

Preface

The purpose of this book is to analyze several clinical, ethical and legal questions related to the use of sedation at the end-of-life. Indeed, it focuses mainly on seven ethically relevant questions related to palliative sedation (PS). These questions are addressed by an interdisciplinary team of internationally renowned specialists in the fields of bioethics and palliative medicine. Each of the contributors analyses a particular question or dimension of the general topic from the perspective of his/her respective discipline (palliative medicine, bioethics, law, philosophy and theology). Thus, the book as a whole offers helpful clinical, ethical and legal criteria to provide guidance to health care professionals, patients and their relatives in the adequate use of PS. Among them are, for instance, the specific goals of care at the end-of-life; the inviolability of human life; the respect for the dignity of the dying; the ethical principles of therapeutic proportionality, double effect, participation in decision-making, etc.

The book's content is the result of the contributions presented at an International Seminar held at the Pontificia Universidad Católica de Chile (August 2011). During this event, each of the contributors received comments and suggestions from the other experts to improve the final draft of their text. This mutual feedback enabled not only the elaboration of a revised version of each chapter, but also the possibility of bringing the experts into a collaborative dialogue. The improved versions of the chapters were in turn submitted to external peer review. Taking into account the reviewers comments, each author produced the final version of his/her text, which is the one included in this book.

This fruitful international academic collaboration took place in the context of research projects, funded by the Chilean Government's National Funds for the Development of Science and Technology (FONDECYT: Fondo Nacional de Desarrollo Científico y Tecnológico, Project No. 1110721) and the Pontificia Universidad Católica de Chile (Projects No. DGP08-120A002 and DGP09-PADH016), as well as by the Manuel Velasco-Suárez Award for Excellence in Bioethics 2010 (granted to the Editor by the Pan American Health and Education Foundation (PAHEF), the Pan American Health Organization (PAHO) and the

Mexican Government). Hence, the book represents a tribute of gratitude from the Editor for the generous funding received from these institutions.

Sedation has been widely used in medicine since a long time, for instance to alleviate pain and discomfort associated with invasive procedures and surgery, as well as to treat extremely agitated psychiatric patients. Nevertheless, its use for symptom-control in advanced stages of incurable diseases was first published in 1990 and it was not until 2000 that the term 'palliative sedation' (PS) was coined. Since then, sedation has been progressively accepted as a therapeutic tool in the care for dying patients (palliative medicine).

'Palliative sedation' is currently considered to be a last resort therapeutic tool for the management of severe, refractory symptoms at the end-of-life. Indeed, the use of sedatives to alleviate the suffering caused by severe symptoms that have not responded to the usual therapeutic interventions seems to be clinically prudent and ethically correct. Nevertheless, in spite of the improvement of medical knowledge related to the use of palliative sedation during the last decade, available empirical evidence is still limited and important points of controversy persist. Indeed, a review of the medical literature suggests that the prevalence and the spectrum of the indications of sedation in the terminally-ill has been progressively expanding over the past years, including nowadays its more frequent use for the management of psycho-spiritual symptoms (e.g. 'existential suffering'). Moreover, the use of sedatives is associated with some adverse side-effects and/or risks, such as respiratory depression and low blood pressure. Although the literature shows that these risks and adverse effects do not occur when sedatives are used by professionals in an appropriate way, they may indeed occur when using sedatives in inappropriately high doses and/or when the dose is increased too rapidly. In this context, some authors have expressed their concerns about the occurrence of imprudent uses, sub-standard applications and actual abuses of sedation at the end-of-life, which may represent a form of 'slow euthanasia' or 'euthanasia in disguise'.

Hence, available empirical evidence about the current use of sedation at the end-of-life raises a number of interesting and controversial clinical, ethical and legal questions. This book focuses mainly on seven ethically relevant questions, which represent its very *leitmotiv*. These questions are:

1. Whether there is an ethically sound difference between PS and euthanasia and physician-assisted suicide.
2. Whether the principle of double effect can be appropriately applied to justify the use of sedation in some cases at the end-of-life.
3. Whether PS might be ethically acceptable in the case of patients that are not imminently dying (agony).
4. Whether decisions to limit medically assisted nutrition and hydration are essentially linked to PS or whether they should be regarded as independent issues.
5. Whether sedation is an adequate response to 'existential suffering'.
6. Whether sedation could ever be used in the case of patients who are not able to give their informed consent (e.g. patients with cognitive impairment of diverse origins, etc.).

7. Whether clinical guidelines for the use of PS are desirable to orient health care professionals, patients and relatives in the adequate use of sedation at the end-of-life.

Actually, these are the questions that the different contributors address, analyzing the points in which a certain consensus about the adequate use of sedation at the end-of-life has already been reached, but also critically reflecting on aspects where important controversy still persists.

Introducing the reader to the current state of the debate, Taboada (Chap. 1) describes the clinical scenarios, the different terms/definitions and some of the existing guidelines for 'palliative sedation'. It becomes evident that the current debate includes a variety of aspects such as: (1) the definition and terminology (e.g. palliative, terminal, deep continuous sedation, palliative sedation to unconsciousness, etc.); (2) the types of sedation that are included under these expressions (intermittent vs. continuous, mild vs. deep); (3) the clinical indications (physical symptoms vs. existential suffering); (4) the concomitant administration vs. withdrawal of medically assisted nutrition and hydration; and (5) the ethical foundations of its clinical applications and its difference with euthanasia and physician-assisted suicide.

Referring to the framework provided by the European Association for Palliative Care (EAPC), Taboada alerts the reader about the existence of inadequate uses, substandard applications and abuses of 'palliative sedation' in terminally-ill patients. A critical analysis of some of the existing guidelines suggests the need for re-thinking the clinical, ethical and theological foundations of this therapeutic intervention at the end-of-life, a task that is successively undertaken by other contributors.

Sullivan (Chap. 2) analyses the role of sedation in the context of the broader 'goals of care' at the end-of-life. Based on a reflection on the anthropological and ethical foundations of the practice of medicine as such, Sullivan proposes to shift the focus of the ethical discussions about 'palliative sedation' to a deeper analysis of 'goals of care' at the end-of-life. He suggests that this shift can help to clarify the distinction between ethically appropriate and inappropriate applications of palliative sedation.

This author argues that 'palliative sedation' should share certain features with ethically appropriate 'goals of care' in palliative care generally. And since these goals preclude intentionally hastening death, he states that the ethical distinction between palliative care and euthanasia is important, and that appropriate 'palliative sedation' – as a set of practices distinct from euthanasia – is clinically achievable. In order to achieve this in practice, the author urges that beyond the development of clinical guidelines, there is also the distinct but equally important task of developing clinical tools and educational resources that teach clinicians how to formulate 'goals of care' regarding 'palliative sedation'.

The concrete way in which 'palliative sedation' is actually performed in clinical practice is addressed by Walker (Chap. 3). In fact, the author gives the reader a bedside perspective on palliative sedation for the treatment of refractory symptoms,

most notably agitated delirium and dyspnoea, which are the primary symptoms requiring palliative sedation.

This author also describes the practices used at one of the world's leading cancer centres (namely the University of Texas' MD Anderson Cancer Center). He provides in this way an insight into the benefits and risks related to this clinical intervention and also a sense of the aspects that need to be carefully monitored when performing, in a responsible and prudent way, sedation at the end-of-life.

Although palliative sedation is most often used to relieve physical symptoms at the end-of-life, many guidelines for palliative sedation specify that 'existential suffering' is also a legitimate indication for this intervention. This is perhaps one of its most controversial indications. In fact, most of the chapters of this book deal with this issue in one way or the other. So, Rodin et al. (Chap. 4) focus specifically on 'existential suffering' as an indication for palliative sedation, with a consideration of the clinical and ethical questions and controversies which this practice may raise. These authors suggest that the validity of existential suffering as a criterion for palliative sedation is undermined by the ambiguity in its definition and by the practical difficulties in its assessment. Indeed, this term has been used by some to include virtually all psychological symptoms. The suggestion to limit this term to mortality-related concerns may not improve specificity in its usage, since mortality is inevitably a context that shapes all psychological concerns near the end-of-life.

It is interesting to note that Rodin et al. regard 'existential suffering' as a symptom that arises not exclusively 'within the patient', but also from the social context. Hence, they suggest that mobilizing support of the family, any others who may matter, and the multi-disciplinary palliative care team at the end-of-life may all help to diminish or alleviate existential suffering at the end-of-life. They even state that the occurrence of intolerable suffering at the end-of-life may be secondary to the failure to institute appropriate interventions earlier in the course of the disease. Thus, Rodin et al. consider that the use of deep continuous sedation until death to treat 'existential suffering' raises a number of ethical questions, for instance, that it may be regarded as a form of euthanasia in that it causes a 'social death' and the permanent loss of awareness at a crucial moment of a person's life. Moreover, they suggest that the use of deep continuous sedation can also become a covert form of 'slow euthanasia', particularly when the criteria of refractoriness and unresponsiveness to other interventions, including temporary sedation, have not been met. Hence, they conclude that the justification of palliative sedation for existential distress will require greater uniformity and clarification regarding the definitions of existential distress, the criteria for intolerability and refractoriness to treatment, and an early routine referral to mental health experts for the evaluation and treatment of existential distress.

In Chap. 5, Boyle shows how the ethical principle of double effect can help to clarify the moral issues surrounding palliative sedation, specifically by drawing the distinction between hastening a patient's death intentionally or as a consequence of the unintended side effects of sedatives. Aware of the fact that this traditional ethical principle has been frequently misunderstood or misapplied, before developing its application to palliative sedation, Boyle gives an accurate account of its origins and

essential content. This author argues that in its application to end-of-life care, double effect states that it can be morally good to shorten a patient's life as a foreseen and accepted but unintended side effect of an action undertaken for a good reason, even if it is agreed that intentionally killing the patient or shortening the patient's life is wrong. Nevertheless, certain conditions need to be fulfilled. Following Anscombe, Boyle reformulates the conditions of double effect as follows: that the action having the bad side effect be good in itself (that is, independent of the bad side effect), that it be done for a good purpose, that the action causing the bad side effect be proportionate to the evil caused, and most importantly the intentional condition – that the bad effect not be a means to the good effect.

It is interesting to remark that, when dealing with the specific question about the moral justification of the use of sedation at the end-of-life, Boyle analyses separately two problems: the suppression of consciousness as such on the one hand and the risk of shortening life on the other. He thinks that the application of double effect proceeds in the latter, but not in the former. Nevertheless, in the case of the intentional suppression of consciousness, the author introduces a further interesting distinction. He states that, although the principle of double effect does not usually prove to be necessary for justifying the ethical permissibility of suppressing a patient's consciousness in the context of the management of refractory symptoms, its application is actually relevant to those cases in which sedation might prevent the patient from executing important moral and religious duties at the end-of-life. So, Boyle remarks that in such cases the prevention of the opportunity for executing moral duties should occur only as an unintended side effect of the treatment, if there is a proportionately serious reason for doing so. This distinction is relevant to cases of 'existential suffering', which is an issue that the author also explores in this chapter.

With regards to the problem of shortening a patient's life through the use of sedatives at the end-of-life, Boyle emphasizes the importance of the distinction between intending and foreseeing. He specifies that although the medical literature suggests that the risk of actually hastening a patient's death through the use of sedatives is not the rule, but rather the exception, double effect can indeed be applied to justify its use, but only if the expected shortening of life caused by the sedation is a side effect and not an intended result.

So, Boyle's conclusion is that "double effect is an important tool both clinically and in public debate for situating end-of-life treatments, and for getting clear about whether or not actions that look like intentional killing really are that. In the light of that clarification, the acceptance of terminal sedation as a part of palliative care for the dying is not precedent for euthanasia, although some questionable uses of terminal sedation may in fact be intentional killing."

Similar questions connected to the precise content, extension and applicability of the principle of double effect to the case of sedation at the end-of-life are further explored by Miranda (Chap. 6). In agreement with Boyle, this author emphasizes that the principle of double effect has been frequently misinterpreted and misapplied, due to a lack of a proper understanding of its philosophical foundations and specific content. Hence, he accurately examines the type of actions that need to be

justified by this principle, stating that only those acts that cause effects or a state of affairs that would be never lawful to directly intend – either as an end or as a means – fall under the field of application of double effect. In doing so, the author stresses the importance of both the distinction between intended and foreseen effects and the idea that this principle presupposes the existence of intrinsically bad actions, which would be always morally wrong to pursue.

Miranda reviews the interpretation of the principle offered by contemporary authors within the Natural Law tradition (such as Grisez, Finnis and Boyle) and takes into account two different types of criticisms that have been made to their position: Aulisio's criticism, stating that double effect can be also applied outside an 'absolutist' tradition, and Anderson's objection, suggesting that even within an 'absolutist' context, double effect does also apply to the sort of harms that it would be lawful to directly intend. The analysis of these criticisms gives him the opportunity to clarify important points concerning the precise content and proper field of application of the principle.

After making these important clarifications, the author analyses in depth the question of whether the administration of drugs that reduce a person's awareness are the type of actions that need to be justified by the principle of double effect. His accurate analysis of the scope of application of this principle leads him to the conclusion that palliative sedation does not need to be justified by double effect reasoning, but rather by the principle of totality and proportionality in medical care. In other words, he suggests that in order to justify the act of reducing a patient's level of consciousness – which might be considered as a bad effect – it is sufficient to have proportionately serious reason. Like Boyle, Miranda does not see a serious reason to hold that reduction of consciousness as such is an effect that would be always wrong to directly intend as a means for a proportionately serious clinical necessity. Nevertheless, he specifies that if sedation would hasten a patient's death, the application of the principle of double effect would be necessary to justify this bad effect, as it corresponds to the type of effects that would be always wrong to directly intend. Similarly this occurs with the total and permanent abolition of a patient's consciousness, which also corresponds to a state of affairs which would never be lawful to directly intend.

In Chap. 7, Keown offers an overview of some basic concepts central to a legal and ethical analysis of palliative sedation. In particular, this author deals with the concepts of 'sanctity of life', 'best interests' and 'autonomy' which are key to understanding when palliative sedation is legally and ethically defensible. The author suggests that only after these basic concepts have been soundly understood is it possible to address specific questions such as, for example, whether it is ethical and lawful to administer sedatives with intention to shorten a patient's life, or when the patient is not 'terminally ill', or as a response to 'existential suffering', etc.

Keown's proposal is that the most important concept underlying the ethical and legal analysis of palliative sedation is the 'inviolability of life'. Indeed, he argues that respect for the patient's autonomy – in spite of its evident importance – ought to be always subordinated to the respect due to basic human goods, among which human life is the first. In fact, it is a necessary condition for exercising freedom.

An interesting clarification in the context of the current debate about sedation at the end-of-life is Keown's distinction between medical judgments based on the benefits related to a patient's 'quality of life' and judgments about what can be considered as a 'beneficial quality of life'. According to this author, the former can have a place in medical decision-making, while the latter may result in arbitrary discrimination against certain types of patients and an eventual lack of respect for the inviolability of their lives.

In the context of drawing the ethical and legal difference between palliative sedation and euthanasia, Keown stresses the importance of distinguishing between 'direct' and 'oblique' intentions of our actions, a distinction that had been already addressed both by Boyle and Miranda in the previous chapters, as the difference between 'intended' and 'foreseen' effects of human actions. In accordance to his previous affirmation of the inviolability of human life as the most fundamental criterion to judge the ethical and legal justification of the use of sedatives at the end-of-life, Keown strongly rejects acts that directly intend to hasten a patient's death.

Given the fact that legal regulations vary from country to country and since the International Seminar that led to the preparation of this book was held in Chile, an analysis of the legal situation regarding palliative sedation in Chile was necessary. This task was undertaken by Vivanco (Chap. 8), who focused her analysis mainly on three questions: (1) whether palliative sedation is legally justifiable in the context of contemporary medicine, (2) whether it can be conceived as a patient's right, and (3) whether it can be distinguished from other legally non-admissible acts, such as euthanasia or medically assisted suicide (which are actually illegal in most countries).

This author argues that although in Chile there is no explicit legal regulation regarding either palliative sedation or euthanasia, the former can be considered as a part of the patient's right to adequate palliative care, while the latter would be considered illegal, as it is contrary to the Chilean Constitution. In order to draw such a clear-cut distinction between palliative sedation and euthanasia, the author analyses the differences between both according to: (1) the agent's intention, (2) the content of the informed consent, (3) the procedure, and (4) the expected result.

The interest of this chapter in the context of the overall aim of the book rests precisely in the fact that it provides an insight about the situation in Latin-American countries (exemplified in Chile), where little has been published about this subject. And it is certainly interesting to be aware of some cultural differences regarding these controversial issues.

An accurate exploration of the contextual history of end-of-life care is provided by Henry in Chap. 9, particularly as it relates to the contentious advent of sedation as a therapy of choice for the palliation of a subset of terminally-ill patients. This historical account enables both a better understanding of the need and potential use of clinical guidelines for sedation of terminally-ill patients and recommendations for future research in the field.

The author compares the practical orientations proposed by the main clinical guidelines, focusing his attention especially on the statements that relate to the seven ethically relevant questions that constitute the book's *leitmotiv*. It is interesting

to note that there are actually some significant differences in the solutions proposed in different countries.

Henry suggests that the published literature to-date regarding the use of palliative sedation continues to identify inconsistencies and variances in application with regard to its prevalence in current practice, the overall effect (outcome) of sedation on the patient, the family and health care team, the practice and impact of providing (or not) hydration and nutrition in the dying process when sedation is employed, and the decision-making processes in place when this therapy is being used.

The author concludes that clinical tools (namely clinical protocols and pathways) derived from well established guidelines can improve the consistency and quality of care. In fact, he suggests that the main usefulness of guidelines, consensus statements and frameworks on palliative sedation is to help mitigate unnecessary and inappropriate uses of this therapy.

Henry's conclusion is strongly criticized by Scott (Chap. 10), who sustains a very critical standpoint on the publication of clinical guidelines, suggesting that they can have quite negative effects on judicious medical decision-making. Hence, the author insists on the need for education, to train medical personnel in the habit of making prudent clinical judgments in each particular situation. He states that although guidelines may have a role in clinical practice, they entail the risk of being used in a mechanical way that might end up substituting the individual's clinical and ethical reasoning when faced with difficult situations. Hence, the publication of PS guidelines cannot replace the need for a permanent education of health care professionals, patients and family members on sound criteria for appropriate decision-making regarding sedation at the end-of-life.

The chapter concludes by suggesting the current need for re-thinking the clinical, ethical and theological foundations of an adequate use of sedation in the context of the specific goals of end-of-life care.

The book's main contribution is doubtless its interdisciplinary approach to a topic that might seem to be quite narrow, but has actually the particularity of opening up a broad spectrum of very profound questions connected to the 'meaning of life' and the value of a 'good death'. What is truly at stake here is the way in which our societies understand the right of terminally-ill patients to receive a professionally competent, integral and humane care at the end-of-life, a care that enables a peaceful and dignified death, always respecting the 'inviolability of human life'.

The World Health Organization's definition states that palliative care affirms life and regards dying as a normal process, neither hastening nor postponing death. According to this definition, the so-called 'right to die with dignity' cannot be conceived simply as a right to self-determination with regards to death, but rather as a right to live one's life to the end and to be assisted by others in the dying process. Under this perspective, the dying process is understood to pose special ethical challenges to medical professionals as well as to society as such.

The experience with palliative care patients shows that each patient is unique and cannot be replaced. In spite of the similarities of clinical conditions, each individual has a specific constellation of symptoms, which in turn present themselves with different degrees of intensity in each case. Moreover, the personal experience with the

disease, with the medical profession, with the family, with the friends and with society differs as well, generating dissimilar psychological reactions among terminally ill patients. Also the spiritual resources and the coping mechanisms vary according to their respective religious and cultural background. Dying persons have the right to receive integral and competent assistance at the end-of-life, addressing the different sources of suffering of the dying person and their relatives ('total pain'). Palliative medicine was originally conceived as an active and competent answer to these ethical demands. This is precisely the framework in which the adequate use of palliative sedation can find its foundations.

Dying persons correspond doubtless to one of the most vulnerable groups in our societies. Hence, their life and dignity deserve our special attention and protection. If we accept the premise that a person's moral quality is shown mainly in the way in which he/she treats the most vulnerable people, then we may argue that future generations will be able to judge the moral quality of contemporary societies by the way in which we treat the most vulnerable, among which the dying are an important group. Hence, the care for the dying offers a privileged context to test our most fundamental moral attitudes. Indeed, not only the truth of our unconditional respect for human life and dignity are put to trial, but also the meaning and value we attribute to pertaining to the human family.

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