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Follow up questions / clarification from the End Of Life Choices Joint Committee

Palliative Care

4- ***In 2015, a report of a survey of 1800 patients of specialist palliative care services in Australia[2] found that people receiving care from palliative care services frequently experience high levels of pain, other symptoms and psychosocial concerns. Given your experience and the findings of the survey above, in your view is it likely that only 1-2% of patients have refractory symptoms around the end of life?***

More than 2% of patients have refractory symptoms around the end of life in my opinion. On the day I gave evidence to the committee I estimated it to be closer to ten-fold that. The reasons I gave for my opinion are: the patient's pathology may unfortunately result in unremitting symptoms that are unremediable to systemic analgesics. For example, the maximum analgesic efficacy of opioids is less than 40% for severe pain. The synergy of concomitantly administered analgesics may improve that efficacy to 60%. What that means is that in the circumstance of a particularly painful pathology, 40% of the intensity of the base pain will remain despite expert analgesic management. If that 40% remains from what was a mild or moderately painful starting point, then it may be quite acceptable and tolerable to the patient. However, if the starting pain was severe and unrelenting prior to the provision of any analgesia, the remaining 40% may remain intolerable and unacceptable to the patient. Additionally, many analgesics are poorly anxiolytic and not moderate the patient's psychological suffering.

The big picture here is that pain and suffering remains a significant issue in a significant proportion of people despite expert care. This is not a failure of resourcing or provision of services (which remains the biggest problem) but rather a lack of pharmacological and psychological efficacy to manage overwhelming nociception and psychological suffering.

The Doctrine of Double-effect

5. ***The Committee has received evidence that doctors rely on the Doctrine of double- effect:[3]***
    1. ***Do anaesthetists rely on the Doctrine of double-effect when administering pain relieving or sedating medications to patients at the end of life?***

    I don't think that this question really pertains to anaesthesia. Anaesthetists administer anaesthesia and analgesia to patients in a peri-operative setting. The intention is to provide anaesthesia so that surgery can be conducted, and analgesia to potentiate post-operative recovery from that surgery. In the cohort of sick and elderly patients we are managing, the patient is usually dying from their pathology rather than as a concomitant effect of the analgesic plan.

To give my opinion on whether doctors with expertise practising competently in end-of-life symptom control rely on the doctrine of double effect: they probably do. I believe that the doctrine of double effect has at its core that the doctor's primary intent is for pain and symptom relief in a consenting patient, and not to specifically shorten a paerson's life.

2. ***In cases where the Doctrine of double of effect is relied upon:***
    i. ***is any reference to the medication recorded as a cause of, or contributing to, the death on the death certificate and if not why not?***

    Firstly, as this question seems to be related to terminal sedation, it does not pertain to the role of anaesthesia. I can't claim any real expertise to answer it. However, given that patients undergoing terminal sedation are dying from a documented certain pathology it would seem incongruent to record the uncertain contribution of the drugs administered for pain and symptom control.

    ii. ***if a doctor does not know whether the pain relief medication contributed to the death or not, is a death certificate completed? If so, how would a doctor be able to state the cause of death?***

    Again this question does not pertain to the role of anaesthesia. However, the doctor should record what they know to be true on the death certificate. The doctor can be sure of the patient's pathology given the diagnostic and staging investigation. The available data on median survival with that particular pathology in a patient with a particular functional status gives a reasonable indication on when death can be expected. The contribution from analgesics is far less certain and has far less metrics supporting its premise. The doctor is unlikely to record what they don't feel is certain on the death certificate.

6. ***Do you consider the current law in Western Australia adequately protects doctors who rely on this Doctrine when administering sedating or pain relieving medication that may hasten death?***
   If not, what should be changed?

    This question does not pertain to the role of anaesthesia. However, the very presence of the question indicates that the practitioners in this field, the legislators and police are not clear on the details of how to apply the existing laws. This is an important role of this joint committee: to provide clarity of what is acceptable to our society, and recommend changes to existing legislation to provide that clarity.

9- ***In your view is under-dosing likely to be a reflection of medical professionals exercising caution due to uncertainty regarding the lawfulness of the doctrine of double-effect?***

In my view, under-dosing is not a qualified fact. If the effect expected is unconsciousness, then a conscious patient has been "underdosed". If the effect expected is analgesia, then this can be a more difficult metric to judge when titrating analgesics. There is an eight-fold inter-individual variability in response to a dose of opioid analgesics. There is only a two-fold range of opioid blood concentration that will change the effect of that drug from its peak analgesic effect to a significant side-effect such as a reduction in consciousness or respiratory depression. Because of these two variations, there must statistically be both over and under-dosing of patients particularly when titrating to an effect other than unconsciousness. When I am titrating opioids to the peak analgesic effect whilst minimising side effects in sick and dying patients, the lawfulness of the doctrine of double effect is definitely not "front of mind" as my intent is definitely not to harm or shorten the lifespan of that patient. My intent is to provide the best relief I can with the least unwanted side-effects.

10- ***If so, given your view that no period of intolerable suffering is 'acceptably short', does this result in an unacceptable prolonging of the period of suffering for a patient at end of life?***

Having witnessed a lot of death, I believe that it is unrealistic to expect no period of suffering at the end of life when severe pathology exists. Tolerability of that suffering is a very individual experience and is highly variable. Some people can be quite tormented by the hand they have been dealt, whilst others are not. I don't currently see patients left suffering as a result of their doctor being too frightened to administer analgesics because the police may arrest them for doing so. I see people suffering due to the fact that not all pain is 100% treatable and because there are inadequate resources dedicated to palliative care.

As legislators in this arena, please clarify what is acceptable practice and what is not acceptable practice for those clinicians involved in palliative care. I understand that this is very difficult given the breadth of both community and health practitioner views on this mileau. Consensus is unlikely to be reached but clear boundaries are required nonetheless.

15. ***The Committee has heard evidence that apart from the requisite recording of medications administered, instances of terminal sedation are not specifically recorded in the medical record.***
In your view should an instance of terminal sedation be formally noted in a patient's medical record*?*

As previously stated, anaesthetists are not expert in terminal sedation. What is being asked here is regarding the documentation of the intent of the drugs prescribed?

This question is really asking if *terminal sedation commenced* should be documented in the patient notes?

The very fact that this question has been asked is evidence that clinicans who are involved in the provision of terminal sedation may not feel that they have legislative protection for the practice because it may incriminate them as to the intent of the prescription. If they document their intent as "terminal sedation" would that then unprotect them from the doctrine of double effect? Perhaps. It is up to this committee to decide whether this sits within our society's values and if it does- provide the necessary protections to practitioners to competently perform the role.

16- ***The WA Cancer and Palliative Care Network (a unit in the WA Health Department) publishes an information guide titled "Evidence based Clinical Guidelines for Adults in the Terminal Phase."[7]***

1. ***Would you have any concerns about the administration of these treatments in a community (not in-patient) setting?***
   Some concerns, but none insurmountable. In my opinion the care needs to be patient centric. Patients final wishes need to be accommodated: who can be present, what therapies can be administered and what support can be offered.
   However, there needs to be some governance-oversight of medication storage and administration. Who is the person authorised to handle the medications? What happens to the unused medications? Many of these unused medications are disposed of down the sink or sewer without proper tracking of the S8 disposal.
   When the patient dies at home, all of the medical palaver is so suddenly silenced and rendered moot. Those who were attending the patient commence grieving and organising confirmation of death, washing the body and calling the undertakers. Everything that seemed so important an hour before becomes irrelevant.
   Dying in the community will be the preference for many patients and their families and so regulatory hurdles around complying with the poisons act need to be overcome in a practical way recognising that these circumstances are different to those for which the act was conceived and contrived.

2. ***Would a patient be deeply sedated by the following medications:***
   i. ***Haloperidol 2.5mg/24 hrs by subcutaneous infusion + 1 mg hourly prn; and***
   ii. ***Either clonazepam 0.5mg bd + hourly prn; or lorazepam 0.5mg + hourly prn; OR midazolam 5 mg/24 hrs by subcutaneous infusion + 1-2 mg hourly prn.***
   Probably- but it is not a certainty due to the large dose variation built in by the PRN order. The patient may receive either 2.5mg Haloperidol / 5mg Midazolam or up to 26.5 mg Haloperidol / 53 mg Midazolam: a ten-fold dose variation. Coupled with the patient's variable renal function (midazolam has a renally excreted active metabolite), variable GABA down-regulation by previous exposure to other

benzodiazepines or synergy with other co-administered sedatives such as alcohol, opioids, gabanoids, antipsychotics or melatonin. Once again, patient variability in response to doses titrated to the target effect makes this question impossible to give a certain answer.
If the target effect is “deep sedation” then the above regime could probably get that effect with enough doses of those drugs over that time frame of 24 hours.

What is a reversible Drug?
A reversible drug is one whereby the effect of that drug can be un-done by the administration of an antagonist drug: a type of antidote.
For example- most opioid drugs have analgesic and sedative effects by their stimulation of the mu opioid receptors in the central nervous system. If unwanted sedative effects occur (such as may occur following a heroin overdose) then Naloxone can be administered to reverse the sedative effect. The Naloxone also binds to the same mu opioid receptor but with a higher affinity (capacity to bind and stay bound) than the first opioid but it does not stimulate the receptor. The sedative effect is reversed because the inactive Naloxone displaced the active opioid drug. This reversal can occur over a short time period of minutes.
Reversal with an antagonist described above is different to the effect of the active drug “wearing off”. In the absence of an antagonist drug the patient’s normal organ metabolism and excretion of the opioid occurs which reduces the blood concentration of that active drug. When the blood concentration becomes lower than that in the central nervous system, the opioid unbinds from the mu opioid receptors and diffuses back into the blood stream that carries it to the metabolic organs such as the liver and is ultimately excreted from the body. When the concentration of the opioid in the central nervous system reduces, its effects on the brain and spinal cord “wear off”. For the drug effects to “wear off”, the person needs to have a normal blood circulation and metabolic – excretory functions. These physiological process can become deranged in a dying person such that the effects of the drugs don’t wear off as they normally would. In general, this usual process of wearing off occurs over hours rather than minutes (as occurs with reversal as described above).

List of reversible drugs
Most drugs do not have antagonists and therefore rely on normal physiological metabolism – excretion to enable their effects to “wear off”.

Opioids such as morphine, hydromorphone, oxycodone, codeine, methadone, fentanyl, heroin can be reversed with the antagonist Naloxone.

Benzodiazepines such as clonazepan, diazepam, lorazepam, tempazepam, oxazepam, nitrazepam, alprazolam and midazolam can be reversed with the antagonist Flumazenil.

Other analgesic and sedative drugs do not have antagonists and include-
Propofol, Thiopentone, Pentobarbitone, Methohexitone, Ketamine, Alcohol, Haloperidol, Droperidol, Amitriptyline, Nortriptyline, Gabapentin, Pregabalin, Dantrolene, Clonidine, Dexmedetomidine, Melatonin, Tapentadol, Mirtazipine, Duloxitine, Escitalopram and Olanzipine.