Voluntary Assisted Dying Bill 2017
Calvary's Position

Calvary's role in the Victorian Community

Since the establishment of Calvary in 1885, with the arrival of the Sisters of the Little Company of Mary in Australia, Calvary has become well known for the provision of health care to the most vulnerable, including those reaching the end of their life. With more than 12,000 staff and volunteers, 15 public and private hospitals, 17 retirement and aged care facilities, and a national network of Community Care centres. We operate across six states and territories within Australia.

Calvary Health Care Bethlehem in Caulfield, Victoria is recognised as a leader in a Specialist Palliative Care Service.

We support over 4000 patients and their families each year. Calvary is known for

- an innovative model of care,
- interdisciplinary team work in collaboration with the patients, GPs, community health, aged, disability and other health services; and
- our efforts to ensure that care is easily accessible and coordinated across inpatient services, centre-based clinics, a day centre and at home.

Executive Summary – fundamental questions outstanding

Calvary made a submission to the Ministerial Advisory Panel on 10 April 2017.

Calvary does not support the passage of this legislation.

Calvary does not believe that assisting a person to commit suicide, or to end their life directly and intentionally, is an expression of care for someone who is valuable.

Calvary has deep concerns with respect to the **lack of information** about the proposed clinical regimen for voluntary assisted dying in the model being used to draft the legislation; including the known complications, safety and effectiveness.[1]

The model developed by the Ministerial Advisory Panel addresses questions about safeguards related to accessing the scheme but it **does not specify the regimen or drugs that would be used.**

[1] The the Australian and New Zealand College of Anaesthetists made a similar point in their submission to the Ministerial Advisory Panel. On page 16 of the College's submission, they state:

> "There must be disclosure in the legislation of the type, dose and formulation of the lethal dose of medication to be administered and of the alternative methods that may be used if the patient is unable to self-administer or ingest or absorb the lethal dose of medication."

See http://www.anzca.edu.au/documents/anzca_voluntary-assisted-dying-submission-report_2.pdf accessed on 10 August 2017.

We have identified significant issues of implementation, unaddressed in the Ministerial Advisory Panel's *Final Report* and in *the Letter from Ministerial Advisory Panel on Voluntary Assisted Dying to Victorian Parliamentarians dated 7 August 2017* which should be discussed, clarified, debated and ultimately provided for in legislation. This factual information, if provided, would enable legislators better to access whether the clinical regimen is safe, respects human dignity and is consistent with the value of compassion. Both the rationale for and efficacy of the proposed legislation depend on the means, the mode and the manner by which a person obtains their own death. In the words of Dr Owler, "Providing a safe framework for Victorians has been our paramount consideration." **If the clinical regimen is unsafe, gives rise to complications or is ineffective, the legislation will fail to achieve its stated intention and will put Victorians at risk.**

These are threshold issues which cannot be left to be resolved in the eighteen months between the passing and promulgation of the legislation. These are issues to be resolved before the law has been introduced.

Threshold issues which need to be addressed before legislating

We accept that there are a plurality of views on the subject of voluntary assisted dying and that these have been well-represented in the work of the Parliamentary Committee and the Ministerial Advisory Panel that Dr Brian Owler chairs. Calvary will not, however, participate if the legislation is passed.

In addition to the ethical questions which have been ably raised with Members of Parliament and the Victorian community by our sister Catholic health and aged care services and religious leaders, Calvary has concerns about two (2) key or threshold questions.

1. What lethal substance will people use to end their own lives (bring about their own deaths)?

2. Who will assist them (to die)?

The answers to these questions are threshold concerns which we believe should be thoroughly explored and addressed before legislation is enacted and not left to be sorted out later.

1. What lethal substance will people use to end their own lives?

While the model developed by the Ministerial Advisory Panel addresses questions about safeguards related to *accessing* the scheme, it does not specify the regimen or drugs that would be used. Assisted suicide is not a simple procedure with 100% effectiveness. Accordingly, we raise the following issues:

- What drug is proposed for oral ingestion in Victoria?
- Is the drug pharmaceutically available? Who will dispense it?
- Will the Commonwealth Government (through the TGA) allow the drug to be imported and dispensed?
- Will the drug be on the PBS?
- If not on the PBS, what will be the fee to access it?
- Who will credential this scope of practice?

On page 133 of its *Final Report,* the Ministerial Advisory Panel acknowledges the need for an independent process for authorizing the lethal dose of medication and examines existing authorization processes on which the legislation can draw. For example, the report states:

> The *Drugs, Poisons and Controlled Substances Act 1981* requires medical practitioners who consider it necessary to prescribe a Schedule 8 medication to a drug dependent person to apply to the Secretary to the Department of Health and Human Services for a permit to do so. A similar process for voluntary assisted dying will ensure the coordinating medical practitioner had completed every step of the process before the medical practitioner can receive an authorisation to prescribe the lethal dose of medication.

It is important that the Community has information about the proposed lethal medication, how it will be sourced, its efficacy, the risks and benefits. In the words of Dr Owler (on page 1 of the *Final Report*),

> We seek to provide a compassionate outcome for those people who are at the end of their life, while also addressing the concerns of the community. Providing a safe framework for Victorians has been our paramount consideration.

International reports have identified that complications of medically assisted dying are under-reported, however in those countries where assisted dying or euthanasia have been legalised there are reports of patients vomiting under sedation, having seizures, of people who wake up having taken medications they expected would end their life and patients who take up to four days to die after the administration of lethal drugs.[2]

In some cases oral drugs fail to be effective and have to be followed by intravenous drugs directly administered by clinicians. Until the protocols that will be used to undertake medically assisted dying have been shown incontrovertibly to be safe the legislation is premature. Safeguards in the legislation are not the same as having safeguards in place to ensure the safe introduction of clinical practices in accordance with existing standards. The latter should be our first priority.

Whether the outcome of the legislation under consideration is compassionate and safe will depend heavily on a thorough analysis and understanding of the efficacy and risks of the proposed lethal medication(s). What are they?

In addition, people will need answers to other questions they have.

- Will the assisted dying procedure (pre and post care) have an item number? If not, who will then pay for the assessments required? The individual or the state? Who will pay for access to a psychiatrist if required?
- Who pays for the administering of medication when it is taken?
- How many assessments can you have? If you have one assessment, then the timeline expires and you haven't

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[2] See for example, Emanuel EJ, Onwuteaka-Philipsen BD, Urwin JW, Cohen J. Attitudes and Practices of Euthanasia and Physician-Assisted Suicide in the United States, Canada, and Europe. *JAMA.* 2016;316(1):79–90. doi:10.1001/jama.2016.8499; accessed at http://jamanetwork.com/journals/jama/article-abstract/2532018 on 10 August 2017. Problems and complications are discussed on page 86 as follows:

> There are no flawless medical procedures; all procedures and interventions can have complications. Determining the rate of problems and complications related to euthanasia and PAS has been challenging because of definitions and the lack of witnesses. For several years, Oregon reported no complications. Between 1998 and 2015 (average number of deaths per year, 55), Oregon reported absence of data on complications for 43.9% of cases, no complications for 53.4%of cases, and regurgitation of medication in 2.4%of cases as the sole complication. The state reported that between 2005 and 2012, 6 patients (0.7%) regained consciousness after ingesting the lethal medications but paradoxically does not classify this as a complication. The median time between ingestion of barbiturate and death was 25 minutes, but the range extends to 104 hours—more than 4 days. The number of prolonged deaths—those taking longer than a day—is not reported in Oregon. In Washington state, for 2014 and 2015 combined, the data are less complete. For the 292 reported cases, 1.4% of patients regurgitated the medications, and 1 patient experienced a seizure. It is unclear if any patients in Washington state regained consciousness. Only 66.8% of patients died in less than 90 minutes, while the range extends to 30 hours.
> A comprehensive 2000 study of problems and complications in 649 Dutch cases (prior to the actual legalization) revealed a higher frequency of problems with PAS than with euthanasia. Technical problems with PAS, such as difficulty swallowing, occurred in 9.6% of cases, and complications such as vomiting or seizures occurred in 8.8% of cases. In 1.8%of PAS cases, patients awoke from coma and in 12.3%of cases time to death was longer than anticipated or the patient never became comatose. For euthanasia, 4.5%of cases had technical problems, such as inability to find a vein for injection, and in 3.7% of cases patients had complications such as vomiting, or myoclonus. In 0.9% cases patients awoke from coma, and in 4.3% of cases time to death was longer than expected or the patient did not become comatose. These data are 16 years old, and 13 years of legalization may have reduced the complication rate. There are no data from other countries, including Belgium, on problems or complications with euthanasia or PAS.

acted, can you continue to do this? Or will it be capped?

2. Who will assist them (to die)?

The legislation will be structured on the basis that self-administration of the lethal dose will be the norm. The legislation will make provision, however, for medical practitioners administering the lethal dose of medication when people voluntarily request assistance because they are physically unable to self-administer. On page 141 of the *Final Report*, the Panel observes:

> In the majority of cases, a person who is eligible for voluntary assisted dying will self-administer the lethal dose of medication. The Panel notes the general view among stakeholders that self-administration of a lethal dose of medication is a powerful safeguard to ensure voluntary assisted dying is in fact voluntary. The Panel acknowledges that stakeholders generally supported medical practitioners administering the lethal dose of medication for people who voluntarily request assistance when they are physically unable to self-administer. Stakeholders were concerned that it would be unfair and discriminatory not to allow this.

The Report, on pages 140-144, proposes the regulatory framework which would govern "medically assisted" dying and Recommendations 36-40 capture the proposed safeguards the legislation will put in place.

Again, however, there is no discussion either of the regimen to be used nor the drugs required. A patient will likely be required to take a chain of increasingly strong medicines including: a drug to prevent vomiting; a drug to reduce anxiety; and then a lethal drug to stop their breathing. Evidence from overseas shows complications can include: seizures, failure to induce coma, and a longer than anticipated death, requiring a physician to euthanize the patient.

The Canadian regimen uses an intravenous system with five separate drugs administered. See Appendix.

a. Midazolam – for sedation (also used in colonoscopy, etc.)
b. Lidocaine – to anaesthetize the vein because the third injection can cause pain.
c. Propofol – an anesthetic agent to induce deep sedation (myocardial and respiratory depression)
d. Rocuronium – to paralyse muscles so breathing ceases
e. Bupivicaine – to stop the heart.[3]

This is a complex regimen. As noted above, many things can go wrong. It is essential to make clear who will do the administration and what training they will have.

If drugs are not administered appropriately, the person seeking VAD may end up being conscious, paralysed and unable to breathe; surely the opposite of a compassionate end.

Once doctors understand what is actually required of them to administer a lethal dose of medication, they may be less willing to participate.

Other concerns

[3] See University Health Network (UHN) *Medical Assistance in Dying Framework* accessed at http://www.psychiatry.utoronto.ca/wp-content/uploads/2016/06/MAID-Framework-Aug-6.pdf on 10 August 2017. The protocol is available at http://www.uhn.ca/healthcareprofessionals/MAID/Pages/MAID_intervention_process.aspx

The VAD legalisation involves a **social issue, not a health issue**. Its introduction will, however, have **significant impacts on our health system** which haven't been considered.

The premise behind the proposed legislation is that it is an individual's right, and is being proposed for a small minority of the population. It is expected that the majority of people who request VAD will do so in terms of concerns relating to independence, dignity, fear of being a burden rather than issues related to symptom management.

There has not been a *targeted* consultation with the health sector, who will be responsible for overseeing and administering this system change; nor the Commonwealth who have responsibilities for aged care services, primary care, policy leadership for palliative care and workforce training.

Calvary believes that the VAD legislation amounts to a sweeping societal reform that is being introduced without understanding all the consequences.

Some of the consequences which need further thought may be summarised as follows:

- Determining how long a person has to live is not an exact science and is a challenge even for the most qualified doctors. The Victorian model provides for a patient to request assisted suicide if they are expected to die within 12 months. At one year, the margin for error significantly increases and many clinicians would find it a difficult assessment to make. Patients are at risk of ending their life when they could potentially have several more years to live.
- There is very poor death literacy within the community. Most people don't know what palliative care is, even fewer people have completed advance care plans, yet with this legislation Victorians will be expected to make informed choices about accessing VAD.
- The proposed legislation is silent on families being involved in the decision making process. As a specialist palliative care provider, we deal with conflict within families and the decision making process at the end of life on a frequent basis.
- As a society we are making every effort to counteract suicide, yet we are now proposing legislation that would recognise that some suicides are acceptable and that health professionals will assist in that process. We already know the impact that suicides have on families and those close to the individual.
- More care needs to be taken in determining how the vulnerable will be protected, which takes **into account signs of risk factors for the coercion or abuse of persons who are dependent on the care of others** – such as family violence, substance abuse, gambling addiction and mental health issues.
- It needs to be made clear who will be responsible for providing family support, counselling and conflict mediation, bereavement counselling for people choosing VAD.

Doctor-Patient and Patient-Hospital and Clinician-Clinician Relationships

- The VAD legislation potentially changes the role of the doctor in our society. By asking our doctors to participate in this process we are potentially **undermining the patient/family trust**; **not just in doctors but our health care system**.
- **What is the potential impact on the access of vulnerable populations to health services**? Will they be further marginalised through fear of a system that is perceived to support gravely ill people to end their lives?
- Nearly 50% of deaths occur in a hospital. Will patients be able to access assisted dying in a hospital setting? What are the implications for both public and private hospitals? How will health services deal with other patients who object? What safeguards are needed for staff? Similar concerns will arise in aged care settings.
- How will health workers work side by side with each other if there is difference in opinion? One colleague is willing to participate in assisted dying work, the other is not. How does this affect the team? Will this be detrimental to patients? What skills will be needed to manage this?

Issues related to good end of life care

Access to palliative care is not universal nor equitable across the state. Under the proposed legislation patients are to be made aware of what palliative care is available to them. What happens if someone lives where palliative

care is not available? What is the approach that will be taken? How will people meaningfully engage with any palliative care options?

Concluding remarks

As a significant provider of health care in Victoria, we raise these concerns with you because of the ramifications of proceeding with legislation before all the major questions have been answered. In particular, it is important to know and to have evaluated the efficacy and risks of the lethal medication which will be used. It is important to know exactly what will be involved if a doctor is to assist another person to end their own life.

Calvary submits that it is not in the public interest to proceed with the legislation. On page 200 of its Final Report, the Ministerial Advisory Panel recommends an 18-month period between the passage and commencement of the voluntary assisted dying legislation. This is to allow time to prepare for implementation. Given the social significance of the proposed law, good public policy development suggests that all the major questions are addressed before enacting legislation.

The Hon. John Watkins, AM
Board Chair

15 August 2017

Appendix

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab

Information for intravenous medications for Medical Assistance In Dying

This document is to provide background information. It is recognized that care may be modified to meet the best interests of the individual patient. The following medications are to be administered by the physician on the Intervention Team.

It is recommended that a "Do Not Disturb" sign be placed on the door to the patient's room and that all cell phones and pagers of staff participating in the procedure are either turned to silent mode or left with a colleague to decrease the potential for interruptions during the procedure.

1. **Intravenous access**
   The importance of reliable intravenous access is emphasized to ensure successful uninterrupted administration of all the medication.

   For central lines or peripherally-inserted central catheters (PICC):
   - Site is secured
   - Blood can be withdrawn
   - Saline 10cc flush is given with little or no resistance
   - Gravity set flows freely

   For peripheral lines:
   - Size 20G or larger (18G, 16G)
   - Site is secured
   - Saline 10cc flush is given with little or no resistance. There is no evidence of interstitial flow, swelling around the site, or pain throughout the duration of the flush
   - Gravity set flows freely
   - Consider a second peripheral intravenous line if there is a history of difficult access, "blown" IVs, intravenous chemotherapy, or if the primary IV is 20G or smaller

2. **Intravenous setup**
   Intravenous setup includes a 1L bag of Ringers Lactate or Normal Saline connected to a free-flowing gravity set connected directly to the IV catheter.

   Because of noisy alarms, temperamental tubing sets and a machine-dictated delay in diagnosing compromised or interstitial venous access, electronic pumps and electronic pump sets are not recommended.

All other intravenous infusions should be discontinued to avoid backflow of medications.

Run IV at 50-100mL/hr until time of injection, and then run "wide-open."

3. **Medications**
   - The pharmacy department will prepare two complete kits including all pre-filled syringes labeled as described below. The kits will be dispensed from the pharmacy department by a pharmacist to a member of the MAID team on a patient-specific basis pursuant to a prescription from the intervention physician that has been verified by a pharmacist.
   - Physician to administer all medications completely , sequentially and rapidly as detailed below with minimal or no delay between syringes .
   - If a gravity set is not used consider flushing with 10mL of saline after every syringe.
   - Midazolam 10mg (1mg/mL = 10mL). Use 10mL syringe. Label as
     Syringe A: midazolam
     For deep sedation/coma
     Consider Aadvising those who are present that the patient may gasp following administration of this medication.
     Inject over 10 seconds
   - Lidocaine 2% 100mg (20mg/mL = 5 mL). Use 5mL syringe. Label as
     Syringe B: lidocaine
     Necessary for peripheral venous access only
     For reduction of discomfort on injection of propofol
     Inject over 5 seconds
   - Propofol 1000mg (10mg/mL = 100mL). Use two 50mL syringes. Label as
     Syringe C: propofol and **Syringe D: propofol**
     For induction of coma, myocardial depression, respiratory depression, and vasoplegia
     Warn the patient that there may be some discomfort on injection, and that the goal of lidocaine is to relieve this but some patients may still experience pain.
     Consider advising those who are present that after the injection is completed an assessment of awareness will be completed.
     Inject each syringe continuously and promptly over 30 seconds
     After completing the injectios, check eyelash reflex and whether there is any response to verbal stimulus. If there is no response to stimuli then proceed to injection of rocuronium.
   - Rocuronium 200mg (10mg/mL = 20mL). Use 20mL syringe. Label as
     Syringe E: rocuronium
     For muscle paralysis

Consider advising those who are present that cardiac arrest can occur up to 20 minutes after respiratory arrest has occurred. In other words, the patient's heart may continue to beat for some time after the procedure is complete.
Inject promptly over 5 seconds

Rocuronium should always be administered after propofol, even if respiratory and/or cardiac arrest has already occurred with propofol alone.

A minimum of time should elapse between the administration of midazolam, lidocaine and propofol, i.e. these should be administered in a short sequence.

Painful stimuli (e.g. sternal rub, trapezius squeeze, pressure on orbital bone or nailbed) should be avoided as these may cause distress to those who are present, and are likely unnecessary.

Should there be a response to stimuli, do not administer rocuronium. Instead, administer a further:

- Midazolam 10mg (Syringe 1)
- Propofol 1000mg (Syringes 3 and 4)

Then check for response to stimuli. If there is none, then administer rocuronium 200mg (Syringe 5)

- Bupivicaine 0.5% plain (5mg/mL = 80 mL). Use 2x 50mL syringes. Label as **Syringe F and G: bupivicaine**
  For inducing asystole
  Inject continuously and promptly over30 seconds per syringe

It is anticipated that all of the prefilled syringes will be used for each patient . For whatever reason should this not be the case (e.g. patient changed their mind to proceed) ensure all unused pre-filled syringes are returned to the pharmacy department for proper tracking and disposal.

Step	Syringe Label	Drug	Rate of administration
1	Syringe A	Midazolam	Over 10 seconds
2	Syringe B	Lidocaine	Over 5 seconds
3	Syringe C	Propofol (1 of 2)	Over 30 seconds
4	Syringe D	Propofol (2 of 2)	Over 30 seconds
5	*confirm coma achieved*		
5b	If still responding to stimuli, administer second set of midazolam and propofol from second kit		
6	Syringe E	*Rocuronium	Over 5 seconds
7	Syringe F	Bupivicaine (1 of 2)	Over 30seconds
8	Syringe G	Bupivicaine (2 of 2)	Over 30 seconds

* Rocuronium should only be administered once coma is ascertained