

Presidency of the Council of Ministers



**DEEP AND CONTINUOUS PALLIATIVE SEDATION IN
THE IMMINENCE OF DEATH**

29 January 2016

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Introduction

The subject was initially brought to the attention of the Committee by Prof. Francesco D'Agostino; at a later date Hon. Paola Binetti posed a query (given in the attachment) inviting the Committee to go into the ethical aspects of deep sedation in more depth, asking in particular whether or not it can be distinguished from euthanasia.

Deep sedation is an issue that is linked to the subject of palliative care, which the Committee dealt with in the Opinion *Pain therapy: bioethical guidelines (2001)*. In drafting the Opinion the Committee puts forward a number of reflections with the aim of clarifying the definition and ethical conditions of deep sedation at theoretical level, as well as offering practical guidelines for healthcare professionals.

The Committee criticises the expression 'terminal sedation' which is used in literature owing to the ambivalence and imprecision that it conveys and proposes the terminology 'deep and continuous palliative sedation in the imminence of death' to indicate the intentional administration of drugs, in the dosage required, to reduce to the point of annulling the patient's state of consciousness, in order to alleviate pain and the physical and/or psychological refractory symptom which has become intolerable for the patient in the imminence of death.

The NBC identifies a number of conditions that are ethically indispensable for the carrying out of deep sedation: an incurable illness in an advanced state; imminent death; the presence and assessment of one or more refractory symptoms or acute terminal events with intolerable suffering for the patient; the informed consent of the patient. The procedures for the application of deep sedation require proportionality, the monitoring of drug usage and the entering of the procedures in the medical record.

The Committee addresses the distinction between deep sedation and euthanasia and for this purpose, procedures and outcomes, considers that deep and continuous sedation, which is continued until the patient's loss of consciousness, must be recognised as a healthcare treatment and not confused with euthanasia or assisted suicide or consensual homicide.

The question of the patient's informed consent is specifically dealt with, as well as advance care planning, also relying on advance statements about medical treatment, deep sedation in paediatric patients and the professional training of healthcare workers.

In its final recommendations the Committee stresses that it is a fundamental right of the dying person (adult or child) to receive adequate support aimed at controlling suffering in the respect of their dignity. Particularly with regard to children, the Committee recommends that the parents be suitably informed and supported on the issues linked to deep and continuous sedation and that the best interests of the child are respected and that their will is respected too within all possible limits.

Lastly, a full application and integration of Law No. 38/2010 will hopefully be implemented, regulating palliative care and pain management in Italy, since unacceptable inequalities are found among regional areas.

The Opinion includes two appendices: a normative and a technical/medical one.

The Opinion contains a personal remark by Prof. Carlo Flamigni and a statement by Prof. Demetrio Neri, explaining the reasons for their dissent from the document.

The group was coordinated by Prof. Lorenzo d'Avack, who supervised the drafting with the contribution of Profs. Rodolfo Proietti and Laura Palazzani.

A number of experts were invited to give their professional advice on the subject during the plenary session including Prof. Carlo Peruselli, President of the Italian Society for Palliative Care (26 June 2015), Prof. Rodolfo Proietti, full professor of anaesthesiology and reanimation at the Catholic University of the Sacred Heart (25 September 2015) and Prof. Ferdinando Cancelli, palliative care physician (25 October 2015).

The document was debated in the plenary sessions of 20 November, 11 December 2015 and 29 January 2016, and approved with votes in favour by the members: Amato, Battaglia, Canestrari, Caporale, Casonato, D'Agostino, Dallapiccola, Da Re, d'Avack, De Curtis, Di Segni, Frati, Garattini, Gensabella, Morresi, Nicolussi, Palazzani, Proietti and Toraldo Di Francia and voted in favour by the advisory members: Benato, Bernasconi and Petrini. The members Flamigni and Neri voted against the document and Zuffa abstained.

Caltagirone, Scaraffia, Sargiacomo and the advisory members Conte and Palamara were absent at the voting but endorsed the Opinion at a later date.

Lorenzo d'Avack

1. Preamble

The NBC has already dealt with end-of-life issues on various occasions¹. In tackling this subject it has deemed it appropriate to place great attention on palliative care and pain management, understood as cure and care, aimed at managing the patient's physical-psychological suffering and social support, in order to improve their "quality of life" in the respect of their "dignity". It also had the opportunity to reaffirm that the fight against physical-psychological pain comes into the primary tasks of medicine and society.

In the Opinion *Pain therapy: bioethical guidelines* (2001), the promotion of hospital facilities and hospices was recommended in an attempt to move towards the "hospital without pain", professional training courses for healthcare workers, and the widespread diffusion of information on this to citizens.

It stated that, in taking into account the will of the patient and their concept of life and health, healthcare workers should assess pain control in light of the idea of "quality of life" that every person has the right to formulate for his or herself. It was stressed once again how pain management came into those rights, and which the citizen can ask to be respected and fulfilled by the competent bodies. These are rights that must come into the healthcare guaranteed by art. 32 of the Constitution and which must be fully taken into consideration in the promotion of human rights. In other words, pain control was already highlighted as being an integral part of what a person can and must expect from medicine and healthcare professionals. An excellent reason to recommend that pain control should fall under the "essential and uniform levels of healthcare".

With its attached recommendations, this Opinion had a decisive impact on the modification of the regulations regarding palliative care and pain management in force in Italy: Law No. 38/2010 'Provisions guaranteeing the access to palliative care and pain control'. Nevertheless, even though this law made reference to pain control in all stages of the illness, particularly in the advanced and terminal ones, it is necessary that this fundamental right of the patient (adult or minor) to receive suitable support aimed at the management of physical-psychological suffering with the aim of improving the quality of life in the respect of their dignity and will is actually carried out.

At the same time, an increased awareness in the medical profession is required with regard to the value and efficacy of palliative care, also in the terminal stages of life. In fact the law alone is not sufficient if at the same time a new approach to patients' suffering is not asserted. While it is true, as specified later on, that deep sedation has specific characteristics with respect to palliative care and pain control, it is also evident that the development of these practices is connected to the establishment of a widespread medical culture that is capable of looking at the patient's suffering as an integral part of the illness that the doctor is called upon to treat.

¹ NBC's Opinion on the *Draft Resolution on assistance to the terminally ill*, approved by the Committee on the Environment, Public Health and Consumer Protection of the European Parliament, 1991; *Bioethics with childhood*, 1994; *End-of-life issues in bioethics*, 1995; *Pain therapy: bioethical guidelines*, 2001.

The fact that there is still a lot to do is also demonstrated by the world data on opiates used in medicine, underlining their underuse in Italy.

Indeed, not everything foreseen by the laws in force has so far been fully realised in organisational and professional terms. Report to Parliament on the state of implementation of Law No. 38/2010 of 2015 highlighted that there is a noticeable difference between what is possible and dutiful to do and what in practice is actually done. This is all the more so that during the last decade palliative care has developed to such a degree as to represent a new discipline in medicine and presupposes the organisation of treatment and assistance that is taking on great importance in the world, also because the epidemiological scenario of the population of the developed countries is changing: life expectancy is growing exponentially every year and consequently the number of people affected by chronic-degenerative pathologies is increasingly rising, in the advanced or terminal stage of which palliative care represents a fundamental support for patients and their next of kin. In 2014 the WHO unanimously approved a document that commits all states to developing palliative care and sets it down as a fundamental human right². In the same year the WHO also published, together with the Worldwide Palliative Care Alliance (WPCA), the *Global atlas of palliative care at the end of life*³, in which an estimate is given of the global number of adults needing (or who might need) palliative care in the terminal stages of life as being over 19 million.

There is therefore a widespread awareness that an attempt is being made in this care to give efficient answers to the real needs and rights of the population.

For this reason, the Committee deems it appropriate to return to end-of-life situations with this document, focussing on the problem of deep and continuous sedation in palliative care: this reflection will take into account the ethical issues arising from this, the progress in medical science, common practice and the need to implement a number of normative aspects.

2. Terminology and definition of the practice

Within the general context of palliative care, generally speaking palliative sedation consists in the intentional reduction of the patient's consciousness to its possible phasing out, in order to alleviate the physical and/or psychological refractory symptoms.

The administration of palliative sedation can be carried out in different ways:

- *moderate/superficial*, when it does not completely take away consciousness or *deep*, when it comes to the phasing out of consciousness;
- *temporary* (if for a limited time), *intermittent* (if administered alternately, according to the oscillation of circumstances) or *continuous* (if extended until the death of the patient).

In its various modalities, palliative care is given to a patient with an advanced incurable disease.

Herein the Committee sets out to refer to palliative sedation in the specific modality: deep, continuous, with impending death. The imminence of death

² WHO Resolution EB134.R7. *Strengthening of palliative care as a component of integrated treatment within the continuum of care*, January 2014.

³ Worldwide Palliative Care Alliance (WPCA), World Health Organization (WHO), *Global atlas of palliative care at the end of life*, 2014.

refers to the condition of expecting death in a lapse of time ranging from a few hours to a few days, according to the diagnosis and prognosis of the medical team.

The expression 'terminal sedation' is often used in literature. The Committee considers that it is an expression that should not be used as it creates ambiguities⁴. The adjective 'terminal' can be used to indicate the final stage of life (agonic stage with inevitable evolution towards death). Or it can be used to say that by means of such treatment an end is put to the patient's life. Lastly, the definition could be referred only to the irreversible nature of the sedation.

The Committee proposes the terminology 'deep and continuous palliative sedation in the imminence of death' to indicate the whole procedure, bearing in mind the above mentioned distinctions, like 'the intentional administration of hypnotic drugs in the required dosage, in order to reduce the level of consciousness to the point of phasing it out, to alleviate or take away the perception of an intractable physical or psychological refractory symptom, which would otherwise be intolerable for the patient, in a condition of incurable terminal illness close to death'.

In order to understand this therapeutic treatment a definition of 'refractoriness of the symptom' is also needed, given that this circumstance is, together with the patient's consent, priority to legitimate deep sedation. While there is the complex task of defining the concept of refractoriness of a symptom, above all in consideration of situations not only strictly physically but also psychologically stressful, the NBC makes reference to the one in the Recommendations of the Italian Society for Palliative Care (SICP): 'The refractory symptom is one that cannot be adequately controlled despite aggressive efforts to identify a tolerable and efficient therapy practised by an expert and that does not compromise consciousness'⁵. Among the most frequent refractory symptoms are dyspnea, intractable distress, nausea and persistent vomiting, delirium, psychomotor agitation, psychological or existential distress. A number of indispensable conditions are to be observed in this definition. In all the clinical situations that require deep sedation, it is of vital importance to first of all verify the actual refractoriness of the symptom by assessing that: a) its control cannot be achieved through an adequate and proportionate dosage of drugs (the lowest level of sedation able to alleviate the refractory symptom, with the least number of negative side effects); b) any different or further non pharmacological treatment is not able to guarantee relief to the patient or relief such as to make the suffering tolerable within an acceptable time. Both the clinical and ethical appropriateness of the choice depend on this diagnosis. Therefore, the state of refractoriness of a symptom must be ascertained and monitored by a team of palliative care experts made up of physicians, nurses and psychotherapists. The use of drugs must always be monitored and appropriate to the depth, continuity and duration of the sedation and an accurate record together with documentation entered into the patient's medical record should be kept of the clinical case and the degree of

⁴ The Italian Society for Palliative Care (SICP) in its document *Recommendations of the SICP on terminal sedation/palliative sedation* (2007) also highlights the ambiguousness of the adjective "terminal", which can "be understood both as a prognostic element referred to the stage of illness and as a definition referring to the irreversibility of the sedation".

⁵ Italian Society for Palliative Care (SICP), *Recommendations*, cit., p. 10. (See Technical/medical appendix to the Opinion).

sedation reached⁶. For the purposes of an assessment of the decision-making process and its application, a retrospective evaluation of the way in which the sedation was carried out is undoubtedly useful and to be recommended. This retrospective record should allow all the actors involved to understand on which bases the treatment was decided and what the controversial aspects have been, in order to improve the understanding of such situations in the future.

From the experience gained over many years of palliative medicine in different countries (United Kingdom, France, Switzerland, Italy, Spain etc.) it is considered that a protocol for deep and continuous sedation can be adopted in the presence of a number of pivotal events: - the patient's informed consent; - an incurable illness in an advanced stage; - impending death, generally expected within a few hours or days; - the presence of one or more refractory symptoms or acute terminal events with intolerable distress for the patient. These circumstances must be present simultaneously in order to legitimate the treatment from an ethical point of view.

The bioethical question also arises from the relationship between the starting of deep sedation in the above described conditions and the suspension of treatment constituting therapeutic continuity in the care of the terminally ill, guaranteed by means of the continuity of the vital functions supported artificially (e.g. oxygen therapy, hydration, artificial feeding, etc.).

The Committee points out that as far the connection is concerned between 'deep sedation' and the need/duty to suspend all the vital support therapies, each case must be judged singularly, taking into account that many of these treatments are symptomatic and necessary in order to alleviate suffering. It is important that the patient is monitored regularly and does not undergo disproportionate and needless interventions.

With particular reference to hydration and nutrition, in most of the patients in the imminence of death, artificial nutrition/ hydration is not indicated owing to the serious concomitant changes of the metabolism. Furthermore, a patient that is still able to feed and hydrate him/herself or for whom nutritional and/or hydration support is prescribed and received cannot normally be treated with deep and continuous sedation insofar as death is not likely to be expected within a short time.

3. Deep and continuous sedation in the imminence of death and euthanasia

The NBC stresses from the very start that in this Opinion it does not set out to deal with the ethical problem posed by euthanasia or assisted suicide or consensual homicide. It sets out to consider, at a descriptive level, whether the use of sedative drugs up to the loss of the state of consciousness to give relief to unbearable suffering in the last hours or days of life (deep and continuous sedation in impending death) can be considered an act of euthanasia.

There are differences between the two situations, already outlined and unanimously approved in the context of palliative care⁷, which place deep sedation and euthanasia on two different levels. The journal "*European Journal of Palliative Care*" of 2003 published a piece of work by the European

⁶ See art. 7, Law No. 38/2010, where the obligation is foreseen to enter the detection of pain in the medical record.

⁷ Differences formalised among others by the European Association for Palliative Care in 2003.

Association for Palliative Care (EAPC)⁸ in which it was highlighted that, at the level of objectives, outcomes and procedure, sedation and euthanasia are two different cases. On 19 November 2015 the EAPC confirmed this standpoint in a “*White paper*”⁹ which updates the previous 2003 document.

With regard to the objectives, procedures and outcomes, sedation is a therapeutic act having as its goal the alleviation or elimination of the distress and suffering of the dying patient through the management of the refractory symptoms, while euthanasia, according to the definition most widely used today, consists in the administration of drugs which with the patient’s consent are aimed at bringing about their immediate death.

From the medical literature it appears that the average survival rate of sedated terminal patients does not differ from that of patients who are not sedated and some research carried out in 2003 showed that patients sedated for over one week before dying, in conditions of serenity and placed in a condition of greater stability from a physiological point of view, survived longer with respect to those not sedated¹⁰. A systematic review on the subject of deep palliative sedation was published in the *Cochrane Review* confirming that patients sedated in this way do not have a lower survival rate with respect to those not sedated¹¹.

Deep sedation therefore is not indicated as a treatment that shortens life, if applied appropriately, and cannot be considered as an act directed at death.

4. The patient’s consent

By the expression “institutions” is meant the whole set of subjects that in various ways intervene in the process of “government” of drug administration and which have the responsibility of guaranteeing the quality and safety of clinical treatment: National Health Service, the Health Ministry, the Superior Institute of Health, AIFA, hospital facilities, ethics committees, doctors and judges.

It must be highlighted that Law No. 38/2010, even though referring to the autonomy of the patient, does not tackle the specific problem of information and consent to palliative care.

For deep sedation, a part of palliative medicine, one cannot forego a therapeutic approach model centred on the patient as the protagonist of treatment and informed consent therefore seems to be a fundamental element of the care relationship. To speak of consent in these situations does not of course mean signing a document, as much as rather letting the patient’s awareness with respect to their prognosis grow and embracing their desires, in the context of the patient/doctor treatment relationship. The decision-making process must be stated in the therapeutic alliance, between patient/family and patient/healthcare operators and such alliance should lead towards not only an

⁸ *Euthanasia and physician-assisted: a view from an EAPC Ethics Task force* (2003, 10, pp. 63-66).

⁹ L. Radbruch, C. Leget, P. Bahr, C. Müller-Busch, J. Ellershaw, F. de Conno, Vanden Berghe, *Euthanasia and physician-assisted suicide: A white paper from the European Association for Palliative Care*, “Palliative Medicine”, 2015, Nov 19.

¹⁰ N. Sykes, A. Thorns, *The use of opioids and sedatives at the end of life*, “Lancet Oncology”, 2003, May, 4(5), pp. 312-318.

¹¹ E.M. Beller et al., *Palliative pharmacological sedation for terminally ill adults*, “Cochrane Database Syst Rev.”, 2015, Jan 2, 1.

informed consent, but also a shared one. In fact, rather than the acquisition of consent to specific painkilling treatment, the reaching of a basic agreement is considered fundamental, or the search for a 'shared trust' on the basis of a number of desires, life choices, values manifested by the patient and gained within the relationship with the healthcare professionals. The decision to begin deep and continuous sedation should therefore be characterised by proceeding cautiously, guaranteed by a number of opinions in a shared decision, and taken at the end of exhaustive information given on the evolving seriousness of the symptoms of the terminal stage, the objectives and modalities of sedation, with explanations at clinical and ethical levels.

In the explanation of the procedure it is important to anticipate the answer to questions that are asked most frequently so as to reduce the risk of incomprehension or misunderstandings to a minimum. It is necessary that the consent is personalised, considering that each case is presented differently and that the patient's desires and their possible changes during the illness are respected¹². Just as it must be considered that patients can voluntarily refuse deep sedation. It is clear that suffering and pain are perceived subjectively and the individual can attribute a religious sense or nevertheless a personal feeling to it or may want to maintain a contact with the world surrounding them or live the moment of death all the way.

It must be underlined that the will and desires expressed in the consent are even more difficult to ascertain in the end-of-life situations in which deep palliative sedation is proposed, where the presence of refractory symptoms or the previous attempts at pain sedation with narcotic painkillers can lead to the clouding of consciousness, consequently hindering the patient's capacity to express their last will and to communicate with others. The subject of consent and end-of-life choices thus entail the need to face the question of advance directives for medical treatment within the patient-doctor collaboration, a subject already dealt with by the Committee¹³. Here it is important to recall the "Guide on the decision-making process regarding medical treatment in end-of-life situations" (Council of Europe, DH-BIO, 2015) which states: "Regardless of the legal scope of advance directives in any given legal system, they will always have more weight in the decision-making process if they correspond to the actual situation and are drawn up in the light of a specific medical context. This is the case of the patient who finds him/herself in the condition of understanding the consequences of his/her illness". Therefore, before situations in which the patient's consciousness is failing with the consequent hindrance to the capacity to express their last will, the Committee considers it opportune that the value of the advance directives be recognised within the shared advance care plan.

Even though in the first place the patient must give their informed consent, and should they not be able to give consent, this must be given by whoever legally represents them or by their next of kin, the decision to resort to sedation must always be a therapeutic decision shared by the healthcare team who thus assume the relative responsibilities for this in the same way as they would for all the other therapeutic decisions taken in the course of medical care.

Lastly, it is stressed that also the patient, who refuses treatment or various types of treatment or who refuses to make use of instrumental support

¹² With regard to this, see the modalities for a consent modulated on the needs of the single case: Italian Society for Palliative Care, *Information and progressive consent in palliative care: a shared evolutionary process*. Recommendations of the SICP, 2015.

¹³ NBC, *Advance treatment statements*, 2003.

techniques of the vital functions, entering an end-of-life process, has the right to benefit from pain control and, should there be refractory suffering, to deep and continuous sedation¹⁴.

5. Deep sedation of paediatric patients

Paediatric patients pose particular problems with respect to adults concerning pain and sedation.

It must be recalled that when one speaks of minors one is referring to a wide category of different subjects. Children's incurable illnesses are very different from those of adults (the haemato-oncological ones are fewer than 25-30%) differing from each other and are often characterised by an "undulatory" course, with sudden unexpected worsening and improvement, whereby the stage of supposed 'terminality' cannot always be identified with certainty. It must always be considered that pain in children can bring about short and long term negative effects and influence their behaviour, cardiovascular and neuroendocrine system and the prognosis. It is therefore vital to avoid painful procedures as much as possible and rather treat the pain safely and effectively¹⁵.

As far as children are concerned, there has been a growing tendency over the years to include them in the decision-making about their care. The Code of Medical Deontology sets down that the doctor should give the child the most appropriate information for diagnosis, prognosis, the prospects and possible alternative diagnostic-therapeutic interventions planned for the purpose of involving them in the decision-making process (art. 33) and shall duly consider the opinions expressed by the minor in all the decision-making processes regarding him/her (art. 35). Nevertheless, the possibility that the minor, still at a very young age, can uphold his own autonomy at a practical level seems difficult to realise. It must be added that the course of the illness, pain and death of a minor, especially if not a new born baby, is different for the family and doctors involved in their care with respect to that of an adult. The medical history of a child who cannot be saved from death gives rise to complex psychological and emotive mechanisms involving and conditioning the family and the medical staff themselves. These are among the main reasons for which a communication relationship is established between the medical team, the sick child and their family, characterised by ongoing dialogue and an open exchange, whereby thanks to this alliance the best interest of the minor is achieved and, as far as possible, the respect of their will.

In its Opinion *Bioethics with childhood* (1994), the National Bioethics Committee put forward a series of reflections and recommendations with regard to the involvement of the child in therapeutic care. As far as the treatment of children is concerned ethics committees were advised to always seek the consent/dissent of the child over 7 years of age together with that of the parents and to consider the consent/dissent of the adolescent of 14 upwards obligatory and overriding with respect to that of the parents.

Considering also the changes in the reaching of maturity and awareness of children recorded by the human and social sciences and the variability of the psycho-social conditions, it is necessary to invoke flexibility when considering

¹⁴ NBC, *Conscious refusal and renunciation of healthcare in the patient-doctor relationship*, 2008.

¹⁵ See the *Charter of the Rights of the Dying Child - The Trieste Charter*, 2014.

these suggestions which represent useful guidelines rather than regulations. “Nevertheless – writes the NBC – it is certain that children and adolescents are subjects of knowledge, which is more or less evolved and with an infinite number of attributes during their development, with an ongoing need for profound respect... It must always be remembered that even the very young child has a peculiar cognition of himself and his sick and suffering body that cannot be reached by adultomorphic cognitive schemes and has processing mechanisms of kinesthetic corporeal experiences, which are equal to the knowledge systems attributed by adults in a chronological increase”¹⁶.

This is all the more reason therefore why each critical patient in the paediatric age group must have a care plan that will identify and give adequate pain control and, should it be necessary, sedation to reduce agitation and distress. The treatment administered must be appropriate with respect to the patient’s needs and the extreme goal of deep sedation should be specific for each different case. Even the measuring of pain is a standard of care to be applied with validated methods, suited to the age and type of patient and represents the best indicator of efficacy of the ongoing treatment. It is nevertheless necessary to bear in mind that in children there are other distressing symptoms as well as pain, such as dyspnea, convulsions, psychomotor agitation, which when refractory need sedation to relieve the suffering¹⁷. This type of palliative sedation is theoretically and in practice not necessarily irreversible and can be reduced and suspended according to the child’s needs.

Art. 7 of Law No. 38/2010 states the obligation to enter the presence of pain in the medical record. Scientific literature on the subject shows that even before the age of 3 evaluation instruments can be used in which the child associates his/her own pain with photographs or drawings that represent different degrees of joy and pain¹⁸.

In the same way as for adults, the aim of the pain management must be defined a priori and redefined in time in compliance with a care plan and dialogue with the family must follow the same communication logic foreseen in the other cases for capable or incapable adults. Also in these cases the aim of the communication is to give information and involve the next of kin. In this regard the family must be helped to understand and possibly share the motivations leading the healthcare professionals to propose such treatment. The parents must have an adequate amount of time to discuss their opinions and feelings and to ask questions.

From both an ethical and juridical point of view, a particular problem might arise if the parents are opposed to deep sedation therapy being carried out on their child. It must be highlighted that parents have a responsibility towards their children, which is that of taking care of their fundamental interests. The guarantee of what remains of a life without suffering in these dramatic situations and the respect of dignity until death are two essential parameters in identifying what is best for the child. In the case of disagreement between doctors and

¹⁶ National Bioethics Committee, *Bioethics with childhood*, 1994, p. 57.

¹⁷ S. Postovsky, B. Moaed, E. Krivoy, R. Ofir, M.W. Ben Arush, *Practice of palliative sedation in children with brain tumors and sarcomas at the end of life*, “Pediatr. Hematol. Oncol.”, 2007, Sep., 24(6), pp. 409-15.

¹⁸ Wong/Baker Faces Rating Scale, Oucher Scale.

parents over these decisions, it can be helpful to have the opinion of the paediatric ethics committee when possible¹⁹.

It must also be considered that in the paediatric age group there are not many readily available painkillers that are suitable for children and hence the need to make recourse to “off label” therapies; although complicating the problem even more so from a bioethical point of view, such need can never represent a formal pretext to deny adequate sedation for children.

6. Hospice and professional training

Training is needed in the individual construction of reflection and collegial discussion so that each healthcare professional might deal with more and more frequent complex situations involving a number of ethical aspects in clinical practice. Both in the contexts of the initial training and ongoing professional training, the focus must be on the importance of the learning of teamwork processes. The training should also be extended to all those involved in end-of-life care (nurses, psychologists, social workers, religious assistants). Lastly, specific studies are recommended that take into account the complexity and peculiarity of the situations that arise and which are often the result of advancements in medicine and medical techniques. These studies on decision-making processes should encourage interdisciplinary approaches, linking human sciences and medicine and fostering the development of ethical competences.

Law No. 38/2010 sets down the outline for the realisation of a structured system, aimed at guaranteeing even highly complex socio-healthcare responses over the entire country, which, as such, presuppose the adequate training of the personnel having to interact during the course of treatment.

In such a viewpoint, in parallel with the definition of pain control and palliative care networks, it has been made possible to benefit from the training courses foreseen by the above mentioned law to allow the various professional categories to look more in detail at the specific clinical-healthcare competences and to broaden the planning and management capacities of the integrated diagnostic-therapeutic courses. With this goal a specific “palliative care” discipline has been set up, in which deep sedation is included and the categories of the professionals involved in this are defined²⁰.

Nevertheless, the application of the above legislation is far from being satisfactory at an operational level by the Regions, with unacceptable inequalities among regional areas to be found. In fact the actual application of the Italian law does not follow the traditional north-south divide, but has the outline of a patchy inhomogeneous map. Even the universities in Italy have done little for the application of art. 8 of the law which foresees masters aimed

¹⁹ See art. 37 of the Code of Deontology where it states with regard to children: “In the case of opposition by the legal representative to the necessary and undeferrable treatment of minors or those lacking capacity, the doctor must inform the judicial authority; if there is a danger or serious risk to the health of the minor or the incapable, the doctor must nevertheless proceed without undue delay and in accordance with the need for indispensable treatment”.

²⁰ In particular with the State-Regions agreement of 7 February 2013 was identified, for the professional category of physicians – Area of diagnostic medicine and services – the discipline of “palliative care” for the purposes of public competition rules for the access of doctors to facilities set up to be part of the palliative care network.

at training suitable professional figures to work in the sector with inevitable negative outcomes on the quality of the care given to the patients.

A specific reference must be made to the paediatric world. Art. 5 of the law foresees hospital and regional services with professional figures that have specific competences and experience in the field of palliative care and pain management for paediatric patients.

However, just as in adult care, likewise for the treatment of children there are regional differences and paediatric palliative care is generally insufficiently diffused over the country²¹. Most of the children who are down for palliative care die in inadequate conditions, without the necessary relief from painful symptoms, usually in hospitals and rarely in dedicated residential facilities (paediatric hospices)²². Children in the terminal stage of illness, which may lead to the need for deep sedation, must be cared for and assisted in an environment in keeping with their age, have all round and continuous care, must be able to express and see their emotions, desires and expectations being embraced and must have their family and those dear to them suitably assisted in the organisation of the treatment.

Generally speaking, in the management of palliative care and in particular deep sedation are embodied the traditional ethical principles guiding clinical decisions: non maleficence, beneficence, informed consent and equity. It is fundamental that such principles are used in the best interest of the dying person or whoever is suffering. Nevertheless, in this question the unbalanced attention by medicine still seems to prevail to the objectives of care and recovery with respect to palliation and the relieving of the pain and suffering caused by the pathology. Not sufficient account is taken of the fact that a good end-of-life care is possible and that painful death is avoidable. This is serious since it is in this very context that the bioethical aspects can enter into conflict with the organisational ones. In fact, the insufficient diffusion of palliative care in Italy, for both adults and children, which is patchy with macroscopic differences from region to region, generates intolerable and unfair inequalities clashing with the principle of justice.

The Committee is aware that the problems of an ethical, deontological and social order are all the more delicate and complex the more extremely vulnerable people are being dealt with who are between life and death. These are situations that can bring about deep changes in the life of the dying persons and their family and/or in which the patient's dependence on the healthcare personnel is 'maximum', as in the case of an incurable child close to death.

²¹ At present only nine Regions have formally approved the setting up of the paediatric network of CPP + TDP (Basilicata, Campania, Emilia-Romagna, Liguria, Lombardy, Piedmont, Umbria, Veneto and PP. AA. of Trento and Bolzano) and only five of these (Basilicata, Emilia-Romagna, Liguria, Lombardy and Veneto) have actually created it. Only in Veneto is there a paediatric hospice and only five Regions have set up at least a Reference Centre with a multi-disciplinary team, dedicated to the paediatric palliative care (CPP) (of which four are in the north: Emilia Romagna, Lombardy, Piedmont and Veneto; there is only one in the south: Basilicata).

²² Even if in Italy there are no official numbers regarding the presence of children in need of palliative care, on the basis of forecasts it can be calculated that every year there are about 11,000 minors (age 0-17) with incurable pathologies. A survey carried out in the Veneto Region shows that in Italy there are 15,000 children needing a palliative care approach and that half of these need specialist palliative care or, that is, the ongoing intervention of professionals exclusively dedicated to paediatric specialist care working in specific multi-professional teams. At present only a small part of these children can benefit from this appropriate palliative care (Commission for paediatric palliative care, http://www.salute.gov.it/imgs/c_17_pubblicazioni_580_allegato).

Therefore the management of these particularly vulnerable people needs to be entrusted to professionals expert in the sector of this specific palliative care, who are suitably trained under the bioethical profile, able to identify and always keep in mind what the best thing to be done and the best treatment for the dying patient is.

It is important that the staff dealing with end-of-life situations is part of a therapeutic team already acquainted with the patient and their family insofar as this can facilitate the transition, undoubtedly not without distress, from needless curative treatment to deep and continuous sedation, avoiding the mistaken interpretation of therapeutic abandonment.

7. Recommendations

The Committee:

1. Considers that it is legitimate to adopt a deep and continuous sedation protocol in the presence of three contextual situations: - incurable illness at an advanced stage; - imminence of death, generally expected within a few hours or days; - presence of one or more suitably assessed symptoms refractory to therapies or of acute terminal events with serious physical and psychological distress.

2. Stresses that it is a fundamental right of man and therefore of the dying person (adult or minor) to receive adequate support aimed at the control of suffering in the respect of their dignity. Therefore, even though the legislation in force (art. 2, Law No. 38/2010) makes explicit reference to pain management in all the stages of the illness with particular reference to the advanced and terminal stages of the same, it is necessary that the patient's right is actually enforced. Also the patient, who becomes part of an end-of-life process following their refusal or retraction of one or more treatments or the use of instrumental support techniques of the vital functions has the right to benefit from pain control and continuous and deep sedation in the case of refractory suffering.

3. Reaffirms that for the goal, procedures and outcomes, continuous deep sedation, which is extended to the loss of the patient's consciousness, must be considered a healthcare treatment and not confused with euthanasia or assisted suicide or consensual homicide.

4. Deems a suitable amount of information necessary for the patient's informed consent, given in progressive and modulated terms, also in advance with respect to the progression of the illness.

5. Considers it appropriate that, before situations in which the patient's consciousness will fail in the long run, consequently hindering their capacity to express their last will, value be given to advance statements within the shared care plan.

6. Recommends that the parents be suitably informed and supported concerning the issues linked to the deep continuous sedation of paediatric patients. It is essential that good communication is established between the dedicated medical team, paediatric patients and their family, characterised by continuous dialogue and open exchange. The best interest of the minor is priority and their will must be respected too, within all possible limits.

7. Considers it necessary that for all cases of deep sedation the decision must be suitably justified and entered into the medical record, as expressly foreseen also by art. 7 of Law No. 38/2010.

8. Recommends a specific and ongoing training also in bioethical issues of the healthcare professionals who deal with this terminal stage of the patient. The training should involve also specific studies of medical records of previous cases in order to gain awareness of the complexity and peculiarity of the situations, without neglecting the study of advances in knowledge on deep sedation. Interdisciplinary research should be encouraged, linking the human and medical sciences.

9. Looks forward to the full application and integration of Law 38/2010, which governs palliative care and pain management in Italy, since unacceptable inequalities among regional areas still abound.

NORMATIVE APPENDIX

- In the 90s norms existed in Italy which, introduced to limit the use and abuse of drugs, had hindered the prescribing and application of efficient painkillers and in particular opiates and this lasted until the changes introduced by Law No. 12 /2001.

- The National Healthcare Plan 1998/2000 (D.P.R. July 1998) considered it necessary to intervene with actions aimed at an enhancing of analgic therapies, as well as a development of palliative care for terminal patients, with particular attention to oncological cases.

- The Decree of the Health Ministry of 28 September 1999 (National Programme for the creation of palliative care facilities) foresaw the realisation of hospices; the setting up of the assistance network for terminal patients; the assessment of care quality; the definition of regional competences in this regard.

- The State-Regions Agreement of 2001 envisaged the Hospital without Pain project of which various versions were to appear and which is mentioned in art. 6 of Law No. 38/2010. This project was insufficiently put into effect, despite the fact that at the time of the agreement guidelines had been drawn up for the Regions aimed at adopting the necessary proceedings in order to spread the philosophy of the fight against pain both in facilities for hospitalisation and treatment and in the out-patient care processes.

- The National Healthcare Plan 2003/2005 extended the category of patients involved in palliative care also to non-oncological ones. Furthermore, many concepts were also adopted which were already in the definition of palliative care published by the WHO²³ and by the European Association for Palliative Care (EAPC) and particularly important aspects were highlighted. Among others, “to review a number of normative aspects regarding the use of painkillers, improving the availability of opiates, simplifying their medical prescription, lengthening the therapy cycle and making their use possible at the patient’s home too”.

- Law No. 38/2010 is at present the organic set of regulations on palliative care. In art. 1 it foresees “the right of the citizen to access palliative care and pain therapy”, and identifies two separate care networks, one for pain and one for palliative care dedicated to adults and a single network the includes both pain management and palliative care for children dedicated to patients in the paediatric age group. It very clearly underlines how the healthcare facilities

²³ WHO, *Definition of palliative care* (<http://www.who.int/cancer/palliative/definition/en/>).

delivering palliative care and pain control must guarantee an individual care plan for the patient and their family, in the respect of the fundamental principles for the safeguard of the dignity and the autonomy of the sick person, without any discrimination; of the safeguard and fostering of quality of life at every stage of the illness, in particular in the terminal one; and of an adequate healthcare and socio-healthcare support of the patient and their family. Art. 2 of the law, in mentioning national palliative care networks and pain therapy, makes explicit reference to pain management in all stages of the illness, with particular reference to the advanced and terminal stages of the same, even if deep sedation is not explicitly mentioned (art. 5, par. 3).

- With regard to pain therapy this law must be accompanied by the Single Text of the laws on drugs and psychotropic substances, prevention, care and rehabilitation of the relative states of addiction. The Single Text has been changed and integrated on numerous occasions over the years. In fact, this law simplifies the prescribing of non-injectable drugs: the NHS doctors are thus allowed to prescribe these drugs by using the simple NHS prescription format.

- The Agreement of the permanent Conference on Relations between the State, the Regions and the autonomous Provinces of Trento and Bolzano of 16 December 2010 on the “guidelines for the promotion, development and coordination of the regional interventions within the network of palliative care and pain therapy”, established that specifically dedicated facilities should be created dedicated to the coordination of the palliative care and pain management network²⁴.

- The agreement between the Government, the Regions and the autonomous provinces of Trento and Bolzano of 25 July 2012 sets down the minimum requirements and the organisation modalities necessary for the accreditation of the assistance facilities for terminal patients and palliative care and pain control units, and also sets out the identification of the network facilities²⁵. The minimum requirements and organisations needed for the accreditation of the residential, home, hospital and territorial facilities are thus defined, identifying qualitative and quantitative standards for the drawing up of the organisation models for the treatment of adults and children in palliative care and pain management.

- The State-Regions conference agreement of 10 July 2014 identifies the professional figures that can operate in the palliative care and pain management networks and in paediatric palliative care and pain control. The agreement set down the contents of the training courses foreseen for the various professional figures.

- The stability and agreement Law of 22 January 2015, contextually with the drafting of the Agreement of 10 July 2014 through a parliamentary passage

²⁴ On this subject the Italian Society for Palliative Care, *Recommendations on terminal sedation/palliative sedation* (2007) made a number of recommendations. In the same way also other international organisations like the European Association for Palliative Care, at a later date produced a series of important documents. In 2013 upon initiative of the Fondazione Lefebvre D'Ovidio Onlus the *Charter of the rights of the dying child (the Trieste Charter)* was published. Even the Code of medical deontology in this 2006 version and the more recent 2014 one explicitly attributes the task to the doctor of not only giving treatment aimed at the recovery of the patient, but also to give him relief in suffering and accompany him to his death (arts. 3 and 39).

²⁵ By pain therapy network is meant a functional aggregation of pain management activities, delivered in different healthcare settings with the goal of improving the quality of life of the people in pain and to reduce their degree of disability.

that overcame the critical issue relative to the doctors who work in the regional palliative care networks without being in the possession of a specialisation, who were therefore excluded from the application of the regulation. For this purpose, the State-Regions Conference adopted an agreement on 22 January 2015 whereby the outline of the Health Ministry decree was approved setting down the criteria for the certification of the three-year experience in palliative care.

TECHNICAL-MEDICAL APPENDIX

Assessment of level of sedation and drugs used.

There is no unanimous agreement on the choice of sedation scale, even if, for practical use, the use of a simple scale is to be preferred, easily applicable and reproducible in different contexts. The most widely used ones are the Rudkin and the Ramsay Sedation scales.

Scale of Rudkin

1st level: patient awake and oriented

2nd level: drowsy but arousable

3rd level: eyes closed by responsive to verbal stimuli

4th level: eyes closed but responsive to physical stimuli (not painful)

5th level: eyes closed and unresponsive to physical stimuli

Scala di Ramsey

1st level: if awake patient anxious, agitated or restless

2nd level: if awake patient cooperative, oriented, tranquil

3rd level: if awake patient responsive to commands only

4th level: if asleep patient has brisk response to light glabellar tap or loud auditory stimulus

5th level: if asleep patient has sluggish response to light glabellar tap or loud auditory stimulus

6th level: if asleep patient has no response to light glabellar tap or loud auditory stimulus

By deep sedation is meant either the 4-5 level of the Rudkin Scale or 5-6 level of the Ramsey Scale.

The choice of drugs

To date the first choice for drugs and the most commonly used is midazolam (short-acting benzodiazepine) even if other drugs can be used such as diazepam or propofol.

The opiates (morphine, fentanyl, remifentanyl) are not indicated for their mainly analgesic affect. If they are already being administered to treat pain, they must not be suspended but associated with the sedative-hypnotic drug.

The dosage of the drug used must be quickly increased until it reaches the therapeutic goal and changed according to the varying level of sedation so as to avoid inopportune awakening or an excessive depth of sedation.

Refractory symptom

A symptom that cannot be adequately controlled despite every effort to find an effective therapy that does not compromise the state of consciousness.

The most frequent symptoms defined as refractory in impending death are:

- dyspnea
- *delirium*
- psycho-motor restlessness
- nausea and uncontrollable vomiting (as in intestinal occlusion)
- pain
- psychological or existential distress.

The refractoriness of a symptom must be assessed by a team of physicians expert in palliative care and pain management.

A personal remark by Prof. Carlo Flamigni

The necessary premise to my dissent concerns our specific activity, which is one of reasoning over bioethical issues and not one of finding or endorsing juridical stratagems that allow citizens to avoid criminal sanctions for having chosen a type of behaviour that is considered morally licit by the conscience of most people. In the case in point the problem concerns the doctors and their relationship with euthanasia: we are well aware that this is a choice that is made by many healthcare professionals in a great number of public and private facilities, and which stops being a choice if the doctor feels himself observed, something that can quite normally happen in some institutions. To establish that to take away a person's life must be considered an illicit and criminal act, even if it is a question of easing the departure of a human being torn apart by suffering that is destined to go on until their death, even if the person asks us to do this as an act of mercy, is up to the law, and in Italy the law prohibits euthanasia and punishes compassionate doctors. Finding the way to disguise euthanasia by making it pass as a necessary deed, compassionate and licit, is a possible operation, and praiseworthy from certain points of view, but which should not concern us, as we ought to entrust it to the knowledge of the scholars of law or to the imagination of politicians.

In very simple terms therefore, the document takes into account the fact that a definition of death exists; that giving death is prohibited (and punished) by the law; that continuous deep palliative sedation does not hasten (perhaps) death and is not therefore forbidden by law. I would like to make some observations on this point.

Continuous deep palliative sedation should be used only in the imminence of death, and this entails the need for a definition, which is impossible to give in medicine: I have seen people with a prognosis of a sudden and very close death (all the doctors smile when Mimi's doctor sings "The consumption only leaves her a few hours to live"). I ask therefore: seeing that medicine has no certainties and is based on statistics, which Gauss curve and which standard deviations are we referring to? And shall we propose a different one for each morbid condition? And after how long can justice intervene and demand that the sedation be interrupted? And what are the consequences of this, considering

that waiting times of a number of years can be envisaged what with appeals and delays?

Second point. On several occasions at the beginning the document refers to an intervention aimed at improving the quality of life (“.... In the light of the quality of life” “aimed at improving the quality of life”). In my opinion the quality of my life has one judge only and that judge is me: but if I am unconscious and will never have my consciousness back again, I cannot give this judgement, either for good or for worse. If, during the course of continuous deep palliative sedation you torture me, you do not worsen the quality of my life, I am not there to perceive the harm that you caused me and I will never wake up to be able to experience it. The word life refers to the possibility for participation or the hope for participation, things that are both absent in the case in point: I am alive if I have awareness of myself (or I will have awareness of myself) if I can (or will be able) to remember my past, imagine my future, reason with you...I am not alive if all that remains of me is the most vulgar part of my biology, the beard that grows, the intestinal peristalsis: my being alive is witnessed by my voice saying rational and sensible things, not the noise of my stomach rumbles.

Third point. In the debate the problem of the administration of drugs was dispatched by stating that in the case in point they do not shorten survival. Where is the evidence for this? No drug is without effects on at least one of the functions of the organism, they are all harmful in some way or other. Aspirin included. In order to affirm that these drugs are absolutely incapable of shortening life, double blind studies are needed on a huge number of patients, above all if we imagine the complexity of the problem and its modifications (undoubtedly not macroscopic) induced by sedation. I believe that it is only fair to admit that one possibility of interference with the duration of life exists, but that this is a question of a very short time. How short? A minute? What is the tolerance, after how much time do we have to admit to having shortened an existence? One minute? An hour? More? And why? Is it not true that even a single minute of our existence is precious (I have heard a very well-known bioethicist say this)? This embarrassing question should be sufficient to convince a magistrate to open an inquiry into continuous deep palliative sedation.

Last point. Palliative care is mentioned on various occasions in the document. I looked up the term *to treat* in the Italian dictionaries and I found more or less the same definitions:

- To give the sick person the therapies necessary for recovery;
- To fight a morbid state with therapeutic means.

I seem to recall a position that has long been held by the Catholic bioethicists who held that MAP is not medical treatment as it modifies the condition of sterility and that therefore it should not be carried out in hospitals. I imagine that it could be maintained that continuous deep palliative sedation is not a treatment, taking into account the meaning of the term *treatment*. And if it is not treatment then what is it? And which facility or institution is really suitable for the treatment of these patients? Perhaps it would be better to gloss over this.

Well then, if I am a patient who is going through hell because of an illness which has no hope of recovery, if I know that this suffering will continue, interspersed with more or less long periods of consciousness, if I fall asleep,

each time that the morphine has its temporary effect, terrorised by the idea that I will wake up tormented by my suffering; and yet if someone advances the hypothesis of continuous deep palliative sedation and proposes it to me, what I understand is that I am being offered the possibility to choose a good death and I accept it happily, astonished rather by the fact that Italy has finally legalised euthanasia.

After all, this document, which finally makes a compassionate act legal (but does it with an enticing hypocrisy) and allows many doctors working in intensive therapy facilities to be able to practise without having to fear justice, is from a practical viewpoint a very good thing, with the only defect of being voluntarily forgotten by ethics, which is a very bad choice if we recall the name of our Committee.

Carlo Flamigni

Statement by Prof. Demetrio Neri

This note does not set out to be an annotation to the document “Continuous deep palliative sedation in impending death”. It is just a declaration in support of the negative vote that I cast on the above mentioned document.

As will be remembered, in the December sitting I had proposed the elimination of the whole third paragraph of the document, pointing out that deep sedation is a morally appreciable practice owing to its intrinsic features and does not gain, or lose anything, by being descriptively different from other practices like euthanasia, assisted suicide or consensual homicide. My proposal was rejected by the assembly. I take note of this, but it has put me in the position of not being able to approve the document. The basic reason is that to the question that the NBC sets out to debate in this paragraph (in lines 140-143) my answer is: yes, deep sedation is an act of euthanasia and I – and this is not just recently – am convinced that it – together with, and not with the exception of, other actions – is a good thing that it is part of the group of options available to individual end-of-life choices, in such a way that whoever asks for it, or agrees when it is proposed, can do so because it corresponds to their moral choices and not because it is the only available option. It could also be pointed out that, at the beginning of the third paragraph, the document chooses to not take into account the ethical problems linked to euthanasia or assisted suicide or consensual homicide, confining itself to describing the objective differences existing among these three practices and deep sedation. Nevertheless, admitted that (but not conceded: see below) the discourse manages to keep within these descriptive limits, I asked myself what use the mere description of the factual differences could be (which moreover, as such, nobody is doubting) between deep sedation and the other above practices. To answer the question posed by Hon. Paola Binetti? It is difficult for me to think that when Paola Binetti asks us to clarify the “boundaries” that separate deep sedation from euthanasia she has in mind purely factual, descriptive “boundaries”. To reassure the doctors that in applying deep sedation they are not carrying out an act that can be defined euthanasic? But – as remarked in the assembly debate – the doctors would rather be reassured that they are not carrying out an act that can be defined as a crime and in our legal system there is no specific crime of

euthanasia. They should be remanded on the crime of consensual homicide; but – apart from the difficulty, shown in the doctrine and jurisprudence, of attributing euthanistic facts to this crime – I do not think that tasks of such a nature concern the NBC. In any case, this specific juridical aspect has been set aside for some time now. Therefore the document could have done without this paragraph and the moral appreciation of deep sedation and the study of its proper application modalities would have had nothing to lose.

I now move on to clarify why I wrote the above “permitted, but not granted”. Even though I appreciated the effort to keep at a descriptive level (I stress however, to avoid any misunderstandings, that I intend – and I have always intended – such “descriptive plan” as that of the various moral standpoints, not that of the factual differences of the acts and facts), I am convinced that in these issues it is inevitable that judgement values creep in, which it might be a good idea to make plain (descriptively) rather than conceal referring to the simple description of the factual differences between deep sedation and the other above mentioned practices. As such the description contains nothing that makes it possible to conclude that the first is appreciable and admissible at a moral level (I shall not deal with the legal level) and the others are not. A value judgment needs to be added to the description and this is inferred from the decisive choice made by the palliative care movement in favour of palliative care and deep sedation and to the exclusion of active euthanasia upon the patient’s request or assisted suicide. See with regard to this point 7.2 of the SICP document, referred to on more than one occasion in the NBC’s document: it says that the distinction is made “both at empirical (clinical) level and ethical level” (my italics). This previous, and selective at moral level, decisive choice is also to be found in the NBC’s document: or, at least, it is difficult to infer it. For example, in lines 117-121 are listed the four circumstances that must be present simultaneously in order to “ethically” legitimate deep sedation: but the same circumstances can accompany the case of a patient who refuses deep sedation and asks to be given a substance that puts an end to his life. Why would those circumstances, in themselves considered and descriptively speaking, “ethically” legitimate the first and not the second? It seems to me that the only difference lies in the different orientation of the person, but this has nothing to do with the descriptive and factual level, but with the existential plane of the life choices and values of that person. If, in the presence of the three other conditions, the request/consent of the patient is morally acceptable only if it is already (descriptively?) framed in what the medical profession considers what can or not be done, what is the point of speaking further on, in the paragraph on informed consent, of “embracing their desires” (line 173) or to seek “a shared trust based on a number of desires, life choices, values manifested by the patient” (lines 177-178)? It would appear, and selectively so, only those desires, life choices and values can be embraced that come into the group of those that the medical profession considers to be ethically acceptable: and is there not a value judgement going on here? In all this are we still on the descriptive plane? Actually, the text just referred to is completed with “and gained within the relationship with the healthcare professionals” (177-78). Now apart from the fact that it seems rather limiting to speak in terms of desires and, even more so, of choices and values (which are or should be those that are gained in the course of a whole lifetime), the sentence seems to want to say that only those desires, life choices and values can be considered that the patient gains within the context of the relationship with the medical team,

perhaps changing those previously held. If this is the right interpretation, the passage comes to mind in which Plato (I am not able to find the quotation) suggests that doctors should establish with their patients (only the “free” ones and not the slaves) what today we would define as a communication relationship: but with the aim of “making them docile and law-abiding by rhetorical means”: this is most “insidious” form of medical paternalism!

Allow me to add an observation on another point of the document which (among others, of lesser importance) does not convince me. At the end of the second paragraph is the question about the relation between deep sedation and the interruption of other treatments. According to some (and I am among those) the giving of deep sedation necessarily requires the interruption of other treatment (see, for example, the recent French law), but the document states that at “each case must be judged singularly, taking into account that many of these treatments are symptomatic and necessary in order to alleviate suffering”. According to me it is not easy to understand what this means: if it is decided, with the patient’s consent, to use continuous deep sedation because with the other treatments the distress and suffering cannot be eliminated, what is the point, in deep sedation, of continuing to administer treatment that has evidently been inefficacious? And moreover who decides, as the patient is in deep sedation? And on what bases? With regard to artificial hydration/nutrition, it just says that when the patient is at the end of their life this treatment is generally contraindicated (from the clinical point of view I suppose) and when instead it is indicated (always clinically I presume) the patient is not dying and is not eligible for deep sedation. This is a way to bypass the crucial point and that is (as was brought to our attention in one of the hearings) whether the patient wants or does not want to undergo this treatment: clinical appropriateness or inappropriateness does not equal moral appropriateness or inappropriateness (as instead is sometimes stated in the document).

Demetrio Neri

ATTACHMENT:

Question posed by Hon. Paola Binetti to the National Bioethics Committee

To the National Bioethics Committee

To the kind attention of the President Professor Francesco Paolo Casavola

And copy forwarded to the Vicepresidents:

- Professor Lorenzo d' Avack (substitute vicepresident)
- Professor Riccardo Di Segni
- Professor Laura Palazzani

Preamble

Law No. 38 of 15 March was enacted in **2010** concerning “Provisions to guarantee the access to palliative care and pain therapy” (Official Gazette No. 65 of 19 March 2010). As is by and large recognised, this is a very innovative law, which for the first time guarantees the access to palliative care and pain therapy by the sick person, in the context of essential levels of healthcare, for the purposes of ensuring the respect of dignity and autonomy of the human being, the need for health, equity in access to assistance, quality of treatment and its appropriateness to specific needs. Among the first in Europe, in art. 1 the law safeguards “the right of the citizen to access palliative care and pain therapy”, and identifies three assistance networks dedicated to palliative care, pain therapy and children with medical illnesses. The law stresses very clearly that the healthcare facilities supplying palliative care and pain management must guarantee an individual care plan for the patient and their family, in the respect of the fundamental principles of the safeguarding of the patient’s dignity and autonomy, with no discrimination whatsoever; the safeguarding and promotion of the quality of life in every stage of the illness, the terminal one in particular, and an adequate socio-healthcare support for the patient and their family.

As is well known the law changes the Single Text of the law on the subject of drugs and psychotropic substances, prevention, care and rehabilitation and the relative states of addiction (DPR 309 of 1990), simplifying the prescribing of these drugs by using the simple NHS prescription. At the same time however The Agreement of the permanent Conference on Relations between the State, the Regions and the autonomous Provinces of Trento and Bolzano of 16 December 2010 on the “guidelines for the promotion, development and coordination of the regional interventions within the network of palliative care and pain therapy”, established that specifically dedicated facilities should be created dedicated to the coordination of the palliative care and pain management network.

When it mentions national palliative care networks and pain therapy, art. 2 of the law makes explicit reference to pain management in all its stages of the illness, with particular reference to the advanced and terminal stages of the same, clearly envisaging the possible access to forms of deep sedation.

To quote it says: *“The national network for palliative care and the national network for pain management, to ensure the continuity of care of the patient from the hospital facility to their home and includes the whole offer of territorial healthcare facilities, hospitals, the professionals and diagnostic and therapeutic interventions available in the Regions and autonomous Provinces, dedicated to the provision of palliative care, pain management in all the stages of the illness, with particular reference to the advanced and terminal stages of the same, and to the support of the patient and their next of kin”*; and later on in article 4, para. 2, it states: *“The campaigns referred to in paragraph 1 shall promote and diffuse awareness of the importance of palliative care in the public opinion, also paediatric palliative care, and pain management, for the purposes of fostering the culture of fighting against the disease and the overcoming of the prejudice relative to the use of drugs for the treatment of pain, illustrating the fundamental contribution for the protection of the dignity of the human being and the support for the patients and their next of kin”*.

The real question

In these times of parliamentary debate it is repeatedly asked by a number of MPs of different parties, in office and in opposition, to schedule the numerous draft laws presented during the XVII legislature, which have as their central theme the so-called Living will, and which was long debated in the previous legislatures, in particular in the XV and XVI. Some of these draft laws explicitly ask the Italian law to acknowledge also the various requests for euthanasia, along the lines of what is happening in other countries outside Europe too. In this question a number of colleagues maintain that the law on palliative care, approved five years ago, making forms of *pain control possible in all the stages of the illness, with particular reference to the advanced and terminal stages of the same* (deep sedation), already constituted a sort of opening in this sense. Instead this was peremptorily excluded during the parliamentary debate of Act 38 on palliative care, as can easily be seen from the proceedings relative to the approval of the law itself.

I therefore ask for a clarification of the boundaries that separate the administration of drugs, as foreseen by Law No. 38, for complete pain control, until its suppression, from possible forms of euthanasia that instead clearly and directly aim at the suppression of the patient. I also ask for the ethical reasons for deep sedation to be specified with particular attention to the patient's informed consent and the decision-making modalities when the consent has not or cannot be expressed.

Having at the time presented a draft bill on palliative care and been rapporteur in the House on the same law I would be particularly interested in having an answer from the NBC before going back to scheduling bills which issue precise requests for euthanasia, as well as speaking about the so-called living will.

Sincerely

Paola Binetti

MP, member of the XII Committee