraosseous infusion (IO) requires technical expertise and regular experience, and is not recommended electively for MAID.

5. For oral self-administered MAID, clinician presence at the provision is recommended to intervene with IV medications to complete the MAID provision in case of delay or complications with the oral preparation.

6. Clinicians should know their contingency plan for failed vascular access or administration of medications prior to starting any provision. This plan will vary depending on local context. If clinicians are unable to establish IV access prior to the administration of medication, provision should be deferred until such time when non-emergent help can be obtained.

7. If a complication occurs with either IV or oral self-administration, and clinicians are unable to obtain subsequent IV access, clinicians should decide whether the patient's condition allows for another clinician to be called to the scene to aid in obtaining access. Technical proficiency from regular practice and routine use is mandatory before considering intraosseous infusion emergently for a MAID complication.

8. If a patient's condition does not allow for another clinician to come to the scene and it is decided that the patient requires immediate IV access, the clinician may have to call EMS (i.e. 911).

9. If 911 is called, the clinician should request EMS to insert an IV and release the patient on scene, and/or ask them to call their online medical director for a similar order.

10. If EMS are unable to insert an IV or to release the patient on scene (or refuse to do so), the clinician providing MAID should accompany the patient to hospital to help direct further care.

11. Should a patient present to an emergency department as a result of complications of MAID in the community, and the validity of the MAID process can be confirmed to the satisfaction of the care team, it is appropriate to provide supportive and symptomatic care without attempts at resuscitation or overdose reversal. Further administration of medications to hasten death should only be considered by the clinician who assessed and obtained the consent for MAID.

Potential Complications with IV MAID in the Community

The vast majority of MAID provisions taking place in the community are done using parenteral medications administered intravenously by a clinician trained in providing MAID. The advantages of IV MAID are that it is suitable for almost all patients, is well tolerated with minimal side effects, and has rare failure rates. The disadvantages of IV MAID are that it requires the potentially painful insertion of an IV at the end of life, requires the presence of a clinician, and that the final act of medication administration may be perceived as diminishing agency and reducing autonomy for the patient.

Medication protocols for IV MAID are outlined elsewhere. Regardless of the protocol being used, none will fail if administered properly. Therefore, the most significant complications associated with IV MAID administration are the inability to obtain IV access or the loss of IV access during the provision.

Global experience

A review of 649 cases of euthanasia and assisted suicide in the Netherlands published in NEJM in 2000 outlines some data on complication rates with IV MAID (2). In that case review, there were technical problems with obtaining IV access in 5% of cases, including difficulty finding a vein or problems with the IV catheter itself. There were patient complications in 3% of cases, such as muscle spasms, myoclonus, cyanosis, gasping, or vomiting. There were problems with completion, mostly a longer than expected time to death, in 5%. Unfortunately, this case review does not provide specifics on what medications were being used.

Canadian experience

As of yet, there has not been any systematic recording of complications with IV MAID in Canada. However, in a survey of 335 Canadian emergency physicians, 3 reported having seen patients come in to the emergency department because of a failed IV administration of MAID or an inability to obtain an IV in the community (3). It is likely that the majority of cases of IV failure are resolved in the community either with re-insertion or with the assistance of another clinician.

Prevention

Given the possible complications with IV MAID outlined above, there are several steps that MAID clinicians should take to prevent them from taking place.

The first is to include a discussion of possible complications with IV MAID as part of the consent process with patients. This should include a discussion of potential difficulties with the IV, potential side effects from the medications, and the possibility of losing vascular access during medication administration. Patients should be consented for the insertion of two peripheral IVs prior to the IV provision in case one of them fails.

Unless the MAID clinician inserts IVs as part of their regular practice, then an additional clinician should be readily accessible who is particularly skilled at IV insertion (e.g. a community care nurse). If clinicians are unable to establish IV access prior to the administration of medication, provision should be deferred until such time when non-emergent help can be obtained. EMS should not be called for routine non-emergent IV insertion.

Vascular access should be evaluated at the time of the assessment, and within a close interval of administration if several weeks or months have elapsed since the MAID assessment.

Appropriate equipment should be present for troubleshooting IV access. At a minimum this should include multiple cannula sizes, but may potentially include kits for obtaining central access or adjunct equipment such as vein finding devices.

The clinician should check that the IVs are patent, and in the vein. This can be done by drawing back on the line for blood. If this is ineffective, saline can be injected to assess for ease of administration and the absence of swelling proximal to the IV insertion site. Patency can also be confirmed by the free flow of intravenous fluids to gravity, again with the absence of significant swelling proximal to the insertion site.

The clinician should be prepared with additional supplies of medications in case medications are injected into the interstitial tissues during administration.

The clinician should have a plan in place in case IV access is lost, medications have been administered, and they are unable to obtain further access. This may consist of another clinician on call who is able to come and assist, an agreement with local EMS to provide IV access without transporting to hospital, or an agreement with a local hospital for direct admission to a under a clinician with admitting privileges for such a circumstance.

In all cases of MAID in the community, documentation should be present that clearly demonstrates the patient's consent to the provision and to any subsequent care, as well as an official provincial DNR order or equivalent in case of EMS involvement.

Treatment options

Depending on the complication, there are several treatment options available to MAID clinicians in the setting of IV MAID in the community:

Side Effects or Delayed Time to Completion

As mentioned above, IV medication sequences used in MAID are generally very well tolerated and highly effective. However, should side effects (gasping, myoclonus, etc.) occur, clinicians should be ready to augment doses of medications through an IV as needed for patient comfort and provision completion. Clinicians should also be prepared to accelerate or omit parts of the protocol. For example, midazolam can occasionally cause paradoxical agitation, in which case clinicians should be prepared to quickly administer propofol without the preceding dose of lidocaine. Specifics of medication protocols may be found in other documents. Clinicians should routinely bring a complete second set of iv medication to every provision.

Loss of/Inability to Obtain IV Access

If patients are amenable, clinicians should consider establishing a minimum of 2 peripheral IV's for provisions, particularly if access is challenging. If IV access cannot be reliably obtained, or there is doubt about the reliability of the access that has been obtained, then the provision should ***stop*** prior to the administration of that, or additional medications, until further assistance is obtained. Central venous access (ie. PICC) should be considered if peripheral access is not possible.

If IV access is lost during the administration of medication and a second peripheral IV has been established, medication administration should be switched to the second IV. If a second IV has not been established, immediate attempts to obtain subsequent access should be made. During this process, subcutaneous or IM administration of sedative medications for patient comfort may be administered according to clinician's judgement.

If subsequent access cannot be obtained, clinicians should decide whether IV access is needed without delay, or if the patient can wait for another clinician skilled in IV insertion to be called as backup to come to the scene and obtain definitive access.

If access is required without delay, or if there is no other clinician available, the clinician on scene will have to decide whether to call EMS to provide care on scene or to transport to hospital. In all cases when EMS is called, it should be discussed whether it is possible for EMS attendants to obtain IV access and leave the patient on scene with the clinician responsible for the MAID administration without transporting to hospital. EMS may need to consult with their medical control for approvals as required.

If transport to hospital is required, the clinician should accompany the patient. If the clinician has privileges at the receiving facility they will be able to continue to provide care. If not, they will be able to help direct care that is provided. In these exceptional circumstances, it will be up to the treating team at the receiving facility to decide if they are able to provide IV access under the direction of the MAID clinician. The clinician will be unable to administer medications for MAID at the receiving facility unless they have privileges. Transport back to the patient's home or long-term care facility may be considered if the patient's death is not expected to be imminent, otherwise they could be admitted for comfort care.

No clinician should administer life-ending medications who was not involved in the MAID assessment and consent process. This is supported in a survey of 335 Canadian emergency physicians, where 75% said they would feel comfortable inserting an IV in these circumstances, with the patient's own clinician resuming care after this was done. However, 15% said they would not, with an additional 10% expressing serious reservations or a qualified yes (3).

Potential Complications with Oral MAID in the Community

The amendments to the criminal code that allow for MAID explicitly allow for the option of oral self-administration (4). Arguments in favour of an oral, self-administered option include allowing greater geographical access to MAID, increasing the number of clinicians willing to take part in the provision, and allowing for greater autonomy and less medicalization of the end-of-life experience for patients (5).

There have been exceedingly few reported cases of oral self-administered MAID in Canada so far: 5 as of the end of 2017 according to the 3rd Interim Federal Report (1), and 13 according to a CAMAP white paper published in April 2018 (6). However, these low numbers may in part reflect unfamiliarity with the practice and the previous unavailability of an effective, easy to administer oral option. In the fall of 2017, a pharmaceutical company received approval by Health Canada to distribute secobarbital, the oral barbiturate of choice for self-administered MAID in Oregon, Washington, and the Netherlands. It has been speculated that rates of self-administration may now go up (7).

Given a generally higher rate of adverse effects, prolonged time to death, and higher failure rate of oral self-administered MAID, it will be important to consider prevention and response to complications from oral MAID in the community, even if total numbers remain small overall.

Global experience

In the aforementioned review of MAID cases in the Netherlands published in the 1990s, there were problems with completion of oral MAID (using barbiturates) in 16% of cases (including a delay to death, failure to induce coma, or re-awakening). The range of time to death

was 1 minute up to days, with a median of 30 minutes. 3.5% of cases had vomiting and 2.6% experienced extreme gasping. The clinician present elected to administer additional IV MAID medications in 18% of cases due to the above problems (2).

In a review of 165 oral MAID cases in the Netherlands between 2013-2015, 9 patients showed some retching and 3 patients fell asleep before being able to complete the medication. 6 cases took longer than 60 minutes before death occurred. Additional IV medications were administered for the completion of the provision in 9% of cases (8).

A review of the Oregon data from 1998-2015 (a total of 991 self-administered cases; intravenous MAID is not legal in Oregon) shows that in roughly half of cases patients did not have a medical clinician present at the time of ingestion (9). For the cases where a clinician was present and data is available, there was a complication rate (not including delay) of 4.9%, mostly involving regurgitation. There are 6 reported cases of patients regaining consciousness after administration. Of the cases where data is available, the reported time from ingestion ranges from 1 minute to 104 hours, with a median of 25 minutes. EMS was involved in less than 1% of cases.

A case report of a patient in California being brought to the ED and being partially resuscitated after self-administering oral MAID at home was published in 2017, and serves to illustrate the many possible moments for miscommunication or error should an event like this occur, and the importance of clear documentation and communication between patients, family, and clinicians (10).

Canadian experience

There have been 13 reported cases of oral self-administered MAID in Canada, all with clinician presence according to a white paper published by CAMAP in March 2018 (5). Details are available for 10 of the cases that were performed in BC, where the prescription and process for oral MAID are standardized. According to the information available:

- Most cases involved the administration of phenobarbital, morphine, and chloral hydrate
- In three cases where it is known, average time to death was one hour or less. In two cases, death occurred between 60 and 90 minutes
- In five cases the oral administration was unsuccessful by 60 minutes, and required IV medications to complete the process
- In one case using the DDMP2 mixture (Diazepam 1g, Digoxin 50mg, Propranolol 2g and Morphine 15g) time to death was 135 minutes, and no clinician was present for the death.

There has been a single reported case of EMS being called and the patient being transported to a hospital as a result of adverse effects or a delayed death, highlighting the importance of clinician presence to monitor appropriate ingestion and progression to death.

Prevention and preparedness

Given the greater risk compared with IV MAID, it is especially important that clinicians of oral MAID discuss with patients the potential for adverse effects from oral MAID as part of the initial consent process. Clinicians should obtain consent in advance for any treatments that

might be administered to deal with complications that arise, including symptomatic therapies, as well as the insertion or re-insertion of IVs for the administration of parenteral MAID medications.

We strongly recommend that clinicians should be present with patients during oral self-administration of MAID, and should remain present until the patient's death (in some jurisdictions, such as BC, this is already mandated by a College practice standard). If the primary clinician does not routinely insert IVs, there should be an additional clinician readily available who is proficient in the insertion of IVs. If a patient refuses the presence of a clinician in a province/territory where clinician attendance is not mandatory, the clinician prescribing the MAID medications should be readily available to be called by the patient or any other persons present should a complication occur.

It is suggested that clinicians consider inserting an IV before oral self-administration takes place, in case medications for symptom control or conversion to IV MAID is required.

Clinicians should be prepared with additional therapies for symptom control (e.g. anti-emetics, sedatives) as well as back-up IV MAID medications when using oral therapies. Clinicians should have a plan for dealing with these complications, as well as a pre-established cut-off time for when they will consider oral medications to have delayed beyond a reasonable time and will proceed with the administration of IV MAID. This should be discussed with the patient in advance.

The clinician should have a plan in place in case IV access is lost and they are unable to obtain further access. This may consist of another clinician on call who is able to come and assist, an agreement with local EMS to provide IV access without transporting to hospital, or an agreement with a local hospital for direct admission to a under a clinician with admitting privileges for such a circumstance.

All patients who are undergoing MAID in the community should have documentation with them at all times clearly indicating their consent to MAID, and their wish not to be resuscitated (preferably an official directive for EMS, if available in their jurisdiction).

Treatment options

Side Effects or Delayed Time to Completion

Given the fairly high rate of side effects and delayed time to death that can occur with oral MAID, clinicians should be ready to administer subsequent doses of medications through an IV as needed for patient comfort and provision completion. Specifics of medication protocols may be found in other documents.

There is no clear cut-off for what constitutes 'delayed time to death' or 'failed oral MAID.' As mentioned above, clinicians should decide with patients in advance at what point they will consider inserting an IV and completing the provision with parenteral medications.

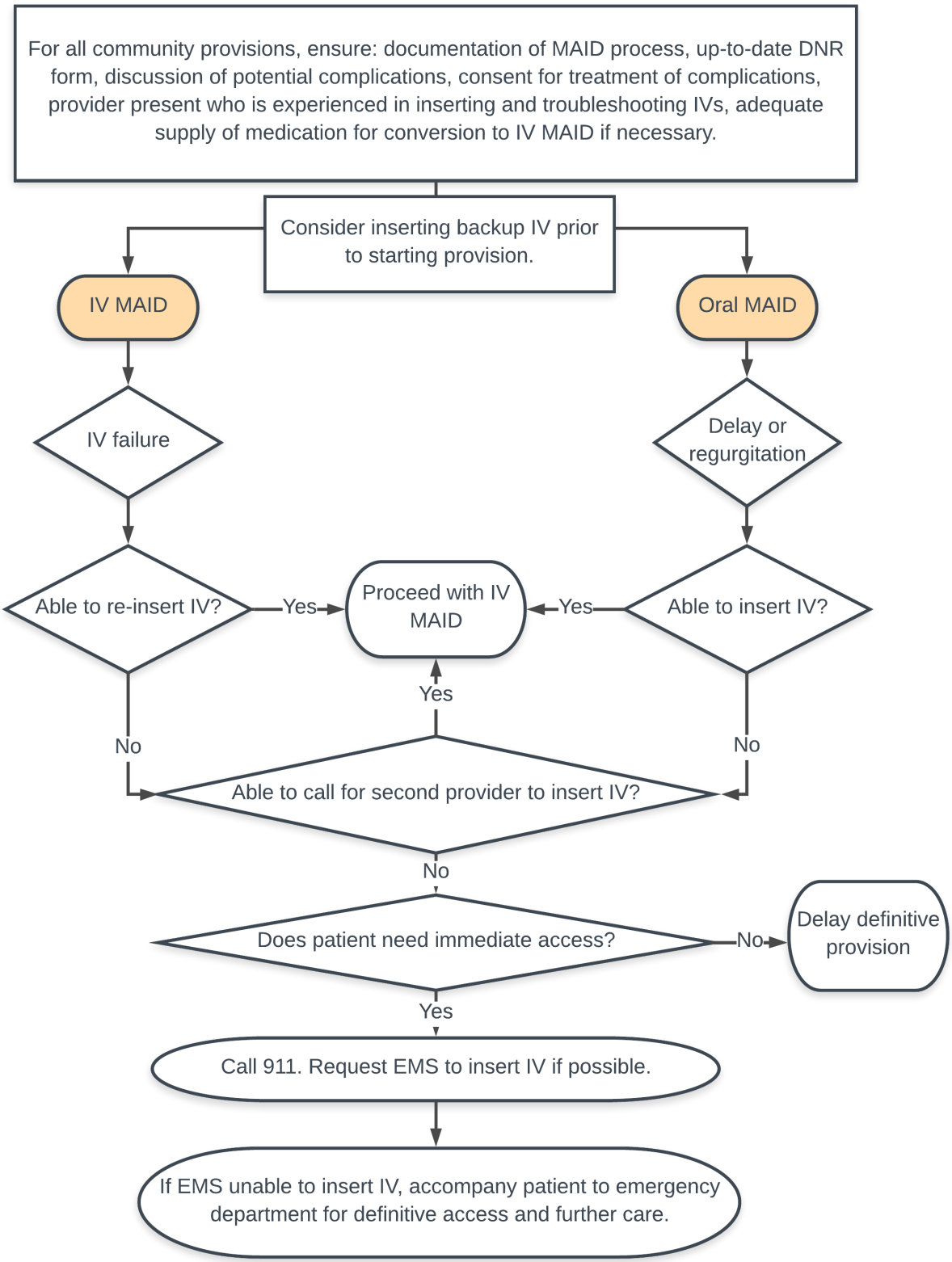
Delayed Time to Completion and Inability to Obtain IV Access

If clinicians decide to administer IV MAID medications due to a delayed time to death during oral self-administration, access should be pre-existing or quickly obtained. However, if there is any delay, subcutaneous or IM administration of sedative medications for patient comfort may be administered according to clinician's judgement.

It is possible that patients who self-administer oral MAID in the community may present to the ED without a clinician accompanying them. In these circumstances, the ED physician will have to decide what constitutes sufficient evidence that the patient's state is the result of an

approved MAID process. Ideally patients will have clear documentation of the MAID process with them at all times, as well as a standardized do-not-resuscitate order, if available. In the aforementioned survey of Canadian emergency physicians, the top three acceptable pieces of evidence to demonstrate a valid MAID process were documentation from the prescribing clinician (91%), speaking directly with the prescribing clinician (81%), and advance directives from the patient stating intent (70%) (3).

Summary Flowchart



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