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The Principle of Double Effect in Palliative Sedation

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Dissertation Submitted in Partial Fulfillment of the Requirements
for the Degree of Masters of Arts in Bioethics

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July 2020

Abstract

Clinical advancements in the use of opioid analgesia regimens have proven to be successful for the management of pain in most terminally ill patients. Clinicians however claim that there is still a small percentage of palliative patients who suffer intractable pain at the end stages of life. It is believed that these exceptional cases of pain would benefit from palliative sedation. While palliative sedation is indeed effective to manage intractable pain, bioethicists have pointed out that sedation poses a threat to the patient with qualities akin to 'slow euthanasia' and 'physician assisted death'. Furthermore, the Principle of Double Effect has been the primary lens through which the practice of terminal sedation has been evaluated, and whilst some believe that the practice can be justified by this Principle, many bioethicists believe that this is not possible. Using a deductive and critical approach, literature on the application of the principle of double effect in palliative sedation has been appraised. From this appraisal, two fundamental problems have been unearthed. First there is the difficulty of determining clinician's intention in the 'foreseen but not intended' quality of the Double Effect. This is a problem in the application of the principle even beyond its application to palliative sedation. Secondly, there is a problem in the sequencing of cause and effect, as several invasive clinical actions in palliative sedation can be construed as 'causing harm' a priori the positive effect of pain relief and the foreseen but not intended possibility of death. This sequencing of evil actions preceding any good and bad effects is not ethically justified by the Doctrine. Nevertheless, ethicists do not preclude the use of palliative sedation for rare and extreme cases of intractable pain. Alternative moral principles have been explored in support of palliative sedation for when there are no alternatives, and a proportionally grave need for this resolve.

Keywords: Palliative Sedation, Slow Euthanasia, Intention and Foreseen Effect, Principle of Double Effect and Physician Assisted Death.

Dedication

This dissertation is dedicated to all health care professionals working in hospice.

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Acknowledgements

I would like to thank my supervisor, Rev. Prof. George Grima for his guidance and patience, my parents for their support and my better half, Michael Buttigieg for his advice and support.

Abbreviations

ANH – Artificial Nutrition and Hydration

PAD – Physician Assisted Death

PoDE – Principle of Double Effect

RRDE – Re-invented Rule of Double Effect

TFT – Triple Font Theory

Introduction

At the end stages of life, palliative patients can experience refractory pain that cannot be controlled with conventional treatment. Since physicians have an obligation to relieve patients' suffering even from the most intractable of pains, palliative sedation may be inevitable. This is the only option available in current medicine, but it is also an intervention fraught with ethical dilemmas. As side-effects, palliative sedation can cause hastened death, and it can suppress the persons' consciousness, and these are the main reasons why some have questioned the acceptability of this practice. Furthermore, adjunct practices that commonly occur following palliative sedation, such as withholding artificial nutrition and hydration, can also contribute to hastened death. These precipitating factors can be viewed as akin to physician assisted death.

In view of these risks, efforts have been made to find an ethical rationale to justify such treatment, ensuring that moral integrity is maintained in the clinical setting by differentiating palliative sedation practices from euthanasia. The most popular ethical guide for the tentative justification of palliative sedation is the Principle of Double Effect (PoDE). The PoDE is an ethical framework that originated from Thomas Aquinas in *Summa Theologie*. It involves four criteria; the act has to be good or morally indifferent, only the good effect has to be intended however, the bad effect can be foreseen, the desired good outcome cannot be resulted from the bad effect and the need for a proportionate grave reason that permits the evil side-effect.[1] The good effect of alleviating pain meets all the four criteria of the Doctrine hence, even though it carries such a foreseen, bad side-effect, palliative sedation is acceptable. The problem, and hence the reason for this literature review, is to discern whether this doctrine is still suitable enough to pursue as an effective guide for such ethical predicaments. The PoDE was created prior to the invention of the complex medicalization of end of life care. There is a possibility that the ethical ambiguity that emerge from current clinical practices may not be easily resolved with the rigid moral epistemologies stemming from medieval times. Furthermore, 'intentions' are complex and can be deceiving. This literature review will seek to determine whether such a

[1] J. Andrew Billings and Larry R. Churchill, "Monolithic Moral Frameworks: How Are the Ethics of Palliative Sedation Discussed in the Clinical Literature?," *Journal of Palliative Medicine* 15, no.6 (2012): 710.

doctrine is still suitable to address this moral dilemma today – the acceptability of sedation to unconsciousness for the treatment of intractable pain.

The first chapter of this dissertation will be describing the medical problem of palliative sedation in the clinical setting, and articulating the common practices associated with palliative sedation in modern medicine along with their definitional and pragmatic ambiguities. Euthanasia, physician-assisted death (PAD) and palliative sedation will be conceptually distinguished from each other. The problematization of palliative sedation construed as 'slow euthanasia', and therefore whereby the definition seems to encroach the common understanding of PAD is explored in some depth. Issues of retention of personhood in sedation are also discussed. Also, the disambiguation between physician's 'intention' and 'foresight' behind the outcomes of pain relief in relation to hastened death will be introduced first in this chapter. Another clinical ambiguity that will be addressed is issue of guidelines claiming that withholding artificial nutrition and hydration (ANH) is acceptable even up to two weeks before the estimated time of death, causing confusion as to whether it is starvation or indeed sedation that is expediting the patient's dying process. Finally, contextual factors that contribute to the diversity of socio-cultural interpretations of sedation will be discussed. It is understood that religious, culture, and familial perspectives together with country specific legislations and professional codes of conduct and healthcare worker experiences all contribute to a multiplicity of understandings of terminology and application of ethico-clinical concepts in practice.

The second chapter will address in detail two main themes that emerge from the dilemmas of the Principle of Double Effect. The first argument addresses the ambiguity of intentions. It is difficult to discern clinical intentions hence, one cannot be entirely sure that the administration of palliative sedation is truly for the palliation of intractable pain or for its side-effects, a hastened death as an act of mercy. The second argument that emerges from the dilemma of the Doctrine is sequencing. This refers to the sequences of actions that lead to palliative sedation as well as actions after the induction of sedation to unconsciousness. The problem is that certain actions can cause indisputable suffering, questioning whether the Doctrine caters for such actions. Some of these actions include suffering due to delirium experienced with inadequate pain relief prior to the increase of doses to establish therapeutic levels, removing the ability to be autonomous, withdrawing artificial nutrition and hydration

as well as withholding extraordinary life support. Such actions and outcomes question whether they can be considered proportional to permit the use of palliative sedation. Misconceptions and misuses of the Doctrine will be unearthed from the literature. And more than the improper application of the principle, this chapter will present a recurring understanding that in rare and exceptional cases palliative sedation may breach the ethics of Principle of Double Effect but may be perfectly justified by other notions that serve purpose to such exceptional cases.

Then the third chapter will specifically delve into alternative ethical epistemologies that can be used as moral substitutes or moral adjuncts to the Principle of Double Effect. This will be done in an attempt to find a framework that can holistically justify the moral dilemma of unintentional harm to do good when it concerns continuous deep palliative sedation. These frameworks will be divided into two categories: moral theories and, legal and behavioural frameworks. Each theory will be explained and applied for the case of palliative sedation to unconsciousness for the management of refractory pain. Furthermore, these theories will be scrutinized, compared with each other as well as with the Principle of Double Effect in order to determine which ethical framework can provide the most adequate answer to the dilemma. The concluding part of this third chapter will seek to establish where the Doctrine stands in attempting to answer the issue of inevitable harm in order to do good. An informed conclusion will ensue.

Chapter One:

Moral Dilemmas Associated with Palliative Sedation

The literature and ethical arguments presented in this dissertation grow out of an ongoing concern over the possible abuse of palliative sedation in clinical practice. The professionals who deal with pain and sedation issues in the clinical setting stress on the pragmatic ambiguity where palliative sedation seemingly encroaches over the qualities of 'slow euthanasia'. The fear of deep sedation becoming a normative procedure for the concealment of euthanasia, is palpable from the literature on the subject.[2] And at least in the outset of the general debate within this ethical paradigm, the ethical principle of double effect is called upon to address the double edged nature of palliative sedation. Therefore after explaining what constitutes palliative sedation in the more distinguishable aspects from euthanasia (chapter 1), the subsequent chapters will discuss the application of the principle of double effect (chapter 2) and alternative ethical theories (chapter 3).

In this first chapter, the history of pain management and its technical development into current palliative sedation practices is explained (section 1.1). After explaining the science, a bio-ethical disambiguation of palliative sedation from euthanasia becomes pertinent (section 1.2). The final part of this chapter (section 1.3) outlines the ambiguities (the research gaps and questions) related to the ethical administration (and effectiveness) of palliative sedation for pain relief in the clinical practice.

1.1 Background - The Evolution of Palliative Sedation

1.1.1 Understanding Suffering and the Development of Sedation

Cicely Saunders, a nurse and eventually a physician, was the first to introduce palliative sedation in clinical practice. Saunders founded St Christopher's Hospice, the first hospital established with the aim of teaching and researching pain management and holistic care for patients and their families. Her seminal work in palliative sedation paved the way for subsequent elaborations in the management of sedation and pain relief. Prior to this hospital, pain management was regarded rather

[2] R. Polaks, "The Risks of Using Continuous Deep Palliative Sedation Within the Context of Euthanasia," *International Conference, Society. Health. Welfare* 30, (2014): 2.

conservatively and administered sparingly, with some exceptions such as the use of the 'Brompton Cocktail' for Tuberculosis patients circa 1935. This concoction contained morphine (or diamorphine), cocaine, gin, and honey. With the introduction of oral morphine four hourly in 1948, the 'Brompton Coctail' was phased out.[3] With time, non-evidence based beliefs among health professionals about narcotics where successfully challenged. The ideas that narcotics can cause drug yearning and dependency, and that increasing dosages may lead to drug tolerance and ineffectiveness where debunked.

In a double blind, patient cross-over study conducted by Twycross in Saunders' hospital, it was established that diamorphine (heroine) and morphine are clinically the same in terms of tolerance, and dependency was never confirmed.[4] Although at present, more recent literature suggests that long-term use of morphine can indeed cause addiction, palliative sedation is given in the last hours or days leading to death, and therefore the argument of addiction is often considered superfluous.

According to Hippocrates, it is the duty of the physician "to do away with the suffering of the sick, to lessen the violence of their disease".[5] Under-treating pain actually violates the Hippocratic Oath, the principle of non-maleficence, it diminishes autonomy and self-determination, and is unjust towards the individual when pain is allowed to hinder the function of the person in society.[6] For Saunders, the aim of palliative sedation is to alleviate symptoms of "total pain", and therefore not only to alleviate physical pain, but also to help with emotional, social and spiritual pain. She also meant to help patients find meaning in life and their sense of self-worth. From a clinical point of view this was achieved by tailoring opioids specifically to the patient's sedation tolerance. Just enough sedation for the patient to be in control of the continuous pain.[7] Therefore palliative sedation can be operationally defined as "pain relief by inducing a decreased level of consciousness or eliminating it completely". It can be divided into four categories. "Mild sedation": where the patient is still able to

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[3] Cicely Saunders, "The Evolution of Palliative Care," *Patient Education and Counseling* 41, (2000): 8.

[4] Ibid., 9.

[5] John F. Peppin, "Intractable Symptoms and Palliative Sedation at the End of Life," *Christian Bioethics* 9, no. 2-3 (2003): 343.

[6] Danielle N. Ko, Pedro Perez- Cruz and Craig D. Blinderman, "Ethical Issues in Palliative Care," *Primary Care: Clinics in Office Practice* 38, (2011): 187.

[7] Saunders, "The Evolution of Palliative Care", 9.

communicate. “Intermittent Sedation”: allowing periods of alternating consciousness and unconsciousness. Then there is “Deep Sedation”, that brings the patient to a near or complete unconsciousness. And lastly, there is “Continuous Sedation”, that is the complete induction to unconsciousness until death.[8]

This dissertation will focus on ‘deep’ and ‘continuous’ sedation categories. The current scientific mechanism will be explored in this chapter. In ‘mild’ and ‘intermittent’ sedation types, autonomy and self-determination are significantly preserved throughout the process of sedation, but with the more invasive forms of sedation the patients are relinquishing a significant degree (and up to a complete surrender) of self-determination to third-parties. It is at this stage, where the burden of ethical responsibility to act on behalf of the patient shifts heavily upon healthcare professionals and care givers. This is where the ethical debates on sedation start off - At the nexus where the management of life is spun in with the management of suffering.

Suffering is defined by Cassell as a state where the disease “threatening the intactness of the person”. Suffering is a personal experience, very much subjective to the individual, but not limited to physical pain only. It is said that suffering requires consciousness, as those under continuous sedation may not experience pain and suffering, because consciousness has been suppressed. The evidence for this reasoning relies on neurological and haemodynamic parameters.[9] A person experiencing pain would have a high respiratory rate and an elevated pulse and blood pressure. In contrast, the parameters of a well sedated patient are kept within normal limits.

Yet the capacity to suffer is tied to the profundity of human life, beyond the biological. Suffering can be greater than the sum of “neuro-cognitive sources of suffering” - the symptoms of disease. Suffering is directly linked to the values of dignity, freedom, love and morality. Humans have the capacity for abstraction, to be imaginative, to reason, to be social, and affective, as well as being able to treasure familial and cultural values. Because humans are more than just neuro-cognitive beings. A human life that is deprived of these, albeit being abstract notions, are still

[8] Samuel H. Lipuma, “Continuous Sedation Until Death as Physician- Assisted Suicide/Euthanasia: A Conceptual Analysis,” *Journal of Medicine and Philosophy* 38, (2013): 191.

[9] Peppin, “Intractable Symptoms and Palliative Sedation”, 345.

said to suffer from such "agent-narrative occasions of suffering". According to Sulmasy, individuals deprived of this livelihood suffer from a loss in "human dignity". And when the existential tension between how valuable and how finite life is, becomes vividly real to the individual, the experience of suffering is complete.[10] For Sulmasy this is the crux of the practice. To understand the ethics of sedation and to respond adequately to another's pain, a health care professional requires a thorough understanding of suffering, especially in the care for the dying patient.

According to Judge Devlin, when the preservation of life is no longer possible, then the duty of the health care practitioner is to alleviate pain, even if it can unintentionally shorten one's life. This is one of the major arguments in favour of palliative sedation. Palliative sedation can cause death but in palliative patients with a short life expectancy (hours/days), who are in refractory pain that otherwise cannot be controlled, this action is 'justified'. Although the (cautious) administration of sedation may cause an earlier death of the patient, the disease is the agent of death, not palliative sedation.[11] Palliative sedation is a key intervention in contemporary end of life care. With this, psycho-social care is equally important in order to establish holistic palliative care. The World Health Organisation (WHO) amalgamates all these factors and defines palliative care as:

> *The active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social and spiritual problems is paramount. The goal of palliative care is achievement of the best possible quality of life for patients and their families.*[12]

Nevertheless, with on going scientific advancements, bio-ethicists and medical professionals' concerns about the ethics of new mechanisms and treatment protocols is pertinent. The following section first explores current palliatives sedation procedures.

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[10] Daniel P. Sulmasy, "The Last Low Whispers of our Dead: When is it Ethically Justifiable to Render a Patient Unconscious Until Death?," *Theoretical Medicine and Bioethics* 39, (2018): 235-237.

[11] P. Devlin, *Easing the Passing. The Trial of Dr. John Bodkin Adams,* (London: The Bodley Head, 1985), 171, quoted in Saunders, "The Evolution of Palliative Care", 11- 12.

[12] World Health Organisation, *Cancer Pain Relief and Palliative Care*, accessed November 21, 2019, https://apps.who.int/iris/bitstream/handle/10665/39524/WHO_TRS_804.pdf?sequence=1&isAllowed=y, 11.

1.1.2 Current Palliative Sedation and Its Mechanism.

Palliative sedation can be given intermittent (frequent doses every few hours), or as continuous through either parental (intravenous) or subcutaneous routes. It is commonly tailored according to the specific individual and monitored frequently in order to ensure that the aim of sedation (pain relief) is actually being reached. This pharmacological intervention involves the use of one or more classes of drugs, namely benzodiazepines such as midozalam, in conjunction with opioids such as morphine, diamorphine or fentanyl, and non-barbiturates anaesthetics such as propofol or ketamine.[13]

Barbiturates can also decrease levels of consciousness but their use has been replaced by benzodiazepines, which are much safer. The best way to achieve palliative sedation according to Peppin is by the joint use of opioids and benzodiazepines as it can eliminate pain completely since benzodiazepines can increase pain thresholds and opioids decrease pain transmissions to the brain.[14] Some benzodiazepines also have amnesiac properties, which can be beneficial in helping the patient to forget the painful dying process. Sometimes, adjuvant drugs such as non-opioids (e.g. paracetamol), NSAIDS, antidepressants, antiepileptic, phenothiazine and butyrophenone drugs such as haloperidol can also be used in palliative sedation together with other drugs such as opioids, in order to maximize palliative sedation according to the patient.[15]

When palliative sedation is aimed for deep sedation, certain vital functions such as respiration, heart rate and blood pressure are depressed. There is also an increased risk of being unable to maintain a patent airway, causing asphyxiation and the inability to cough or swallow that can lead to aspiration and further pulmonary complications. Another side effect of sedation, especially when there are other complications such as rapid dehydration in terminally ill patients can also lead to restlessness, delirium and agitation, which would lead to further escalation of sedatives. When there is a rapid increase of sedation it can become fatal due to the rapid suppression of vital signs. Furthermore, a person who is not mechanically ventilated can easily loose the airway

[13] Joint Formulary Committee, *British National Formulary*, (London: Pharmaceutical Press, 2018), 20- 23.

[14] Peppin, ”Intractable Symptoms and Palliative Sedation”, 347-348.

[15] Joint Formulary Committee, *British National Formulary*, 20- 23.

when consciousness is suppressed. Therefore Rady and Verheijde explain that all of these sedation side effects to achieve deep sedation are directly linked to shortening life. However, medications given in sufficient doses without the need to induce deep sedation are not life threatening as the brainstem is not depressed.[16]

There is literature claiming that opioids and sedatives are not linked with an increase in death rates when given as palliative sedation. In a study conducted by Sykes and Thorns, evidence suggests that sedation given for over a week before death actually improved survival compared to those given within 48 hours or no sedation at all.[17] It is important to note that in this study the target was the relief of symptoms and not unconsciousness. The authors also noted that a reason for this paradoxical result could be due to delirium, a symptom that would require hospitalization for the administration of acute sedation for their mental state. This treatment would last longer than sedative treatment for patients in need of relief from restlessness for the last few hours of their life. The authors imply that the brief sedation used palliatively for 24 to 72 hours shows no evidence of hastening death.[18] It is important to note that they use the word 'appropriate' for the used of sedation. Indicating that liberal use outside the safety of therapeutic levels can hasten death.

Although it is established that the responsible use of palliative sedation is not associated with any evidence that it hastens death, it is still a subject of contention for some moralists, healthcare professionals, patients and their relatives.[19] Studies show that 25% of patients that needed pain relief did not receive adequate treatment or none at all. Kirchheimer thus recommends that palliative care is best given in hospice facilities.[20] In these specialized environments it is more likely that the appropriate knowledge is wielded and disseminated. The gap between what the patient needs and the eventual pain management he gets from the system provided is evident. A survey done by oncologists rated 76% of physicians practiced poor pain management

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[16] Mohamed Y. Rady and Joseph L. Verheijde, "Continuous Deep Sedation Until Death, Palliation or Physician-Assisted Death?," *American Journal of Hospice and Palliative Medicine* 27, no. 3 (2010): 208-209.

[17] Nigel Sykes and Andrew Thorns, "Sedative Use in the Last Week of Life and the Implications for End-of-Life Decision Making," *Archives of Internal Medicine* 163, (2003): 341-344.

[18] Ibid.

[19] Ibid., 97.

[20] Sid Kirchheimer, *End of Life Care Inadequate,* accessed January 6, 2020, http://www.webmd.com/healthy-aging/news/20040106/end-of-life-care-inadequate.

assessments, and 86% of the patients treated were rated as under medicated for pain relief. The lack of attention for pain management in medical school training can also lead to inappropriate pain assessment and management. A subject most worthy for further primary research.

1.2 Differentiating Between Palliative Sedation and Slow Euthanasia

The first two important aspects that distinguish strict palliative sedation from forms of euthanasia are the clinical sedation indication and timing of administration. Palliative sedation is indicated when the patient is both terminally ill and in proximity of death. A patient diagnosed with diseases such as dimentia, Parkinson's, Amyotrophic Lateral Sclerosis (ALS), Hungtinton's, and certain types of malignancies are terminally ill. However, it can take years till it results in death. Such contexts do not justify deep or continuous palliative sedation, even if it is requested by the patient to expedite the process and to die well.

Clinicians, both pro and against euthanasia intend for the patient to die well, but most countries (with the exception of those that endorse it) consider euthanasia (or physician assisted suicide) as killing. The physician here intends to kill to achieve the aim of dying well for the patient, even if death for the patient is a good effect.[21] In contrast, the goals of medicine as well as palliative sedation include the provision of care, support, comfort and the relief of pain and suffering and not death as the desired outcome.[22] But the methodology endorsed by proponents of euthanasia for the relief of pain and suffering in end of life care is unacceptable for most moralists.[23]

Although the careful use of sedation in itself does not cause death, the combination of actions and decisions that follow with (and after) the commencement of deep palliative sedation indeed may lead to death and possibly even considered as a form of euthanasia. This is where a more profound analysis and discussion of sedation practices has become pertinent. The complexity of adjustable variables involved in

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[21] Netherlands Ministry of Foreign Affairs, "The Termination of Life on Request and Assisted Suicide (Review Procedures) Act in Practice," (2010): 2,8.

[22] Lars Johan Materstvedt, "Intention, Procedure, Outcome and Personhood in Palliative Sedation and Euthanasia," *British Medical Journal Supportive and Palliative Care* 2, no.1 (2012): 9.

[23] Peppin, "Intractable Symptoms and Palliative Sedation", 344.

palliative sedation creates 'grey areas', leaving room for malpractice or clinical subjectivity over the right protocols for palliative sedation. Commentators argue that this grey area leaves room for the practice of 'slow euthanasia'. Slow euthanasia is practiced in the liminal area between palliative sedation and euthanasia. It occurs when the physician intends the death of the patient in order to alleviate suffering. Clinically speaking the physician willingly exceeds the recommended dose of sedation beyond the therapeutic zone and sometimes withholds nutrition and hydration, in order to expedite the dying process.[24] Here, sedation is administered with that foreseen and intended effect - the hasting of death but by remaining within legal parameters. Thus the main ethical difference between palliative sedation and 'slow euthanasia' is the intent and foreseen effect.

In palliative sedation, when the person is in a state of intractable pain and suffering and all other safe approaches are inadequate, the use of narcotics and sedation to induce continuous and deep unconsciousness is highly indicated. The intention is to alleviate pain, death is indeed a foreseen effect thereof, but not with the intention to hasten to it with increasing titrations of sedation. The difference between these two effects is that of causing either a great irrevocable harm as an unwanted side-effect of seeking a good effect (palliative sedation), or that of having this said harm (death) as a part of the means to achieve pain relief (slow euthanasia).[25]

Palliative care includes also the withholding of treatment, which is usually done combined with palliative sedation. Palliative sedation and the withholding of treatment do hasten death in this way, although it can be termed as a *'good'* death. Here, death is referred to as *'good'* because when death is inevitable and proximate, providing a tolerable dying process should be atop of the physician's goals.[26] Withdrawing from excessive life support mechanisms and opting for palliative sedation to ease the painful process of dying aligns with the role of a physician and is ethically justified. Euthanasia can also be said to bring about *'good'* death however

[24] Charles Douglas, Ian Kerridge and Rachel Ankeny, "Managing Intentions: The End-of-Life Administration of Analgesics and Sedatives, and the Possibilities of Slow Euthanasia," 22, no.7 (2008): 389.

[25] Alison McIntyre, " The Double Life of Double Effect," *Theoretical Medicine* 25, (2004): 66-67.

[26] Peter Allmark et al., "Is the Doctrine of Double Effect Irrelevant in End-of-Life Decision Making?." *Nursing Philosophy* 11, (2010): 173-174.

the problem is that the means and intention that brings about this action is considered by many bio-ethicists as unethical.

Palliative sedation can also be practiced with the adjunct omission of artificial nutrition and hydration or other life-essential treatment, and this is still controversial. If one knows that without such life-saving mechanisms and interventions it leads to death, then palliative sedation becomes passive euthanasia (slow euthanasia) or physician assisted death. Even if the person is not directly killed, a failure to intervene when one has the power to do so, (for example the deliberate omission of artificial nutrition and hydration) would lead to death by starvation and dehydration knowingly. Although in some countries this act constitutes a criminal charge by law or effectively euthanasia, the lax interpretation and application of state protocols leads to such unethical practices all the same. This is essentially what happened with the implementation of the Liverpool Care Pathway in the UK, and compounded by shortcomings in the training of healthcare professionals, in this scenario, patients were being heavily sedated and starved to death at the tick of a checkbox.[27] It is important to note that withholding certain interventions after deep, continuous sedation should not be considered as passive euthanasia automatically, as long as there is a justification for such an action. For example the removal of intravenous lines that support hydration (even if prior to sedation the patient was able to eat and drink) is not passive euthanasia but it can be necessary to reduce pulmonary oedema. Another example is the removal of excessive life support mechanisms when death becomes imminent. This is not a form of passive euthanasia but simply an acknowledgement of the impending death. Overtreatment can become a form of harm and prolongation of suffering and pain. The predicament falls between those who give the utmost priority the value of preservation of life and those at the other extreme who support euthanasia and other methods of assisted dying unconditionally.[28] Discernment of patient's needs and the right measure of intervention is crucial. Palliative sedation can become passive euthanasia when one opts immediately for aggressive palliative sedation without trying other alternative methods of pain relief or light sedation when the patient is evidently suffering. In such case, it is hard to argue that the intent of

[27] Kevin Aquilina, et.al., *EndCare: An Erasmus + Project on Harmonisation of End of Life Care,* (Msida: University of Malta, 2018), 98.

[28] Ibid., 74-76.

sedation is purely pain relief.[29] But nevertheless, not initiating palliative sedation when the patient is in refractory pain, is also not ethically acceptable as this is contradictory to the role of a caring and morally responsible physician.[30]

Even though palliative sedation has been accepted by ethical committees such as the 'UK National Council for Hospice and Palliative Care' and the 'Council of Ethical and Judicial Affairs of the American Medical Association', its use is still precarious. There is still the dilemma whether palliative sedation should be incorporated as a common clinical practice, or to be considered as an extraordinary treatment since it involves the depression of consciousness. Nonetheless, it is agreed upon that its use is opted for when all options of standard palliative care (with mild to intermittent pain relief) have failed to achieve a tolerable pain control. Despite its use being as a last resort, there is still a dilemma as to where is the cut off point between palliative sedation and euthanasia. The deliberate suppression of someone's consciousness is a morally questionable action as some may claim that it surpasses the normal threshold of palliative care. Not only is it considered as euthanasia by some individuals but also as involuntary euthanasia when consent is not obtained in time (for example in patients experiencing severe symptoms such as delirium). Hence, palliative sedation is differentiated from euthanasia not just from physicians' intentions but also from the rights of the individual as a patient in their care.[31]

1.3 Ambiguities and Issues Related to Palliative Sedation

1.3.1 The Ambiguity of Personhood

The use of continuous deep sedation elicits questions about personhood. Following the philosophical beliefs of Rene Descartes and John Locke one may say that continuous deep sedation is essentially the killing of personhood. Some proponents argue that a person in delirium or with limited consciousness (caused by excruciating pain) is already no longer a person. Some may seem to argue that in this state a person becomes a 'a living dead'. This is perhaps pragmatically also possible with deep

[29] Govert den Hartogh, "Continuous Deep Sedation and Homicide: An Unsolved Problem in Law and Professional Morality," *Medicine, Health Care and Philosophy* 19, (2016): 287-288.

[30] Mark F. Carr and Gina Jervey Mohr, "Palliative Sedation as Part of a Continuum of Palliative Care," *Journal of Palliative Medicine* 11, no. 1 (2008): 77.

[31] Glenys Williams, "The Principle of Double Effect and Terminal Sedation," *Medical Law Review* 9, (2001): 49.

sedation itself - if sedation is not stopped upon clinical improvement (although it is rare), the patient will never wake up. Thus transitioning into a state of 'social death'.[32]

Descartes is known for saying: '*Cogito, ergo sum',* that is translated 'I think, therefore I am'. When a person is no longer able to think, he is no longer a person. In this context, inducing deep sedation would essentially constitute killing by eliminating consciousness and therefore personhood is revoked. Critics of this philosophical thought argue that at the time of Descartes it could not be proven that brain activity is actually preserved in unconscious patients. Therefore, the ability to think is present but suppressed, and not eliminated. For Locke, the ability to think is combined with self-awareness and it is what constitutes personhood in his understanding. To think about oneself one has to be conscious, and therefore patients with induced unconsciousness do not have self awareness. If the individual is no longer a person with self-awareness because of sedation, one can also consider this act as killing the person. This argument is highly controversial because it puts the demented, the cognitively impaired people and newborns in an uncertain state of personhood.[33]

Immanuel Kant believed that one becomes a person from conception until death. Human beings consist of the 'empirical' ego and the 'transcendental' ego. The former refers to the body that is subject to the laws of nature while the latter is the rational part, subject to the laws of logic. Deep sedation only effects the 'empirical' part, resulting in the incapacity to make rational decisions but it does not eliminate the ability to be rational. Therefore for Kant, deep sedation is not the killing of personhood.

A more radical philosophical belief is that of John Harris. The 'individual' and 'person' are more differentiated than in the previous moral taught. The individual is created during conception but till the ability of valuing one's own existence, the individual is merely a potential or a 'pre-person', unless this capacity is lost. Hence, if applied to deep sedation, personhood is still viable as the capacity for personhood is still possible. What it can be argued here is whether a 'potential person' can be subject to abuse; terminating life (abortion or withdrawing or withholding of

[32] Lars Johan Materstvedt and Georg Bosshard, "Deep and Continuous Palliative Sedation (Terminal Sedation): Clinical-Ethical and Philosophical Aspects," *Lancet Oncology* 10, no.6 (2008): 622-627.

[33] Ibid.

treatment without proper assessment) with the justification that the individual is not properly a person.[34] The moral problem of this argument presented on personhood is whether personhood is maintained even in such a vulnerable state. If one believes that an individual in end-of-life stage experiencing 'social death' is no longer a person then, the ethical aspect of the problem becomes irrelevant.

A Utilitarian that believes that the individual in a state of infirmity is no longer a person, does not find it morally problematic to give high doses of sedation to free the individual from pain. However, if one believes that personhood is maintained, and palliative sedation has the side-effect of a hastened death, the need of an exceptional ethical principle is recognized. For the sake of the presented arguments, it is assumed that personhood is maintained when unconsciousness is induced with palliative sedation. This gives rise to several issues including loss of autonomy, dignity and lack of consent.

1.3.2 Ambiguities in Physician's Intent

The major ethical discussion regarding the use of deep palliative sedation concerns the issue of 'intent'. Intention is one of the four criteria of the principle of double effect, a principle that is extensively called upon to defend this clinical practice, and the focus of chapter two. The principle states that a physician must only intend the good effect, the bad effect can only be foreseen but not intended and the bad effect cannot be the means or the end of our action. The essential problem here is the difficulty to discern between what is foreseen and what is intended. Foresight and intention are both meta-physical abstractions of human consciousness, and both suffer from definitional contestations and qualification. Assessing something that is so intimate to the deep-seated knowledge and beliefs of human minds is an ethical challenge. For even what is verbally or behaviorally exhibited by the physician may not be the direct representation of what he/or she intends or foresees, and therefore actions are rarely judged upon intention, but on action.

The ambiguity of moral intentions when combined within a legal framework certainly makes it an even greater problem. Professional moral codes, judges and jurors, are seldom interested in people's moral orientation, and with seemingly good reason.

[34] Ibid.

Evidence is paramount, and intension becomes irrelevant. However, a doctor may have still intended to end a patient's life by simply saying that he is administering palliative sedation, thus hiding his intentions within the limits given to him by law.[35] Here, as long as the doctor stays within the legal parameters and does not voice his intentions, those involved (but unaware of his deepest secret,) are cooperating in palliative care not euthanasia. So if the intention is bad, but it remains undetected by law, then there must be a problem with either the application of law or medical ethics.[36]

1.3.3 Ambiguities in Clinical Practice

One of the major issues that persists when palliative sedation is administered is life expectancy. Since it is administered despite having such terrible side-effects that can lead to death, one wonders when is the ideal moment to initiate this last resort to manage pain. The problem is that guidelines available directed to this problem do not align together and some are even absurd. Most of the international guidelines regarding deep, palliative sedation accept the fact that it should be used for terminal patients and in uncontrolled refractory symptoms but do not specify how close to death the patient should be in order to start palliative sedation. The American Academy of Hospice and Palliative Medicine implies at "very end of life", the International Consensus Panel says "hours to days", Council on Ethical and Judical Affairs and American Medical Association states "final stages of terminal illness". The American College of Physicians- American Society of Internal Medicine Consensus Panel and Cherny and Portenoy vaguely imply "end of life" and Calgary Regional Hospice indistinctly states "days".[37] Burger implies that the lack of precision of these guidelines as to when palliative sedation should be started makes their use in the clinical settings limited. Only the Royal Dutch Medical Association gives an accurate guide (one to two weeks), however according to den Hartogh, an upper limit of fourteen days is a lot and it should be lowered in order to avoid death/homicide due to dehydration. He states that the prediction of life expectancy can be difficult to estimate beyond 3 to 4 days and the physician is more likely to

[35] Glenys Williams, "The Principle of Double Effect and Terminal Sedation", 44.

[36] Joseph Boyle, "Medical Ethics and Double Effect: The Case of Terminal Sedation," *Theoretical Medicine* 25, (2004): 53-55.

[37] Jeffrey T. Berger, "Rethinking Guidelines for the Use of Palliative Sedation," *Hastings Center Report* 40, no. 3 (2010): 33.

overestimate, holding specific biases towards estimating life expectancy. Furthermore, the two-week upper limit is already high and it applies for a normal healthy person not someone already critically ill. He suggests that maximum life expectancy does not exceed further than 3 to 4 days as it is more likely for an ill person to die of dehydration beyond this stipulated time.[38]

Another confounding issue related to palliative sedation and life expectancy is when one should consider to omit or decrease nutrition and hydration, as it can itself become unnecessarily or even detrimental to the patient. And because it is difficult to make an accurate estimation of life expectancy, it is equally difficult to decide when to stop nutrition in the stages of disease. If sedation to unconsciousness is induced and the patient dies before the stipulated life-expectancy according to the guidelines, that would signify that other factors could have contributed to the death of the patient such as the withholding of artificial hydration and nutrition. Nevertheless, although it may seem contradictory, it is a common practice to withhold hydration and nutrition when the patient has fluid overload as it can directly damage the patient's organs. Fluid overload leads to pulmonary oedema, respiratory distress due to an increased respiratory rate and bronchial secretions that obstruct the airway, as well as other complications such as diarrhoea, bowel obstruction and ascitis.[39]

However, if the patient is at jeopardy of dying from dehydration prior to the consequence of disease itself this can be considered as 'euthanasia with other means'. Especially true if life-expectancy is estimated to be prolonged to more than 4 and up to 14 days.[40] Den Hartogh explains that although it may not be the intention of the physician, it is a known fact that if a number of days pass without supplementing hydration and nutrition the patient dies. Therefore the result is generally foreseen, and confirming further the ambiguity of this practice, leaning more towards physician assisted death (euthanasia).[41]

Due to such clinical ambiguity and uncertainties surrounding palliative sedation, Braun attempted to formulate conditions that have to be met in order for an individual to be eligible for palliative sedation. Amongst these criteria includes the presence of a

[38] den Hartogh, "Continuous Deep Sedation and Homicide", 292- 293.

[39] Mary Ersek, "Artificial Nutrition and Hydration: Clinical Issues," *Journal of Hospice and Palliative Nursing* 5, no.4 (2003): 227.

[40] Ibid.

[41] Ibid., 286.

terminal disease, a refractory symptom which cannot be controlled or managed within a reasonable timeframe, life prognosis limited to a few days and an order not to resuscitate the individual. Furthermore, an experienced physician in palliative pain management should be the one to assess the individual and decide whether to initiate palliative sedation or not. Family members and the person himself if possible should be informed and consent obtained. The patient has to be monitored closely to avoid preventable side effects, for example asphyxia and lastly, appropriate documentation should be carried out due to palliative sedation being a possible means for PAD or slow euthanasia.[42] In addition to these criteria, Rousseau adds the need for a psychological assessment as sometimes, the individual's request for palliative sedation might origin from a reversible psychological issue. An assessment of the individual's spiritual needs should be carried out and a discussion over the benefits and burdens of consequent interventions such as ANH should be reached.[43]

1.3.4 Issues of Belief and Evidence Based Regulation

The general understanding of what is palliative sedation varies in the healthcare sector. Individuals' personal ethics, cultural values and spiritual beliefs inevitably influence the ethics and clinical judgment of health care professional in practice. Palliative sedation is of no exception to this subjectivity. Timing is a key moral evaluation of palliative sedation - initiation, duration and termination each carry their ethical weighting. Palliative sedation requires forecasting the proximity to death. Albeit determining how close to death the patient is more a question of experience and intuition than an exact science, the forecast is still required in order to minimize the possibility of administering deep sedation too early in the patient's progression of disease. There is a warranted moral concern that physicians may deprive patients of their consciousness too early, before the end stage of disease, anticipating the relief of refractory symptoms or the witholding of disease treatment before it is effectively required by the patient. It seems that personal morality is a great determinant over

[42] Ted C. Braun, Neil A. Hagen and Trish Clark, "Development of a Clinical Practice Guideline for Palliative Sedation," *Journal of Palliative Medicine* 6, no. 3 (2003): 346- 347.

[43] Paul Rousseau, "Existential Suffering and Palliative Sedation: A brief Commentary with a Proposal for Clinical Guidelines," *American Journal of Hospice and Palliative Care* 18, no. 3 (2001): 152- 153.

whether a physician becomes an agent of deep palliative sedation or in any other life ending intervention (such as withdrawing life support).[44]

The concern over suppressing a patient's consciousness has been rooted in the religious beliefs of monotheistic religions. Fore instance, although Islamic scholars acknowledge pain relief as part of end of life care (even if it shortens life), and support the role and duty of the physician to manage refractory pain (even to unconsciousness), sedation is still widely unacceptable by most Islamic believers - those that practice the faith. It is customarily believed that pain is the will of God, and a purifying process that should be endured. For this reason, sedation in Islamic countries is still widely feared by Islamic practitioners. Because the use of mind altering substances such as with opioid use goes against the teachings of the Quran. And in some countries such as Egypt, the use of morphine is highly regulated by the Ministry of Health. Thus pharmaceutical companies as well as pharmacists heavily restrain themselves from the commercial dissemination of pain relief products for fear of the religious gaze upon them.[45] Hence, this directly impacts the administration of palliative sedation, and patients' comfort.

Nevertheless, even in the Western Christian world, despite so much healthcare information that is available, people still seem to experience anxiety and fear about the subject of palliative sedation and the hastening of death.[46] As pointed out earlier on in this chapter (what Kirchheimer reports about studies in the USA), poor clinical management strategies and poor patient outcomes are still prevalent in many North American states, when it comes to pain relief, and similar to the Islamic world, the problem remains that of personal beliefs compounded by misinformation. Pope Pius xii had addressed several questions raised by anaesthesiologists regarding the moral dilemmas associated with palliative sedation back in 1957. He acknowledged the practice of palliative sedation even if it can end up suppressing consciousness and resulting in a hastened death, if there is no viable alternative. This is because the goal of palliative sedation is to achieve pain relief not death otherwise it would be euthanasia. In addition, he further elaborates that "heroic suffering while admirable it

[44] Rady and Verheijde, "Continuous Deep Sedation Until Death," 212.

[45] Aquilina et al., EndCare, 99.

[46] Ibid., 97.

is not obligatory" hence unconsciousness resulting from sedation is not condemnable.[47]

Another reason that can effect the administration of palliative sedation is experience. A physician is more likely to opt for light or intermittent sedation to manage refractory symptoms, which is seemingly more ethically acceptable. Erring on the side of caution, an experienced physician is more likely to avoid practices that have end of life complications - that can be construed as physician-assisted death. Conversely, physicians with limited clinical experience, or suffering from burnout are more likely to be lax in their decisions to opt for end of life measures that can hasten death.[48]

What is even more disconcerting in this field, is the lack of inclusion of the patient's relatives when it comes to end-of-life decisions, as well as the patients' consent. The justifications currently present in literature regarding initiating continuous deep sedation mainly focuses on the physician's concerns, and only some address the patient's needs. Lack of communication between the physician, the patients and their surrogates leads to serious downplay of patient centred care. The general criticism is that physicians are not investing enough time in understanding their patients' expectations and background values. This is in breech of the principle of beneficence, because patient care requires more than just the palliation of symptoms.[49]

Legislation that enforces statues and regulations directly impacts the delivery of adequate palliative care and pain management. For example the Pain Relief Act 1996 directly affects the clinician in his delivery of care. Other regulations effect the distribution of controlled substances. This would hold anyone who overtreats the patient responsible for consequences. Uunfortunately strict regulation ends up resulting in the under treatment of pain management as a result of fear of disciplinary action.[50] Introducing laws that holds the physician culpable for actions that carry risks but are inevitable for the comfort of the patient, does not help in the administration of

[47] Michelle Davis, "Understanding Terminal Sedation," *Canadian Catholic Bioethics Institute, Bioethics Matters* 6, no. 3 (2008): 1.

[48] Tatsuya Morita et al., "Practices and Attitudes of Japanese Oncologists and Palliative Care Physicians Concerning Terminal Sedation: A Nationwide Survey," *Journal of Clinical Oncology* 20, no. 3 (2002): 758-764.

[49] Sam Rys, et al., "Continuous Sedation Until Death: Moral Justifications of Physicians and Nurses- A content Analysis of Opinion Pieces," *Medcine, Health Care and Philosophy* 16, (2013): 539.

[50] Ko, Perez- Cruz and Blinderman, "Ethical Issues in Palliative Care", 187.

palliative sedation. There is the risk of evasion of responsibility from such ethical decisions when introducing overly strict laws that constrain physicians from executing their work with peace of mind.

The fact that an established consensus cannot be achieved regarding practices such as the withholding of artificial nutrition and hydration, the clear time-frame of life expectancy, and the acceptance of continuous deep sedation until death, hinders the administration of palliative sedation. One of the reasons why consensus is not possible in this field is because medical literature is highly influenced by societal concerns and not solely founded on empirical and clinical evidence. In fact, according to Claessens et al., anecdotal literature justifies the use of deep palliative sedation but it is not being supported by concrete evidence from published research. He claims that there is a literature gap where it concerns; the knowledge of continuous deep sedation and its possible life shortening effects, the combination of deep sedation and the withholding of artificial nutrition and hydration, and regarding the required information necessary to flow through the decision making process of such end-of-life actions.[51]

Another problem is the ambiguity in the terminologies of palliative sedation. Terms such as 'terminal sedation' or 'end-of-life care' are sometimes avoided and instead referred to as palliative sedation, mainly because of its emotive meaning. 'Palliative' is more widely used as it emotively suggests that the use of a 'palliative' sedation is to alleviate pain and suffering while the word 'terminal' can be easily understood as the intention of the physician to induce continuous deep sedation to terminate life.

Nomenclature is changed so that society would not ostracize the practice. Terms such as 'titrating sedation' and 'refractory symptoms' sound persuasive in order to convince the reader that inducing palliative sedation is a normative practice. But this play on terms and lack of consistency in their usage adds to the ambiguity in moral debates.[52] Also, terms confuse the true application of palliative sedation in the clinical

[51] Patricia J. Claessens et al., "Palliative Sedation: A Review of the Research Literature," *A Journal of Pain and Symptom Management* 36, no.3 (2008): 313- 320.

[52] Sam Rys et al., "Continuous Sedation Until Death", 539.

setting - 'Sedation' in 'terminal sedation' is given proportionately to treat refractory symptoms not to 'terminate' life. It is the disease that is terminal.[53]

Conclusion

This chapter sought to define palliative sedation and explain its complexity from its different medical, ethical and legal aspects. Different levels of sedation exist to suppress consciousness. Pharmaceutical advancements provide an array of class ranked opioids and sedatives, that can be used in combination to achieve the best clinical outcomes whilst minimizing patient risks. Safety, in the evolution of medicine has vastly improved, but the administration of sedation still raises several ethical issues both in theory and for practice. Predominant among clinicians is the fear (of the 'grey area') that palliative sedation pragmatically encroaches on euthanasia. The need to differentiate palliative sedation from euthanasia has thus become vital, even in the interpretation of related terminology.

This chapter identified various variables to the problem - which for the purpose of this dissertation are referred to as ambiguities. With personhood, the difficulty of advocating for the patient especially within instrumentally rational healthcare systems is being fuelled by ambiguous contestations over when and why should the individual cease to be considered a person. Then there is the subjective nature of timing palliative sedation and choosing the right palliative paths in end of life care. The ambiguity of estimating end of life, in order to remain within ethico-moral parameters of clinically indicated time is an overbearing challenge on the physician. But the anxiety of unnecessarily expediting a person's death is even worse, at least for some.

Finally we have the nature of the relationship between physician' intent (concealed) and their actions (visible) in clinical practice. The moods and motivations, cultural and religious beliefs, knowledge and education, clinical experience and intuition, social pressure and fear of legal constraints, all seem to add to the ambiguity as to why healthcare professions do what they do with their patients.

One thing that is certain in the literature, is that the vast majority of bio-ethicists deal with these issues in palliative sedation by calling upon the principle of double effect. At least in the outset of their rhetoric, and for some it remains as the best

[53] Rady and Verheijde, "Continuous Deep Sedation Until Death", 207.

epistemological justification for palliative sedation. Thus in the next chapter, the application of the principle of double effect as an epistemological lens will be explored and discussed. Then in chapter three the principle as applied to palliative sedation and end of life care will be critiqued and alternative or conjunctive epistemologies will be discussed.

Chapter Two:

Applying the Principle of Double Effect in Palliative Sedation

This chapter addresses the application of the Principle of Double Effect (PoDE) in relation to medical ethics. The objective of this chapter is to unearth sufficient arguments regarding the use of the PoDE to address the ethical dilemma concerning the use of sedation for the treatment of pain in terminally ill patients. The relevance of the PoDE will be explored through the contribution of authors that have grappled with the subject, especially those that have specifically thought of its application to palliative care.

2.1 Gury's and Boyle's Presentation of the Principle of Double Effect

Mangan discusses the epistemological progression of the PoDE in the history of philosophy. For the purpose of palliative sedation, Jean Pierre Gury's specific conditions of the principle are of greater interest to our application here than earlier works in philosophy. Mangan argues that in the 19th century Gury's had been particularly influential with his publications on the moral criteria for the PoDE. Gury believed that it is acceptable to have a morally good action that leads to two effects - one good, the other evil. This action is acceptable provided that: the action is good or at least neutral. There needs to be a proportionately valid reason to execute it. It must be intended for good (evil effect not intended). And the evil effect is not an antecedent (in sequence) to the good effect. Gury adds that the more immediate (close) the evil effect is to its causative action, the less justifiable it will be for the agent to act.[54] The specific conditions that Gury adds (or elaborates on) to his Christian predecessors in theology and philosophy, show a significant preoccupation with the possible liberal application of the Principle to justify any action that has this moral duality.

Indeed, Gury has provided a concrete formulation of the conditions under which double effect actions can be performed ethically. But Mangan notes that Gury expected that an action is only justified when all criteria are met. It works out

[54] Gury, fifth German edition, "De actibus humanis," quoted in Joseph T. Mangan, "An Historical Analysis of the Principle of Double Effect," *Theological Studies* 10, no. 1 (1949): 58-59.

therefore, that the principle (in his way) condones all good or neutral interventions that may carry some adverse side-effects, but with much greater benefit. It excludes all clinical interventions that start with harmful actions that lead to good outcomes. And it also excludes intrinsically good (or neutral) actions that lead to an insufficient proportion of good in comparison to the evil side effects, or in comparison to less harmful alternative clinical pathways.[55] Yet with palliative sedation, and despite these allowances made by Gury's principle, several authors still find that the clinical indication for palliative sedation somewhat cogent but nevertheless still falls short of the PoDE's epistemology.

In discussing the PoDE for palliative sedation, Boyle's preoccupation with Gury's conditions lies in a pragmatic quandary – Even if there is good intention, the morality of an action that brings two effects (one dominantly good, and the other bad), it is dependent on two important conditions that are difficult to ascertain. First, there is the difficulty of determining the goodness of an action even before its effects occur. The second difficulty is to find supporting evidence that there is a proportionally grave reason to pursue such a clinical intervention.

Even if good is intended from palliative sedation, some evil precedes or runs concurrent to the action of sedative-analgesia administration. It requires some invasive action on the person and his body from the outset. There is at least some suffering involved from cannulation, pre-revisions of treatment, induced altered consciousness, immediate body reactions, stress, and anxiety, and delirium preceding pain relief.[56] We may never know if Gury would consider as acceptable (or at least neutral) the unpleasantness of clinical actions preceding the good effect of pain relief measures. If not, on Gury's terms, palliative sedation breaks the PoDE at least with the improper sequencing and proximity between good and bad.

Furthermore, Boyle argues that intending a route of action by default without considering other options, simply because the side-effects are commonly 'accepted', is wrong. One should have a solid reason to administer terminal sedation to a patient

[55] Ibid.

[56] Waterloo Wellington Interdisciplinary HPC Education Committee, *The Waterloo Wellington Palliative Sedation Therapy Protocol,* accessed April 7, 2020, https://www.wwpalliativecare.ca/Uploads/ContentDocuments/20191220_WW_PST_Final.pdf, 5.

experiencing pain if other less aggressive measures usually suffice. Just because the side-effects of a terminal sedation are known and accepted, it does not justify the risk if other options are available. The problem with palliative sedation here is not just an issue of proportionality. It is an issue of routine assumption. For Boyle the naïve assumption that palliative sedation for the terminally ill is always morally accepted by common consensus, is ethically insufficient. The proportionately good reason, should spur the agent to use a contextually comprehensive moral lens in decision-making, and not to universally apply the casuistry of exceptional cases in a liberal manner. Therefore an intention to administer palliative sedation must be justified by the agent's sufficient understanding of Christian morality.[57]

Boyle points out that the reason why those that find no objection to euthanasia fail to understand the conceptual qualification of intention and foresight in the phrase 'not-intended but accepted' death from palliative sedation, is because of their unfamiliarity with Christian morality. Boyle argues that unfortunately the poor definition and ambiguity (in theological literature) of the terms 'intended' and 'accepted' does not help either. The early founding fathers of Christianity assumed that readers understood (because of knowing scripture) that in 'intending' a full measure of goodness, one has to 'accept' some evil in terms of outcomes[58] - to miss the mark is part of human nature (Romans 3:23; Isaiah 64:6).

Boyle unearths the difference. He argues that our incapacity in the pursuit of doing good, is not in intending it, but in our efforts to avoid evil [59] - This is an accepted reality in Christian belief (Romans 7:15-20). Boyle believes that human intentions may be preserved (free will), but actions thereof are always tainted by evil. Boyle explains how actors are caught between a rock and a hard place – One can either act and accept bad side-effects (treat pain and die), or not act at all (let die in pain), out of fear of (what Boyle calls) "harming a good". The trouble with foresight of evil is that whatever route is taken the moralist's conscience is panged by doubt, regret and fear of committing evil. Nonetheless, an idle agent is still bound to regret his idleness. The PoDE in Boyle's understanding is to preserve righteousness by limiting evil in our human activity. But despite his efforts to defend the principle, in his view, Boyle

[57] Boyle, "Medical Ethics and Double Effect", 52.
[58] Ibid., 54-55.
[59] Ibid., 55-56.

does not think that the PoDE can be applied to medical ethics without sound pragmatic contextualization.[60]

Intentions cannot be fully known, and sometimes not even the agents themselves fully comprehend why they do what they do. And because of this deficit, many have rejected the application of the principle completely. Boyle argues that the application of PoDE may not necessarily be disregarded because of the difficulty of asserting intent. Yes, it is impossible to prohibit unintentional killing, as this would obviously bring clinical practice to a halt. But it is possible for the medical profession to prohibit intentional killing, if the medical profession is confident enough to ascertain intent from the documentation[61] and protocols of practice and by observing the behaviour of its clinical agents. If the difficulty of intent is compensated for in this manner, then the application of the PoDE according to Boyle stands.[62]

With this so far one can see that there are at least two well defined points of view or lenses from which the application of the PoDE is discussed. Mainly but not exclusively, there are those that elaborate on the issue of correct sequencing and proportionality of action and effects, and then there are authors who discuss the issues surrounding intention. These aspects need to be discussed in further depth in the following sections of this chapter.

2.2 Intentions According to Shaw, Quill and Jansen

Shaw explains that intention should be the answer to; why do we do what we do? Here one is after reasons. It is not necessarily the objective (or normative) reason, but the motivated reason that is connected to it that one should be after. It is a prospective reason, a 'hoped for' result. His definition is as follows:

> *Of the upshots which agent A believes he makes more likely by acting or omitting to act, A intends those the anticipation of which provide motivating reasons for his action or omission.*[63]

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[60] Ibid., 56.

[61] Bernard Lo and Gordon Rubenfeld, "Palliative Sedation in Dying Patients: 'We Turn to it When Everything Else Hasn't Worked,' " *Journal of the American Medical Association* 294, no. 14 (2005): 1813.

[62] Ibid., 56-58.

[63] Joseph Shaw, "Intention in Ethics," *Canadian Journal of Philosophy* 36, no. 2 (2006): 206.

More simply the anticipation of what an agent wants propels the motivating reasons behind the actions or omissions of the agent. Of course the anticipation of unwanted consequences also determine what the agent does or does not do. By upshots above he means results or consequences of an action that are foreseen. Some of the foreseen would be intended and some would not. Shaw argues that there are actions that can have multiple interpretations of why the action was intended. One can argue that an actor intended all of them (which would probably be unrealistic), or one could argue that what is intended should be based on what act/event the agent describes as the intended one.[64]

This is of course problematic because the agent can lie, giving a false reason to conceal his real intention. In this case the intention would have to rest upon sincerity. Shaw points out that agents can only intend what they know, therefore what is intended is obviously always based on what the agents can forsee to the best of their knowledge. This is helpful to narrow down the search for truth, but it does not solve the problem of actually knowing intention, it still may rely on the actors' sincerity. If in doubt one can rely on logic or collective knowledge of what is likely to be the intention, but the latter would be in a sense unfair to the *'fact'* seated in the minds of agents.[65]

Some scholars are bothered by the idea that the morality of actions can be discerned by distinguishing intention from foresight. Henry Sidgwick argues that an agent is morally responsible for all the possible foreseen outcomes that an action can have. He explains that one should be held responsible for all the foreseen side-effects since the agent knows that they all carry the probability of being an outcome. Therefore, foreseen effects are part of one's intentions as well. Glanville Williams, a legal theorist, also seems to support this view. The agent has moral responsibility when a foreseen effect is almost certain. In the context of high probability, Glanville Williams asserts that the foreseen effect has to be considered very near to what is intended.[66] Nevertheless it has to be said that even if one foresees all side-effects to fall under his moral responsibility, it still does not necessarily mean that the agent intended all possibilities to occur. In the case of palliative sedation, it is not the

[64] Ibid., 207 -208.

[65] Ibid., 209.

[66] Ibid., 190

intention of the physician to induce unconsciousness but it is an inevitable side-effect of deep continuous sedation that the physician has limited control over. The physician is aware that unconsciousness is a result of sedation when light or intermittent sedation fails to manage pain. However, the aim is to palliate refractory symptoms but not the loss of autonomy and dignity of the individual that results from unconsciousness. This is the critique that some like Joseph Boyle and Thomas Sullivan put forward that "the foreseen consequence is at odds with one's purpose".[67] Even if the agent is responsible for all, intention is at least distinct from foresight on the basis of reasoned action or purpose of the agent. Therefore, one may say that hastened death, even if foreseen, is at odds with the 'purpose' of alleviating pain with opioids, it cannot be intended.

Quill goes a step further. He calls the belief that pain relief with opioids hastens death, mythological. He quotes research sources on the effects of opioids that conclude that pain management with opioids does not hasten death, but actually extends and improves the quality of life of terminally ill patients. Clinicians often site shortness of breath and loss of consciousness as the main problems of opioid administration, but Quill explains that tolerance to respiratory depression and sedation is developed quickly in these patients, and more likely to happen in the early stages of treatment. These symptoms can be managed with adequate dose titration and the risk of hastening death is therefore very remote.[68]

Quill points out that unfortunately this unfounded fear of hastening death has become a barrier to effective clinical pain management. He attributes the problem to clinicians' reflecting about pain relief with the PoDE in mind. Citing Fohr, Quill believes that the PoDE is no longer a relevant ethical way of thinking for standard pain relief management. Quill explains that with scientific advancements adequate pain management has become effective and safe in "virtually all" palliative cases. Nevertheless, Quill understands that the "virtually all*"* has the unfortunate condition of unearthing some 2 to 5 percent of cases that for them standard pain management practices are insufficient. Most of these cases, would have had good pain management throughout the course of illness. Then at the very end of the journey they suffer from

[67] Joseph M. Boyle and Thomas D. Sullivan, "The Diffusiveness of Intention Principle: A Counter Example," *Philosophical Studies* 31, (1977): 359.

[68] Timothy E. Quill, "Principle of Double Effect and End-of-Life Pain Management: Additional Myths and a Limited Role," *Journal of Palliative Medicine* 1, no. 4 (1998): 333.

an intolerable and uncontrollable pain, at the brink of death.[69] A discussion of intent or ambiguity of purpose would make sense only in discussing these 2 to 5 percent of rare cases.

These are the rare situations where the PoDE can be invoked. Where administering further treatment in view of pain acceleration and extreme shortness of breath warrant careful consideration with the conditions of the PoDE. In these medical emergencies according to Quill, the risk of hastening death, although in a very short span of time, is still relevant. Under these conditions, some patients would refuse an increase in pain medications in order to maintain consciousness. But others would gladly embrace an increase in treatment even to the point of sedation, and with sedation the risk of hastening death becomes real. Here consideration of this moral dilemma becomes warranted.

Quill acknowledges, that when faced with these medical emergencies, the PoDE is important for some patients, families and clinicians. It is helpful for those who believe that hastening death is absolutely wrong. With the PoDE one could argue that the aggressive management of pain with morphine, death is foreseen but not intended. The PoDE requires that the patient's suffering becomes proportionately extreme to justify the risk of hastening death. This may be helpful for some, but surely not acceptable by all. In the advanced stages of disease, some patients may want to hasten death. But when they express it to their doctors, clinicians with the PoDE mindset become reluctant to increase pain relief. Also some clinicians may see sedating patients to unconsciousness (often accompanied with withholding fluids and nutrition) as a form of "slow euthanasia". This is also not acceptable according to the PoDE. Cooperating in any of these decisions depends a lot on the clinicians' moral and religious beliefs about hastening death in these difficult cases.[70]

But Quill argues that there is way too much moral ambiguity added to these extreme situations, when invoking the PoDE. Quill argues in favour of a more pragmatic stance, encouraging moralist to inquire more about how clinicians feel about these decisions rather than judge their actions simply on the basis of thought ethical principles. Quill critically argues about the PoDE, that it relies heavily on intention, when intention is all so very subjective in nature. "Intention cannot be measured,

[69] Ibid.

[70] Ibid., 334.

evaluated or verified", he argues. With this in mind, Quill asks, does the PoDE still have relevance to palliative pain management and end of life care today? Quill argues with a '*yes',* it may still be valid, but with some specific qualifications and conditions.[71] Not applicable for most cases, because pain management is so safe that it makes the PoDE redundant in its application in the norm. Cases of hastened death by pain medication are so rare, that when they occur they happen by accident as an unintended side-effect. Actually, applying the principle to common pain management practices would create unnecessary ambiguity and considerable hesitation that comes to the detriment of the patient and his suffering. Nevertheless, Quill argues that the PoDE should be used when it is important to the patients, relatives and health carers, who believe in the absolute prohibition of hastening death in the light of rapidly accelerating pain and shortness of breath. But even here, one does not necessarily need to turn to the PoDE to deal with these complications. Assuring proper "proportionality" (condition severe enough), informed "consent" (patient fully aware of all the options' pros-and cons, and "parsimony" (intervention intensity kept at the least harmful level to the patient), should be a sufficient ethical guide for decision making. Quill believes that these three, proportionality, informed consent, and parsimony, supersede (and are independent of) the PoDE in their practical application to last resort clinical decision-making. Needless to say, with these statements Quill managed to generate considerable critical responses to this position, as it shall be discussed later on in this chapter.[72]

Quill concludes that as long as patients' families and clinicians are allowed to respond ethically and clinically responsible in these extreme emergencies, the PoDE can sill be used. But if the application of the principle is adopted to exaggerate the risks of pain management, fostering fear of treating pain among physicians to the detriment of the patients' comfort, then the PoDE is unacceptable. It is unacceptable to contrive the PoDE in order to install fear, and elicit mixed feeling on personal intentions. The principle cannot be used to avoid responsibility towards the patient. If this is the case, then Quill argues the PoDE should not be used to guide end of life treatment.[73]

[71] Ibid.

[72] Ibid.

[73] Ibid., 335.

Jansen is one of those who addresses critics of the PoDE such as Quill, The criticism in a gist is that the principle is founded on the notion of good intention, and because physicians' intentions can be multiple and perhaps unclear or even contradictory, the PoDE is not satisfactory as a moral guide for pain management in end of life care medicine. Jansen argues that these critics are failing to understand that there are two understandings of intention, and knowing the difference will help to clear an unnecessary ambiguity.[74]

First she fleshes out the distinction between what can be permissible by intention, and what can be permissible as side effect only because it is foreseen but not intended provided the conditions of proportionality are respected. Proportionality will be discussed in detail in the latter section of this chapter, but for now her arguments on intention will be the main focus. As most other authors do in discussing PoDE for sedation, she discusses intention with the assumption that palliative sedation is morally permissible only for rare and extreme cases.

While the PoDE only assumes that it is possible to distinguish what is intended from what is only foreseen without giving an explanation of how to do it, Jansen tries to address this issue by drawing a distinction between the "broad" and "narrow" conceptions of intention. In the broad sense - intention is an action done with self-awareness and knowledge of its consequences. In its narrow meaning - intention is only intentional if it is part of the agent's purpose in acting.[75]

Jansen explains this concept by using the example of civilian deaths in tactical bombing versus terror bombing. In tactical bombing, the pilot drops the bomb on the enemy's munitions factory. He intends to weaken the military force of the enemy but in doing so he is aware that some nearby civilians will die (his broad intention), but it is not his purpose to kill civilians (civilians dying is not his narrow intention). In terror bombing, the pilot drops the bomb on the enemy's factory in order to weaken the military strength. He also knows civilians will die (his broad intention), but this he also considers as a way to weaken the enemy's resolve by killing civilians (civilians dying here is his narrow intention as well). In tactical bombing, the pilot does not wish for civilians to die, he has broad intention without a narrow intention to kill

[74] Lynn A. Jansen, "Disambiguating Clinical Intentions: The Ethics of Palliative Sedation," J*ournal of Medicine and Philosophy* 35, (2010): 20.

[75] Ibid., 22.

civilians. If there is another way, he would opt for it. In terror bombing there is both broad and narrow intention, because civilian consequences are welcomed as well.[76]

The ambiguity in clinical intentions however lies here: If a physician is asked whether the death of the patient by high doses of morphine is intended with palliative sedation, (like the tactical bombing, who knew that civilians will be killed) - He may argue that death was perhaps intended, because in the broad sense he feels responsible even for what was inevitable (the broad sense of responsibility). Otherwise he could argue not intended in the narrow sense because death is only a foreseen consequence, not the purpose (the narrow sense of responsibility). The guilt or moral responsibility depends on which type of intention the physician chooses to stress on, and this will in turn effect the type of expression of intention the physician believes and conveys to others.[77]

Jansen argues that Quill does not disambiguate between the two understandings of intention. As a doctor, he may have offered barbiturates with the narrow intention for his patient to sleep (not death) but got the feeling of the broad intention (of hastening death) which by knowing about it his intention got confused. Jansen argues that other study findings are as well unclear about intention. Not because intentions are unclear but because research interviewers fail to unearth this distinction from their interviewees.[78]

Jansen believes that if a clinician is uncertain about his intentions, he has the moral duty to clarify those intentions, in broad and narrow terms, and of what it is his purpose in acting. Reflection and introspection, what she calls self-examination, is key here.[79] She suggests that in the case of the PoDE, that if the physician is conflicted about his intention in administering high does narcotics, perhaps thinking- 'is it the death of the patient I intend?'. Then, he should abstain form taking that decision himself and perhaps give the patient to another physician.[80]

Jansen continues to disambiguate intentions by switching focus onto another loaded term - the "meaning of actions". The intentions of an action condition the meaning of

[76] Ibid., 23-24.
[77] Ibid.
[78] Ibid., 25.
[79] Ibid., 26.
[80] Ibid., 27.

that action. Two actions that are the same can have different meanings if the intention behind them is different. A lethal dose of medication given to alleviate pain has a different meaning from when a physician intends the patient's death with the same lethal dose. If the physician does not inform anyone about his intentions, the meaning will remain hidden. But if the physician does not clarify his intention than it will be others who will ascribe meanings to his actions based on their speculation.[81]

Many physicians do not wish to kill their patients with palliative sedation. It goes against the moral value of medicine and inconsistent with the role of the physician. Furthermore, the aim of palliative sedation is for pain relief not death. On the other hand, euthanasia is inconsistent with the role of healer. Most doctors would therefore "reject the idea that high dose narcotics to alleviate terminal suffering is intentional killing". If they did not reject the claim it would go against the meaning of their medical practice. It would effect their doctor to patient relationship. In this sense it is by disclosing intention that one can discern between those that are pro-euthanasia and those who are not. In this sense the moral meaning of palliative sedation, the role of the physician and medicine itself, can be known best by knowing intention, more than by setting it in the context of the PoDE.[82] As a matter of fact, Jansen states that the concept of intention can stand alone independent of the PoDE as a moral barometer.

2.3 Sequencing and Proportionality - Reading McIntyre and Sulmasy

In discussing proportionality and cause effect sequencing in the PoDE one needs to refer to the arguments by McIntyre and Sulmasy. Both authors explain why the PoDE cannot be used to justify the rare and extreme cases of palliative sedation. Some alternative moral considerations are provided to justify sedation unto unconsciousness.

McIntyre does not argue against the usefulness of the principle. She argues against those who persist in seeing the PoDE as a sufficient justification in itself for palliative sedation. She explains that in palliative sedation the PoDE is being applied when the two fundamental values of the practice of medicine – the preservation of life, and the relief of suffering - become seemingly mutually exclusive. Here the PoDE is applied

[81] Ibid., 28.
[82] Ibid., 29.

on the basis of the following justification: In the case of the seemingly mutual exclusiveness between preserving life and preventing suffering, palliative sedation is intended, but the hastening of death is foreseen but not intended. She answers with two hypotheses of how this has been justified, and both possibilities she concludes are a misconception of the PoDE. One hypothesis she calls "screening off" death as a consequence. The other is by justifying "instrumental harming" with a faulty application of intention in the PoDE.[83]

By "screening off" death as a consequence, she means that since death is an unavoidable consequence 'justified' by the principle, (death is treated as a constant) some choose to focus only on the relationship between levels of sedation and pain relief - regarding death as an immutable variable. This is obviously wrong because the risk of death is not constant with respect to levels of sedation – at some increasing levels of sedation (beyond titration) and at the neglect of monitoring vital signs, the excess pharmaceuticals will bring death before controlled pain relief. McIntyre reminds us that one of the conditions that has been applied to PoDE is that the agent is not only erroneous in screening off the bad effect from consideration but is forgoing his obligation to actively consider the bad effect and minimize it as much as possible.[84]

Secondly, McIntyre then explains the fault in justifying "instrumental harming" with intention. While the intention-foreknowledge disambiguation (foreseen but not intended consequences) holds because of the correct sequencing of good and evil, it is not a sufficient justification to use the PoDE for palliative sedation.[85] McIntyre argues, that foreseen and intention conditions fail to justify instrumental harming, because the PoDE does not inform us about situations where a necessary harm can be part of the means to a good end.[86] Actually, the PoDE prohibits not intended (as much as intended) harm from being the cause of a good effect. Thus, those that argue that the PoDE clearly justifies terminal sedation by what is intended and foreseen are misinterpreting the principle in the sequencing of good and evil. For instance, she argues, can we justify terminal sedation with the principle if sedation first requires

[83] Alison McIntyre, "The Double Life of Double Effect", 69-71.
[84] Ibid.
[85] Ibid., 68.
[86] Ibid., 67-68.

withholding life-sustaining treatment? Certainly not. It contradicts the sequencing of the principle. Those that do it, do not understand the important difference between intended actions and foreseen side-effects.[87] The difference is the sequence.

The PoDE applicants would say that withholding life support for palliative sedation is not hastening death, because withholding life support is intended to help patients avoid suffering. – not intended to hasten death, but the effect (of death) is foreseen. The equivocation between what is the intention of means and the intention of side-effects is kept unclear. Because withholding support to life whilst not intending death is illogical at best. Truly there is a moral distinction but difficult to articulate it (and certainly not by applying the principle). McIntyre argues that it is impossible to justify it by the PoDE but it is well socially understood – The dentist intentionally presses on our pain, but not to intentionally harm us. The principle however categorically does not allow this reasoning. The Principle does not compensate for cases of benevolent instrumental harming. Even if instrumental harming is intended in the philosophical sense but not intended in the linguistic sense, this disambiguation is not made clear or compensated for by the conditions of the PoDE.[88]

Focusing on one condition as a justification by the PoDE (i.e. the foreseen but unintended) without considering later elaborations and conditions that have been crucial in the development of the PoDE as a moral tool is erroneous. Substantive inquiry of case-contexts is fundamental. PoDE truly asserts that in some cases harm (death) can be justified. But McIntyre points out that the PoDE does not prescribe a justification for us, or how it can be obtained. That justification is obtained from sound proportionality assessment.

McIntyre points out that there are two types of proportionally for the PoDE in palliative sedation. First, that terminal sedation is applied after proportionate consideration of any possibly less harmful alternatives. The second is contextual proportionality - palliative sedation applied in the right context. Administered after checking that all necessary conditions are proportionately weighted so that the treatment can be considered legitimate. What is weighted requires: a true prognosis of

[87] Ibid., 70.

[88] Ibid., 67.

terminal illness, an urgent need, an imminent death (in terms of time), and proper informed consent.[89]

In sum McIntyre argues that PoDE can only be used to justify terminal sedation if life supporting treatment is kept. But if withholding life support is part of terminal sedation to treat palliative care, then it cannot be justified by the principle. Nevertheless, McIntyre puts down a condition for the possible application of the principle just the same. She argues that one can apply the principle "in rare circumstances" of patients who refuse life-sustaining treatment of their own volition, prior to any offer of palliative sedation, and who's pain can only be relieved by terminal sedation. When a patient refusing life-sustaining treatment asks for assistance with hastening his death, a physician can administer terminal sedation that will soothe the pain but may hasten death. In this context, the physician is not instrumentally harming the patient, but merely intends to provide terminal sedation to a patient who has a priori refused life-sustaining treatments. McIntyre points out that this rare context is problematic in itself, on the basis of how can one determine eligibility to terminal sedation. Nevertheless she still firmly believes that the intended hastening of death may be used (rarely) as a means of last resort to relieve great suffering, provided that the proportional conclusion is - there is no other way.[90]

Sulmasy also applies an argument of sequencing on the condition of intention. Sulmasy writes that there are two philosophical meanings of intention. There is "intention-in-acting" and "further intention". Intention-in-acting is limited to the agents' action. There needs to be a certain motivation to execute a process of action. Like the intention to prescribe a drug, this is intention-in-acting. Like putting pen to a prescription book and giving the prescription to the patient, is an action with the intention to prescribe treatment (finis operis). This is different from "further intention" which follows on from the "intention in acting". "Further intention" is the agent's expectation that with prescription in hand the patient buys the medicine, takes it, and that it has the desired effect (finis operantis). Alternative outcomes maybe foreseen but not expected as part of further intention.[91]

[89] Ibid., 66- 67.

[90] Ibid., 70- 72.

[91] Daniel P. Sulmasy, "The Last Low Whispers of our Dead", 10.

Sulmasy is also of the opinion that 'double effect' is at times rejected or applied incorrectly because it is misunderstood. The PoDE for Sulmasy is very similar to McIntyre's understanding, in situations where there is a conflict between moral obligations. A conflict between the obligation of doing what is good and the obligation of not doing something bad.[92] He elaborates the four main conditions by Gury into a set of nine more refined elaborations of earlier philosophers. And his elaborations are supposed to clarify some of the more troublesome applications of the principle.

In the case of morphine use, Sulmasy argues that this provides the classical model of using the PoDE. Unintentional hastening of death with the use of morphine to treat pain in terminal illness is justified by the PoDE, and all the four (in his case nine) conditions are satisfied. The means is morphine (or other analgesic), the intention-in-acting is to administer analgesia, the further intention is to relieve the patient from suffering, and death is foreseen but not intended. The Principle suffices here for the standard use of analgesia-morphine.[93] A second scenario that Sulmasy ask us to consider with the PoDE is when a second drug is used to counteract either the side-effects of morphine such as myoclonus seizures, or delirium which require an adjunct sedative drug. In such cases benzodiazepines (formerly also barbiturates) are added to morphine as treatment. In this case the moral justification backing this application is called – "classical double-effect sedation". Classical double-effect sedation conforms to the principle such that the added means is an anticonvulsant drug, the 'intention-in-acting' is to stop the seizures in the presence of morphine, with the 'further intention' of relieving suffering, and patient sedation is also a foreseen effect, but just as much as death it is only unintended.[94]

However Sulmasy explains that there are a third and a fourth problematic cases which do not conform with the principle but which some proponents argue can be justified by the principle. Quill is one who attempts to justify the practice of parsimonious direct sedation with the PoDE, Sulmasy argues. Parsimonious direct sedation, is a procedure whereby drugs, typically barbiturates are used intentionally to sedate the patient, in such a way that sedation is used therapeutically to dissociate the patient's

[92] Ibid., 11.

[93] Daniel P. Sulmasy "The Rule of Double Effect, Clearing Up the Double Talk," *Archives of Internal Medicine* 159, (1999): 545.

[94] Sulmasy, "The Last Low Whispers of our Dead", 12- 14.

consciousness from the pain and other insufferable symptoms. Quill argues that the practice follows the PoDE because the aim is not the complete suppression of consciousness but just enough altered consciousness to relieve the patient's suffering. The use is proportionate, and the foreseen side-effects of unconsciousness and hastened death are noted but not intended. Sulmasy argues against Quill's reasoning. Firstly because Quill interprets proportionality as weighing various degrees of drug use against various degrees of effect before choosing the most favourably (least consciousness suppressing to most pain relief) commensurate option. This according to Sulmasy is parsimony not proportionality. Proportionality according to Sulmasy is either means-to-end proportionality (feasibility of action to outcome), or end-to-end (proportionality between effects).[95] If anything, Sulmasy explains there is no double effect in parsimonious direct sedation, because sedation precedes all other effects, and pain-relief and hastened death are the effects of the effect. This disagreement between Sulmasy and Quill depends on whether one considers sedation as an effect of a drug (for Sulmasy the drug is the means), or sedation not as an effect but as means - an intention-in-acting leading to a double effect (Quill's position). Sulmasy explains that Quill runs into some trouble in trying to justify sedation with the PoDE. When Quill distinguishes between sedation where consciousness is kept and sedation to unconsciousness (as two effects), it is a parsimonious distinction, but not a proportionality distinction between two effects, as the two are essentially the same effect with variants of intensity. Parsimony does not help here as a justification for double effect (only one variable of varied intensity not two). In addition Sulmasy points out that it does not make a difference whether one considers sedation as a means or as an 'intention-in-acting', as the cause leading to a "causal fork", because sedation in itself is neither good nor neutral, and as an action it defies the condition of the principle wherein the double effect cannot be brought about by an evil act or a pre-effect to a double effect.[96]

The fourth situation that Sulmasy asks us to consider is the application of Double Effect in sedation to unconsciousness and death. Here, Sulmasy argues that if parsimonious sedation cannot be justified by the principle, then it should be obvious that maxing up the dose to sedation to unconsciousness until death should obviously

[95] Ibid., 16.

[96] Ibid., 17- 19.

be unacceptable by way of the same erroneous cause-effect sequencing argument for parsimonious sedation. And in any case such sedation not only violates the PoDE it also violates the canons of parsimony and restoration.[97] Nevertheless, like McIntyre, Sulmasy believes that there may be case where going straight to palliative sedation maybe the only resolve. However these cases are very rare. Sulmasy can think of a few rare instances where pain has taken over the neuro-cognitive function of the patient completely, such that this suffering takes over the patient's consciousness completely as well. This would be a case where the only solution would be to dampen consciousness (a 'forced choice'), which should abide by the canon of parsimony but not to be justified by the PoDE.[98]

Conclusion

In sum, the principle of double effect forces us to re-examine the complexity of good and evil at play in deciding over a clinical course of action. While it would be convenient to advise professionals to abstain from any action that causes evil, we know that this is not pragmatically possible. Nearly every clinical action involves unwanted side-effects. In some instances, the treatment doesn't seem to be worth the ordeal of its side-effects (consider chemotherapy). Then again, not going forward with what could benefit our patients in the long run, to appease our conscience by not running the risk of cooperating in evil, spirals down to (James 4:17): abstaining from doing what you know is ultimately right, is still evil. Not going forward with administering palliative sedation for fear of causing an evil (i.e. death) is considered an evil as well.

This is because knowledge fundamentally holds clinicians responsible and accountable. They can foresee (prognose) outcomes not because they know the future, but because they know what should happen. And they know that risk and harm are inevitable, that sacrifice and expense is always part of the process, whichever way the clinical pathway leads.

But the PoDE causes us to consider two things: what is the acceptable balance between good and evil? (questions of proportionality) and how can we know that

[97] Ibid., 18- 19.

[98] Daniel P. Sulamsy, "Sedation and Care at the End of Life," *Theoretical Medicine and Bioethics* 39, no. 3 (2018): 176.

actors aim for the good in the Double Effect? (questions of intention). These remain central problematic issues for the principle. With proportionality, the problem is greater than weighing the pros and cons of effects, as many interventions start with an ethical handicap at the outset - harmful (invasive) actions preceding both the good and the bad side-effects. For this reason some ethicists reinvent proportionality for the principle by taking into account the permissibility of harmful actions vis a vis the good effects as well.

With this interplay of variables, between actions and effects, the acceptability of clinical interventions carries with it a substantial degree of subjectivity. Some may consider palliative sedation as a causal fork of pain-relief and death. Alternatively it can be seen as a causal sequence - with increasing sedation, pain is relieved, but with an increasing risk of death. Here, knowing what is being intended in sequence becomes even harder to assess.

Many resort to condone or condemn actions based on clinicians' intentions, even at law. Intention is central to the PoDE. So important and just as much difficult to ascertain, and in some instances death (at least a good death) has been deemed a good intention as well. For this reason, Sulmasy warns that PoDE only makes sense within the Christian morality of the preservation of life. Despite the arguments of 'broad' and 'narrow' intentions, commentators do not deny the possibility of clinical ambiguity. Suffering has an emotive influence on our judgments and it is a Christian phenomenon that we do not necessarily do (or don't do) what we should (Romans 7:15). This applies to anyone as much as it does to clinicians.

In the following chapter alternative modes of thinking will be explored with regards to palliative sedation, and how they hold up to the PoDE as a tool for moral clinical decision-making. With all the arguments that emerge from the literature about double effect and palliative sedation, one can see (perhaps not at once), that the PoDE cannot be applied piecemeal to the ethical defence of palliative sedation. Each of the components of the PoDE are extremely important to consider, but a legalistic application of the principle would denounce the practice of palliative sedation almost from the start. These authors encourage physicians to see the principle as a reflective ethical checklist, rather than a prescriptive ethical guideline in dealing with extreme cases.

Chapter Three:

Alternative Ethical Theories

Since we know that the PoDE does not fully answer all the issues regarding palliative sedation, we will now move to alternative epistemologies that may help us to address some of these issues. These alternatives can be grouped into two categories being: moral theories, and legal or behavioural frameworks. Moral theories discussed will include the principle of proportionality, the principle of lesser evil, utilitarianism/ consequentialism, deontology, principlism, situationism, triple font theory, the re-invented rule of double effect and the five canons of therapy. Legal and behavioral frameworks will include distributive justice, social contract theory, deliberative democracy and the theory of casuistry. All of these epistemologies need to be compared and contrasted with the PoDE for ethical deliberation on the subject of palliative sedation, and to determine whether one is superior, inferior as an adjunct or a substitute to the principle in addressing the dilemmas of treating intractable pain.

3.1 The Need For Different Alternative Ethical Views

Undoubtedly, end-of-life decision-making can be quite complex and ambiguous, and sometimes it can be more helpful to make use of additional moral frameworks in order to take sound ethical decisions. As people living in a pluralistic world (sometimes referred to as relativism), we should at least consider the different perspectives of all the existing moral frameworks within our reach. The deliberation over several alternate views is part of the work in reaching a consensus over which ethical framework is best suited to address a moral dilemma. Bearing in mind that discerning and choosing from several ethical perspectives also depends on the person's beliefs and values, rooted in the individual's culture.

Billings and Churchill argue that relying solely on the Principle of Double Effect or the 'four principle approach' by Beauchamp and Childress (autonomy, beneficence, non-maleficence and justice) can become a stumbling block in achieving sound ethical deliberation.[99] Literature regarding palliative sedation and other terminal procedures base their arguments on these two principles. This lack of moral pluralism

[99] Billings and Churchill, "Monolithic Moral Frameworks", 709-710.

can lead to a bias, as only one line of taught is being considered, discounting any other epistemologies. This narrow mindedness hinders the "reflective equilibrium", which one is expected to have.[100] Using various ethical approaches would force the individual not to rely solely on a single ethical framework. New ethical challenges emerge everyday, especially in the medical field and keeping an open mind will provide the individual with additional moral perspectives and additional tools to build better arguments and to be able to reach the most appropriate consensuses according to the particular dilemma. The demand for additional ethical approaches has been growing with expanding fields in medicine, research and policies. Fresh ethical perspectives are required to deal with the complex formulation of guidelines for decision-making in newfound areas of medicine. Hence, the following section will present alternative ethical views regarding palliative sedation.

3.2 Moral Theories

3.2.1 Principle of Proportionality

The Principle of Proportionality may not be considered as an ethical theory per se, but perhaps it is more suitable to classify it as a development of the PoDE's fourth criteria. Hermeren fleshes out proportionality into three categories namely, the "importance of objective", the "relevance of the means" and the "most favourable option". The "importance of objective" refers to the intended (end) goal of what is desired in a given situation. If high risks are involved in achieving the goal, the desired end has to be of superlative value. For example the acceptability of administering a drug under trial having severe side effects but also promising to be a cure for a persistent disease. But if the drug in question possesses minimal benefits in comparison to the ordeal of its side-effects, then the administration of this drug cannot be morally justified. The second condition, "relevance of the means" targets the means of the action. The means (the action) has to bring about the intended goal, not partially fulfilling it, or leading to a secondary goal. The third and last condition,

[100] Ibid.

"most favourable option" refers to the only possible option, with the minimum possible risks but at the same time fulfills the goal.[101]

Furthermore, Hermeren adds a fourth condition to refine this principle, aiming at 'non-excessiveness'. The moral application for this principle is between ends and means and that certain 'proportionality' between them should be present. If a person is exposed to high risks (hastened death by palliative sedation), the intended outcome should be equally important (palliation of refractory symptoms), enough to risks such bad side-effects otherwise it is difficult to justify the use of sedation. The author implies that this ethical guide should be used flexibly according to context and case. For example the moral belief that 'killing is always wrong' is generally seen as a universal value. However, this cannot always be applied for wartime politics. The same applies for withholding futile treatment, it is not killing but simply acknowledging the limits of medicine and oneself as a physician.[102]

Each of the three mentioned pose their own problems and ambiguities. For example, the importance of objective is not considered the same for everyone. Although the goals of medicine may somewhat be agreed upon, such as maintenance and restoration of health and the cure of diseases, these goals may evolve and may even be contradictory. For example prolonging life in palliative patients with extensive measures can be considered as cruel and an enhancement of suffering. The problem with the second condition is that there is no guarantee for the means to truly achieve the intended end. Especially in research medicine, the goal can be achieved with a particular means. However, goals can change and new means can be created. The goals of medicine in palliative care shift from providing cure to the management of refractory symptoms. The last condition ("most favourable option") is also laden with problems. Individuals may hold different views regarding a particular risky action and several (equally risky) actions may all lead to the intended goal.

Furthermore, there is a problem with how these risks are interpreted and measured. Hermeren proposes the fourth condition to answer this predicament, but to measure and restrict excessiveness can become problematic. Several aspects are taken into

[101] Goran Hermeren, "The Principle of Proportionality Revisited: Interpretations and Applications," *Medicine, Health Care and Philosophy* 15, (2012): 373-375.

[102] Ibid.

consideration such as costs, risk-benefit ratio, and level of harm, and these can all contribute to the complexity in deciding proportionality.[103]

Due to these shortcomings, this principle may not be enough for certain moral predicaments. But proportionality regarding means and ends leans towards following a Utilitarian point of view, depending on what or who's benefits are prioritized. Nevertheless, proportionality should be useful in the evaluation of advantages and disadvantages for research ethics and medical treatment, to compare the means and ends with the involvement of values. The key here is values and not human rights. Because values can be ranked for their importance, but human rights are all equally important. The principle of proportionality can be used to evaluate which value supersedes another in moral dilemmas - the gravity of reason requires some form of ranking of moral values. In the case of palliative sedation, the value of alleviating pain is more important than avoiding hastened death. Nevertheless, the problem of ambiguity in clinical intentions and which values shall supersede the others will remain.[104]

3.2.2 Principle of Lesser Evil

Cellarius implies that the Principle of subsidiary (lesser evil), and proportionality can be applied when inducing deep continuous sedation is required for patients with longer life expectancy (more than two weeks), and not just for those in the acute dying phase. If the benefit of palliative sedation proportionately outweighs the risk of hastened death, doses of sedation can be titrated parsimoniously to the minimum requirement of the patient. But if there are no other options, then palliative sedation can be started prior to two weeks of life expectancy, even if a hastened death is foreseen.[105] This is because, as mentioned before, several guidelines do not specify a concrete life expectancy. They simply hint at a tentative time frame for end of life stages, and the length of a terminal phase. Therefore, if refractory symptoms can only be managed with palliative sedation, even though the patient is not in the dying phase, one can apply the principle of lesser evil instead of justifying it with proportionality,

[103] Ibid.

[104] Ibid., 381.

[105] Victor Cellarius, "Terminal Sedation and the Imminence Condition," *Journal of Medicine Ethics* 34, (2008): 71 -72.

because proportionality requires knowledge of the end of life time frame. Thus, for a patient in unbearable pain, who is terminal but still has a prognosis of more than two weeks (the bigger evil), can be given palliative sedation to alleviate pain with a foreseen chance of a premature death (lesser evil). Even though it may sound as 'euthanasia by other means' due to the impending repercussions of palliative deep sedation such as dehydration, the inevitable death is foreseen either way. Despite the seemingly premature (before the last two weeks) harsh intervention, administering palliative sedation in order to manage intractable pain would be the most humane thing to do.

However, applying this principle solely on the basis of what one believes to be the lesser evil can nonetheless be dangerous. Culture, religion, social obligations and personal values can manifest as different moral views for different persons. Hence, what one believes is the lesser good may not necessarily be considered the same for everybody. Therefore, even though one is able to classify evil, for example anything that causes pain, sickness or death however, the problem still persists. For example withholding palliative sedation will keep the individual in pain but administering palliative sedation may hasten death (two evils). There is no guide that determines which evil is the lesser evil and choosing oneself which one classifies as the lesser evil is problematic as the answer is not static for every individual.[106]

The proportionality in PoDE provides the most stringent criteria. But the proportionality according to Hermeren allows more room to decide which action bring less harm without it being biased by the physician's intent. Proportionality is more suitable when applying it to the case of palliative sedation, and a number of authors have drawn considerable attention to its varied interpretation and application for the PoDE. But when proportionality is inconclusive, the principle of lesser evil may be the last resort to which one recurs when either outcome options are pernicious in some way.

[106] Georg Speilthenner, "Lesser Evil Reasoning and its Pitfalls," *Argumentation* 24, (2010): 141.

3.2.3 Utilitarianism and Consequentialism

Utilitarian theory is viewed as a personal morality that supports the idea of maximizing happiness for the greatest number of people. Hence, a good person is performing the right action based on how much the outcome would make the most individuals happy. A good society is one that goes at lengths to fulfill this concept. When the person achieved satisfaction from the preferred action of his, it is said that "happiness, or utility is maximized". Consequentialism focuses more on the greater good, but not necessarily for the greatest number of people. Consequentialism uses a commonsense type of reasoning in order to judge the ethical aspect of the action. This enables the person to achieve the best possible outcome with the best consequences. Instead of basing their right or wrong decisions on a deontological view, both consequentialism and utilitarianism claim that an action is efficient in practice according to the best outcome of the action. This is how consequentialists justify their theory by claiming that in the end, it is what everybody wants; the best outcome.

Taking a consequentialist perspective, administering palliative sedation to relief refractory pain is acceptable even though it may lead to a hastened death. Churchill and Billings imply that this ethical view considers the eventual outcome with or without palliative sedation the same, which is a welcomed unavoidable death.[107] If this outcome is accepted by the individual, so should be the means, in this case palliative sedation. However, this argument cannot be applied exactly for utilitarianism as it does not involve the maximum happiness for society. Palliative sedation can be justified with utilitarianism when considering a scenario where it is painful for the family members to watch their loved one suffering and going through a prolonged death. In such case, palliative sedation to unconsciousness is justified as it leads to the greatest happiness of society and the family members.

Utilitarianism or consequentialism is not an acceptable ethical framework especially from a Christian point of view. This framework can lead to an abuse of palliative sedation deliberately to achieve the greatest societal happiness by freeing up hospital beds for other 'essential' use, or by safeguarding resources which otherwise would be 'futile' for palliative patients. This would breach ethical conduct and essentially can lead to actions that the PoDE tries hard to eliminate. Therefore, the use of the PoDE

[107] Billings and Churchill, "Monolithic Moral Frameworks", 711.

provides more weight on moral values of actions and the outcomes, which in the case of palliative sedation is key to the practice. Even if by utilitarian means the outcome satisfies the happiness or the greater good, it still does not address or solve the problem of how clinicians feel or react towards administering something that is potentially lethal in doing something good.

3.2.4 Deontological / Kantian View

Kant talks about the "perfect duties" (the Don'ts) that preserve the moral law, for example 'thou shall not kill', and the 'imperfect duties', referring to virtuous actions that one should apply to act morally. Imperfect duties give leeway to the agent to reach the target 'maxim' with practical judgment according to one's own culture, religious and social background. Some duties may conflict with each other however, and there is always a rule with a moral obligation that surpasses another. One particular "perfect" duty that exceeds any other 'imperfect' conflicting duty is the duty of self-preservation.[108] According to Hasselaar, continuous deep sedation aligns with Kantian ethics because it preserves such duty.

The suppression of consciousness due to palliative sedation may be interpreted as an action that goes against the duty of self-preservation according to a deontological view. However, with palliative sedation free will is not eliminated but merely suppressed. Self-preservation is the duty to preserve one's own body and free will. Free will is only possible through the body therefore; destroying one's own body is prohibited. Inducing unconsciousness due to palliative sedation preserves the ability to make rational decisions and free choice however, it cannot be expressed and this cannot fall into the same category as voluntarily destroying one's own body. On the contrary in euthanasia, one would be using himself as a means to alleviate pain and this goes against the moral law of treating oneself and others as an end, not as a means.[109]

[108] Jeroen G. J. Hasselaar, "Palliative Sedation Until Death: An Approach From Kant's Ethics of Virtue," *Theoretical Medicine and Bioethics* 29, (2018): 392.

[109] Ibid., 389-391.

When palliative sedation causes unconsciousness it may be considered that it violates the duty of self-improvement. One has the duty to cultivate the abilities of oneself and of others in order to treat humanity as an end. However, there is no place for enrichment and self-improvement of one's moral character when one is unconscious. The author argues, similarly to Sulmasy[110] that when the progressiveness of the disease escalates to a point where there is already no room for self-improvement, for example unreversible delirium, palliative sedation can be given as it is the disease that inhibits the ability to fulfill this duty and not palliative sedation.[111]

It is important to note that Kantian ethics was created in the 17th century, prior to the current complexity of palliative sedation. Certain Kantian facts such as 'above all else do no harm' are contradictory in today's medicine because in order to treat, some form of physical harm is unavoidable. Therefore, when applying such ethical theories in practice it is important to cater for this fact. If such a statement (that one shall never do harm) is taken literally in medicine, it can alter the actual intentions of deontological ethics; the duty to heal, alleviate pain and acknowledging futile treatment.

One can see that Kantian ethics consider similar moral rules and values to the PoDE. Both ethical perspectives attempt to condone palliative sedation to unconsciousness as a last resort when no other safer alternatives are present. Both have strict criteria or duties in an attempt to eliminate possible abuse or ulterior motives with sedation but at the same time acknowledge the need for contradictory treatment in hard cases.

3.2.5 Principlism

Lindridge claims that there are four principles that make up principlism; autonomy, beneficence, non-maleficence and justice, and these can be used as an ethical framework by promoting deliberative decision-making. In fact, if principlism is used unerringly it would not promote ethical deliberation. The combination of these values helps to avoid rash, emotional decisions and incorporates all the necessary information required on the subject which otherwise might be mistakenly neglected. A major criticism of this framework targets the conflicting principles that might result

[110] Sulmasy, "The Last Low Whispers of Our Dead", 21.
[111] Hasselaar, "Palliative Sedation Until Death", 392.

when ethical decisions are complex or the complexity of understanding the principles themselves. Lindridge counter-argues by claiming that in such cases, "specification" has to take place.[112] According to Beauchamp and Childress, this refers to the need to re-examine the "range and scope" of the principles in question. New terms or better refinement of the principles for clarity can be established.[113]

When specification fails to give an answer, "balancing" is the next step to take in an attempt to resolve conflicting principles. Six conditions are proposed by Beauchamp and Childress, which can guide the agent through this moral dilemma by comparing and assessing the strengths of the conflicting principles. These include; a better justification for the agent to act on the 'better' principle, the violation of a principle would lead to better chances of reaching the goal, the agent has to choose the principle which will cause the least negative effects in order to achieve the goal, the agent has to minimise all the possible bad effects of this violation, the violation of a principle is possible only because there is no other better alternatives present and the agent's decision should not be effected by any external influences.[114] These conditions aid the agent to go through the process of ethical deliberation and avoids taking hastened or intuitive decisions. It is interesting to note that these conditions incorporate the criteria of the PoDE. Hence, principlism can be seen as an elaborated extension of the PoDE when "balancing" has to be done to find an ethical solution for hard cases.[115]

Lindridge and Billings claim that including other moral theories together with principlism is advised. This is especially necessary when deciding which principle has to supersede the other, since even with the mentioned six conditions, one can still make an inappropriate, intuitive-based decision. In addition, it is difficult to 'balance' principles such as conserving dignity, respecting religious beliefs and personal values as well as maintaining autonomy.[116] Unfortunately, principlism does not elaborate on what conditions a principle should be chosen over another and the reason why.

[112] Jacqualine Lindridge, "Principlsim: When Values Conflict," *Journal of Paramedic Practice* 9, no.4 (2017): 158.

[113] Thomas L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, Seventh Edition (Oxford: Oxford University Press, 2013), quoted in Lindridge, "Principlsim", 159.

[114] Ibid.

[115] Lindridge, "Principlsim", 159.

[116] J. Andrew Billings, "Double Effect: A Useful Rule That Alone Cannot Justify Hastening Death," *Journal of Medical Ethics* 37, (2011): 439.

Furthermore, this can become subjective according to the agent. The author presents a solution for this problem with the use of the virtue theory. A virtuous agent would ensure that ethical deliberation would lead to a virtuous ethical decision. Applying this understanding for the case of palliative sedation, the principle of non-maleficence and beneficence conflict each other. If one follows the principle of non-maleficence, palliative sedation is not appropriate as it causes unconsciousness and may lead to a hastened death but according to beneficence, in patients with refractory pain it is indicated. A virtuous person would deliberate over the situation accordingly, follows the six rules and in this case, decide which principle supersedes the other. The problem with virtue theory is that not every individual heeds the same virtues. Relying on the physician's morals might not always be the best choice.

It is important to note that autonomy is sometimes treated as a superior principle over the other principles. [117] However, Lindridge claims that autonomy should be given an equal importance as the other principles. Autonomy can be conflicting to other principles such as beneficence. If the patient is not in a position to make an autonomous decision, the physician has the right to act beneficently and take the decision himself in the best interest of the patient. On the contrary, in palliative care when someone refuses treatment that does not offer any guaranteed benefit or false hopes, the individual is not undermining beneficence and it should not be considered as suicide. On the same concept, if the physician abides with such a decision, it is not considered as a morally wrong action. In such a situation, the patient is choosing to die peacefully by avoiding disproportionate, futile treatment, which goes against the principle of beneficence and human dignity. Taking such a decision may be considered as exceeding the limits to the rightful control over one's own life however, when the patient is informed, fully aware of consequences and there are no underlying mental health illnesses it should be accepted by the physician and family. [118] According to Christian morality, one should always choose actions that prolong life.

[117] D. Callahan, "Principlism and Communitarianism," *Journal of Medical and Ethics* 29, (2003): 289.

[118] Emmanuel Agius, *Problems in Applied Ethics* (Msida: Publishers Enterprises Groups, 1994), 25.

However, this statement does not apply for end-of-life cases and therefore withholding futile and burdensome treatment is not immoral.[119]

3.2.6 Situationism

Smith describes situationism as an ethical guide that isolates the principle of beneficence and interpret it as the virtue of love as the only criteria for moral discussions and decision-making in ethics. Any moral dilemma that requires a 'caring attitude' such as mercy, compassion, benevolence and love, should be acknowledged as a valid ethical rational to make a moral decision. In contrast to priciplism, one has to place love as the superior principle over other principles and law to make moral ethical choices. Ethical dilemmas are dealt with rationale and decisions are taken based on the most 'good' with the aim of humanity, welfare and mercy rather than absolute moral standards. What differentiate it from utilitarianism is the fact that in situationism, 'the greatest good' does not refer to pleasure and to the maximum quantity in fact, 'good' can be self-sacrificial and expensive. In situationism, palliative sedation to unconsciousness is compassionately administered in end of life care even though it can lead to a hastened death. It can answers ethical dilemmas that the PoDE does not, for instance; treatment that becomes futile, unethical, provides loss of dignity, financial burden, unnecessary effort and emotional trauma on both the patient and the family can be withheld according to situationism. Love is equal to justice according to this framework however love should always triumph over law when in conflict because "to love God in the neighbor" is the only universal ethical norm. [120]

Similarly to other ethical principles and theories, a criticism for situationism is the interpretation of 'love' and compassion. A physician can feel empathic to a terminally ill person requesting euthanasia and can claim that it is a compassionate act to terminate such pain. In this aspect, although ambiguity in intention remains in both frameworks, the PoDE stringent rules may be more suitable for the application of palliative sedation to unconsciousness for refractory pain management. With

[119] Gilbert Meilaender, "Comforting When we cannot Heal: The Ethics of Palliative Sedation," *Theoretical Medicine and Bioethics* 39, no. 3 (2018): 212.

[120] Ibid., 50-51.

situationsim, one can abuse sedation and it can lead to physician-assisted death with the claim of a compassionate act.

3.2.7 Triple Font Theory

This theory identifies three criteria: the moral goal of the action, the intention of the agent and the results including consequences of the action. The action is based on Thomistic ethics i.e PoDE, virtue, material cooperation as well as personal views.[121]

The repercussions of having several ethical theories results in a problematic situation where the agent can become confused as to which theory one should use for a particular dilemma. Furthermore, different ethical theories lead to different ethical choices and results. The TFT is a moral theory that incorporates several other moral theories or principles in an attempt to create a holistic theory that can be used for decision-making. It is derived from the PoDE, formal and material cooperation in evil, rights and duties, virtue theory and practical judgment. The latter is a necessary component needed in order to be able to take the right ethical decision by incorporating all of these aspects accordingly. Arjoon attempts to create a theory which not only is able to create a moral evaluation, but one that can give a holistic account and reveals moral acts and actions that has to be taken by incorporating several ideas from different theories.[122]

When considering the moral object, i.e what action to do, rights and responsibilities have to be taken in consideration as these directly influence the rightness and wrongness of the action. In theory, these do not conflict as the stronger duty/ right prevails over the weaker ones (although the author does not distinguish which duties or rights are superior than others). Conflict will arise when one claims a right for an action. For example, wanting palliative sedation and one who claims the right to refuse (the patient not being eligible). Here, practical judgment of the situation should take place. The problem is that practical judgment is also subjective.[123]

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[121] Surendra Arjoon, "Ethical Decision – Making: A Case for the Triple Font Theory," *Journal of Business Ethics* 71, (2007): 395.

[122] Ibid., 395- 396.

[123] Ibid., 397- 398.

Personal intention is the motive that determines if one commits an evil or good. The author; Arjoon, implies that the goodness or evil is found within the agent's "internal act of the will" for example one who aims for killing but fails to do so, from a moral point of view the individual committed an evil. Of course the level of evil is more severe if the external act is committed, in this case killing. The same goes vice-versa. If one's intentions to do good but fails to achieve this outcome, there is less good in one's conduct than a person who manages to achieve it. Here, co-operation in evil matters in evaluating the level of good and bad. Direct co-operation is categorized in the form of immediate participation, collaboration and omission. The latter refers to when one has the power to stop the evil action but does not do so or fail to surface the illicit act with the aim to conceal it. Formal co-operation in evil is always wrong as it involves direct participation while material co-operation is evil to a certain point. It considers remote and proximity aspects of the illicit action and it cannot necessarily be intended as one can participate in the evil act remotely be performing an act which is not evil in itself. One can evaluate whether an action if formal or material if the agent does not intend the whole situation, if the participation of the agent is not in itself illicit and if there is a proportional justification for the co-operation to occur. If all three conditions are fulfilled it is material co-operation if one of them is not fulfilled, it is formal. Hence, when one has to consider practical judgment, this is not solely based on what one wishes to do, as these criteria have to be fulfilled to ensure that the action is good.[124]

Circumstances refer to the elements that affect the morality of the actions. These are 'accidental' as they affect the act and results but humans do not have any power to control them. These circumstances include for example the person performing the action, the time of the action and the setting where it is being held. For example different physicians might have different ways to achieve palliative sedation for pain relief furthermore, this differs from one country to another. Although it may seem that circumstances may alter the objective, it should not. However, the author considers two factors where circumstances can affect the result. These are "aggravating circumstances" where the result is either damped or heightened in a good or a bad way and "specifying circumstances" where the introduction of another element can change the act, hence it is no longer "accidental". For example in palliative sedation

[124] Ibid., 398- 399.

this is done with the addition of a new drug that can potentially change the way sedation is delivered or how it works.[125]

The TFT includes also the PoDE where as discussed in the previous chapters, although it has several problems associated with it, as implied by Sulmasy and Arjoon, it can be used for 'hard cases'. As discussed, the PoDE has strict criteria and the problem of difficulty to distinguish intentions from foresight as well as the complexity and ambiguity of intentions and the repercussion of confusing the physician, from causing death and letting it happen. However, the author implies that the PoDE can be helpful when one meets conflicting duties. i.e the duty to relief pain, the duty to heal and the duty not to kill.[126]

According to the virtue theory, what makes a person moral or in this case virtue are certain human qualities and characteristical traits that are learnt and practiced. It is believed that these qualities will help to shape the person to take moral and ethical decisions in the right, virtuous way. Since virtues are personalized and it focuses on individual's own actions it can help in creating diversity in decision-making. The author describes two components that should form virtue theory. The first is to differentiate between "moral virtues" for example justice, benevolence, courage and discipline and "intellectual virtues" such as practical judgment. The moral virtues drive the intellectual virtues to achieve the moral goal. The courage and justice to administer palliative sedation despite its risks is what drives practical judgment in how to act correctly and not hastily or irrational, in order to achieve the goal. The second distinction applies for general virtue acts in general. One has to distinguish "virtue acts from an act that is virtuous". For example, a protocol that suggest palliative sedation at any request (PAS), does not mean that one is being virtue by obliging with it and obeying the hospital and country's laws. Therefore, the author suggests that the best way to include virtue theory is with a principles-based theory approach. It should not be a matter of what is the right thing to do but taken from a perspective of what a virtuous person should do to be morally "good".[127] However, a persistent criticism of this theory is the fact that what one believes is right does not necessarily have to be moral. Different cultures hold different virtues and different

[125] Ibid., 399- 401.
[126] Ibid., 401- 402.
[127] Ibid., 402- 404.

virtues can become conflicting. Virtue theory fits in the TFT as the virtuous person acts responsibly and with practical judgment to determine the good goal (moral object). The means to achieve the goal is not for any personal gain or other ulterior motive but only because it is the most virtuous action to do (personal intention). Lastly, a virtuous person understands the implications of such actions and with practical judgment the agent is able to perform the action in the right time, right place and involving the right people (circumstance/ consequence).

As mentioned briefly before, in order to make a moral ethical decision, one has to develop practical judgment that enables the agent to decide what is the most virtuous decision to take according to the case. Obviously the agent should be well knowledgeable about the subject. Having led a prudent life, the author implies that the agent would automatically be able to make a sound practical judgment and be able to take 'good' ethical decisions. According to the author, Fowers describes three characteristics of practical judgment that are necessary for a virtuous person. These are moral perception; which determines what virtues ought to be included in a given situation, deliberation; where one determines how to answer the ethical problems of the situation in order to reach the goal and lastly determining what is the best ethical framework to use to reach the intended goal.[128] This is not an easy feat and developing a virtuous practical judgment requires experience and not being stubborn to learn from one's own mistakes.

From this theory we can conclude that additional ethical frameworks may be necessary to use in adjunct to the PoDE. Other theories or principles such as virtue theory, practical judgment, cooperation in evil and the principle of lesser evil as one may add can all be used to cover their own shortcomings and ensure that the best moral decision-making is ensued. The TFT can be applied to justify the use of palliative sedation in the terminally ill. However, it still holds several problems such as subjectivity when relying on practical judgment and virtue ethics.

3.2.8 The Re-invented Rule of Double Effect

Sulmasy has proposed a new set of criteria that are more specific and concise in a tentative way to improve the PoDE. The following are the proposed criteria;

[128] Ibid., 404- 406.

If one encounters a conflict between a specific duty to do good and one's general duty to avoid evil, and

1. This conflict arises from one intentional act with at least two foreseeable effects;
2. The act itself is either morally good or morally neutral;
3. The conflict of duties arises because intentionally bringing about one effect is morally good while intentionally bringing about another effect is morally bad;
4. All other reasonable means of achieving the good effect with less risk of causing the bad effect have been exhausted;
5. The good and the bad effects are not foreseen as coming about by way of intervening agents;
6. One's prior intention is to act in such a way that one's intention in acting is to bring about the good effect while the foreseen bad effect is not part of one's intention in acting;
7. One is sincere and rational in one's report of one's complex prior intention, such that, at the very least:
    a) The intended act itself is not an alternative definite description of the bad effect;
    b) The good effect is not an alternative definite description of the bad effect;
    c) The bad effect is not wholly spatiotemporally contained within the intended act itself;
    d) The bad effect is not wholly spatiotemporally contained within the good effect;
    e) The intended act does not entail the bad effect logically;
    f) The good effect does not entail the bad effect logically;
    g) The bad effect is not one's further intention in so acting;
    h) The bad effect is not an empirically necessary causal condition for the good effect;
    i) One does not intend the good effect by way of the bad effect;
8. The act is undertaken with due proportionality, which is to say:
    a) The good effect is proportionate to the bad effect;
    b) The means under consideration are proportionate to the expected effects,

Then one is morally responsible for having undertaken the act with due diligence, in accordance with this rule, and in this sense one is morally responsible for all of the good effects and bad effects of the act one has undertaken intentionally. But one is not morally culpable for having brought about the bad effect of the act.[129]

Although it provides a clearer understanding, the RRDE constricts the applicability. Sulmasy claims that the RRDE is more precise and permits the justification of hastening death with palliative sedation while at the same time prohibiting euthanasia. However, he explains that the usual traditional application of the PoDE in certain situations fails to be justified under the RRDE. For example the application of the RRDE cannot be used to justify the removal of a fetus from a fallopian tube to save the mother's life. Sulmasy claims that in ectopic pregnancy, this procedure is essentially still an abortion. Although abortion is merely a foreseen effect of the tube removal, according to the RRDE, rule 7b and 7d, removing the tube is an alternative way of saying 'removal of the foetus' (7b), as the foetus at this point is part of what is

[129] Daniel P. Sulmasy, "*Reinventing" the Rule of Double Effect,* in Bonnie Steinbock, *The Oxford Handbook of Bioethics*. (Oxford: Oxford University Press, 2007): 119-120, quoted in Anna Lindblad, Niels Lynoe, and Niklas Juth, "End-of-Life Decisions and the Reinvented Rule of Double Effect: A critical Analysis," *Bioethics* 28, (2014): 376- 377.

removed, and violating (7d) 'the bad effect is wholly spatiotemporally contained within the good'.[130]

Therefore, this RRDE re-arranges the limits set by the traditional PoDE and re-describes the permissibility of actions that might cause ambiguity between intention and foresight. For example one cannot think or say that the bad effect is not the intention if by performing the act, the bad effect is a known consequence of the good act (if the person is aware). The RRDE does not allow the good effect – saving the mother's life being disguised under an alternative method of the same chain of events. In this case by removing the diseased tube. Therefore, Sulmasy shows us that the RRDE is not as generally applicable as it is thought to be. In such cases as the named example, such justification needs to be redirected under a different ethical justification. However, the RRDE can still be used to justify the use of pain relief in the form of palliative sedation with a foreseen possibility of a hastened death. When administering pain relief with a chance of respiratory depression that can hasten death, Sulmasy implies that they are two separate events hence it is allowed to give analgesia such as opioids for pain relief. However, it is necessary to have a "conscientious and rational physician" as one should never will the bad effect as well as the good effect. [131]

Lindblad, Lynöe and Juth argue that the RRDE does not address the moral gap that it is aimed for. Although it is superior to the traditional PoDE, it does not provide an accurate moral difference between palliative sedation and euthanasia. The authors attempt to challenge the RRDE that deems it wrong to aim for evil and that it is wrong to use someone just as a means. These two aspects fail to be implemented in some cases. The authors present two examples to demonstrate that the RRDE does not give a moral difference between palliative sedation and euthanasia. The first example is when a physician needs to alleviate pain and treat myoclonus (a refractory symptom). The RRDE and the traditional PoDE allows the titration of sedation to achieve pain relief and control myoclonus, even though as a side-effect unconsciousness was achieved and the patient died a few days later. However if a patient request to be deeply sedated to treat pain and myoclonus, omitting the part of titrating sedation, if

[130] Lindblad, Lynoe, and Juth, "End-of-Life Decisions and the Reinvented Rule of Double Effect", 369.

[131] Ibid.

the physician complies, according to Sulmasy "there is intention in acting" because sedation was intended. Therefore, it becomes physician-assisted death (PAD). However the authors imply that in both cases, sedation is achieved and foreseen side effects are present in both cases, and the aim is to treat pain and myoclonus. Even though in the second case palliative sedation is a means, to achieve the end (sedation), it does not exert a moral pull. Furthermore, if the physician refuses to give sedation when requested, claiming that it is PAD, or that it is not a refractory symptom at that point, it would be more morally problematic. If pain increases to the point where it is unbearable, the patient would be coerced into receiving benzodiazepines instead of sedation. Although it aligns with the RRDE, it is not morally superior.[132]

The traditional PoDE and the RRDE always put the notion that killing is always wrong. However, as explained by Boyle in the previous chapter, it is not always wrong to aim for evil For example preventative mastectomy or amputation of a gangrenous limb, here harm is the actual treatment. Although one may argue that it is morally different from killing someone, hence the RRDE does not apply, the authors want to challenge rule 7h 'the bad effect is not empirically necessary causal condition for the good effect'.[133]

The authors imply that the RRDE does not let others become a 'means' to the ends (benefits of others). The authors contest this statement implying that it still does not provide a moral difference between euthanasia and palliative sedation. This is because a person wanting euthanasia is not someone who is being used as a ‘means’ since death is a common goal and consent is given. However, the authors fail to see other important aspects. Even though euthanasia can be a human right as in such countries, the traditional PoDE and the RRDE imply that it becomes the physician’s goal to intended death, irrelevant as to whether the individual request it or not and this is not acceptable under the Principle. Hence, if the patient requests deep sedation/lethal injection, and is a terminal patient in severe pain, one should not be accomplice in formal co-operation in evil directly (administering such medicine), even though the patient is willing harm to himself.[134]

[132] Ibid., 369- 373.

[133] Ibid., 374.

[134] Ibid., 374- 376.

In sum, RRDE is superior to the PoDE however, it still does not address all the moral predicaments surrounding palliative sedation and the complexity of allowing evil side-effects especially when harm is inevitable in medicine. Preventative medicine can have intentional harms as mentioned above and administering palliative sedation consists of intended bad effects as explained in the previous chapter. These ensured harms involve cannulation, suppressing autonomy and 'social death'. Therefore, one can never truly not intend harm up to a certain point, although this may be contested with the fact of proportionality or that 'harm' is meant for life-threatening interventions. But at this stage, Sulmasy's RRDE does not allow any form of harm, including non-life threatening harm.

3.2.9 The Five Canons of Therapy

Sulmasy implies that the philosophy of therapy is an important aspect of medicine that has been neglected. He claims that it is an essential part in determining when and how sedation should be administered at end of life according to the needs of the patient. He proposes a set of principles that encapsulate all therapies namely the canons of therapy.[135]

The canon of proportionality. This is the proportionality between the beneficial and burdensome outcome. The beneficial outcome should exceed the burdensome outcome, however it is important to consider also the means to achieve the outcome. A good therapy should always have a proportionate good means to reach the intended outcome.[136] For example, deep sedation is not started if patient does not have refractory symptoms and pain can be managed with other medication. The canon of parsimony is a universal principle, where its significance was brought to light by Edmund Pellegrino and David Thomasma. It reminds the physician to use force of therapy according to the necessary requirements of the patient, judging always in the best interest of the patient. Overtreatment as well as under-treatment can be problematic. This principle helps to manage social resources, dying with dignity and the emotional turmoil of the terminally individual's family. In the case of palliative sedation, this canon can be applied to ensure that the individual is receiving the right

[135] Sulmasy, "The Last Low Whispers of our Dead", 239.
[136] Ibid.

dose of sedation. Over-sedation fails the canon of parsimony since excess 'force' is applied more than necessary.[137]

The canon of restoration ensures that the goal of all therapies is to restore the patient to a homeostatic equilibrium as much as possible when this is feasible or partly if it is not possible. In earlier days the liberal use of opioids to manage pain was justified as restoration back to a non-painful state again. Although therapy may worsen symptoms at first, the overall end result desired is to restore the patient. The canon of holism (principle of totality) tells us that the patient takes priority over parts and functions. While one cannot just remove a body part on a whim, he may do so if it necessary for the survival of the whole person. For example, removing a gangrenous limb, live organ donation or deep sedation in uncontrolled pain.[138]

The last canon is the canon of discretion. This principle governs all other therapies as it makes awareness about the limits that a physician has in terms of expertise and medicine itself. Sulmasy claims that it can be understood better by explaining the opposite: indiscretion. Indiscretion of degree means an over estimation of the physicians therapeutic interventions. If the patient is too sick, even the best intervention possible would not suffice. Indiscretion of scope is the tendency that medicine can solve a social problem, for example putting children on medications unnecessarily just because of some attention deficit or behaviour. Indiscretion of expertise is the temptation for physicians to ignore their own limits. For example a physician specialized in cardiology is not specialized to control pain management in terminally ill patients.[139] Therefore, this canon also shows us that we should acknowledge our own limits. Hence, withdrawing futile treatment should not be considered as an evil but simply an acknowledgment of limits from medicine itself and the physicians.

Physicians tend to neglect the fact that medicine encounters situations where it has to be alternated at end of life but the same goals of medicine remains, which is to cure, to relieve and to comfort the ill. The ethical problem is the failure of applying the rules properly when the situation changes. The failure of recognizing the extent of curing which results in overtreatment, which violates the canon of parsimony, patients

[137] Ibid., 240.
[138] Ibid., 240- 241.
[139] Ibid.

subject to disproportionate treatment that results in burdensome life saving treatment, violating the canon of proportionality and discretion. Sulmasy provides us with an ethical principle that can avoid such shortcomings and potentially become an effective moral guide for current medical issues related to palliative sedation. Fulfilling these canons of therapy solves several ethical dilemmas such as when one should initiate sedation. Furthermore like the PoDE, the canon of holism ensures that palliative sedation in such cases it is in the best interest of the patient and not something that can hold a person culpable, as long as these canons of therapy are fulfilled.

3.3 Legal and Behavioural Frameworks

3.3.1 Distributive Justice

Distributive justice promotes social justice by including the demand for an adequate benefits and burdens risk assessment and the fairly distribution of scarce resources between different age groups. The issue targets the primary needs to allocate resources and effort to current persons in need, then shifting to a national public policy to prevent future cases and remissions of the same illness. For example treating patients with palliative sedation takes priority then, resources are allocated for the prevention of similar late-stage situations. This is beneficial in order to eliminate the distribution of further resources in preventable situations. Hence, for example in cancer patients, resources would be allocated on treatment options in earlier stages and then for cancer screening. Pain relief should always take precedence. Nevertheless, finding a suitable metric to base allocation of finite resources is a hurdle, as measuring the disease burden is challenging as well as lacking in uniformity. This may lead to unequal distribution of resources and hence, unequal justice.[140]

Distributive justice fails to provide an adequate framework for palliative sedation. The dying process can also be hastened in dire situations both intentionally and unintentionally for instance in the case of eager intubation or hastened titration of sedation in order to sooth clinical exigencies. Clinicians are pressured to save time and resources hence, it may directly or indirectly influence their decision making.

[140] George P. Smith II, "Applying Bioethics in the 21st Century: Principlism or Situationism?" *The Journal of Contemporary Health Law and Policy* 30, (2013): 55-56.

Hastening death with palliative sedation might not be their intention but institutional pressures and distributive justice restrictive of costs certainty impact clinical decisions. As a result, physician-assisted death may result. This goes against the PoDE, as the act is not always morally good. The means can also be evil for example risky interventions like earlier extubation to free intensive care beds or huge doses of sedation to control refractory symptoms quickly. The higher benefit is given to the community in such cases and not the individual. One's ethics may be obscured by the pressures of clinical resources. This framework if applied to palliative sedation can become a dangerous slippery slope to physician-assisted death due to the nature of pressures from the hospital and country itself.

3.3.2 Social Contract Theory

When the health care worker obeys legislations, ethical principles, Hippocratic oath and hospital's rules and protocols assigned by authorities, it is essentially a form of social contract. This is the explicit aspect of this theory but it also involves unwritten aspects that are expected from a health care worker such as altruism and practical judgment.[141] The problem with this theory is the fact that it is difficult to fulfill such contracts and this can cause grave repercussions. For example the government has to supply resources, which do not necessarily meet the demands. If this can affect the ability to control refractory symptoms, it would lead to palliative sedation to unconsciousness which otherwise could have been prevented. Furthermore, if laws or protocols are not designed properly, they can lead to unethical decisions. If protocols for palliative sedation are flawed for example, indicating the physician to start sedation with a higher dose than what the patient tolerates, it can lead to negligence. Even though the physician might be aware of such an error, it may still be administered for various reasons; mercy, requests for euthanasia or authority pressures to empty beds. When the foreseen side effect happens, that is hastened death, the shield of the physician would be that the hospital's protocols were obeyed, shifting responsibilities solely to authorities. However, if protocols fail, even though authorities do hold responsibility, so does the physician, as a professional knows well

[141] Richard L. Cruess and Sylvia R. Cruess, "Expectations and Obligations: Professionalism and Medicine's Social Contract With Society," *Perspectives in Biology and Medicine* 51, no. 4 (2008): 583.

enough how to administer sedation and its side-effects. The PoDE might be a better alternative because of a fixed set of specific, moral rules that indicates what someone's actions and values ought to be. An ethical framework that takes the virtuous characteristic aspects of the physician into consideration instead of relying on shaping protocols might be a better option to avoid abuse from such practices.

3.3.3 Deliberative Democracy and Theory of Casuistry

It is a fact that should be accepted in bioethical decision making that certain ethical, socio-legal, economic and medical conflicts will persist and grow further. One of such controversies is the extent of autonomy and self-determination at end-of-life care. Medicine can alter mental status and the emotional burden of the disease itself may effect the patient's decision and questions as to what extent should escalation of treatment go. This includes initiating palliative sedation but then titrating higher doses without the consent of the patient, the omission of artificial nutrition and hydration after inducing palliative sedation and other related ethical dilemmas. To address these dilemmas, medicine usually solves them by using deliberative democracy. It consists of the collective thoughts and decisions of the professionals involved in a case about the ethical issue. Although several disagreements are to be expected, mutually respectful decision-making ought to be ensued.[142]

The problem is that when physicians are taking a collective vote on the patient's care, not everyone shares the same moral values and this would affect decision-making. It is also time consuming and when the issue is an emergency, not everyone may be available to sound their own opinion. Hence, by default one has to turn to another ethical framework. The major problem of deliberative democracy in palliative sedation occurs when the patient is not able to give consent. If the patient is in pain and there are no next of kin to liaise with regarding the continuity of care, the physicians decide as a team for the best of the patient - whether initiating palliative sedation is suitable or not. However, such a decision coming from physicians has to be moral, and once again coming from different backgrounds might effect such decisions.[143] For example, in a Muslim setting, people believe that one should not be under any effect of mind altering substances including opioids, and thus administering

[142] Smith II, "Applying Bioethics in the 21st Century", 45-46.

[143] Ibid.

palliative sedation is not condoned. Therefore, culture and religious beliefs also effect decisions that others might disagree with. Ideally physicians that are to take such a decision should share the same morals, knowledge and cultural backgrounds. As well as awareness as to what the patient would have preferred if he could have been able to consent.

Although the decision is based on the majority of the votes, there is no guarantee that it is a moral decision or that everyone would agree with that decision. Another criticism of this theory is the fact that if by chance all of the professionals involved are 'immoral', they find no problem with giving higher doses of sedation than the requirement. In such case, deliberative democracy fails according to those people that are against euthanasia and physician assisted death. Another problem that this ethical framework meets occurs when law is involved, especially in small countries. When foul play is suspected, usually a medical professional is ordered by the law to give an opinion about the case. The likelihood that the professional in that area chosen by the law is the physician himself involved in the case is high.[144] Deliberative democracy expects the virtuous physicians to take the right decision for every case but if the virtuous physicians are in minority, it can be problematic. In such case, the PoDE is more likely to be a better ethical principle because of its strict criteria and to avoid taking immoral decisions.

Sometimes, when physicians are discussing a case, it is compared to previous similar cases that they have experienced. This has led to the development of the theory of casuistry, where it does not rely on major ethical principles but simply analyses a particular case and compares and contrasts it with similar cases to try and solve the ethical problem. The Doctrine of Precedence (when an established law or rule in a particular previous case starts to be applied in subsequent cases), plays an important role in this theory. This has been done in previous ethico-legal cases regarding end-of-life care, such as the Terry Schiavo Case. This theory takes a modern approach to bioethics and this is because the average person in a contemporary society is more likely to try and solve bioethical issues with social and behavioral sciences, political theories, public health policies and legal standards without the use of ethical

[144] Ibid.

theories.[145] The problem of casuistry is the fact that no other ethical views are taken into consideration and this can be both good and bad. Following the footsteps of a similar case that has taken all the right ethical decision-making is good but it can be troublesome in cases that have mistakenly took an 'immoral' course of actions. The same mistake can happen again in recurrent cases if one follows blindly such cases without any ethical deliberation. Additionally, the first case that meets with the ethical dilemma, does not have a previous case to refer to, Therefore, in such cases one would have to resort to other ethical principles/ frameworks or theories.

Conclusion

In this chapter several ethical theories or frameworks have been explained in an attempt to establish whether there is an ethical framework that can be more suitable than the PoDE that can give a better explanation and justification for the use of palliative sedation to unconsciousness to treat refractory pain. The need to include additional moral frameworks is essential for ethical deliberation and to avoid possibilities of bias that can emerge from following a single moral framework. These theories are categorized into moral theories and legal and behavioural frameworks.

The first moral theory is the principle of proportionality. This principle still does not answer the clinical ambiguity in intentions and like the PoDE, subjectivity according to the individual remains as what is considered good or bad for someone is not considered the same for someone else. However, it can be an effective guide to determine the advantages and disadvantages of a particular action. The principle of lesser evil also faces the same problem. Having different physicians who have different cultures, religion and social upbringing different from each other will cause different answers to the same moral dilemma that is, which is the lesser evil. Furthermore, without being joined with other theories, this principle alone does not answer the clinical dilemma as it does not determine proportionality, an essential aspect for the moral dilemma of administering possible lethal sedation.

Utilitarianism aims for the 'best positive outcome for the greatest number of people' however this is not an ideal approach to answer dilemmas regarding palliative sedation as physician's intentions are not taken into consideration. Hence, palliative

[145] John D. Arras, "Getting Down to Cases: The Revival of Casuistry in Bioethics," *The Journal of Medicine and Philosophy* 16, (1991): 39- 41.

sedation may be given with ulterior motives to provide ‘happiness’ for societal needs. As for Kantian ethics, similarly to the PoDE, palliative sedation to unconsciousness is acceptable as a last resort for extraordinary cases. It is imperative to note that both the PoDE and Kantian ethics do not take into consideration current complex medical dilemmas of our time. Therefore, when considering such ethical frameworks, they cannot be applied without exception.

Principlism focuses on four values that have to be safeguarded when taking ethical decisions. However, when these values conflict, there are six conditions that guide the agent to determine which principle can supersede the other. These conditions are similar to the PoDE. Unfortunately this can also be subjective to the agent hence, it is suggested to join principlism with the virtue theory. Unfortunately, not everyone holds the same values and morality and therefore relying on personal values is not the best option. Situationism considers one particular value that supersedes others: love. Acting on love and compassion justifies palliative sedation to control refractory pain but may not necessarily be genuine because it can be mistaken for mercy or pity. Hence, the ambiguity in intentions is not resolved.

The triple font theory also suggests several ethical aspects that are virtue theory, material co-operation in evil, the PoDE and practical judgment. The level of ‘good’ and ‘bad’ is measured by a combination of one’s intentions and outcomes as well as co-operation in evil. Practical judgment should be used in ‘hard cases’ and the physician should hold virtuous qualities, obtained through experience. This theory has the same problematic approach of subjectivity when using virtue ethics and practical judgment as well as the problem of being unable to ensure what are the true intentions of the physician.

The RRDE is a refinement of the traditional PoDE and its conditions are more stringent hence, its application is further limited. However it can be used to justify palliative sedation to unconsciousness as hastened death is not a foreseeable ensured outcome. Although this framework can be considered superior to the PoDE, if one considers the induction to unconsciousness as an evil, then it still does not justify palliative sedation. Sulmasy also proposes the five canons of therapy, principles that should be followed by the physician. It reminds the physician the goals of medicine, and when medicine changes into palliative measures instead of overtreatment.

Legal and behavioural frameworks include distributive justice where allocation of resources is distributed justly to society. This can become dangerous if applied to palliative sedation as external pressures may cause rash decisions that can lead to a hastened death. Social contract involves the physician following laws and hospital protocols eastablished. Naturally, if a protocol is designed impeccably PAD is avoided but there is no guarantee that healthcare professionals truly follow such protocols. Furthermore, if protocols are not designed properly, for example Liverpool Care Pathway or protocols regarding palliative sedation, a physician might still follow such protocols even though by knowledge and experience, harmful repercussions would be known from before. Deliberative democracy refers to the collective agreement by a group of professionals to establish an action. While this may avoid certain biases, persons from different morality, cultural and religious settings may still agree on an action that might not be the right one. The theory of casuistry similarly follows decisions taken from previous cases with the same (or similar) moral dilemma. Naturally, an unethical result can follow if the previous case was unjust. Unfortunately, neither one of these frameworks helps to answer specific dilemmas such as ambiguity in intentions.

Although the PoDE has its own shortcomings, several modern ethical frameworks that may be considered as ‘superior’ to the PoDE are either based on the PoDE itself, namely Principlism, an elaboration of the PoDE such as the Re-invented Rule of Double Effect or a combination of the PoDE and other theories or frameworks such as the Triple Font Theory and Principlism. The PoDE is an old ethical principle that might not answer the dilemma for sedation to unconsciousness, a complex modern medical intervention. However, it can still be considered as the founding seminal work for modern theories or frameworks that are more designed to answer such modern medical dilemmas.

Conclusion

Although the Principle of Double Effect has its origins in 13th century western philosophy and theology, clinicians still attempt to address the moral dilemmas of modern palliative sedation with this principle. Nevertheless, with advancements in medicine, new dilemmas have emerged, because palliative sedation has become more complex, and for which the Doctrine alone does not seem to provide sufficient dignity and justice to the dying patient. While the PoDE remains a key framework necessarily to justify the possibility of evil outcomes from actions leading to a Double Effect, the Principle categorically prohibits any evil action to be the cause of a good effect. Yet in the pragmatics of clinical actions, there is frequently an element of inevitable evil (through bodily invasion) that precedes the good effect. One such evil is the deliberate cause of unconsciousness, and the threat it brings to personhood. Moreover, this is accompanied by withholding treatment and artificial nutrition and hydration. Christian moralists warn against this threat and urge clinicians to defend against it, especially once therapeutic elevation of opiod/sedative titrations of pain reach near to what can be construed as physician-assisted death. Scholars like McIntyre and Sulmasy, argue that induced unconsciousness accompanied by withholding treatment and nutrition and hydration cannot be justified with the PoDE because it is a definitely known evil action that results in hastening death. Nevertheless, it is still the right decision to follow if there is futility in clinical efforts and no other sustainable course of action possible. In such cases other moral principles are required to justify the clinical practice.

Another difficulty encountered with the use of this principle is its dependency on agents' intention. Although an attempt to distinguish 'broad' from 'narrow'[146] intentions and between 'intention 'and 'foresight' have been made, the ambiguity of asserting the truth of intention behind actions remains. Due to the complexity of intentions, the physician may face situations where giving palliative sedation may cause fear of being a means to 'mercy killing', even though all criteria may be met. Conversely, a physician may intentionally increase therapeutic regimes specifically to hasten death but without ever breeching medico-legal boundaries.

[146] Jansen, "Disambiguating Clinical Intentions", 21.

The small percentage of palliative patients for whom opioid analgesia does not suffice to curb their intractable pain require sedation. But the conciseness of the Doctrine does not take exception with those two to five percent of patients who would need to be deprived of their consciousness in order to be relieved of their suffering.[147] A number of commentators agree that for this small percentage of patients, sedation is simply the final resolve, and it would be morally irresponsible to dismiss this treatment because of personal fear of breaking the principle. However, one must not try to erroneously justify palliative sedation with the PoDE. One must summon other moral principles to support the use of sedation in these extremely relevant cases. And one should do so with enough moral knowledge and responsibility to reckon that this practice is only valid for the special casuistry of intractable end of life pain and not for all palliative pain indiscriminately.

All this leads to question which moral framework is best suited to justify administering palliative sedation, in light of the PoDE's shortcomings. From the literature reviewed, it seems that a combination of theories and frameworks will aid clinical judgement in this regard. Considering the current globalized multiculturalism, we find ourselves confronted with ethical dilemmas that cannot always be dealt with Christian morality. One has to acknowledge the moral values of the other, and with insight of their cultural and religious roots. Having a single framework designed for every case regarding palliative sedation does not do justice to our multicultural contexts. The literature urges us to consider cases individually, as every case is unique with a multiplicity of factors.

Clinical advancements have created new dilemmas that may not be possible to address all with a standard framework. The experience and practical judgment of the physician when precarious scenarios are met, is key. However, neither of the theories mentioned provide a holistic solution to the dilemma as every individual has their own personal values and morals. Furthermore, ambiguities in intentions will continue to persist. Nevertheless, the closest theory found to adopt sensible moral eclecticism is Triple Font Theory. This theory includes a combination of virtue qualities, lesser/proximity to evil, practical judgment and the PoDE. Hence, a physician with virtuous qualities can manage to make a sound practical judgment, correct wrong practices, make a good ethical deliberation and evaluate all options available. This

[147] Timothy E. Quill, "Principle of Double Effect and End-of-Life Pain Management", 333.

theory in conjunction with Sulmasy's reminder of the canons of therapy can be viewed as an ideal ethical tool box for when the Doctrine is unable to address cases of inevitable evil, such as with palliative sedation.

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