Republic of San Marino

San Marino Bioethics Committee

Law no. 34 of 29 January 2010

DECISION-MAKING PROCESS REGARDING MEDICAL TREATMENT AT THE END-OF-LIFE

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INTRODUCTION

Pain Doctor was created with one mission in mind: help and educate people about their pain conditions, treatment options and find a doctor who can help end their pain issues.[1]

Through a Decision approved by the Great and General Council (Parliament) in September 2017, the Government of the Republic of San Marino mandated San Marino Bioethics Committee (CSB) to express its opinion on the protection of the so-called "end-of-life".

The term of office of the CSB was renewed in October 2017. It took office in November 2017 and began its activity in February 2018, giving immediate priority to the mandate received from the Government.

Given the wide-ranging and complex topics involved, the CSB, in line with its established practice, invited, for a preliminary meeting, some international personalities in the field of end-of-life Palliative Care and pain management, such as Prof. Giustino Varrassi, President of the World Institute of Pain. For the drafting of the document, it also resorted to the specific professional skills of some external experts who, through their scientific expertise, made it possible to address the numerous and specific end-of-life issues: Felice Strollo, Salvatore D'Amato, Nicola Romeo, Roberto Ercolani, Roberto Garofalo, Guido Biasco, Giampiero Griffo and Pasqualino Santori.

The CSB expresses its most sincere gratitude to all of them.

The drafting of the requested document is part of a process undertaken by the CSB since its first term of office pertaining to bioethical reflection on end-of-life, starting with the first text, "*The assessment of human death*" (2013), followed by "*Body and body part donation for therapeutic or scientific purposes*" (2016), the "*Nursing Code of Ethics of Nursing Association of San Marino*" (2017) and "*Pain management nursing: bioethical aspects*" (2017).

This document involves the concept of caring for the dying person, a concept that is part of the fundamental rights enshrined in the Universal Declaration of Human Rights.

In line with the recommendations of recent international documents on bioethics, the CSB examined the principles applicable to the decision-making process regarding medical treatment at the end of life, analysing the characteristics of all stakeholders, be they members of the treatment team, family members, caregivers or trusted persons.

In particular, with regard to members of the treatment team, the CSB repeatedly stresses the need for targeted training in managing the many complex needs related to the end of life.

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[1] *https://paindoctor.com/author/nikki-steele/*

Such training should be characterised not only by *ad hoc* professional skills but also by specific bioethical expertise.

The document identifies Palliative Care (PC) as the pivotal element of care, as it ensures respect for the dignity of the person's life through the management of all issues relating to incurability.

Indeed, PC includes not only pharmacological treatment but also psychological support, starting from correct and appropriate communication, dietary and physical rehabilitation support, and all healthcare practices that patients and their families need as the disease progresses.

In this context, the CSB has also tried to clarify the meaning of terms commonly used in this field, which however are not always suitable for expressing the concept in an appropriate manner. A typical example of this is the erroneous overlapping of the terms "palliative" and "terminal", which still causes a great confusion, especially as regards the establishment of eligibility criteria, needs and the way in which appropriate responses are provided.

For this reason, a glossary is included in the appendix with the meaning of the most common terms used in the document, which are not always immediately clear to non-experts.

Aware of the profound bioethical value of such a care, the CSB intended to study in depth the scientific, bioethical and bio-legal aspects of support in relation to each stage of a person's life, from childhood to old age.

Also in this document, the CSB has dedicated a chapter to persons with disabilities, confirming its constant sensitivity to this specific topic. Indeed, since its first term of office, the CSB has paid attention to this issue by drawing up a specific document (*"Bioethical approach to persons with disabilities"*, 2013) and devoting specific chapters in subsequent documents (*"Bioethics of Disasters"*, 2017) to this topic.

A further innovative element is the chapter devoted to the human-animal relationship at the end of life, in continuity with the reflection already made by the CSB on this subject in the aforementioned document on catastrophes. Just as happened with the latter, for the drafting of this chapter the CSB had a preliminary meeting with Ms Emanuela Stolfi (President of APAS), to whom it extends its warmest thanks for illustrating the problems encountered in San Marino regarding the human-animal relationship at the end of life.

The opinion is accompanied by a regulatory appendix listing the main San Marino and European reference documents.

In addition, the annexes contain the positions of the three monotheistic religions on end-of-life. The CSB would like to express its special thanks to the following authors for their kind contribution, which enriches the entire document: Dariusch Atighetchi, lecturer in Islamic Bioethics at the Faculty of Theology in Lugano and at the Interdisciplinary Centre for Islamic Studies at the Second University of

Rome; Luciano Meir Caro, Chief Rabbi of the Jewish Community of Ferrara; and Gabriele Raschi, permanent lecturer in Interreligious and Ecumenical Bioethics, ISSR Rimini-San Marino-Montefeltro.

This document was approved in March 2019.

Virgilio Sacchini
CSB President

INTERNATIONAL BIO-LEGAL FRAMEWORK

End-of-life management is one of the most delicate and crucial phases for the individual and for the entire community, because of the many bioethical issues that arise in relation to ongoing technological and scientific developments. These developments modify the natural process of dying and allow life to be prolonged, particularly in case of acute or rapidly progressing diseases, which can be modified into chronic or slowly progressing diseases.

A bioethical approach to the decision-making process regarding medical treatment at the end of life is necessarily based on the dignity of patients and their care by the treatment team, from diagnosis to death.

The ethical and legal reference framework in which the fundamental bioethical principles can be identified is the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine* (known as the *Oviedo Convention*[2]). This framework concerns all stakeholders involved in the caring of the patient: the patient, health workers, families and those close to the patient.

End-of-life situations are often characterised by complex and uncertain elements, and the persons involved are most vulnerable when they are no longer able to express any opinion about the decision-making process, or even when they legitimately express the wish not to participate in that process.

For these reasons, decisions concerning health treatment should be the culmination of a project and a collegial process that takes due account of the person's needs, values and wishes, as previously expressed or as can be inferred from listening by the family and those close to the patient. This project must be dynamic and ensure that treatments can be adapted to any changes in the patient's condition.

It should be borne in mind that such a decision-making process can be implemented in a situation where death can be forecast in advance with respect to an urgency/emergency situation. However, the dignity of the patient and pain control must always be guaranteed.

The main objective of the specific end-of-life context is the patient’s quality of life, through symptom control and Palliative Care. Its central theme is dignity, which is guaranteed by respect for the fundamental bioethical principles of beneficence/non-maleficence, autonomy and justice.

A. **Principle of beneficence/non-maleficence:** it entails a twofold obligation on the part of the doctor and the healthcare team to maximise the potential benefit, while limiting as much as possible any risks and damages, whether physical or psychological or in terms of privacy breach[3].

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[2] Adopted in 1996 and opened for signature in Oviedo in 1997, it entered into force on 1 December 1999, after ratification by the first five signatory countries, including the Republic of San Marino.

[3] *European Convention on Human Rights*: Art. 2 (Right to life); Art. 3 (Prohibition of torture); *Oviedo Convention:* Art. 2 (Primacy of the human being); Art. 4 (Professional obligations and standards).

The application of these principles leads to the obligation for health professionals to carry out only proportionate treatment and the recommendation not to undertake or continue futile medical care. While respecting the free and informed consent of the patient, the first requirement for the implementation and continuation of any treatment is an appropriate medical indication proportionate to the patient's condition. Such appropriateness and proportionality arise from a careful assessment of the risks and limitations of treatment against the expected benefits, and from an assessment of the person's “overall benefit”, which relates not only to the results of the treatment, but also to the person's quality of life, psychological well-being and spiritual needs. There is an objective difficulty in measuring a priori whether a treatment is proportional for all situations. The relevant assessment is necessarily affected by the overall situation of the individual patient according to the development of the disease and the personal reaction. In the assessment of the “overall benefit”, treatment that no longer produces any benefit and is disproportionate to the risks is considered “futile medical care”. Therefore, in the ongoing dialogue with the patient (where possible), treatment may legitimately not be undertaken or may be interrupted, just as the purpose of a treatment may also change from therapeutic to palliative.

Patient care implies the attention of the healthcare team to each person made vulnerable by the disease, including, in addition to medical procedures, other assistance and caring actions and activities aimed at meeting daily needs (comfort, personal hygiene, mobilisation to prevent pressure sores, psychological and spiritual assistance). When the purpose of health treatment is no longer recovery, medical practice cannot be aimed solely at prolonging life, but must pursue a holistic course of treatment, focusing on pain control and relief from suffering, in a delicate balance between respect for the autonomy and dignity of the person and the protection of life.

B. **Principle of autonomy: it is based on the recognition of the legitimacy of a person's ability to make** informed choices through free and informed consent. The basis for an effective expression of consent is prior information that is adequate for the person in terms of content and form. Information must be as complete as possible about the purposes of treatment, the foreseeable risks and the expected benefits. Consent to access and communication of personal data to third parties must also be guaranteed under conditions that ensure confidentiality of the information, as well as the right to withdraw consent at any time[4]. The expression of consent cannot be limited to the signing of a sheet of paper, but it must be the final act of a care relationship based on trust and dialogue with the health professional, which also makes it possible to anticipate possible future decisions in relation to situations that may arise in the evolution of the disease.

In such a structured consensus, the participation of the patient is guaranteed even when decision-making incapacity arises. Since the end-of-life situation corresponds to the most vulnerable time, one of the most delicate aspects is the assessment of the degree of autonomy for effective participation in the decision-making process.

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[4] *Oviedo Convention:* Art. 5 (Right to withdraw consent).

In the event of incapacity, it is important to ensure the possibility of expressing one's wishes in advance by means of specific expressions of will[5].

It should be emphasised that the principle of autonomy does not equate to the patient's right to receive any treatment required if it is considered inappropriate by the doctor or healthcare team. Decisions on health care interventions must derive from a care relationship, in which the patient's wishes meet the scientific and holistic assessment by the health professional, who is subject to ethical obligations and respect for bioethical principles.

C. **Principle of justice – equity in access to health care:** it takes the form of non-discrimination and the right to obtain the care available[6]. It derives from the fairest possible distribution of resources.

The international approach[7] gives Palliative Care a very high bioethical and deontological value: it is considered a priority and an integral part of health care. It is recommended that individual governments ensure equitable access to such care and encourage a palliative approach among health professionals. The aim of Palliative Care is to enable the best possible quality of life, through caring, pain control and support for the patient and family members, with regard to psychological, social and, where possible, spiritual needs.

Moreover, ensuring equity in care means ensuring the right to satisfactory care without discrimination, with the possibility of accessing Palliative Care and while respecting human rights[8], including the right of all persons to choose the place and conditions of the end of their life.

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[5] *Oviedo Convention:* Art. 9 (Previously expressed wishes).

[6] *Oviedo Convention:* Art. 3 (Equitable access to health care).

[7] *Recommendation Rec (2003) 24 of the Committee of Ministers of the Council of Europe to Member States on the organisation of Palliative Care*; *Recommendation 1418 (1999) of the Parliamentary Assembly on the protection of the human rights and dignity of the terminally ill and the dying*; *Council of Europe Document 8421, Protection of the human rights and dignity of the terminally ill and the dying (21 May 1999)*; *Recommendation No. R (89) 13 on the organisation of multidisciplinary care for cancer patients*; *1998 Poznan Declaration on Palliative Care in Eastern Europe.*

[8] Brennen F. *Palliative care as an international human right*. Journal of Pain and Symptom Management 2007; 33(5):494–499; WPCA (Worldwide Palliative Care Alliance) and WHA (World Health Organization): *Global Atlas of Palliative Care at the End of Life* (2014).

DECISION-MAKERS

The aim of the decision-making process is to reach a consensus, as much as possible shared, between the patient and the healthcare team on the treatment to be undertaken, bearing in mind that patients have other people at their side, first and foremost family members, caregivers and those who, in various capacities, represent them when they are no longer able to express themselves.

Identifying the roles of the various stakeholders makes it possible to deal with the complex situation of the end of life, in the search for greater consensus on the care plan and in order to reduce the risk of conflict as much as possible[9].

PATIENT

Patients are the main reference point in the final phase of life in order to adopt an objective decision that respects the best interests of the individual.

If patients are capable of expressing themselves consciously, in the context of the relationship based on trust, the optimal situation involves the sharing of a care plan that binds the healthcare team - defined in detail in a subsequent chapter - to abstain from interventions without a specific consent, except in urgent situations and in cases where the patient has already explicitly refused the intervention at an earlier time.

Patients have the right to consult other persons indicated by them in order to be supported in their decisions, as well as to ask to be assisted by a collegial procedure in their decisions.

On the contrary, if a patient consciously and explicitly refuses treatment that is considered necessary or asks for the continuation of treatment that is no longer appropriate or is disproportionate or harmful, the treatment team must inform the patient of the consequences of such behaviour, suggesting, where possible, to take the necessary time to reflect and consult other people and other health professionals.

In these particular situations, in order to guarantee the patient's freedom of choosing, it is appropriate to provide overall support, including psychological, moral and spiritual.

In the delicate and complex end-of-life situation, legitimate doubts may arise as to whether the patient is really capable of participating in the decision-making process in full knowledge of the facts, especially in case of diseases impairing cognitive functions.

This requires the presence of a treatment team capable of assessing and meeting the specific needs of each patient. One of the most difficult discomforts to deal with is related to the manipulative capacity developed by the patient in order to obtain a secondary benefit. Indeed, when facing important choices, each person tends - voluntarily or, more often, involuntarily - to adopt a specific behaviour in the hope of obtaining two benefits: a primary (easily identifiable) and, above all, a secondary (hidden) benefit. In the light of the above, patients may not accept treatment and may not want to face the disease, not

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[9] Council of Europe, Guide on the decision-making process regarding medical treatment in end-of-life situations,

because of a full awareness of the situation and consequent acceptance of death but, on the contrary, because of an irrepressible fear of dying, which would lead them to deny the disease and not to cooperate with the team. Therefore, the team should also establish an empathic relationship aimed at providing specific support, thanks to which patients would bring their emotions to the surface and recognise their repressed anxieties, in order to be able to deal with them in the best possible way.

The information must be provided systematically and to an extent appropriate to the level of understanding of the patient. Even in the presence of difficulties in terms of perception and expression, patients must be regarded as persons in the full sense of the term, so that the treatment team can best guide the therapeutic choice on the basis of the wishes that patients can communicate and the reactions that can be inferred from their behaviour. Irrespective of their legal value, a valid point of reference is also represented by the wishes previously expressed, in the form of a document or verbal communication to family members or persons affectively close to them, by those who - due to degenerative diseases, coma, brain damage, etc. - are no longer able to take part in the decision-making process.

Any signed expressions of will should take precedence over any other non-medical opinion expressed[10].

LEGAL REPRESENTATIVE

As already mentioned, a patient may not be able to give valid and informed consent to a therapeutic intervention.

This may depend on minority age, on the prior adoption of formal measures limiting capacity or even on natural incapacity, i.e., on the effective condition, also as a result of the clinical situation, that affects capacity to consent.

Minors or incapacitated persons retain the right to the enhancement of their understanding and decision-making capacities. Therefore, the treatment team must provide them, in a manner appropriate to their cognitive abilities, with the information necessary to make valid choices about health and treatment proposals.

With regard to minors, informed consent to health treatment is given or refused by the persons exercising parental responsibility. In such cases, the minors’ wishes must be taken into account in proportion to their age and degree of maturity.

As far as the incapacitated persons are concerned, informed consent shall be given, as far as possible, by them.

In the case of disqualified persons, informed consent is given or refused by their legal representative, in consultation with the disqualified persons where possible.

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[10] On this subject, see Chapter: **“Previously expressed wishes relating to health care”**.

If a support administrator has been appointed for the necessary assistance or exclusive representation in health matters, informed consent shall be given or refused also by the support administrator or only by the latter, taking into account the will of the beneficiary in relation to the degree of the latter's capacity to consent.

Any choice of treatment must aim at protecting the minors’ or incapacitated persons’ psychological and physical health, while fully respecting their dignity.

TRUSTED PERSON

Trusted persons may be appointed in writing by any person of legal age who is capable to consent. They must also be of legal age and capable to consent.

The appointment must be accepted in writing and may be revoked, without the obligation of giving any reasons, at any time in the same way as the appointment.

The indication and acceptance of the assignment are contained in the previously expressed wishes relating to health care.

Trusted persons have the task of assisting, advising and supporting patients in the treatment process, acting on their behalf and representing them in their relations with the treatment team, always respecting the patients’ wishes[11].

FAMILY MEMBERS AND PEOPLE CLOSE TO THE PATIENT

The role of family members and people close to the patient may vary depending on the place of care (home or inpatient and care facilities). Moreover, different views and approaches to end-of-life may emerge within the family and lead to conflicts that are difficult for the healthcare team to manage. Therefore, consultation with family members and close friends requires particular expertise in choosing the right timing and manner of approach.

First of all, it should be made clear that no way of communicating bad news is better than others, since every person is different, and every case is specific. In this regard, it is necessary to assess the key aspects of each situation in terms of characteristics of the patient and the disease, the foreseeable development time of the latter, and the resources of the network (family, close friends), in order to try to ensure the best possible support for the patient in the phase of accepting death.

Considering the bonds of affection, the involvement of family members and close persons is important both to better understand the wishes and values of patients and to help them accept the disease and its progression to the moment of death. Indeed, supporting the patient towards the end of life also means involving and supporting family members and close friends, who can only convey trust and support to the patient if they are fully convinced of the fact that all therapeutic strategies adopted are geared to respecting the dignity and beneficence of the latter, that all forms of abandonment or futile medical care

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[11] On this subject, see Chapter: **“Previously expressed wishes relating to health care”**.

have been avoided, and that the entire healthcare team has taken full care of their loved one with Palliative Care.

Although they can in no way replace the wishes of the patient or bind health care decisions, family members and those close to the patient are an important point of reference in the decision-making process and, precisely because they are involved in choices, they deserve to be supported in facing their loved one's disease first and then in working through the grief.

TREATMENT TEAM

The overall care of the person in the advanced and terminal stages of the disease is undertaken by several professionals in a team, in order to best focus all the healthcare activities on patient-centred care, according to the modern vision of care that has now superseded the old disease-centred approach. In this way, greater emphasis is placed on the relational aspect of care, rather than on the often overly technical approach of earlier stages of care. According to this system, the doctor is both the person responsible for clinical/care choices and, as such, the point of reference for building the necessary relationship of trust between patients, their families and all other operators in the team: nurses, physiotherapists, psychologists, social assistants, social and health workers, spiritual and/or moral assistants, General Practitioners (GPs), etc. This approach aims at integrating into a single vision the many facets characterising the suffering of patients and their families. In order to perform such a delicate task, the team must both have solid knowledge background and shared operational methodology in relation to the specific skills, and have acquired essential information on the personal history, religious and/or moral convictions, living environment and other key features of the person undergoing treatment.

As already mentioned, this composite operational group also includes the GP, whose role is better highlighted in a dedicated paragraph of this document.

The team members, trained to “treat and heal”, must have achieved a cultural reversal within themselves enabling them to accept the sense of powerlessness, to the point of living with it on a daily basis without experiencing professional frustration, which would otherwise be inevitable. Even more than in “traditional” professional situations, it is therefore necessary for the team members to be properly trained to accept death as a natural life event and to absorb and manage the emotions and feelings generated by the relationship inevitably established in the meantime, which cannot be fully processed solely by virtue of the individual member's high technical and professional skills.

The team must also identify a case manager, i.e. the person who coordinates the whole process of care.

Another basic component of the treatment team is the family caregiver[12], who is fundamental in the whole system. Family caregivers are responsible for most of the information and communication concerning the patient, including the sometimes delicate existential choices linked to individual preferences and the general vision of life and the world. Caregivers have important characteristics, as

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[12] For a specific discussion of caregivers, see the relevant chapter.

they are necessarily called upon to act as carers - thus collaborating with all the other members of the treatment team - but at the same time deserve consideration as focus of care. Indeed, they must face predominantly affective requests, which are often painful, intense, sometimes conflicting and unexpressed, linked to the duty and desire to meet the needs of the relative, a condition that requires immediate attention and comfort. Indeed, because of the high emotional-affective pressure to which they are subject, caregivers represent a problem, both because they run a high personal health risk and because they are a potential disruptive element capable of hindering the entire process of caring for the patient, to whom the team is committed to providing an end-of-life support.

DOCTOR

Doctors have a primary role in decision-making, in terms of ability to assess the clinical situation of the patient, and of professional responsibility.

They provide patients with the necessary information falling within their competence and draw up the care and treatment plans with patients or, if this is not possible, with the persons involved in the decision-making process.

The doctors’ task is to support patients able to consciously express their wishes in the decision-making process. Otherwise, at the end of the collegial process involving all health professionals, taking into account also any wishes previously expressed, they adopt the clinical decision based on the best interests of the person being treated.

GENERAL PRACTITIONER

Included *ex officio* in the treatment team, the GP or "family doctor" plays a role of fundamental importance in the entire care process. As mentioned above, the historical memory of patients’ health and diseases is based on the relationship between them and their doctor, who is the repository of the clinical steps already taken and who is called upon to be the guarantor of future choices. Indeed, the knowledge that GPs have of their patients is not limited to the state of disease of that moment, which is the last act of a subjective history that is unique and different from all others. Such knowledge also extends to the memory of a younger life stage, free from disease, and can therefore reasonably allow a more adequate and coherent interpretation of the current condition.

The role of GPs has often been called into question as a critical element in the collaboration with the Palliative Care doctor, because of the risk of a conflict of opinions in the care process. It is therefore worth drawing attention to the teamwork that normally characterises Palliative Care, both at home and in hospices. The team is made up of professionals who complement each other. This means that the presence of two doctors cannot be interpreted in terms of substitution or vicariousness, but in terms of cooperation. In European protocols, according the most recent vision of the role of the GP, the latter is - above all in the initial stages of care - the protagonist and “case manager”, supported by the other members of the team and, as far as pain therapy and other more specifically palliative therapies are concerned, by the Palliative Care specialist. Subsequently, with the worsening of the clinical conditions as death approaches, there will be a gradual increase in home visits by the Palliative Care doctor, although always with the continuous and constant participation of the GP.

PALLIATIVE CARE DOCTOR

The Palliative Care doctor undertakes Palliative Care, i.e. the care of the physical, psychological and spiritual needs of a patient with a chronic progressive incurable disease, and of the patient's family. Palliative Care doctors have the skills to deal with any kind of need, but their presence is essential and exclusive when the needs considerably increase. Overwhelming physical pain, prolonged existential stress, severe dyspnoea, chronic degenerative heart diseases and neurodegenerative diseases are some examples where specialist “palliative” clinical expertise is necessary.

The Palliative Care doctor is therefore called upon to deal with needs that may arise at the beginning of any disabling disease up to the most complex part of the end-of-life. The Palliative Care doctor's expertise in assessing the progress and terminality of the disease is therefore important, as this assessment is the basis for Palliative Care interventions.

Identifying elements that suggest a prognosis of imminent death appears more challenging in non-oncological diseases than in neoplastic diseases. The recent publication of documents drawn up jointly by several specialist scientific societies (internal medicine and anaesthesiology) can be considered a valuable support, especially in situations that are more difficult to interpret[13].

For some time now, in order to facilitate prognostic judgement and to identify when and which palliative actions should be implemented, the so-called "surprise question" has been proposed. This is a simple question ("would you be surprised if this patient died within 12 months?") that doctors, in general, and Palliative Care doctors, in particular, ask themselves when faced with a chronic incurable patient on the basis of a general clinical assessment.

Therefore, the specific action of the Palliative Care doctor takes the form of the application of Palliative Care, which, taking into account the patient's life expectancy imposed by the clinical condition, is not aimed at recovery or, often, stabilisation, but rather is guided by the unavoidable worsening of the pathological process.

As a consequence, in specialised medical care, the skills required cannot be limited to the technical component alone, while taking the utmost account of the impeccable exercise of due diagnostic and therapeutic actions. Indeed, patients experiencing a condition of incurable disease, especially in the advanced and terminal stages of the disease and of life, require the broadest possible understanding of the psychological and social implications and of their spiritual needs, in a holistic vision of care.

The Palliative Care doctor is part of, and often coordinates, the Palliative Care team, which includes competent nurses, but also psychologists, bioethicists and, if necessary, spiritual assistants, as well as

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[13] SIAARTI – Bioethics Study Group – Coordinator Dr. Alberto Giannini *“Grandi insufficienze d’organo “end stage”: cure intensive o cure palliative? - “Documento condiviso” per una pianificazione delle scelte di cura”* - Document approved by the Governing Council of SIAARTI on 22 April 2013.

other specialists who may intervene in the management of organ failure (nephrologists, pulmonologists, gastroenterologists, haematologists, cardiologists, neurologists, ...), with the aim of resolving symptoms and meeting the patient's needs.

Finally, within the treatment process, the Palliative Care doctor also has the task of supporting the decisions of patients when they are able to consciously express their wishes. Otherwise, at the end of the decision-making process involving all members of the treatment team, and taking into account any previously expressed wishes, the doctor takes the clinical decision based on the best interests of the patient.

PAIN THERAPIST

The pain therapist is the medical expert in drug therapy and minimally invasive and infiltrative techniques aimed at controlling both acute and chronic physical pain[14].

The disciplinary background of the pain therapist is anaesthesia, although many Palliative Care doctors who are not anaesthetists acquire specialist skills in terms of chronic physical pain control. However, worth specifying is that the global pain of patients is addressed with a multidisciplinary approach, involving, in addition to the pain therapy specialist and the Palliative Care doctor, all professionals making up the treatment team and, if needed, any other professionals.

The role of the pain therapist is to provide the team caring for the terminally ill with primary expertise in physical pain control. In cases of chronic degenerative disabling or incurable disease, the professional's skills must be extended to the analysis and ability to take care of the emotional component of pain, which expresses a state of suffering and is expressed as global pain.

The pain therapist assesses, together with the General Practitioner, and subsequently, directly as a supervisor, the characteristics of the patient with pain through an in-depth anamnesis, algological examination, performance and interpretation of the most appropriate examinations, the use of the most adequate equipment and validated questionnaires to identify the type of pain, which will make it possible to plan treatments and assess their effectiveness.

In order to best perform such a delicate and important function in the global treatment of chronic pain, pain therapists are able to agree with the GP and the whole team, and to communicate adequately to patients and their families, the treatment options, care goals and end-of-life care, harmonising their own communication methods with those of the treatment team.

Therefore, pain therapists are fully integrated in the context of Palliative Care.

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[14] These skills derive from training that includes knowledge of the anatomy and pathophysiology of the nociceptive system and the indications for the use of physical and psychological therapies, the ability to perform locoregional blocks, the ability to implant drug delivery devices and electro-stimulators, as well as technical competence in neuroaxial, plexic and peripheral nerve blocks.

NURSE

Because of the time spent with patients approaching the end of their life, the nurse is a connection between these patients and the rest of the team. The choice to work in hospices, or more generally to deal with Palliative Care, should be free and voluntary. Indeed, nurses working in this context must have a natural and strong predisposition to "take care of others" and be naturally inclined to adopt a multi-dimensional approach and assessment method, which take into account not only health aspects, but also socio-economic and cultural ones.

Palliative Care nursing recognises the patient as the primary focus. For the nurse who receives specific training in "traditional" care, it is a matter of implementing a new organisational and assistance model based on care that is no longer oriented towards recovery but focused on the concept of quality of residual life. It is an interdisciplinary model with a high level of integration, which is flexible and dynamic. The guidelines of the European Association for Palliative Care (EAPC) emphasise the indispensable elements of the Palliative Care nurse's technical and cultural background, represented both by a great ability to work in a team and by high ethical, clinical, psychosocial, communication and relational skills. Nurses have the duty to ensure the best possible protection of the quality of residual life for their patients with appropriate, effective and efficient interventions. In order to be able to fulfil this duty, they are required to receive specific continuous vocational training[15]. In this context, it is clearly necessary to guarantee nurses both the requested technical training in Palliative Care and the psychological, relational and communication training needed to deal with patients and their families.

PHYSIATRIST AND PHYSIOTHERAPIST

In the context of care, a particularly important role is played by the physiotherapist. However, it should be clarified that the physiotherapist is involved to all intents and purposes in Palliative Care as this can begin long before the end of life, at a time when the control of functional abilities is an essential part of the patient's quality of life. The first phase of care can therefore legitimately include a physiotherapeutic intervention still oriented towards the recovery and functional maintenance of bodily motility, albeit in the logic of respect for a person in an advanced phase of disease. This is the level of appropriateness in which Physiatrics and Rehabilitation find their place.

The physiatrist and the physiotherapist are the health professionals who directly deal with rehabilitation, understood as that "...process of problem solving and education during which a person is enabled to achieve the best possible level of physical, functional, social and emotional life, with the least possible restriction of operative choices [...]"[16]. With regard to Palliative Care, the limits to these objectives are given, on the one hand, by the type and evolving nature of the disease and, on the other, by the resources available. In end-of-life situations, when it is clear that *restitutio ad integrum* is not possible,

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[15] As indicated in Chapter V, Articles 35 to 40 of the "*Nursing Code of Ethics of Nursing Association of San Marino*" (2017).

[16] *Guidelines for rehabilitation activities approved by the Permanent Conference between State and Regions* (1998). Basaglia N. *Trattato di Medicina Riabilitativa*. Idelson-Gnocchi Editore, 2000.

rehabilitation can focus on the objective of following the evolution of the disease in order to put in place interventions to address secondary damages (characterised by the painful component induced directly by the disease) and prevent tertiary damages (represented by the consequences of the disease on the anatomical structures not directly involved), as well as identify strategies to compensate for functional loss and adapt the environment to the new needs of the patient. To be effective, any rehabilitation project must be focused on clear, achievable and neatly planned objectives oriented towards a better end-of-life quality.

By their very nature, rehabilitation interventions are carried out with the contribution of several dedicated professionals working as a team. They imply that the patient is taken care of through the implementation of a rehabilitation project and programme consisting of a set of proposals drawn up by the rehabilitation team, coordinated by the physiatrist and aimed at achieving common objectives as effectively and efficiently as possible.

An essential professional component in the rehabilitation team is the physiatrist, who is responsible for the individual patient's rehabilitation project and programme: his/her task is not so much that of diagnosing and treating the basic disease, which is already defined by the other specialists in the treatment team, as that of assessing the situation and establishing the rehabilitation diagnosis and prognosis. This latter activity requires the ability both to predict the spontaneous evolution of the condition and the possibility of modifying it over time according to the person's functional priorities and expectations, and to deal with the consequences of the underlying disease at a functional level. The physiatrist is also responsible for planning rehabilitation interventions and prescribing the necessary aids to compensate for the functional losses that inevitably occur when the clinical picture is particularly compromised.

Within Palliative Care, the physiatrist is on the one hand part of the group of specialists who make up the end-of-life treatment team and on the other hand acts as an intermediary between this team and the physiotherapist as a member of the rehabilitation team.

The physiotherapist is the health professional who, as part of the rehabilitation team, assists the patient in the specific process and implements, to the extent of his/her competence, the therapeutic programme according to the instructions of the physiatrist. The Palliative Care physiotherapist must have the basic knowledge and skills of any physiotherapist, such as knowledge of motor skills, the ability to perform a functional assessment, to design/implement a therapeutic intervention and to work in a team. However, he/she must also have acquired the knowledge and skills necessary to implement Palliative Care and to care for the patient and his/her family when the disease is not yet in an advanced stage, in an attempt to enhance and strengthen present abilities, while seeking to improve deficient functions, to participate in the treatment of pain, especially due to immobilisation, and to progressively shift the focus of the intervention from merely rehabilitative to end-of-life care.

Like other professionals in daily contact with the patient, it is essential that the physiotherapist shows empathy and adopts the attitude of someone who understands the suffering of others. Another fundamental element of the physiotherapist’s cultural and professional background is the ability to identify a communication channel, not necessarily verbal, useful for understanding the expectations of patients and their functional priorities within the perimeter of the disease. In this way, the physiotherapist is able to work with the patient to orientate the rehabilitation intervention based on appropriate and achievable objectives according to the evolution of the disease, with the aim of achieving, as much as possible, the desired results and, when necessary, supporting the capacities of acceptance and resilience that allow the patient to activate coping mechanisms[17].

What has just been described is part of the perspective of maintaining the objective of overall care of the patient, whose quality of life is to be improved and to whom a dignified death is to be guaranteed as long as possible, avoiding the feeling of abandonment that often accompanies the lack of prospects for recovery.

The Italian Society of Palliative Care (SICP) defines a set of professional competences classified according to the following levels of specificity:

A. **basic level:** knowing how to recognise a terminally ill patient and how to relate to Palliative Care services;

B. **specialist level:** skills required by a physiotherapist working within a multidisciplinary Palliative Care team;

C. **coordination level:** specific competences needed to carry out coordination or management of Palliative Care in the various assistance facilities of the Palliative Care network[18].

SOCIAL AND HEALTH WORKER

Social and health workers provide special support in basic care, aimed at meeting the hygiene and care needs of the patient. They work in hospitals, at home and in socio-residential and semi-residential care facilities, in liaison and collaboration with other professionals responsible for health and social care. As in the case of the latter, the care activity is also enriched by a relational value and is aimed at caring not only for patients, but also for their living environment, and takes the form of direct assistance, domestic/hotel help and hygiene-health and socio-assistance intervention.

These professionals are increasingly present in multi-professional Palliative Care teams. They are involved in several ways in assisting end-of-life patients, who have various needs and problems. Social and health workers support nurses and physiotherapists not only in the daily hygiene assistance but also in the enhancement of - and support to - the patient’s residual abilities, as well as in the support to the caregiver and the family.

The core competencies of social and health workers involve the central role of communication, understood as the establishment of helping relationships with patients and families. Effective

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[17] SICP, *Core Curriculum del fisioterapista in cure palliative. 2013.*

[18] Id.

communication is based on the authenticity and sincerity of the interpersonal exchange between the worker and the patient well beyond the daily physical contact, which is also therapeutic. The central element of the relationship between the social and health worker and the patient is a real willingness to communicate, i.e. to listen and speak in a way that is both frank and prudent, establishing direct eye contact and adopting a calm and comforting attitude.

Furthermore, the specific tasks of the social and health worker include alerting team members to new or unexpected situations, participating and collaborating in team activities, and contributing to the planning and implementation of care activities.

PSYCHOLOGIST

Psychologists analyse patients from the point of view of depressive components, placing them along the continuum "life support" - "acceptance of death" and, if necessary and useful, undertake to strengthen their resources.

They play a direct and an indirect role. The direct role is played in the relationship with patients and those closest to them, while the indirect role is played in the support provided to health professionals committed to the patients' well-being. Indeed, the continuous contact with the taboo and the fear of death both in patients and people close to them and in professionals entails a strong risk of burn-out or, to the contrary, of excessive detachment in the "therapeutic" relationship.

To be able to help the patient, the team must first of all be able to deal with the difficult issue of the end-of-life. In order to avoid that each case generates different emotional repercussions in professionals, which in the long run may undermine individual safeguards and resilience, the frustration caused by the relationship with the disease and death must always be questioned.

For this reason, the psychologist should ensure:

Support for a person's end-of-life request

- Assessment of depression (to define suicide risk)
- Support for life (to avoid futile medical care)
- Palliative Care

Support for family members and close friends

- Phase prior to death: choosing time and method for communicating the patient's request; support for participation in the patient's choices
- Culminating phase: supporting Palliative Care of end-of-life patient
- Post-death phase: support for working through the grief

Support for health professionals

- Facilitating understanding of the concept of death
- Combating the risk of burn-out
- Combating excessive detachment

TRAINED VOLUNTEERS

Trained volunteers are now widespread and appreciated in a number of situations since they autonomously and voluntarily decide to devote part of their time to care, comfort and support services. Volunteers are also available for end-of-life care; however, because of the special nature of the situation, they must be properly trained. It is therefore desirable to organise specific training courses, using the associations already present in the territory. This training must take into account what is indicated in this document from a medical, psychological and communication point of view. Volunteers cannot and must not replace the specialists already operating but, if requested, they can be present when patients are alone and thus help them and their families.

Whenever they have been included as a simple support to the team, volunteers properly trained and accepted by patients and their families have always provided a positive contribution.

SPIRITUAL ASSISTANT

Dying persons have complex needs that go far beyond simple medical requirements, as well as spiritual concerns, regardless of whether or not they profess a religion[19].

Spiritual needs have long been considered as included in ethical and religious needs, or as identifying with each other. Recently, bioethical literature has called for specific attention to be paid to the “spiritual care” of the dying person[20]. The latter is once again asking questions about the meaning of life, which have long been neglected.

The term "spiritual" contains the concept of "ultimate meaning", "beyond", "transcendent", which goes beyond intuitions and values: the person is attracted to it despite the fact that the concept goes beyond rational understanding.

All human beings can recognise in themselves a call to transcendence, which they accept and express in the way most suitable to them. For this reason, on the basis of the recent bioethical debate, the main international documents[21] recognise the spiritual need of persons as fundamental at the end of their life and recommend the presence in the treatment team of a spiritual assistant or spiritual guide, who can help and support them, and possibly their families, in terms of acceptance and understanding, where possible, of the mystery of the disease and death.

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[19] Dunne T, *Spiritual Care at the End of Life*, Hastings Center Report 31, no. 2 (2001): 22-26.

[20] Hardwig J, *Spiritual Issues at the End of Life: A Call for Discussion*, Hastings Center Report 30, no. 2 (2000): 28-30; Cohen CB. et al., *Prayer as Therapy*, Hastings Center Report 30, no. 3 (2000): 40-47.

[21] International documents that contain references to supporting the patient and family members with regard to spiritual needs as objectives of the end-of-life and Palliative Care team include: *Recommendation Rec (2003) 24 of the Committee of Ministers to Member States on the Organisation of Palliative Care* (adopted by the Committee of Ministers on 12 November 2003); World Palliative Care Alliance, World Health Organization, *Global Atlas of Palliative Care at the End of Life*, 2014; Berlinger N, Jennings B, Wolf S.M, *The Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care near the End of Life*, Oxford University Press, 2013; Council of Europe, *Guide on the decision-making process regarding medical treatment in end-of-life situations*, 2014

Even if spiritual assistants are specifically religious, they are in any case called upon to accept the "question for meaning" by any person, whether professing a religious faith or a non-defined faith, or openly atheist and agnostic. The personal position required of “spiritual assistants” must therefore take account of the need to be as welcoming as possible towards the patient, but at the same time, where they are not specifically asked to express their beliefs, to guarantee the most appropriate neutrality with regard to the religious vision of existence. For this reason, the CSB believes that, in order to guarantee a truly effective service in the performance of this delicate caring task, it is necessary to undergo rigorous and validated training courses that take account of this required neutrality.

Moreover, given the high possibility that the spiritual need may be expressed by the patient at any time during the care process and may involve any stakeholder in the entire clinical process (doctors, nurses, physiotherapists, pathologists and psychologists), it seems appropriate that none of these professionals should feel exempt from the demanding task of bringing their own spiritual positions into play along with those of the patient. In this case, their professional actions cannot, and must not, take the form of a direct answer: when sharing their deepest beliefs, two or more persons will necessarily stay next to each other and live together the same spiritual moment, even if this is determined by the imminent death of only one of them. It is therefore desirable that, aware of the special nature of the mission of caring for the dying, to which the members of the team are called, all of them should be encouraged to undertake their own personal spiritual training, according to their own sensitivity, their own beliefs, and their own propensity to generally humanitarian help, in addition to professional one.

Indeed, it is a moral duty and a sign of respect to help anyone who feels that their certainties are dissolving, by offering them possible means of interpretation and comfort useful to ensure dignity and serenity and by responding to a universal demand for transcendence beyond a specific religious faith.

SOCIAL ASSISTANT

The care of terminally ill patients encompasses all dimensions of an individual's life, not just the clinical ones. Patients’ context of relationships is also decisive in conditioning all aspects of the entire care process. Social assistants play the role of privileged analytical observers of this context and ensure to patients the comfort of their competence and knowledge of the correct procedures within the local administrations and public bodies in dealing with bureaucratic and administrative matters.

Indeed, after having carried out a fruitful survey and enhancement activity, they are electively called upon to provide the resources identified within the relational context. They analyse the affective aspects, elements of cohesion or conflict, of support or abandonment, of comfort or suffering present in the family network surrounding the patient, and implement all the strategies considered useful for the best possible care, modulating them throughout the whole period of care so as to create important relational links with all stakeholders involved with the dying person.

“Caregiver” is an English term adopted internationally in everyday clinical practice and indicates a person who provides ongoing care to someone with a chronic disabling disease.

The caregiver can be a family member (family caregiver) or a friend or acquaintance, irrespective of age, gender and economic interests, or can be a person outside the family employed as a paid professional.

A famous sentence that allows to understand the human as well as the operational position of the caregiver is the one pronounced by Rosalynn Carter several times: “There are only four kinds of people in this world: those who have been a caregiver, those who are currently caregivers, those who will be caregivers, and those who will need a caregiver”.

The caregiver is an essential part of the social care system, a valuable person, to whom aspects of competence, decision-making responsibility and protection are related.

The caregiver must receive information in a clear and understandable way in order to act competently and safely. First and foremost, caregivers must be informed about the natural history of the patient's disease, the treatment strategy and its rationale, the use of drugs and possible adverse effects, and the use of support instruments.

It is the task of health professionals to share with the caregiver all the elements that are useful to carry out an adequate care work. In this way, the caregiver participates in the team's work, also by keeping a diary of the progression of the patient's clinical condition.

Empowerment allows the caregiver to enter into the mechanisms of care and also to address issues of daily management often related to the chronicity of the disabling disease, such as treatment and prevention of decubitus, psychiatric syndromes and delirium, immobilisation syndrome, dehydration, constipation, nutrition.

A caregiver can also adopt urgent decisions, including, for example, requesting invasive or palliative treatment.

Caregivers need to enrich their skills with empathy, prudence, kindness, humility, sense of justice, sincerity and respect, even if the patient is not a family member.

If the caregiver is the patient's trusted person, he/she is also responsible for ensuring that the patient's wishes are respected.

The burden of responsibility and the acquisition of skills may be conditioned by the evolution of the context and may make the caregiver inadequate to the task performed so far. In such cases, the treatment team reviews the care plan and adapts it to changing needs.

If the caregiver is paid, San Marino legislation provides for the certification of functional suitability for understanding, designing, implementing and assessing the integrated care plan[22].

It is therefore clear that the caregiver bears a heavy and protracted psychological and physical workload. In the case of care by a family member, the caregiver easily experiences tension and stress. In many situations, because of a sense of duty or due to financial problems, family care becomes an almost mandatory solution, which in the long run can result in a feeling of entrapment, with negative consequences on the psycho-physical balance of the caregiver.

This can have implications for the patient in terms of decline in attention, reduction in the effectiveness of care, increase in the possibility of errors, and even acts of behavioural and sometimes physical hostility towards the patient, which are not always immediately apparent. The caregiver's emotional stress is sometimes also linked to misunderstandings with the other family members, who may exert pressure or criticism. Moreover, if the family caregiver is young, he/she may suffer from inevitable inner tensions due to the change of lifestyle; if elderly, he/she may be a fragile person and not able to sustain not only physical but also psychological pressure for a long time.

The caregiver may therefore also become a focus and no longer a means of care. Avoiding this means putting in place mechanisms to monitor and protect the caregiver, initially by the other members of the healthcare team but also by the institutions.

Awareness of the significant caregivers' contribution to the welfare system and the economy must be raised and safeguarded by developing services to support them, enabling them to remain in the labour market, if young, and facilitating access to the services of the welfare system.

Shared motions are being filed at a European level and should only be implemented.

CASE MANAGER

The case manager ensures and/or coordinates social and health services, for a clinical management of a specific target population, from admission to discharge. Therefore, he/she is considered a relevant professional in advanced clinical practice, who is able to create a unique model of care centred on the individual patient and to guarantee continuity of care.

Back in 1993, the Case Management Society of America (CSMA) defined case management as "a collaborative process of assessment, planning, facilitation, care coordination, evaluation and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote patient safety, quality of care, and cost effective outcomes". Therefore, the term "case manager" does not refer to a specific profession, but to a set of specialised skills and practices that draw on the training and experience of various professional areas. Since it does not have a strict professional specificity, it can refer to various professionals. In England,

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[22] Delegated Decree no. 21 of 24 February 2016, ratifying Delegated Decree no. 1 of 13 January 2016 "*Measures in favour of the elderly and of persons with disabilities who are not self-sufficient and rely on continued assistance*".

France, Germany and Italy the term “case manager” can refer to nurses, while in other countries to doctors. However, several authors argue that nurses, preferably with a background of coordination experience, are natural candidates for this activity as the case manager’s functions are very close to those of nurses: assessment, planning, implementation and evaluation, enriched with other competences such as the ability to select the case, identify resources, document multiple outcomes and define the patient’s status.

The role of the case manager has three dimensions: clinical, managerial and financial. The clinical role consists in identifying emerging problems of the patient and family, classifying them as real or potential and assessing the patient's physical, psychosocial and emotional condition. In his/her managerial role, the case manager must be able to ensure continuity of care by following the patient in the various care settings and making information on the patient's health status accessible to caregivers in order to guarantee the most personalised and specialised care possible. In his/her financial role, the case manager ensures, in cooperation with the other members of the team, that patients receive adequate care and guarantees the allocation of the most appropriate human resources for the duration of the hospitalisation or stay.

The case manager assesses patients in terms of their suitability to enter the Palliative Care network and directs them, in agreement with them and their families, to the most appropriate care setting (hospice, home, hospital and possibly outpatient clinic).

He/she then takes charge of the case, coordinates processes, ensures continuity of care, and plans care with regard to treatment procedures and interventions necessary to meet the various needs, thus promoting therapeutic adherence by patients and their families. In cooperation with the interdisciplinary team, he/she establishes the objectives and expected outcomes of the treatment and develops a personalised care plan. The case manager is also important in his/her role of collecting and disseminating information about the patient, in order to avoid a common error arising from the fact that inaccurate management of information leads to inconsistency of care and continuity of processes is questioned. Therefore, he/she is the point of reference both for the multi-professional team and for the patient, along the continuum from admission to follow-up at home. He/she is a sort of facilitator of the care process (involving various and different stakeholders), whose aim is to ensure the greatest possible comfort for patients and their families.

Advanced training is required to perform this role[23].

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[23] Indeed, in-depth knowledge of care, organisational dynamics, finance and community resources is required. Advanced clinical practice skills that elevate to the role of case manager include:

- understanding of the care organisation model;
- knowledge of a specific patient population;
- related clinical diagnoses and medical treatments;
- knowledge of resource management, use of care plans, protocols and guidelines;
- recognition of the importance of the concept of patient advocacy and continuity of care.

According to international literature, in order to become a “skilled” and “competent” case manager it is necessary to develop specific skills, such as:

- interpersonal skills: communication, diplomacy, assertiveness, collaboration, negotiation;
- professional skills: knowing how to transmit, knowing how to accept;
- personal skills: knowing how to prioritise, knowing how to delegate (or rather assign responsibility), creativity, self-discipline;

It is therefore strongly recommended that the case manager be adopted and recognised in all health service facilities, in order to guarantee not only a new organisational model that supports and enhances patients throughout their health process and in any care setting, but also a new way of thinking, conceiving and implementing assistance and care for citizens. This must be done according to a multidisciplinary approach and cooperation among the various professionals, based on shared objectives such as the quality of care, efficiency and effectiveness of services provided and containment of costs, with a view to a proper allocation of resources.

BIOETHICS SKILLS AND TRAINING FOR THE TREATMENT TEAM

When patients are able to consciously express their wishes, the health care team has the task of ensuring professional support useful for the adoption of the relevant decision; otherwise, at the end of the decision-making process involving all health care professionals, and taking into account any previously expressed wishes, the doctor takes the clinical decision based on the best interests of the person concerned.

In conclusion, the task entrusted to the treatment team is oriented towards the most effective support possible for patients, especially in the most delicate choices concerning them. When patients prove capable of expressing themselves autonomously, this support function can be achieved by flanking them, building care relationships with each of the team members and maintaining such relationships vital. If, on the other hand, the patient's ability to make a choice is compromised, the team must identify ways of delegating the patient's wishes, in a collegial decision-making process involving all the healthcare professionals and taking into account any wishes the patient may have previously expressed. Only in this way can the final clinical decision truly be considered to be in the best interests of the patient.

Team members involved in the decision-making process of end-of-life care should demonstrate specific professional skills and be supported by bioethical expertise through specific training aimed at managing the many complex needs involved.

First and foremost, professionals are required to undergo ongoing training not only on scientific matters, but also on legislation and guidelines concerning end-of-life care, so that they can in turn correctly inform patients and their loved ones, especially about any requests for practices that are not supported by scientific evidence.

Particular attention must be paid to updates on the most varied treatment situations and discharge plans for patients of all ages, with particular reference to the integrated management not only of pain but also of the symptoms arising from the disease, the condition of the patient and the treatment or, conversely, the withdrawal of treatment.

A key point of training is the ability to manage correct and effective communication on several aspects, the first of which is the patient and his/her entourage. Indeed, learning the most useful ways of acquiring

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- knowledge-based skills: critical thinking, problem solving, research skills.

information on the causes of individual distress makes it possible to recognise at an early stage the signs of psychological, spiritual, existential or moral suffering of the dying person and to become aware of individual values and preferences regarding available treatments, in order to develop care relationships in harmony therewith.

Two other fundamental aspects are the treatment team and, outside this, the professionals with whom the team interacts from time to time. In particular, in order to prevent and resolve conflicts among professionals - and often between them and patients and their relatives - it is important to learn to recognise the professionals' distress and to understand how stress can influence decision-making and the care relationship. Training in good communication is of great help not only in this respect but also in the constant attention to ensure the timely provision of all available information, which is the real "secret" for effective interdisciplinary work and full cooperation with the patient's entourage.

It is easy to understand that this training in bioethics constitutes a profitable institutional investment thanks to the definition of specific criteria of appropriateness and the offer of valid solutions to the most complex problems emerging in the bioethical, deontological and medico-legal fields. Indeed, all this represents a considerable support to the management of end-of-life situations, which can also be expected to have a tangible positive impact on the proper allocation of available resources and on the professional responsibility of the treatment team.

CLINICAL ETHICS COMMITTEE

Clinical Ethics is a practical discipline that provides a structured approach to identifying, analysing and resolving ethical issues in clinical medicine. The area in which its exercise is most elective and its application most rewarding is undoubtedly that of the Ethics Committee, which is not by chance defined as the expression of the "moral conscience of the healthcare institution"[24]. Ethical advice is therefore one of the Committee's most important tasks.

Since the establishment of Ethics Committees, the dilemma has arisen as to how the advisory activity should be organised, i.e., whether this task should be entrusted to the entire group of Committee members or, alternatively, whether it should be carried out by a restricted team belonging to the Committee or by an individual advisor as a recognised representative of the Committee.

The latter approach has the undoubted advantage of speeding up the entire consultative process between the examination of the clinical case and the pronouncement of the opinion, which would otherwise be conditioned by logistical difficulties. However, in attempting to guarantee an effective response within a sufficiently short time frame, it also has the serious limitation of entrusting an opinion of great ethical and practical impact to an individual rather than to a group composed of several persons, which is therefore more representative.

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[24] Sgreccia E, *Manuale di Bioetica. Vol. I: Fondamenti ed etica biomedica.* Vita e Pensiero, 2012.

The Committee bases its actions on the main international Conventions and Declarations on bioethics and human rights.

It is an advisory body supporting those involved in health decisions (patients, family members, health professionals), which is called upon to clarify moral issues and decision-making processes and to prevent conflicts that may arise in the management of the individual's health status.

According to international literature[25], the counselling offered by it can be divided into the following four stages:

- **Medical indications.**
  This is the moment when the case is dealt with by the treatment team in the traditional terms that have always inspired its actions, in accordance with **the bioethical principle of beneficence**. Indeed, at this stage, questions must be answered concerning the patient's actual clinical condition, the therapeutic prospects of the proposed act, the expected outcomes, any collateral damage and any existing alternatives.

- **Patient preferences.**
  The positions that the patient takes or has taken on the entire clinical case involving him/her are taken into account, according to **the bioethical principle of autonomy**. It is important, at this point, to assess the quality and quantity of information that the patient has received and, above all, is able to understand and manage. Ultimately, it seems relevant to understand whether a patient's right to choose is respected to the fullest extent, both ethically and legally.

- **Quality of life.**
  The perspectives arising from clinical decisions are considered in terms that objectively concern the patient's return to a state of normality or, if this is not possible, the overall acceptability of the medical act in the light of the final outcome. The bioethical principles involved are therefore those **of beneficence, non-maleficence and autonomy**.

- **Contextual features.**
  The advisory response also takes into account investigations carried out into possible influences - family, economic, cultural, religious, legal, etc. - that could potentially alter and mystify the choices, thus jeopardising their effectiveness and importance. In the light of the above, the Committee considers the many aspects of the **bioethical principle of justice**.

The importance of the consultancy activity undoubtedly requires adequate and documented competence. Indeed, the issues under consideration cannot in any way be entrusted to the sole good sense of the stakeholders involved in the decision-making processes, and require solid knowledge background on the merits and method of moral choices. For these, there are already training courses in bioethics, in the context of which Clinical Ethics usually finds its proper place. Their purpose is to provide the most appropriate support for the performance of ward activities in a modern professional approach,

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[25] Jonsen AR, Siegler V, Winslade W.J. *Clinical Ethics. A practical approach to ethical decisions in clinical medicine.* McGraw – Hill Ed. 2003.

which is still based on the classic Hippocrates' dictum of treating "according to science and conscience". It would therefore seem desirable that, subject to official accreditation, the above dedicated courses should be provided to professionals most often involved in ethically complex decision-making processes both within advisory bodies, such as Ethics Committees, and in clinical practice at the bedside of patients. In the context of the latter, in particular, working in intensive care or intensive resuscitation units appears to be more burdensome than other activities, since operators often need to make quick decisions about challenging moral cases.

In the light of all the above, given the complex and delicate decisions involved in end-of-life situations, the CSB strongly recommends the establishment of an independent Clinical Ethics Committee, whose members must have, as already mentioned, proven training and experience in clinical bioethics.

CONCLUSIONS

In conclusion, decision-making processes must always place patients at the centre, whatever their legal capacity or ability. Wherever possible, the latter should be directly involved in relation to their ability to understand and participate and should have access to the necessary information about their state of health (diagnosis, prognosis, indications and treatment alternatives).

The principles of good clinical practice also include retrospective assessment of the decision-making process and how it was implemented, with specific attention to controversial and conflicting aspects. Indeed, it is an integral part of a quality approach, the main aim of which is to guarantee respect for the vulnerable person with the widest possible promotion of all measures aimed at respecting the wishes expressed directly or previously expressed wishes. As such, it enables the treatment team to progressively refine its professional and relational skills with regard to people involved in the difficult process of approaching the end of life.

Finally, in accordance with Recommendation Rec (2003)24[26], the decision-making process should be subject to:

- information for all users of the health service on instruments to facilitate dialogue between doctors and patients (e.g. appointment of a trusted person, expressions of will, etc.);
- training of healthcare professionals to adequately deal, in clinical practice, with the ethical aspects of complex end-of-life situations. Particular attention should be paid to the need for learning about collegial decision-making processes. This training could also be extended to other professionals outside the ward, who are involved in caring for end-of-life patients (e.g. psychologists, social workers, spiritual assistants, etc.);
- specific studies taking into account the complexity of end-of-life situations, closely linked to advances in medicine and technology, and encouraging interdisciplinary approaches by combining the humanities and medicine.

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[26] *Recommendation Rec (2003) 24 of the Committee of Ministers to Member States on the organisation of Palliative Care.*

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COMUNICATION

“Communication” is a word of Latin origin whose root recalls a meaningful contact and a shared participation between two or more persons. The context in which it takes place, in its various forms, constitutes the connective tissue that enables individuals to avoid isolation and contribute to the construction of the only organism constituted by the human family[27]. Its meaning is not limited to the mere possibility of the transmission of messages from one person to another, but extends to a further, wider dimension that restores the true essence of being a person[28].

It is well known that communication, like the many human relationships of which it is an expression, takes many forms, some of which are anthropologically relevant, such as parental and/or affective ones. Similarly, the relationship between doctor and patient is also included in its own specific environment of connection, which falls within the broader and more distinctive sphere of “helping relationships”. It follows that the communicative aspects that are part of it have specific characteristics, which deserve special attention and, moreover, require ad hoc training.

Within a care process, "communicating" is a therapeutic act[29]. This is valid for anyone involved, whether as a doctor or as a patient, in any pathological condition and at any stage of its development. In the advanced and terminal stages of the disease, in which the prospect of death, to be communicated and processed, to be prepared for and accepted, is destined to decisively mark the helping relationship between the two persons, this therapeutic intervention becomes even more important.

The CSB believes that, once the diagnosis has been made and the prognosis outlined, communicating the bad news[30] is a necessary step of the utmost importance for the life of patients and the family surrounding them. In this regard, Article 33 of the Code of Conduct states: *"The doctor shall adapt the communication to the capacity of understanding of patients or their legal representative, responding to any request for clarification, taking into account the sensitivity and emotional reactivity of patients, particularly in the case of serious or ominous prognosis, without excluding elements of hope.”*[31]

In this context, it should be added that the communicative message includes at least two characteristics of fundamental importance: comprehensibility and common language.

The comprehensibility of the message to the patient and family members is crucial when communicating the diagnosis of a serious or end-of-life medical condition. In this case, also the emotional reaction that may arise will have to be addressed, always bearing in mind the basic concept of human communication, according to which it is *impossible not to communicate*[32]. Communication is indeed a relationship process

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[27] Spaemann R, *Persons: The Difference between “Someone” and “Something”.* Editori Laterza. 2005.

[28] Ibidem.

[29] Marone F, (ed.), *La medicina narrativa e le buone pratiche nei contesti di cura. Metodologie, strumenti, linguaggi.* Pensa Ed. 2016.

[30] Buckman R, *How to Break Bad News.* Raffaello Cortina Ed. 2003.

[31] FNOMCeO, *Code of Conduct for Doctors and Dentists,* 2014, updated in 2017, Art. 33, “Information and communication with the patient”.

[32] Watzlawick P, Beavin J.H, Jackson D.D. *Pragmatics of Human Communication*, Rome, Astrolabio, 1971.

that is implemented not only with words, but also through non-verbal modes, which are probably its most spontaneous expression. Every activity, such as looking, touching, dancing, listening and, of course, talking, can be a vector of communication. In the field of health care, several empirical studies[33] show that good communication helps patients and their families to trust the doctor and the institutions, to feel guided according to their preferences, understood emotionally and supported in their hope. On the contrary, erroneous or insufficient communication increases emotional stress, exacerbates existential suffering, generates mutual distrust among doctor, family members, patient and institutions, and hinders understanding of the inherent physical and psychological problems.

In addition, the content and mode of expression of speech are the key elements for the success of good communication, especially in critical situations.

The stages and modes of communication are the subject of various theories, but they have a common basis. It is of utmost importance to try to empathise with the person we are talking to and whose feelings and expectations we are trying to perceive. Therefore, it is necessary to understand and process the information that we receive, with the ultimate aim of satisfying as much as possible the expectations in terms of response with a final speech that respects the boundaries of desire and the focus of knowledge. However, the communication process in an evolving health situation cannot be static, since it is destined to follow a process that is necessarily parallel to the clinical, psychological, spiritual and sometimes religious conditions of the patient and aimed at respecting the state of mind of both the patient and his/her family. This requires that such process respects and, where possible, addresses feelings of rebellion, anger, desolation, depression, bitterness at social isolation, as well as despondency about personal and family fate. These conditions must be addressed within a psychological contact and cannot be neglected by any health professional.

One essential element in dealing with communication with the terminally ill patient is the content of communication. In Western societies, the concept of death has historically been considered a taboo. Even today, several decades after the recognition and application of Palliative Care in the care processes of people suffering from life-threatening diseases, communicating the diagnosis, prognosis and outcome is still a demanding task, which is all too often neglected.

The CSB is fully aware of the need for health communication to be adapted to the specificities of each patient, all the more so if the outcome to be communicated is death.

In managing this crucial moment, it is important that the speaker respects the initial expectations of the patient and family members, without passively adapting to them. It should also be borne in mind that, in addition to the right to know all aspects of one's medical condition, the Oviedo Convention guarantees the right not to be informed[34]. However, if the request not to be informed stems from a very strong emotional involvement and/or from a depressive risk, the intervention of a psychologist would certainly

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[33] Gallese V. *The "shared manifold" hypothesis*. Journal of Consciousness Studies, Vol 8(5-7), May-Jul 2001, 33-50.; Gallese V, Goldman A. *Mirror neurons and the simulation theory of mind-reading*. Trends Cogn Sci. 1998 Dec 1; 2(12):493-501.; Ciaciotta S.M. *Comunicare e gestire la crisi.* Maggioli Editore, 2014. EAN: 9788891604859.

[34] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Oviedo Convention), Art. 10 “Private life and right to information”.

be useful. He/she would be called upon to assess the case more thoroughly, including through the use of specific tests, in order to help patients to accept the course of the disease, by strengthening their resources useful in facing the process towards death.

The second fundamental characteristic of the communication message is the adoption of a common language among the operators. In the event of complex clinical and relational situations, the choice must be taken collectively. In particular, when patients are unable to express the consent[35] previously given, the univocal and homogeneous support of family members or the group of close persons, who have been able, over time, to learn about patients' behaviour and desires and can therefore recognise their possible choice to let themselves die, becomes fundamental.

If patients feel misunderstood or, even worse, believe that something is being hidden from them, they tend to look for the missing information in the faces or attitudes of the people around them, whether or not they are health professionals. This carries the risk of misinterpreting the message or, even worse, of abandoning the therapeutic alliance.

A specification must be made with regard to the treatment of paediatric patients. It is essential that a strong relationship is established between the health professional, on the one hand, and both the child and the parent/guardian who has "legal and moral" responsibility for the choices, on the other. However, the members of the Paediatric Palliative Care (PPC) team could fear, by projection, that what they are experiencing externally may one day be repeated in their private lives. This projection can generate considerable stress and a relative risk of de-empowerment or, in extreme cases, burn-out. In order to avoid this danger, not only the family of the child but also the PPC team must be able to count on solid psychological support.

The CSB also considers it highly desirable to make an effort to recognise and use the professional resources of the community to which the child belongs, where the necessary relationships with the treatment team are guaranteed.

All of the above involves elements of extreme bioethical relevance. In particular, if the hoped-for process of acceptance guarantees the person concerned a better quality of residual life, the communication on the true state of health and life prospects linked to the latter complies with the **principle of beneficence**. In other words, communicating the bad news about survival being compromised by the state of disease must be able to raise hopes and effectively pursue achievable goals, such as reducing and eliminating pain and other unpleasant symptoms, or strengthening emotional ties with relatives, or planning how to fulfil the last personal wishes.

Moreover, communicating means giving back and recognising the role of the patient as the first decision-maker, in accordance with the **principle of autonomy**. Indeed, the critical end-of-life situation often requires patients to make difficult, problematic and painful choices, both therapeutically and in many other ways. It is only in full awareness of their condition that patients can make reliable choices. Precise

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[35] Id. Art. 6 "Protection of persons not able to consent".

and timely communication, offered in a humane and affectionate manner, becomes the necessary and indispensable prerequisite for these choices to be freely made by the patient and accepted by the latter's entourage.

The communication process, especially in particular critical situations, must therefore take into account many aspects, which need to be known and addressed in an appropriate way. In other words, competence in dealing with communication with the patient and the family must be based on a technical training and empathic exercise that allow difficult news to be communicated correctly. Within this process, it is necessary to extrapolate elements that, if one is unable to address the problem in the discourse context, may require the intervention of competent specialists.

The contents of the communication are therefore the result of a careful assessment of the emotional and cultural level, as well as of the sensitivity of the patient and the family. Words must be simple, clear and appropriate. The tone of voice and gestures must therefore be consistent with what one intends to communicate. Indeed, as already mentioned, the tone of voice conveys and transmits numerous components that go far beyond the cognitive meaning of the words expressed. Indeed, in the act of pronouncing a word, the linguistic elements are intrinsically associated with the prosodic aspects of intonation and accent and the paralinguistic aspects of tone, rhythm and intensity of speech. Likewise, the attitude of attention or confidence and understanding expressed by gestures, posture and body movements can make the whole communication relationship effective.

Another important element to consider is the effect of the environment on communication. Suffice it to think of the most common repercussions of hospitalisation, such as anxiety, fear, unusual irritability, loss of interest in the surrounding world and demoralisation[36]. Consequently, in the act of communicating, one should always consider the hospital as an environment that is both social and structural, from which the hospice and the home (chosen by, or for those who decide to die in the places where their loved ones live) should be distinguished, in terms of the meaning of communication[37].

Lastly, it should be borne in mind that, in accordance with the **principle of justice**, all healthcare interventions, therapeutic actions and ordinary clinical events must take place in a context of free communication, not least because of the resulting benefits in terms of resource management. Much malpractice stems from inappropriate treatment, excessive care, waste in terms of futility[38], as well as the so-called “defensive medicine”, and is the result of a bad way of managing free communication between doctor and patient or, more generally, between those who manage the provision of care and those who can use it. Indeed, worth recalling is the strong impact that good communication can have in reducing these distorting and wasteful factors, and the fact that clarity of information, without false protection or deception, also plays a part in improving resource management.

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[36] Rachman SJ. and Philips C. *Psychology and Medicine*. London. Temple Smith. 1975.

[37] See in this regard the Chapter: **“End-of-life bioethical aspects specific to the elderly”.**

[38] For the meaning of the term, see the **Glossary**.

In the light of all the above reasons, the CSB considers it unavoidable that communication be included in healthcare training courses. Its practice, the theoretical and technical aspects of its conduct and its relevance as a key element in clinical practice are often neglected in university courses, in more specifically professional courses and, more generally, in current teaching programmes at various levels.

The CSB therefore strongly recommends that these training courses should become an integral part of the professional background of every health professional as soon as possible and that their promotion and implementation should be part of the most valid and modern concept of health care.

Communicating is living. Communicating is treating.

Therefore, communicating well, with clarity, with mutual respect for each other's dignity and in the creation of the best relational context between individuals is always a moral obligation and the basic rule for the best way of living together, until the final stretch of life.

PALLIATIVE CARE AND END-OF-LIFE CARE

WHAT IS INVOLVED

Palliative Care (PC) is about meeting the needs and respecting the dignity of life of persons with chronic degenerative and incurable diseases.

In order to correctly address this subject it is necessary to clarify the terms.

The World Health Organization defines PC as “an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”. Palliative Care is therefore the care that is provided to try to meet the needs of incurable patients and their families.

The profound meaning of PC is inherent in the terms: “Palliating” means covering with the *pallium*, the large cloak worn by the Greeks and later by the Romans over the tunic. The resulting image is that of protection and shelter. The appropriate combination with the word “care” contains the ethical value of support full of pity and *cum*-passion for those who can no longer hope for a decisive therapy, but must be taken care of by the team, together with their families.

Mistakenly, even today many people identify PC as only pertaining to the field of pain. On the contrary, PC more properly involves all issues related to incurability, starting from communication, psychological support, dietary and physical rehabilitation support, to all healthcare practices that patients and their families need as the disease progresses.

New scientific knowledge has initiated a slow but unstoppable cultural revolution, which flanks the concept of “healing” with that of “care”, in the most ancient and profound sense of the term, according to the meaning that Hyginus attributed to the original myth of Cura[39].

This evolved view of the issue has also introduced a distinction in the field of bioethics regarding the modern concept of the right to health. While it is not rationally acceptable to claim an absolute right to “therapy” and healing, it is, on the other hand, legitimate to exercise the right to “care”. Similarly, by invoking the principle of autonomy, the patient can legitimately refuse “therapies” considered excessively burdensome and invasive. Similarly, the doctor may exercise “therapeutic interruption”, but not “therapeutic abandonment”, since no one can avoid the duty of supporting another human being in the last, radical experience of his/her life.

In this context, PC is not only oriented towards the end of life, as is mistakenly believed, but it also takes care of patients’ needs, which may *de facto* already arise at the onset of the disease and therefore need to be addressed promptly and simultaneously with the active treatment of the clinical condition.

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[39] Hyginus, *Liber Fabularum,* 2nd century AD. On the origin of this term, see the CSB document ***“Pain management n...”*** cit.

Finally, PC does not only affect the field of oncology but also all chronic clinical conditions that lead to death or severely impair physical or cognitive autonomy.

PC extends to different development stages of human beings: from infants to children, adolescents, young or mature adults and the elderly. The basic principles on which PC is based are of course the same, but the conceptual and operational approach to the different ages of life must take into account the individual different specificities of each age group.

For this reason, the CSB has decided to examine in greater detail PC and end-of-life issues in the following chapters in relation to the various stages of life and the specific situations of persons with disabilities.

WHO IMPLEMENTS PC

The definition of PC as caring for the needs of an individual with a chronic incurable disease implies care skills whose level depends on the complexity of a specific need.

Therefore, first-level needs, typical of the early stages of the disease process, may require the skills that care staff, doctors and nurses, have acquired in basic training. In contrast, complex care and very difficult care decisions, such as palliative terminal sedation, suspension of artificial hydration or nutrition, treatment of refractory pain and communication of an end-of-life condition require specialist skills. As a consequence, staff caring for incurably ill patients and their families need not necessarily be PC "experts" in the early stages of the disease but must be so in the later stages of caring[40], which are certainly more challenging.

The CSB believes that all health professionals should receive basic pre-graduate training in Palliative Care, which enables them to recognise the needs of a patient suffering from a chronic incurable and invalidating disease (and of the family) and to act in a manner proportionate to such needs. If these needs go beyond the basic clinical skills of any health professional, the intervention of specialists is required. In the medical field, these specialists are identified as Palliative Care specialists[41].

WHERE PC IS IMPLEMENTED (THE NETWORK: HOME, HOSPICE, HOSPITAL)

A modern health care system, especially for cross-cutting issues such as Palliative Care, relies on network facilities, namely the home, hospitals and hospices. At these facilities, which are by definition interconnected, professionals must work in an integrated manner.

Hospice and home are the best defined facilities. The hospital is instead different and more complex. Even today, in many Western countries, patients in the terminal phase of a chronic degenerative disease are admitted to hospital, whose main objective is to treat the acute phases of the disease, not to take

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[40] Dedicated pre-graduate courses may be useful for basic training. Master's degrees or specialisation schools may instead be necessary for certified and qualifying "specialist" training, with an appropriate professional experience. Ongoing training and non-university refresher courses guarantee a refinement of skills on this subject, provided they are extremely focused and conducted by teachers with recognised training, problem-solving and teaching skills.

[41] The profession of Palliative Care doctor is described in the preceding Chapter **"Decision-makers".**

care of terminally ill patients. Moreover, if the hospital has no Palliative Care unit, it does not offer adequate care for the needs of patients and their families. As a result, there is a risk of inadequate treatment characterised by an excess of medical interventions, such as inappropriate resuscitation or sometimes invasive instrumental examinations, which are unnecessary for the purposes of a treatment plan well related to life expectancy.

Strengthening PC network activity means, on the one hand, trying to reduce hospital admissions, supporting related activities on the territory through dedicated outpatient clinics and enhancing home care by recruiting staff able to prepare patients for the unavoidable fatal outcome, with quality of life as a top priority. At the same time, mobile intra-hospital PC teams, flanked by outpatient clinics and, possibly, a continuity care unit, acting in collaboration with organ specialists or systems to care for in-patients with serious chronic progressive diseases, are considered to be measures that can no longer be postponed in modern healthcare.

THE PROFOUND BIOETHICAL VALUE OF PALLIATIVE CARE

Palliative medicine seems to be the only medical branch to suffer from an original form of "schizophrenia": unanimously recognised as a clinical necessity and an ethical duty, it is still scarcely used and is subject to a very wide variety of unfounded biases and false fears in relation to the varying prevalence of an interpretation in terms of futile medical care or a form of slow euthanasia. This shows how far we still are from the intellectual honesty required to understand these issues in depth, even if the failure to use palliative therapy, besides being scientifically and ethically unjustified, is in the medico-legal field an act of malpractice due to inadequate professional conduct.

BIASES

One of the reasons hindering the full implementation of palliative medicine is the persistence of some biases about the use of opioids.

The World Health Organization points out that, despite the publication of numerous international guidelines, there are still health professionals who, for reasons mainly related to unjustified beliefs about the use of opioids and to organisational and institutional difficulties that hinder the availability of drugs[42], lack - or are unable to implement in clinical practice - the necessary knowledge on pain therapy[43].

In particular, the most frequent cause of inadequate pain treatment seems to be the so-called opiophobia, or fear of addiction, despite scientific evidence that it is irrelevant in people who use opioids for analgesic purposes[44].

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[42] Concerning biases about the use of opioids, see: Mercadante S, *Pregiudizi sull'uso degli oppiacei* (HTTP://WWW.MEDINEWS.IT/NEWS,2270); Gunnarsdottir S, Donovan HS, Serlin RC, et al. *Patient-related barriers to pain management: the Barriers Questionnaire II (BQ-II).* Pain 2002; 99: 385-396; Maltoni M. *Opioids, pain, and fear.* Ann Oncol 2008; 19: 5-7.

[43] World Health Organization technical report series. *Cancer pain relief and palliative care* (804). Geneva, WHO, 1990.

[44] Paradoxically, according to scientific evidence patients whose pain is not controlled show an attitude of pseudo-dependence, since they ask for higher doses than those prescribed. This behaviour, which is wrongly attributed to drug dependence, is indeed

Opiophobia, besides conditioning treatment, still represents a cultural barrier not only to the appropriate administration of these drugs, but also to full therapeutic adherence by the patient. The latter increasingly tends to seek - and believe - information from non-scientific sources, such as the social media, which mainly highlight the most sensational aspects of the abuse of these substances, to the detriment of the efficacy guaranteed by rational use under medical supervision.

In addition, it is impossible to continue hospital-based treatment at home if the general practitioner has not received adequate training in this field, or if there are regulatory and bureaucratic obstacles to prescribing opioids and morphine.

ORGANISATION AND COSTS

Expenditure in National Health Services is mainly affected by pharmaceuticals, which are often subject to rationing criteria rather than proper resource allocation procedures based on rationalisation principles and scientific evidence.

Effective pain control is one of the clearest examples of proper cost management, which, at home, is identified exclusively with the price of pharmaceuticals: indeed, when pain is not controlled according to the criteria of appropriateness, the consequent urgent hospitalisation necessarily causes an increase in expenditure.

It should be emphasised that expenditure does not only include economic costs related to the care facility, but also indirect tangible costs - corresponding to the loss of productivity and the lost earnings of patients and their families - and intangible costs - represented by the suffering and the consequent reduced quality of life.

Another economically relevant element, within a modern approach to care and respect for human dignity in suffering, is “continuity of care”. Indeed, the old system of care, based on hospitalisation as the central and often only event of the entire disease process, is now replaced by an innovative criterion. Today, the “hospitalisation” stage of the clinical event is more advantageously concentrated solely on the diagnosis and initial treatment phases. Therefore, the duration of hospitalisation is now shorter than in the past. Moreover, in order to ensure an appropriate continuity of care, it is envisaged that the continuation of care will take place in residential settings (hospices, residential care homes, group homes, etc.) or at the patient's home. This integrated approach presents an undoubted twofold advantage: the inevitable reduction in costs, which used to be borne mainly by the hospital, is flanked by a greater comfort offered by the home or residential home, where a treatment team guarantees the continuation of the care initially provided on the hospital. The change of setting, from hospital to home, takes place in a “protected” way: this means that patients and their families are taken care of, in a virtual "handover" from hospital staff to home care staff, before discharge, at patients’ bedside.

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related to the choice of health professionals to minimise the intensity of pain and can be resolved more simply by adjusting the dosage to achieve an effective result.

The facilities designed to accommodate the patient-family unit, both residential and home care facilities, are integrated in the form of a "network". This means that, in a simple and inexpensive way, they will enable free movement from one care setting to another, according to the (clinical, social and relational) needs that may arise. This "network" includes all care responses related to the patient's clinical case. Therefore, recourse to emergency facilities will be discouraged, inappropriate admissions to other facilities will be prevented, and any futile alternative treatment, which is costly and often a source of further suffering, will be avoided as much as possible.

The creation and development of the "network" and its constituent parts, their integration and the procedures enabling the governance of the system are usually entrusted to specialised personnel with managerial skills and an impeccable knowledge of the delicate dynamics concerning the care of terminally ill patients[45].

In conclusion, it is necessary for all decision-makers to make their choices, in the awareness that the most costly PC is the one that is not effective and is not provided[46].

Therefore, a proper allocation of resources can only stem from adequate pharmacological expertise and continuous scientific updating.

CAN PALLIATIVE CARE BE CONSIDERED A HUMAN "RIGHT"?

A priority bioethical issue is to ensure equity in the provision of PC, given its scope, impact and accessibility[47].

In terms of scope, Palliative Care concerns an important and significant sector of the population in every country. It has been estimated that in Europe three out of four dying people need basic PC and at least half of these need specialised PC[48]; in contrast, in the world, only one in ten people in need of PC has the opportunity to receive it[49].

In terms of impact, suffering affects not only terminally ill patients but also their families. Significant repercussions in terms of pain and suffering can be limited through appropriate Palliative Medical Care.

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[45] AGENAS (Italian National Agency for Regional Healthcare Services), Studio osservazionale sull'applicazione di un modello integrato di cure palliative domiciliari nell'ambito della rete locale di assistenza a favore di persone con patologie evolutive con limitata aspettativa di vita.

[46] Mercadante S*, Pregiudizi.., cit.*

[47] Rogelio Altisent, *Equity and Palliative Medicine in Europe,* speech at the International Conference "20th anniversary of the Oviedo Convention: relevance and challenges", Strasbourg, 24-25 October 2017. (https://www.coe.int/en/web/bioethics/20th-anniversary-of-the-oviedo-convention).

[48] ATLANTES Survey, University of Navarra, *ATLANTES: Human Dignity, Advanced Illness and Palliative Care* (https://www.unav.edu/en/web/instituto-cultura-y-sociedad/proyecto-atlantes).

[49] WPCA (Worldwide Palliative Care Alliance) and WHO (World Health Organization), *Global Atlas of Palliative Care at the End of Life.* 2014. It is the first document dedicated to mapping the need for and availability of Palliative Care globally. It shows that in 2011 some 3 million patients received PC, the vast majority at the end of their lives, and that although most PC is provided in high-income countries, nearly 80% of the global need for PC affects low- and middle-income countries. Only in 20 countries, PC is well integrated into their health systems.

Finally, the accessibility of PC is possible for any kind of health care system based on an effective health care organisation. Indeed, the implementation of pain therapy does not by its nature entail high costs, but is mainly linked to the health training of professionals, unlike in other sectors where high costs are linked to technological development.

Equity in access to Palliative Care stems from the broader statement of equity in access to health care enshrined in Art. 3 of the Oviedo Convention entitled **"Equitable access to health care"**:
"Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality".

A lively international debate has been developing for some years on the issue of inequality in the supply of PC worldwide. Such debate highlights that most countries have neither formal PC policies nor integrated PC services, do not meet basic international guidelines on the availability of PC, and have legislation or policies that restrict access to the use of opioids for medical purposes.

Therefore, it emerges that there is a global disparity in resources and infrastructures dedicated to the care of persons with life-limiting diseases.

Based on this evidence, there is a debate in the literature on the need to include Palliative Care among human rights[50].

The statement that relief from suffering is a joint goal of medicine and human rights and that relief from suffering and pain of terminally ill patients is a human right dates back to the early 1990[51].

Recently, this statement has appeared in numerous international documents and declarations[52].

In particular, in a comment on the right to health dating back to 2000, the Committee on Economic, Social and Cultural Rights (ICESCR)[53] identified among the "main obligations" of the signatory nations also access to health facilities, goods and services on a non-discriminatory basis and the provision of "essential drugs", as defined by the WHO, and considered it fundamental to ensure "attention and care for chronically and terminally ill persons, sparing them avoidable pain and enabling them to die with

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[50] Brennen F. *Palliative care as an international human right.* Journal of Pain and Symptom Management 2007; 33(5):494–499.

[51] Somerville M. *Human rights and medicine: the relief of suffering*. In: Cotler I, Eliadis FP, eds. *International human rights law: Theory and practice.* Montreal: Canadian Human Rights Foundation, 1992:505e522.

[52] Standing Committee on Social Affairs, Science and Technology. *Quality end-of-life care: The right of every Canadian. Final report of the Subcommittee to Update of Life and Death.* Ottawa: Senate of Canada, 2000; Sebuyira LM, Mwangi-Powell F, Perira J, Spence C. *The Cape Town Palliative Care Declaration: home- grown solutions for sub-Saharan Africa*. J Palliat Med 2003; 6(3):341e343; Council of Europe. *Recommendation 24 of 2003.* Adopted by the Committee of Ministers of the Council of Europe on 12 November 2003; Ahmedzai SH, Costa A, Blengini C, et al. *A new international framework for palliative care.* Eur J Cancer 2004; 40:2192e2200; *The Korea Declaration. Report of the Second Global Summit of National Hospice and Palliative Care Associations*, Seoul, March 2005.

[53] United Nations Committee on Economic, Social and Cultural Rights, *General Comment* No. 14, 11 May 2000.

dignity"[54]. The Resolution adopted in 2014 by the World Health Assembly[55], by declaring that PC is a key component of all health systems, takes an important step in urging Member States to develop supporting policies.

Indeed, at a global level, the development of programmes is hindered by the lack of awareness of the existence and specificity of PC among all stakeholders (citizens, health professionals, decision-makers and the media providing information on end-of-life issues).

The implementation of PC projects is particularly difficult in healthcare management models where health is a product based on economically measurable outcomes: according to this model, any treatment offered to incurable or terminally ill patients is a bad investment, whose cost is difficult to justify when aimed at people with an ominous prognosis[56].

In this context, the indications contained in the WHO Programme on Essential Medicines[57] are fundamental. According to these indications, access to PC is part of the basic minimum content of the right to the highest attainable standard of health.

According to these Recommendations, all countries should adopt a national policy on Palliative Care, ensure the training and education of health professionals also through joint international training programmes, promote public awareness, ensure the availability of opioids in all health facilities and guarantee minimum standards for pain relief[58].

Similarly, the Declarations of the United Nations Committee against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment show that denying access to pain relief may constitute a form of inhuman and degrading treatment[59].

It should be emphasised that these United Nations documents do not state an explicit right to Palliative Care. Moreover, the World Health Organization defines health as *"the ability to adapt and to self-manage, in the face of social, physical and emotional challenges"*[60] and therefore it includes the health of

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[54] Committee on Economic, Social and Cultural Rights. General Comment No. 14. *The rights to the highest attainable standard of health (Article 12 of the Covenant),* 22nd Session April May 2000 E/C 12/2000/4, par.43. The importance of this form of care is underlined by the WHO Global Plan of Action for the Prevention and Control of Non-communicable Diseases 2013-2020 agreed by WHO Member States in 2013.

[55] WHA (World Health Assembly, legislative body of the WHO) *Strengthening of palliative care as a component of comprehensive care throughout the life course,* 2014.

[56] Comoretto N, "*PAL-LIFE Project: International Advisory Working Group on Diffusion and Development of Palliative Care in the World'' - First Meeting Report,* Journal of Palliative Medicine, 2017, Sep; 20(9):913-914. doi: 10.1089/jpm.2017.0237. Epub 2017 Jun 6.

[57] The WHO list of essential medicines is updated as of March 2017: *WHO Model List of Essential Medicines, 20th List*: It contains 21 medicines for Palliative Care.

[58] WHO has made general recommendations for different resource countries: in low resource countries, home care is probably the best way to receive good quality care; in medium resource countries, services should be provided by dedicated primary health care clinics and home care; in high resource countries, there is a variety of options, including home care.

[59] On this subject, see the *United Nations Convention against Torture and Other Cruel, Inhuman, or Degrading Treatment or Punishment,* adopted in 1984, and the recent speeches by the UN Special Rapporteur on torture and other cruel, inhuman, or degrading treatment or punishment.

[60] This definition, dating back to 2011, emphasises man's/person's ability to live with the disease in its various stages, while considering that ageing and chronicity will influence how the health status is measured/assessed. This proposal places the

people with limited life expectancy and indirectly also Palliative Care. PC thus becomes part of a health care continuum for all people.

Therefore, in the broad international debate, the right to Palliative Care is discussed, and PC would be implicitly included in the right to health[61].

The CSB is aware of the wide-ranging scope and bioethical importance of the aspects relating to end-of-life situations. Therefore, it believes that the “right” to Palliative Care can be translated into a reasonable and appropriate response to the needs of each individual patient, in the awareness that no health professional, within the scope of his/her professional responsibility, can ever guarantee a total absence of suffering.

CONCLUSIONS

In order to produce a truly useful programme, the discussion of end-of-life management, which is related to Palliative Care, cannot be separated from an assessment of the cultural, social and personal context of patients and their families. The concepts of incurability and imminent death must be analysed in detail on a case-by-case basis. Attachment to life and rejection of death may entail the risk of futile, if not harmful, therapies, which should be avoided, despite the hope that patients or their families may place in them. On the contrary, therapies aimed at the well-being of the patient must be supported, in accordance with what is stated in the Chapter on communication, understood as an integral part of the whole process, and as such to be protected and recognised as “care time”.

What emerges from the above is the need for Palliative Care to be recognised as essential to care, understood as respect for the rights of the patient. The latter’s well being must be guaranteed by the social system at all stages of existence, through facilities organised as a network, where staff with specific skills operates.

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patient/person at the centre of the reasoning, while anticipating that through the development of internal resources, typical of each individual, conditions of disease and disability can also be successfully dealt with.

[61] International Declarations related to the various Palliative Care Societies include: *The Cape Town Palliative Care Declaration*, 2002 (which underlines four key points: 1. Palliative Care is a right of every adult and child with a life-limiting disease. 2. Appropriate drugs, including strong opioids, should be made accessible to every patient requiring them in every sub-Saharan country and at all levels of care. The establishment of education programmes is necessary at all levels of the learning continuum. 4. Palliative Care should be provided at all levels of car. While primary care is emphasised, secondary and tertiary level teams are needed to lead and foster primary level care. Ahmedzai SH, Costa A, Blengini C, et al. *A new international framework for palliative care*. Eur J Cancer 2004; 40:2192e2200 (according to which *"there should be free access to Palliative Care for all cancer patients, as a fundamental human right")*; *The Korea Declaration*. Report of the Second Global Summit of National Hospice and Palliative Care Associations, Seoul, March 2005 (stating that Governments must *"make access to hospice and Palliative Care a human right",* and inviting Governments to include PC as part of all governmental health policies, integrate PC training into the curricula of health care professionals, make all necessary drugs available and affordable, in particular opioids); *Montreal Statement on the Human Right to Essential Medicines* 2005 (which explicitly links the international right to health with universal access to these essential medicines).

1. WHA (World Health Assembly), *Strengthening of palliative care as a component of comprehensive care throughout the life course*, 2014.
2. AIOM (Italian Association of Medical Oncology), *Linee Guida. Terapia del dolore in Oncologia*, 2016.
3. Bruera E. *Sulle Cure Palliative*. Lectio magistralis – Bentivoglio's Seminars (26 March 2011). Collana PalliAttiva © 2012. ISBN 978-88-97620-00-6. EBOOK ISBN 978-88-97620-79-2.
4. Biasco G*. Comunicare e curare. La comunicazione in medicina: dalla diagnosi alle cure palliative.* Collana PalliAttiva © 2013 Pag. 372. ISBN 978-88-97620-02-0. EBOOK ISBN 978- 88-97620-80-8.
5. SIAARTI – Bioethics Study Group – Coordinator Dr. Alberto Giannini Grandi. *Insufficienze d'organo "end stage": cure intensive o cure palliative? - "Documento condiviso" per una pianificazione delle scelte di cura*- Document approved by the Governing Council of SIAARTI on 22 April 2013.
6. Centeno C, Bolognesi D, Biasco G. *Comparative analysis of specialization in palliative medicine processes within the World Health Organization European region*. J Pain Symptom Manage. 2015 May; 49(5):861-70. doi: 10.1016/j. jpainsymman.2014.10.019. Epub 2015 Jan 24.
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10. Borgia L. *Il dolore e le cure palliative: aspetti etici*, in S. Lubrani, *Morfina ultima dea*, Edizioni Tracce, Pescara. 2005.
11. Borgia L. *Il profondo significato etico delle cure palliative*. Professione - Cultura e pratica del medico d'oggi, n. 8 (October 2005), pp. 33-37.Bolognesi D., Centeno C. y Biasco G. *Specialisation in Palliative Medicine for Physicians in Europe 2014* - A supplement of the EAPC Atlas of Palliative Care in Europe. Milan: EAPC Press, 2014.
12. Elsner F, Centeno C, Cetto G, De Conno, F, Ellershaw J, Eychmuller S, Filbet M, Larkin P, Mason S. *Recommendations of the European Association for Palliative Care (EAPC) For the Development of Undergraduate Curricula* in Palliative Medicine At European Medical Schools. Milan: EAPC (European Association for Palliative Care), 2013.
13. Pastrana T, De Lima L, Pons JJ, Centeno C (2013). *Atlas de Cuidados Paliativos de Latinoamérica.* Edición cartográfica 2013. Houston: IAHPC Press.
14. Rhee JY, Luyirika E, Namisango E, Powell RA, Garralda E, Pons JJ, et al. *APCA Atlas of Palliative Care in Africa.* Houston: AHPC Press; 2017.

15. Osman H, Rihan A, Garralda E, Rhee JY, Pons JJ, de Lima L, et al. *Atlas of Palliative Care in the Eastern Mediterranean Region.* Houston: IAHPC Press; 2017.

PALLIATIVE CARE IN PAEDIATRIC PATIENTS

Paediatric Palliative Care is much more than taking care of the child.
***F. Benini* [62]**

Recognising and accepting a child's suffering is very difficult on an emotional level. Therefore, the issue of paediatric Palliative Care often arouses deep unease in our socio-cultural context.

The discomfort in tackling such a complex issue has deep roots and can also be seen in the fact that the Italian vocabulary lacks a term to define the condition of a parent who loses his/her child, unlike a child who loses a parent and becomes an “orphan”, or a spouse who loses a partner and becomes a “widower”.

Defensive denial of the idea of pain, serious illness and death of the child leads, as a natural consequence, to silence on this subject.

Yet the incidence of chronic incurable diseases in children is steadily increasing in Western countries, as medical and technological progress in recent decades has significantly reduced mortality but increased the number of children suffering from serious incurable diseases[63].

Therefore, the issue of chronic progressive invalidating diseases and the consequent need for Palliative Care also in paediatric age is no longer marginal in the context of social and political decision-makers’ consciousness.

PAEDIATRIC PALLIATIVE CARE (PPC)

The World Health Organization (WHO) defines PPC as the “total care of the incurably ill child's body, mind and spirit, which also involves giving support to the family, by taking care of their health, welfare, psychological, social, economic and religious aspects"[64].

The principles set out in this definition are the same as those for adults. However, compared to the latter, these principles inevitably imply a range of conditions that have different clinical development characteristics, life expectancies and social, spiritual, religious and family implications. As in adults, the criteria for undertaking Palliative Care in children are represented by the absence of a therapy that allows the disease to be cured and by the presence of complex needs that require several specialists to be met.

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[62] Paediatrician. Head of the Veneto Regional Reference Centre for Paediatric Pain Therapy and Palliative Care.

[63] In Europe, the ratio of children with “life-limiting” conditions (see definition in **Glossary**), which, according to 2007 estimates, was of 16 cases/10,000 children (0-18 years of age), has doubled in a few years, reaching an estimated 32 cases/10,000 children in 2010 (Fraser LK, Miller M, Hain R et al, *Rising National Prevalence of life-limiting conditions in children in England.* Pediatrics 2012; 129 (4):923-929). In Italy, at least 12,000 children with life-limiting conditions would be eligible for Palliative Care (Benini F, Ferrante A, Buzzone S et al, *Childhood deaths in Italy.* EJPC, 2008; 15 (2): 77-81). In the Republic of San Marino, although lacking precise epidemiological data, it is possible to estimate the presence of about ten minors (0-18 years) with “life-limiting” conditions, with a ratio of about 25 cases/10,000.

[64] World Health Organization, *Cancer pain Relief and Palliative Care in Children*. Geneva. WHO-IASP 1998.

As indicated by the specific commission of the Italian Association of Paediatric Haematology and Oncology (AIEOP), *"Palliative Care does not preclude concomitant therapies; it begins preferably upon diagnosis and continues throughout the disease process, taking care of meeting the needs"*[65]. Since there are several different needs in relation to the worsening of the clinical condition, they require the involvement of professionals with different skills.

The identification of the generally progressive severity of a chronic incurable disease and the related degree of professional competence are schematically divided into three levels[66]:

1) less serious and more frequent conditions, which can be treated by all healthcare professionals (basic palliative approach);
2) more complex conditions requiring expertise from trained professionals, even if not exclusively dedicated to Palliative Care ("general" PC);
3) particularly serious conditions requiring the intervention of specifically dedicated multi-professional teams with a high level of expertise ("specialist" PC).

The care of terminally ill patients generally, though not exclusively, requires a specialist palliative approach.

THE NEEDS OF THE CHILD AND THE FAMILY

The involvement of several different professionals, particularly needed in the most serious health situations, implies an assessment of the typology of needs. Also for this topic, as for the assessment of clinical complexity, a scheme is used in order to identify:

- **clinical needs:** requiring measurement and control of symptoms, in particular pain, after appropriate definition of the care plan;
- **psychological needs** of the child and the family;
- **social needs**, such as education, play, economic support, services;
- **spiritual needs** of the child and the family.

Psychological, communication, social and spiritual needs are often not adequately addressed, and responses are largely delegated to the family, which is also an integral part of the PPC programme, and as such has needs (including economic needs) for which appropriate solutions must be offered.

The whole family participates in the care plan since it involves the whole social and economic costs of the child's incurability.

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[65] Palliative Care Commission of AIEOP (Italian Association of Paediatric Haematology and Oncology), *Le cure palliative pediatriche nei Centri AIEOP*, Position Paper. 2017.

[66] Technical document of the Italian Ministry of Health, *Cure palliative rivolte al neonato, bambino ed adolescente*, 2008. www.salute.gov.it/imgs/C_17_pubblicazioni_797_allegato.pdf.

The experience of a dying child can have devastating long-term effects, not only on the parents, but especially on siblings and other more fragile family members[67]. PPC must therefore also be able to respond to such an emergency with bereavement management and processing programmes, which do not end with death, but follow the family over time.

Some surveys conducted in various countries, despite their geographical, social and organisational differences, have shown a surprising homogeneity in terms of needs[68]:

- families and children prefer care to be provided mainly at home;
- the availability of “relief” services is considered essential;
- accessibility to any PPC services is often conditioned by the place where the child lives and the type of disease, and is higher for those with cancer;
- resources dedicated to PPC are considered inadequate;
- communication among the various professionals caring for the child is difficult and should be implemented;
- there is a need for adequate and specific training on PPC by the health and social care professionals and volunteers involved.

WHERE TO PROVIDE PPC

As in the case of adults, the response to these different and complex needs of children and families essentially involves two models of PPC: residential (hospice or hospital with dedicated units) and home-based.

Both have advantages and disadvantages, although the home-based model generally responds better to the needs of the unit made up of “child-caregiver-relatives-friends”. Home care reduces feelings of fear, isolation and helplessness, allows the child to participate in family activities with an important opportunity for communication and socialisation, and enables other family members to share responsibility for care.

The dualism between hospice and home care is essentially conceptual.

In practice, the availability of paediatric hospices is very limited in most parts of the world. The hospital setting, even in dedicated units, is often inadequate to perform a real “all-round” palliation function. Therefore, at the time being the home care model must be implemented and strengthened as much as possible, in order to avoid resorting to residential care which, as specified above, is rather inadequate and would require economic, strategic-organisational and cultural efforts that would not be easy or quick to implement.

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[67] Nagera H, *Vincent van Gogh. A Psychological Study*. George, Allen & Unwin. London 1967; Solemani H, *Childhood bereavement. The effects on parents and siblings*. Unpublished 1979; Sabbadini A, *The Replacement Child.* Doppio Sogno, London, 1987.

[68] Graig F, Abu-Saad H, Benini F, et al. *IMPaCCT standards for paediatric palliative care in Europe*. EJPC 2007; 14(3): 109-114. Soutter J, Bond S, Craft A. *Families of Misfortune: proposed strategy in Northern Region for the care of children with life threatening illnesses, and their families*. Department of Child Health and Centre for Health Services Research, University of Newcastle upon Tyne, 1994.

The CSB believes that any solution must always be the result of a thorough analysis of the needs corresponding to the clinical course of the disease. It is up to the PPC team to assess, with the active and continuous participation of the family and, whenever possible, the child, the concrete possibilities of responding to the needs, both clinical and non-clinical, also taking into account the available resources.

Moreover, as institutions are also faced with a new and complex demand for care, it is important to provide them with up-to-date epidemiological data, specific guidelines and procedures, indicators and related standards, as well as innovative proposals, so that they can offer services based on best practices[69].

HOW TO INFORM THE CHILD

Particular attention should be paid to information to be provided to the child, because of the obvious need to combine the delicate relationship between the exercise of parental responsibility and the child's autonomy of choice. Indeed, in order to be able to express their consent/disagreement to the healthcare practices that concern them, children must exercise their right to information, to be listened to and to self-determination[70] through a comprehensible language that is appropriate to their development and degree of maturity.

To this end, suitable information materials adapted to the different developmental stages of paediatric age can be a useful aid, as can the collection of minors' opinions on the type of care received, through ad hoc surveys.

Parents must always be involved in obtaining informed consent from the child.

Anyone who, as part of the treatment team, assesses the degree of development and maturity achieved by the child must pay attention to the way in which the relationship between the child and his/her parents is conducted. In particular, it is necessary to verify the absence of any psychopathological conditioning and the right balance between the child's needs for protection and autonomy.

PERINATAL PALLIATIVE CARE

In the vast span of time characterising paediatric age, the period of birth has special features that are extremely delicate and crucial from a bioethical perspective.

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[69] See the **Glossary**.

[70] EACH (European Association for Children in Hospital), *Charter on the Rights of the Child in Hospital* (known as *EACH Charter*), 1988. San Marino legislation recognises this right also through the transposition of the Convention on Human Rights and Biomedicine (known as the *Oviedo Convention*, 1997) and the *European Convention for the Protection of Human Rights and Fundamental Freedoms* (ECHR, 1950).

This is why the CSB has decided to briefly reflect on the bioethical issues of perinatal end-of-life, which are addressed with growing interest in the international literature[71], well aware that the complexity and wide-ranging scope of this subject would require an in-depth study in a specific document.

The Perinatal Palliative Care programme is an ethical and deontological duty in all situations where the initiation or prolongation of intensive support is futile (it does not prolong life or significantly delay death) and causes additional pain and suffering.

The multidisciplinary approach to Perinatal Palliative Care goes beyond pain control and compassionate care, and also involves creating a suitable environment that respects the privacy and dignity of the child and family.

Such care can occur mainly under two conditions:

1- the formulation of a definite prenatal diagnosis of a disease that is incompatible with life or that has an ominous prognosis in the early stages of life[72];
2- clinical neonatal situations judged to be irreversible, for which it is decided to limit intensive treatment[73].

The scientific basis for such an approach to the specific circumstances in question can be found in the numerous international guidelines issued[74], and will therefore not be dealt with by the CSB, which will instead focus on some major bioethical issues:

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[71] Silberberg A, Robetto J, Grillo M. *Ethical Issues in Intrauterine Myelomeningocele Surgery*. New Bioeth. 2018 Sep 20:1-9; Phillips J, Millum J. *Valuing Stillbirths.* Bioethics. 2015 Jul;29(6):413-23; Avelin P, Rådestad I, Säflund K, Wredling R, Erlandsson K. *Parental grief and relationships after the loss of a stillborn baby.* Midwifery. 2013 Jun; 29(6):668-73; Rådestad I, Malm MC, Lindgren H, Pettersson K, Larsson LL. *Being alone in silence – Mothers' experiences upon confirmation of their baby's death in utero* Midwifery. 2014 Mar; 30(3); Kelley M, Rubens CE; GAPPS Review Group. *Global report on preterm birth and stillbirth (6 of 7): ethical considerations.* BMC Pregnancy Childbirth. 2010 Feb 23;10 Suppl 1:S6; Homer CS, Malata A, ten Hoope-Bender P. *Supporting women, families, and care providers after stillbirths* Lancet. 2016 Feb 6;387(10018):516-7; Heazell AE, Siassakos D, Blencowe H, Burden C, Bhutta ZA, Cacciatore J, Dang N, Das J, Flenady V, Gold KJ, Mensah OK, Millum J, Nuzum D, O'Donoghue K, Redshaw M, Rizvi A, Roberts T, Toyin Saraki HE, Storey C, Wojcieszek AM, Downe S; Lancet Ending Preventable Stillbirths Series study group; Lancet Ending Preventable Stillbirths investigator group. *Stillbirths: economic and psychosocial consequences*. Lancet. 2016 Feb 6; 387(10018):604-16; Peters MD, Lisy K, Riitano D, Jordan Z, Aromataris E. *Caring for families experiencing stillbirth: Evidence- based guidance for maternity care providers.* Women Birth. 2015 Dec; 28(4):272-8; Roberts LR, Lee JW. *Autonomy and social norms in a three factor grief model predicting perinatal grief in India.* Health Care Women Int. 2014; 35(3):28599; Roberts LR, Lee JW. *Autonomy and social norms in a three factor grief model predicting perinatal grief in India.* Health Care Women Int. 2014; 35(3):28599; Maureen Kelley, Craig E Rubens and the GAPPS Review Group *Global report on preterm birth and stillbirth (6 of 7): ethical considerations.* BMC Pregnancy Childbirth. 2010 Feb 23; 10 Suppl 1:S6.

[72] For example, cases of incurable diseases (e.g. Trisomy 13, anencephaly, etc.) or extreme prematurity.

[73] This is the case of ventilation or other invasive procedures that are futile since they achieve no real benefit, but temporarily postpone death by generating further suffering.

[74] These include, among others: SIN (Italian Society of Neonatology) and Infant Analgesia and Sedation Study Group, *Linee guida per la prevenzione ed il trattamento del dolore nel neonato*. Biomedia, Milan 2016; RCPCH (Royal College of Paediatrics and Child Health) and Chelsea and Westminster Hospital NHS Foundation Trust, *Practical guidance for the management of palliative care on neonatal units*, 2014; NICE (National Institute for Health and Care Excellence), *End of life care for infants, children and young people with life-limiting conditions: planning and management.* 2016.

A- Correct information and appropriate counselling in pathological diagnosis

The CSB believes that the communication of a pathological diagnosis concerning a foetus/newborn child should be based on the provision of appropriate counselling, the aim of which should not be solely to provide the clearest and most accurate information possible. It should also include “caring” for the parents, who, faced with the unforeseen and emotionally destabilising situation represented by the communication of a diagnosis with an ominous prognosis, are involved in the delicate decisions concerning the care to be given to their sick child.

These experiences of the parents, and of the mother in particular, sometimes complicated by previous negative experiences that make the person even more fragile, condition the inevitable projections concerning the quality of their future life and that of their child/children.

These experiences and this particular emotional fragility of the mother/parents, which characterises the entire birth process, must be taken into account by the treatment team when planning the counselling intervention for them.

Indeed, the destabilising emotional experiences of parents hinder, and sometimes prevent, a clear and lucid understanding of the information provided to them by the treatment team, particularly when the diagnosis is communicated and in the immediately following stages.

For this reason, it is necessary for the treatment team to plan times and modes appropriate to the individual case for effective and empathic communication, while respecting the parents' difficulties and their possible “outburst”, sometimes expressed with explosions of uncontainable rage against the whole world, other times with an impenetrable “silence”.

An important and irreplaceable “moment of care” for parents and the whole family is the fact that the treatment team always meets their requests for clarification, repeats several times what has been already said, and is always at their side as “persons” and not just as doctors.

In seeking the necessary involvement of parents in decisions concerning the care of their child and in guaranteeing their continuous presence and participation, the team must, in these difficult moments, pay great attention not to delegate to the parents any responsibility for the choices to be made about the care of their child.

It should be emphasised that termination of pregnancy due to foetal diseases puts an end to the couple's strongly desired parental plan.

Recent international scientific literature reports on studies carried out in pathological pregnancies in which the child was incompatible with extrauterine life, and therefore terminal, and whose parents were offered access to Prenatal Care and Palliative Care.

This shows that the parents' grieving process is significantly facilitated if the pregnancy is allowed to come to an end by supporting the child until birth, and if parents are enabled to live together with their child after birth, albeit for a short time[75].

Similarly, the possibility of burying the foetus may also contribute to the continuity of the emotional relationship through the presence of a grave[76].

B- Perinatal Hospice

In its most recent development, Perinatal Hospice not only hosts terminally ill infants, but is also a centre of reference for the treatment and study of prenatal diseases. Access to a Perinatal Hospice with these characteristics, in the event of a pathological prenatal diagnosis, constitutes professional and human support for the family, a humane model of medicine that can change the impact and perception of the diagnosis, in a welcoming context that supports the child and the family.

This facility must provide areas for parents and treatment team to meet, even repeatedly, to receive psychological and, where required, spiritual assistance and to care for the newborn baby in places that respect privacy, where parents and family members can share and experience their emotions.

The Perinatal Hospice is therefore not just a medical place: it is also a place of care and relationships, in which true “shared medicine” is implemented, capable of supporting the child, ensuring his/her well-being through Palliative Care aimed at eliminating pain and guaranteeing psychological, emotional and spiritual assistance to the family.

The time spent in this environment is for parents the only opportunity to build up a relative memory. It is therefore essential that the parents are allowed to remain in the child's company as much as possible and have other relatives close to them, as well as to keep a memento of the child, represented by a photo or identification bracelet or other objects that belonged to the child, by means of which they can go through the grieving process.

On the basis of the evidence reported in the scientific literature[77], the CSB considers it fundamental that the couple (family) be guaranteed an appropriate support process from the moment of prenatal

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[75] Guon J. e coll., *Our children are not a diagnosis: the experience of parents who continue their pregnancy after a prenatal diagnosis of trisomy 13 or 18,* Am. J. Med. Genet. (2014, Part A 164 A: 308-318); Cope H. et al., *Pregnancy continuation and organizational religious activity following prenatal diagnosis of a lethal fetal defect are associated with improved psychological outcome*, Prenatal Diagnosis (2015, 35, 761-768).

[76] Scientific literature shows that the impossibility of finding the body of the deceased child delays, and even prevents, the grieving process (on this subject see: Scott J. *Stillbirths: breaking the silence of a hidden grief*. Lancet. 2011 Apr 23; 377(9775):1386-8). Moreover, it should also be noted that, in order to support parents in the grieving process linked to the loss of their stillborn child or child who died before birth, some groups of psychologists have set up dedicated associations (such as, in Italy: *Ciao Lapo*, *ANEP*- National Association of Prenatal Education, *Fondazione il cuore in una goccia)*.

[77] Hoeldtke NJ, Calhoun BC. Perinatal hospice. Am J Obstet Gynecol. 2001 Sep; 185(3):525-9; Calhoun BC, Napolitano P, Terry M, Bussey C, Hoeldtke NJ. Perinatal hospice. Comprehensive care for the family of the fetus with a lethal condition. J Reprod Med. 2003 May; 48(5):343-8; Ramer-Chrastek J, Thygeson MV. A perinatal hospice for an unborn child with a life-limiting condition. Int J Palliat Nurs. 2005 Jun; 11(6):274-6; Lindley LC, Fornehed ML, Mixer SJ. A comparison of the nurse work environment between perinatal and non-perinatal hospice providers. International Journal of Palliative Nursing 2013, Vol. 19, No. 11, pp. 535-540; Guon J. e coll., Our children are not *a diagnosis*… cit.

diagnosis until the grieving process is completed, not limiting it only to the period spent in specifically dedicated facilities, such as the Perinatal Hospice.

C- Pain control in the foetus and newborn child

A great deal of scientific evidence shows that newborn babies, even extremely preterm infants, are particularly sensitive to nociceptive stimulus and respond to it with physiological, behavioural and endocrine alterations that produce even long-term effects[78] due to early and repetitive exposure to this painful stimulus at such a delicate and fundamental time for the development of the nervous system[79].

Infants admitted to Neonatal Intensive Care Units are exposed to painful stimuli because they frequently undergo diagnostic, surgical or therapeutic procedures[80].

In addition to painful procedures, particular attention should be paid to situations of stress or discomfort generated by the unnatural and highly technological environments in which newborns are placed, and their conditions of clinical instability and fragility exacerbate and amplify their suffering.

It is therefore essential to both assess acute pain and discomfort using validated scales in fragile infants[81] and to modulate the intensive care environment according to their specific and basic needs.

The CSB believes that pain prevention and control should be an essential part of perinatal care[82], representing a deontological priority, as well as a bioethical duty of every health professional, in accordance with the **principles of beneficence and justice** due to each person, regardless of age, and in order to guarantee the dignity of each stage of life, especially in supporting the terminal stages of life.

Today, pharmacological techniques allow good control of pain in the newborn, but the next objective is personalisation, through continuous assessment of the symptom and constant verification of the effectiveness of the treatment[83]. It is therefore a new approach that can be described as "comprehensive". Indeed, together with environmental interventions[84], it uses combinations of pharmacological and non-pharmacological techniques to achieve better control of stress and pain, while

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[78] Anand KJS, Scalzo FM*, Can adverse neonatal experiences alter brain development and subsequent behavior?* Biol Neonate 2000; 77(2):69-82. Grunau RVE. *Long-term consequences of pain in human neonates*. In: Anand JKS, Stevens BJ, McGrath PJ, editors. Pain in neonates. 3rd ed. Amsterdam: Elsevier; 2007. pp. 55–76. editors.

[79] Peterson BS, Vohr B, Staib LH, Cannistraci CJ, Dolberg A, Schneider KC, et al. *Regional brain volume abnormalities and long-term cognitive outcome in preterm infants.* JAMA. 2000; 284: 1939–47.

[80] SIN and Infant Analgesia and Sedation Study Group, *Linee guida per la prevenzione… cit.*

[81] For example, preterm babies or babies in post-surgical situations.

[82] Italian Law no. 38/2010 "*Provisions to ensure access to palliative care and pain therapy*" requires doctors and nurses, in their daily work, to recognise sources of pain and report their continuous assessment in the medical record as the 5th vital parameter. This is fundamental to improve therapeutic and care processes in neonatal units. See also Impactproactive and Consumers' Federation, V*ademecum sul dolore. Law no. 38/2010:* http://www.impactproactive.it/wp-content/uploads/vademecum-dolore_feb2015.pdf.

[83] Carbajal R et al*, Sedation and analgesia practices in neonatal intensive care units (EUROPAIN): results from a prospective cohort study.* Lancet Respir Med. 2015 Oct; 3(10):796-812; Carbajal R, Gréteau S, Arnaud C, *Pain in neonatology. Non-pharmacological treatment.* Arch Pediatr. 2015 Feb; 22(2):217-21.

[84] Lago P, Garetti E, Boccuzzo G, Merazzi D, Pirelli A, Pieragostini L, Piga S, Cuttini M, Ancora G, *Procedural pain in neonates: the state of the art in the implementation of national guidelines in Italy.* Paediatr Anaesth. 2013 May; 23(5):407-14.

limiting the effects and adverse reactions resulting from the use of drugs[85]. In particular, worth underlining is the importance of using the technique tested and validated by many studies and called "Sensory Saturation". It consists in providing the newborn baby with a series of stimuli capable of competing with the arrival of pain to consciousness: the importance of this technique consists in enhancing the contribution of parents who, precisely by collaborating, become and feel as an active part in the care of the newborn baby[86].

Pain control must be a primary objective not only in the newborn but also in the foetus.

Only recently has it become known that also the foetus feels pain[87]. This has represented a turning point in invasive prenatal care and in the case of a suffering foetus. In these situations, analgesic and anaesthetic treatment is used, not only to control the current pain, but also to avoid effects that may last over time[88].

The most recent scientific evidence supports the conclusion that the foetus experiences pain at an early stage, as demonstrated by the production of stress hormones[89] and avoidance behaviour. These reactions are the same as those observed in infants subjected to an algogenic stimulus[90].

The fact that the foetus gets in contact with sedative substances in the uterus can only limit painful reactions, as the drugs concerned have no analgesic effect[91] and their concentrations in foetal blood are substantially lower than in maternal blood[92].

In the specialist field, it is now accepted that the therapeutic approach to the foetus suffering from serious diseases and undergoing invasive procedures should not be limited to curarisation[93] but should ensure adequate analgesia[94]. At present, foetal surgical treatment - with the consequent and necessary analgesia of the foetus - has become part of clinical practice[95]. However, if it is not aimed at definitive cure, it is ethically acceptable only if its purpose is to bring a sick foetus to a gestational age more suitable for delivery and to entrust it to the care of neonatologists in a more appropriate condition.

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[85] McNair C, Campbell Yeo M, Johnston C, Taddio A. *Non pharmacological management of pain during common needle puncture procedures in infants.* Clin Perinatol 2013; 40: 493-508.

With regard to the use of unconventional techniques for pain control, please refer to the CSB document “Pain management nursing: bioethical aspects”, 15 May 2017.

[86] Cignacco EL, Sellam G, Stoffel L, Gerull R, Nelle M, Anand KJ, Engberg S. *Oral sucrose and "facilitated tucking" for repeated pain relief in preterms: a randomized controlled trial.* Pediatrics. 2012 Feb; 129(2):299-308.

[87] Anand KJS, Hickey PR, *Pain and its effects in the human neonate and fetus*. N Engl J Med 1987; 317:1321-1329.

[88] It has been documented that pain from invasive procedures in the foetus causes an abrupt release of hormones, such as endorphins, catecholamines and cortisol, into the blood stream as a response to pain stress and, at vascular level, brain dilation.

[89] Giannakoulopoulos X, Sepulveda W, Kourtis P, Glover V, Fisk NM. *Fetal plasma cortisol and beta-endorphin response to intrauterine needling.* Lancet. 1994 Jul 9; 344(8915):77-81.

[90] Smith RP, Gitau R, Glover V, Fisk NM. *Pain and stress in the human fetus*. Eur J Obstet Gynecol Reprod Biol. 2000 Sep; 92(1):161-5.

[91] Bellieni CV, Buonocore G. *Is fetal pain a real evidence?* J Matern Fetal Neonatal Med. 2012 Aug; 25(8):1203-8.

[92] Yoneyama Y, Suzuki S, Sawa R, Araki T. *Plasma adenosine concentrations increase in women with hyperemesis gravidarum.* Clin Chim Acta. 2004 Apr; 342(1-2):99-103.

[93] This consists of injecting the foetus, under ultrasound guidance, into the buttock or thigh or directly into the cord, with a drug that blocks its excessive movement, which would make the procedure too dangerous.

[94] It consists of using drugs to prevent the foetus from feeling pain during the invasive procedure.

[95] Bellieni CV, Vannuccini S, Petraglia F. *Is fetal analgesia necessary during prenatal surgery?* J Matern Fetal Neonatal Med. 2018 May; 31(9):1241-1245.

In the clinical field, the phases of life identified by the terms “adolescent” or “young adult” are a sort of borderland where care facilities do not have a specialist discipline of reference. However, in the transition from childhood to adulthood, major physical and mental changes take place. It is a complex transitional period, in which the processes of intellectual growth, maturation, structuring of feelings and relationships leave the parental context and absolute protection of life to enter the world of autonomy, biological stabilisation and the achievement of personality.

Terminology here is also confusing. The adolescent is considered to be closer to paediatric age, while the young adult has already reached near maturity. However, there is no clear dividing line and the boundary established by age is arbitrary. The transformation from child to adult takes place at very different speeds from one individual to another, and the process is difficult to break down into homogeneous categories.

The onset of a serious disease, especially an incurable one, has a devastating effect because it interrupts a process in which the expectations of a real life with its characteristic projects and hopes are deeply shattered. It is like a house under construction where the architectural design is taking shape but suddenly the work has to be changed without knowing if, how and when it can be finished. Adolescents-young adults, unlike children, are increasingly aware of the fact that they are persons who have the right to claim their life and their role as members of the society.

While the evolutionary process is ongoing, and awareness and autonomy of thought are beginning to be seen more and more clearly, the legal and organisational framework of society places constraints on personal behaviour and choices. When there is a need for care, and especially when there is a need for Palliative Care for a severe and incurable disease, what should help a person who is undergoing a constructive revolution in his/her being a person? The terms “being of age” or “being a minor” imply limitations or concessions to decision-making. In many cases, paediatricians are the official reference professionals; parents, from whom young patients were separating in a more or less painful way before the onset of the disease, come back into their lives, taking decisions for them, which are not always shared. Parents and relatives often believe that adolescents-young adults still lack autonomy of thought and that their affections are disordered, unformed and without the stability needed to deal with critical situations. Similarly, caregivers, who are trained in classical criteria, according to which there is a clear separation between children and adults, are often unable to adequately understand the needs of the patient.

The extent of the problem cannot be defined. Certainly, in the context of adolescent development the number of people needing Palliative Care is not very high. However, when it happens, caregivers are unprepared, inefficient and sometimes harmful.

One of the most frequent attitudes when the disease progresses and worsens is that young people “rush” into the arms of their parents in a sort of regression to the stage of childhood, in which the prevailing behaviour is to rely completely on the therapeutic and care choices of adults, abandoning self-consciousness and full awareness of their own existence.

This attitude in relation to the parents' response can lead to a kind of inner frustration at the intrusion of a “world” that was thought to be abandoned as regards its decision-making control and responsibility. This admission of inability to govern one's own existence then leads to attitudes of instability and depression, which in turn amplify the impairment of the quality of life already severely undermined by the disease.

In this context, care organisations should intervene with strategies that, in addition to the specific treatment of the disease, implement processes aimed at maintaining normality, the possibility of developing projects, and of interacting with the communities of reference, which are numerous and must in turn be helped to assume a conscious role.

In recent years, a number of hospitals have developed programmes aimed at supporting young adults in oncohaematology facilities in terms of their relational, spiritual and psychological needs, as well as their creativity, by promoting cooperation between boys and girls going through the illness and peers ready to work alongside them in a spirit of friendship, support and love. Also thanks to the support of specially created associations and foundations, doctors and psychologists have launched specific programmes focusing on music, singing, meditation, creative writing, photography and yoga gymnastics, which have enabled young patients to open up to dialogue, socialise and expand their horizons in a climate of optimism, hope and listening.

The humanistic component that characterises Palliative Care is specific and predominant in young adults and adolescents. In addition to all measures that need to be put in place to understand, address and treat physical needs, it is essential that psychological, emotional and affective support is well understood as the special feature of this complex and different phase of life. In the latter, the intervention of the competent adult or parent is perhaps less relevant compared to that of the community of people who have the same exuberance and complexity projected into the future existence and who flank those who, more or less consciously, know they cannot have that future, but can reflexively live it through the drive of other peers. This is why Palliative Care for young adults and adolescents calls for the participation of a community of peers and requires places where, in addition to opioids or other drugs to relieve pain, its truly palliative function can be guaranteed by opening up horizons of dialogue, sharing, protection and therefore care.

CONCLUSIONS

Children with incurable and terminal diseases and their families have complex and specific needs, which can also last for long periods of time. They need competent and continuous responses from teams dedicated to Paediatric Palliative Care, which should ensure holistic, continuous, participatory and possibly shared care. Since minors have the same rights to health and care as adults, the principle of justice obliges us to apply also to them the Palliative Care organisation process already applied to adults and the elderly, placing the family and the patient at the centre of the system. Indeed, this system must necessarily evolve from a model centred on the hospital and the disease to a model centred on needs.

Therefore, among these needs, the family must not be forgotten. It represents a relatively stable system of alliances among relatives by blood and affinity, based on a set of rules recognised and legitimised by the community. This system remains almost unchanged throughout life; therefore, in communicating incurable and terminal diseases, the influence it will have on information processing must be taken into account.

The CSB is aware that such an approach constitutes first and foremost a fundamental cultural, as well as social, professional and organisational change, which is unavoidable in order to respond adequately to emerging and special needs.

The basis of this holistic approach is the constant involvement of parents in every clinical decision, whether ordinary or extraordinary, concerning minors, while respecting the principle of autonomy.

Only in case of urgent and non-deferrable interventions for the protection of the child's health and life (cases in which the exclusive decision-making responsibility of the doctor is involved) should the parents always be an indispensable part of the decision-making process. In cases where the child is to undergo experimental therapies, the consent of the parents/guardians becomes binding.

As already stated for adult and elderly Palliative Care, in addition to knowledge of the underlying disease, in order to support the child and the family over the years, it is necessary to have skills related to analysis, exchange of views, communication and teamwork, as well as the ability to deal with ethical and bioethical issues and to offer thoughtful and up-to-date responses. All professionals working in contact with children should have basic skills in PPC.

It is necessary to include palliation in the continuum of care, especially at the level of primary care, and to apply **the bioethical principle of justice,** given that the absence or inadequate integration of Palliative Care in health and social systems is a determining factor in the lack of equitable access to care (67th WHA, Geneva, 19-24 May 2014).

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ARTIFICIAL END-OF-LIFE NUTRITION AND HYDRATION

In approaching this issue, the CSB considers it necessary to preliminarily reiterate that the patient remains the holder of his/her status as a person and of the rights that derive from it, regardless of clinical status. This consideration is at the basis of the following chapter in its entirety.

The term "artificial nutrition and hydration" (ANH) refers to therapeutic procedures aimed at providing sufficient nutrition and hydration for patients who are no longer able to take them by mouth[96].

Their wide use in clinical practice has allowed them to become one of the most reliable and effective treatment tools. This is demonstrated by their constant use and their better adaptability to increasingly widespread prescriptions, especially in economically more developed countries. The undoubted benefits of ANH have led to a significant improvement in the quality of life and to an increase in healthy years of life for a considerable number of people, especially those with chronic diseases.

The adoption of ANH is due to the need not only to enable nutritional and hydration support that would otherwise be impossible, but also, more generally, to improve the biological sustainability of care for each individual clinical condition, which is sometimes metabolically demanding[97]. Even in the advanced and terminal stages of the disease, these remedies are applied within the limits of clinical appropriateness, with the sole aim of reducing the suffering that may arise due to an insufficient intake of calories and/or fluids. For this reason, it seems necessary and legitimate to include them in the Palliative Care protocols[98].

The CSB is aware that, although ANH is part of the large framework of medical therapy, it has an intrinsic specificity. Indeed, the "therapeutic" nature of its use in terms of prescription, routes of administration, pharmaceutical composition and metabolic actions (pharmacodynamics and pharmacokinetics) is undeniable. It is also true, however, that these elements are intended to "sustain the patient's life", they are true substitutes for "food" and "water", and as such have different requirements from strictly defined pharmacological therapies. In the light of the above, their classification is *sui generis* and some bioethical considerations are necessary.

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[96] The route of administration may be enteral or parenteral. In enteral administration, the first part of the digestive tract, which includes the mouth, pharynx and oesophagus, is excluded from food transit; this is done by inserting a naso-gastric tube (NGT), which allows the introduction of food and its direct access to the gastric lumen, or by creating direct communication between the stomach and the external environment by means of PEG (*Percutaneous Endoscopic Gastrostomy*). Both food, made homogeneous and semi-liquid, and specific nutritional preparations can be introduced via this route. Parenteral administration, on the other hand, involves the introduction of artificially prepared nutrients and fluids directly into the circulatory stream preferably via deep venous access.

[97] Carotenuto F., Inelmen E.M., Miotto F. *Guida alla corretta alimentazione nell'anziano disfagico,* Geriatric Clinic - Department of Medicine, University of Padua (Last update 2015).

[98] Guidelines in this area include, among others: PDQ (Physician Data Query) Supportive and Palliative Care Editorial Board. *Nutrition in Cancer Care (PDQ®): Health Professional Version.* PDQ Cancer Information Summaries [Internet]. Bethesda (MD): National Cancer Institute (US); 2002-2017 Nov 17; Italian Ministry of Health, *Guidelines for nutritional processes in cancer patients*, Document approved at the Conference between State and Regions, with Agreement (Rep. Acts no. 224/CSR) dated 14/12/2017.

The CSB notes that the scientific and bioethical discussion to date has focused primarily on the peculiar nature of ANH[99].

Indeed, according to some positions, these remedies are ordinary measures of dutiful care or life-sustenance: nutrition and hydration must, in any case, be ensured until the end of the patient's life, irrespective of the mode of administration (natural or artificial), of whether or not hunger and thirst sensations are present, of life expectancy, of the potential impact on quality of life, and of the patient's current or previously expressed wishes.

According to other positions, artificial nutrition and hydration are always and exclusively medical acts or treatments. They are indeed means of administering, as nourishment, a chemical compound (a solution of substances necessary for survival), which can only be prescribed and introduced into the body through the routes described above, under doctors' supervision, even if the execution is entrusted to nurses or others. In the light of the above, ANH can always be accepted, refused or suspended.

The CSB believes that an in-depth reflection on clinical bioethics in every situation can help to reach a shared position, first and foremost in respect for and to the benefit of the patient, as reference values also for all stakeholders involved in the decision-making process of care.

A POSSIBLE RECONCILIATION

The common element is as follows: the positions set out above seek, for the benefit of the patient, to guarantee the defence of life and, in it, of health understood in its global sense as defined by the WHO. These goals appear easy to achieve in most clinical situations, where nutritional support and hydration are aimed at restoring a normal and vitalistic state of health. More complex are the situations in which the general state of the organism is considered to be irreversibly destined to death in the short term (terminal state of disease) or in the long term (e.g., advanced stage of neurodegenerative diseases) or permanently compromised (as is the case with the so-called "vegetative state").

Decision-making must be aligned with the principles of bioethics:

1. **non-maleficence**: avoiding treatment likely to induce further suffering to the patient in a serious condition;
2. **beneficence**: implementing treatments which, on the basis of a favourable risk-benefit ratio, are effective on the evolution of the disease or improve the quality of life;
3. **autonomy**:
   a. of patients: if they are unable to interact, account must be taken of the choices made at a time when they still had the capacity to consent;
   b. of doctors, who, to their best knowledge and belief, can and must decide according to clinical appropriateness;

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[99] Silveira MJ, *Common sense and compassion: planning for the end of life.* Clin in Fam Prac 2(6):16-46, 2004.

4. **justice:** guaranteeing equitable access to care and the most appropriate therapies, in order to avoid any form of futile medical care or, on the contrary, therapeutic abandonment.

A number of paradigmatic conditions are outlined below as examples of the critical issues and possible bioethical choices that can be made, beyond the normal clinical indications.

a) Terminal state of disease

A first clarification concerns the appropriateness of continuing these treatments at the end of life. A clinical condition that is irreversibly progressive fatally reaches its final stages, albeit not always in a foreseeable timeframe. The approaching end of life naturally involves the impairment of organic functions in a physiological, albeit asynchronous, manner. At the onset of such signs, the need for desisting from nutrition and hydration treatments usually appears quite clearly. In such circumstances, over-medication by means of treatments that may overload the cardiovascular, renal and metabolic functions would precisely become malpractice and cause damage to the patient as a result of a therapeutic error. The opposite attitude of under-medication, which is typical of the withdrawal of ANH in the *a priori* presumption of futility, would also constitute malpractice.

In other words, in the terminal stages of life, the indications for the suspension of nutrition and hydration are fully supported in clinical practice on the basis of clear scientific evidence. Therefore, the continuation of these practices does not constitute compliance with the appropriateness criteria.

This is the most common operational choice in the routine conduct of end-of-life care activities.

b) Advanced stage of neurodegenerative diseases and dementia

Some neurodegenerative diseases provide interesting food for thought and, because of their delicate and dramatic framework, they trigger appropriate in-depth analyses.

The clinical conditions related to these diseases are often characterised by the progressive impairment of neuropsychic functions, with particular regard to the cognitive ones. This is also linked to the increasing impairment of the autonomy and independence of the patient. This progression appears in many cases to be "predictable" not only to doctors, but also to patients, who are properly informed and assisted in the delicate process of acquiring the "bad news" about the underlying disease.

For this reason, in such diseases, artificial nutrition and hydration are among the practices most frequently referred to in expressions of will[100].

The picture described above is radicalised in the particular neurodegenerative state represented by dementia. The latter is defined as *"an organically acquired disorder of the previously acquired intellectual functions: memory (short and long term) and at least one between abstract thought, critical capacity, language, space-time orientation, with preservation of the alert state of consciousness"*[101]. The

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[100] On this subject, see Chapter **"Previously expressed wishes relating to health care".**

[101] *Diagnostic and Statistical Manual of Mental Disorders IV*, 1994.

multifaceted nature of the clinical pictures, aetiological bases and epidemiological distribution is strangely in contrast with the univocal nature of the bioethical issues involved, especially in the terminal stages of the disease. Indeed, also in this case, the impairment of the functions of the Central Nervous System (CNS), especially those related to the cognitive state, has led in the past - and could still lead now - to a reductive view of the rights of the person suffering from dementia. These rights are, of course, the same as those recognised to everyone as a person.

In particular, according to the most accredited scientific indications, in case of dementia, irrespective of the level of severity, the need to ensure nutrition and hydration, even artificially, is recognised. In the terminal states of this disease, as in any other terminal condition, the continuation of such treatments may constitute inappropriate excess behaviour and must, lawfully, be discontinued[102].

c) Persistent vegetative state

The case of the so-called Persistent/Permanent Vegetative State (PVS) is different. The number of such clinical conditions is constantly increasing. This is due to many factors, including increased survival following cerebrovascular accidents or traumas following accidents of various kinds, as well as general improvements in treatment and care conditions in case of chronic and/or progressive diseases with impaired cognitive state. As can be inferred, care in such situations usually refers to life-sustaining measures, which almost constantly include nutrition and hydration, variously accompanied by ventilation or other support practices. In most cases, survival time in such conditions is not short, and can even extend over many years. Therefore, the patient has a considerable impact on the complex care system made up of the family network and the human, health and social resources dedicated to him/her. This is extremely interesting in a number of respects, including the serious emotional, social and economic consequences.

It is clear from the above that permanent/persistent vegetative state is a test case for the related bioethical assessments with respect to the particular life/non-life condition represented by this state and to the related issues for everyone's conscience. The impairment of CNS functions may even expose people in PVS to the risk of not being recognised as a person with full rights. Indeed, the very definition of “vegetative state” could, if misinterpreted, refer to other conditions of life that are not related to human life. Patients in PVS should be considered globally, with their reduced, compromised relational ties, with their previous individual ways of interpreting life and with the outside world's pressing doubt about their “being, not being”.

The CSB therefore considers it appropriate to shift the focus of the questions from the nature of life-sustaining measures and their justified use to the deeper meaning of human life[103].

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[102] SIAARTI (Italian Society of Anaesthesia, Analgesia, Reanimation and Intensive Care), *Grandi insufficienze d’organo end-stage; cure intensive o cure palliative? ‘Documento condiviso’ per una pianificazione delle scelte di cura.* Document approved by the Governing Council of SIAARTI on 22 April 2013.

[103] This is in accordance with the priority given to the value of the person, which is affirmed, *inter alia*, in the “Universal Declaration of Human Rights” (Art 25, paragraph 1): *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security*

Therefore, the decision to continue to ensure life-sustaining measures, without prejudice to a previously expressed will, is based on the recognition of the patient in PVS as a person. On the contrary, an inappropriate interruption of such measures would entail the prior denial of recognition as a person.

CONCLUSIONS

Therefore, the CSB considers that the question concerning the nature of artificial nutrition and hydration is not properly posed. Indeed, it is not relevant to ask what is the intrinsic nature of nutrition and hydration as life-sustaining means, namely whether they are therapies or ordinary means of treatment. Indeed, the question cannot be about the means, but about the objective.

It should be recalled that these treatments, even if clinically indicated, require, in the conscious patient, that they are undertaken within the framework of a therapeutic pact including informed consent, hopefully without any conflicts, by respecting the patient’s dignity, sharing the choices, planning the course of treatment together and strengthening human bonds among the stakeholders of each care process.

Thus, the guiding concept of this document is reiterated, namely that the patient is entitled to his/her status as a person in every condition.

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in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control".

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END-OF-LIFE BIOETHICAL ASPECTS SPECIFIC TO THE ELDERLY

According to the World Health Organization (WHO), more than 40 percent of people over 65 are affected by a chronic disease or a disabling condition, understood as a limitation in the performance of common daily activities[104]. The increase in life expectancy and the chronicisation of diseases that used to be characterised by a rapid evolution towards death entail the risk that an increasingly large section of the elderly population will have to live with an irreversible condition of severe disability and partial or total dependence on others at some point in life.

The associated frailty makes the elderly emotionally vulnerable and often leads them to doubt their own dignity as a person. The medical and objective aspects are therefore associated with the bio-psycho-social dynamics of disability, linked to the need for acceptance of external support to carry out the most basic daily activities. Therefore, the situation is sometimes so compromised that the elderly, most often a woman, is forced into conflict with **one of the fundamental bioethical principles, namely autonomy.** In such conditions, patients try to defend themselves from what they consider to be an undue intrusion into their life and to refuse as far as possible the presence in their home of other people, often strangers, in order to escape an unbearable impairment of their free and conscious range of action. On the other hand, when uprooted from their environment, the elderly may feel pervaded by a painful sense of helplessness, which makes it extremely difficult to accept external help as a solution to a problem they insist on seeing as temporary and transient. The more the latter is rejected, the more it jeopardises the whole system underlying the sense of material and moral security that the person has painstakingly built up over time. Therefore, the **principle of beneficence** requires the caregiver to try as much as possible to help the elderly patient to maintain a high level of self-esteem, by reinforcing the acquired certainties and removing negative thoughts.

As a consequence, the elderly need more than others to be re-educated to meet their needs and helped to enhance their ability to adapt (a process known as empowerment) on the basis of solid information about both the limitations of which they are aware and the degree to which they are accepted by them and their families. In the light of the above, Palliative Care refers not only to the prognostic aspects of the disease but also to the patient's entire life condition and family context. If this care takes place in hospital, due account must be given to the heavy impact that hospitalisation has on the quality of life,

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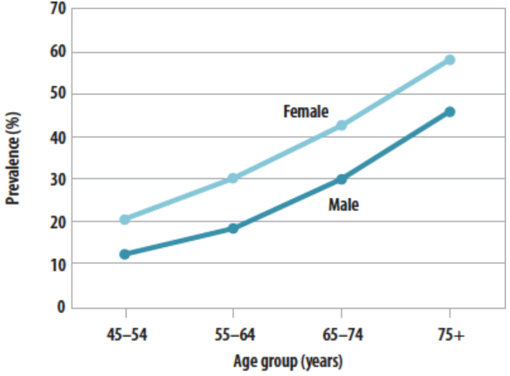
[104] Figure 1. WHO data from 59 countries on the percentage distribution of disability in different age groups (1).



with the immediate onset of an indefinite malaise arising from fear, loneliness and discomfort linked to the feeling of an almost definitive loss of privacy and autonomy.

Among other things, hospitalisation very often leads to serious disorientation in the elderly, who are suddenly deprived of any points of reference in their usual environment, which have remained stable for years. Such a condition, even if it is mostly temporary, often causes a feeling of great bewilderment in family members. Since they are not adequately prepared to notice unusual aggression and/or apathy and/or dissociative phenomena in their loved ones, family members tend to react with attitudes of open contrast, if not rejection and flight, and therefore risk aggravating the patient's psychological situation even further.

The case of hypoactive reaction deserves a closer look. While it is accepted without particular alarm by the treatment team as it is one of the possible ways of adapting to the new environment, this reaction often conjures up alarming scenarios in the family, such as a sudden worsening of the clinical condition with imminent death, to which the health personnel seem indifferent, or, worse, an unjustified but serious distrust towards the treatment team due to the suspicion of a hidden administration of high doses of tranquillisers. For this reason, in accordance with the **bioethical principle of non-maleficence**, it is inadvisable to remove an elderly patient from his/her home in a clumsy attempt to resolve, by hospitalisation, an intercurrent disease, which is not urgent or whose course cannot be positively influenced in the necessarily short timeframe of an ordinary hospital stay.

The therapeutic approach to the elderly with chronic diseases is characterised by a widespread tendency to hospitalisation in rest homes, while waiting for a death, which is difficult to predict in terms of time, rather than in a facility such as the hospital, which is widely recognised as a privileged place for acute diseases. In accordance with the **bioethical principles of beneficence and autonomy**, it would be appropriate to mediate wisely between the needs of the family and the patient and, above all, to draw up a care plan in harmony with the patient's expectations throughout the whole of the bumpy road to death. The latter often involves numerous transitional phases between the home - to which it would be desirable to encourage return in order to continue Palliative Care in an environment that is more acceptable to the person, because it is intrinsically reassuring and hopefully “tranquillising” - and different facilities (from hospital and residential rehabilitation and long-term care facilities to retirement homes).

Especially in the presence of a high risk of treatment-related complications, Palliative Care should be undertaken as early as possible without any discrimination on the basis of disease-free life expectancy, and especially of age. This is the case, for example, with neoplasms, whose clinical impact is usually minimised and whose course is usually “chronicised”.

In the light of the above, the International Society of Geriatric Oncology (SIOG) has long been trying to validate some scales to establish which patients can benefit from aggressive treatment protocols and which are more suitable for palliative treatment. However, to this day, contrary to the **bioethical principle of justice** and due to widespread, albeit questionable, biases and misunderstandings linked to the unconscious mental association of the terms palliative and terminal, it is the youngest who have privileged access to early, high-quality Palliative Care. Indeed, this principle provides for the fair allocation of resources both in terms of equal access to care (an elderly is sometimes discriminated against compared to a young person) and freedom of choice of care setting. In relation to all this, the only ethically and deontologically acceptable benchmark is the appropriateness of care.

Despite the fact that Palliative Care has proved to be extremely useful for frail individuals - in whom even a low level of stress can worsen disability and thus dependence on others, contrary to the **bioethical principle of beneficence** - the elderly - who mostly suffer from long-term incapacitating diseases - are often condemned to endure disabling pain symptoms, which are reported repeatedly but in vain to the treating doctor. In this way, professionals forget to do all they can to ensure that the elderly maintain a good level of global functionality over time, ignoring the fact that the physical component of pain is inexorably accompanied by the emotional one. The latter is characterised by anxious and depressive reactions with a paralysing effect - anger, rejection, fear, confusion, loss of hope and even a sense of imminent death - which are related to the underlying chronic diseases and amplify the suffering. With regard to equal access to care, withdrawal of effective analgesic treatment is a serious socio-cultural limitation and a breach of the **bioethical principle of non-maleficence**: although the pain scale has now become an integral part of the medical record, the problem is often underestimated in the elderly, due to the widespread but erroneous belief that opioids pose a health risk proportional to age.

According to the **bioethical principle of beneficence**, it is essential to inform patients in good time, where possible, and correctly about their health prospects and the timing of the disease, in order to allow them to make well-thought-out decisions in line with the outcome of the examination of their life.

The most critical act in bioethical terms, also from the point of view of the **principle of autonomy**, is precisely the provision of correct information on all treatment options, including possible admission to hospital or other facilities. Some elderly people choose hospitalisation in order to spare their families the burden of terminal care, while others live in a state of mind dominated by the fear of dying alone or in abandonment, and as a solution they seek a privileged relationship in order to meet their need for verbal and non-verbal communication[105].

Finally, on the basis of **bioethical principles**, the treatment team must try to ensure that individual dignity is recognised to any elderly patient psychologically destabilised by the sudden weight of uncertainty or, worse still, imminent death. To this end, the caregiver, to whom a specific section has been devoted, is of great importance.

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[105] In this regard, see Chapter: **“Communication”.**

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END-OF-LIFE AND PERSONS WITH DISABILITIES

In order to address this issue adequately, it is necessary to refer to the CSB document *"The Bioethical Approach to Persons with Disabilities"*[106] (2013), which is the first one on this subject drawn up by a National Bioethics Committee, and to which reference is made for an extensive bibliography and basic texts on which to work.

The correct bioethical approach to persons with disabilities is based on the UNESCO *Universal Declaration on Bioethics and Human Rights* (2005)[107], which links bioethics with respect for human rights, and on the United Nations *Convention on the Rights of Persons with Disabilities* (CRPD, 2006)[108].

In relation to these persons, two approaches should be emphasised in the field of end-of-life care. The first approach, tainted by a very strong negative social and cultural stigma, highlights the unsustainability of a life characterised by suffering, which is *de facto* considered not worth living, and the consequent need to resort to forms of direct or disguised euthanasia. The second approach advocates the defence of life in any form, even to the point of justifying forms of futile medical care. Between these two extremes lies a varied range of possibilities, in which the individual's free choice can be expressed.

The above-mentioned CSB document examined three issues relating to end-of-life (euthanasia, informed consent and the end of life) and stressed the close link between these issues and the negative social stigma attached to persons with disabilities. On the basis of the latter, some economists following Bentham expressed strong doubts - in the view of the CSB completely unjustified and paradoxical - about the possibility of persons living with functional limitations of various kinds being able to claim that they lived a happy life[109]. The issue of assessing the quality of life of persons with disabilities is often debated

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[106] http://www.sanita.sm/on-line/home/bioetica/comitato-sammarinese-di-bioetica/documenti-csb-italiano.html.

[107] http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

[108] http://www.lavoro.gov.it/temi-e-priorita/disabilita-e-non-autosufficienza/focus-on/Convenzione-ONU/Pagine/Convenzione%20Onu.aspx. This Convention represents the international standard ratified by 91.6% of the UN member countries, which clearly recognise respect for the human rights of persons with disabilities, equal and non-discriminatory treatment, access to the same rights as other citizens by overcoming negative stigmas, elimination of barriers, obstacles and procedures that limit their participation in society and promotion of policies, programmes and actions aimed at achieving equal opportunities and non-discrimination. Many documents related to the impact of the CRPD on all issues concerning the rights of persons with disabilities have been published. A complete bibliography cannot be provided here. Therefore, we only mention the most important texts related to bioethics and disability issues. Thiel M(Hg.), *Ethische fragen der "behinderung". Ethical challenge of disability*. Herausgegeben im zusammenwirken mit der Association Herrade de Landsberg, Strasbourg. Zurich-Berlin, Lit verlag, 2014; *Les enjeux éthique du handicap*. Sous la direction de Marie-Jo Thiel. Strasbourg. Presse universitaire de Strasbourg, 2014; Koch T, *"End-of-Life Issues: A Disabilities Perspective"* In *Cultural Issues in End of Life Decision Making*. Edited by Braun K, Pietsch JH, and Blanchette P.L, pp. 285–301. Thousand Oaks: Sage Publications 2000. http://sk.sagepub.com/books/cultural-issues-in-end-of-life-decision-making/n18.xml; Wolbring G, «*Disability Rights Approach Toward Bioethics*». *Journal of Disability Policy Studies*. vol. 14, no.3, 2003. Available at: www.bioethicsanddisability.org. Several publications are available at the following websites: https://scholar.google.it/scholar?q=bioethics+and+disability&hl=it&as_sdt=0&as_vis=1&oi=scholart; https://cbhd.org/content/disability-ethics-bibliography.

[109] Francescutti C, Battisti A, Griffo G, Solipaca A. *Conceptualization and measurement of disability in studies on subjective well-being: a critical review and evidence from the Italian Health Surveys,* pp. In *International review of economics. Journal of civil economy*. Vol. 63/2017, issue 1, March 2017. http://link.springer.com/article/10.1007/s12232-017-0268-5.

without taking into account the WHO definition[110], which emphasises that a healthy condition corresponds to mental and physical well-being and not to absence of disease. The bias just described underlies all those positions according to which it is a legitimate choice to terminate the lives of persons with severe functional limitations. Such an approach has led some people to call for active euthanasia interventions on people with severe functional limitations to be justified[111]. This made it possible in Belgium and the Netherlands to pass specific child-oriented euthanasia laws, which now authorise the active euthanasia of infants with major functional diversities[112]. Some people have even gone so far as to argue that killing persons with disabilities as soon as they are born does not violate any human rights[113].

An essential element to start from is that the group of persons with disabilities represents one of the possible expressions of life forms: no human being is equal to another in terms of characteristics and capacities, performs at 100% of his/her potential, is capable of representing all forms and capacities of human variability. In other words, perfection does not belong to any human being. In this regard, the CRPD emphasises in Article 3 ("Principles") that the guiding principles of the text include *"respect for difference and acceptance of persons with disabilities as part of human diversity and humanity"*. According to this approach, the functional diversities of each human being do not question the entitlement of persons with disabilities to enjoy the same human rights as everyone else. Therefore, people must be respected as human beings[114] regardless of their characteristics and must fully enjoy the principles of non-discrimination and equal treatment (Art. 5 of the CRPD). The idea that there are subhumans[115] recalls some deplorable episodes of mass extermination in the more or less recent past marked by the principle of eugenic selection[116].

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[110] Health, defined by the World Health Organization (WHO) in 1946 as *"a state of complete physical, mental and social well-being and not merely the absence of disease"*, is considered a right and as such underpins all the other fundamental rights to which people are entitled. https://www.dors.it/documentazione/testo/201303/OMS_Glossario%201998_Italiano.pdf.

[111] A list of countries where euthanasia is permitted can be found at: http://www.ansa.it/saluteebenessere/notizie/rubriche/medicina/2016/09/17/eutanasia-sui-bambini-in-belgio-e-olanda-_94d4e8cd-a8aa-4aa3-9192-6ec434c8c698.html.

[112] For the terminology used in this chapter, see Palacios A, Romañach J. *El modelo de la diversidad***.** *La Bioética y los Derechos Humanos como herramientas para alcanzar la plena dignidad en la diversidad funcional*. Madrid, Diversitas-AIES, 2006.

[113] It is useful, in this regard, to quote Articles 1 and 2 of the Universal Declaration of Human Rights:

Article 1 - All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Article 2 - 1. Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

[114] Rodotà S, *Trattato di biodiritto*, vol. V. Milan, Giuffré, 2010-12.

[115] This position is supported by Peter Singer, an American moral philosopher, who has stressed that in case of limited resources, it is necessary to choose to whom social and health measures should be applied. Therefore, persons with major functional limitations should be eliminated, since they are a non-productive cost for society and a social burden for the family and the community. Singer P, *Scritti su una vita etica*. Il Saggiatore, Milan 2004; Singer P, *Pratical Ethics*, Cambridge University Press. Cambridge 1993 (tr. it. *Etica pratica*, Liguori, Naples 1989); Singer P, *La vita come si dovrebbe.* Il Saggiatore, Milan 2003). For similar positions, such as the Groningen Protocol (The Netherlands), see the CSB document, *The Bioethical Approach*…, cit.

[116] For the extensive bibliography in Italian on the active euthanasia practices of the Nazi regime on persons with disabilities, see the CSB document, *The Bioethical Approach*…, cit.

This stigma - characterised by a set of negative elements marking the medical model of disability[117] - still strongly influences the treatments for persons with disabilities, and involves all segments of the population and often all professionals, including those working in the field of bioethics.

There are four end-of-life issues concerning persons with disabilities: approach to disability, contextual elements with which persons with disabilities relate, informed consent and end-of-life support.

APPROACH TO DISABILITY

In recent years there has been an increasing number of cases of persons with disabilities facing the end of their lives in ways that have caused a stir and filled the pages of the newspapers, ranging from assisted suicide, as practised in some countries, to the refusal of medical treatments considered to be futile, and the cost of such treatments in relation to the benefits to the patient and society. In most cases, the context was that of a cultural approach considering the life of persons with a disability to be poor in quality because they needed more intensive support. The cultural and social perception of a person who, for example, lives in an iron lung, reflects the journalistic description that emphasises its negativity, using adjectives such as “poor”, “suffering”, “seriously ill”, etc. This cultural approach, which is unfortunately the majority expression of common sense, has a considerable bearing on the decisions affecting that person. However, if we read the life and works of Rosanna Benzi[118] or Kalle Konkkola[119], we immediately understand that quality of life depends not so much on the consequences of diseases - which can also limit daily activities to the point of forcing total dependence on machines and personal assistants - but on the way in which people are enabled to lead their lives autonomously, with self-determination, independently and interdependently. Stephen Hawkins, the great astrophysicist who died in 2018, is a striking example of this: his image as a scientist was so powerful that his characteristic of using a wheelchair and depending on others in many activities of daily life was not considered relevant. It follows that no one can be considered on the basis of a single characteristic.

In recent decades, partly as a result of advances in emergency-urgency medicine, a new population of persons with disabilities linked to severe acquired brain injury and complex clinical conditions dominated by serious alterations in the state of consciousness ranging from coma to vegetative state (VS) and minimally conscious state (MCS) has emerged and assumed characteristics of high prevalence and increasing incidence. The two conditions just described are defined as extreme disability[120] because, in

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[117] Griffo G. *Models of disability, ideas of justice, and the challenge of full participation* pp. 147-159 in *Modern Italy*, Vol. 19, issue 2, 2014, Special issue: disability rights and wrongs in Italy, (New York), http://www.tandfonline.com/doi/abs/10.1080/13532944.2014.910502.

[118] D’Errico L, *La femme-machine. Vita di Rosanna Benzi nel polmone d’acciaio*. Milan, Meltemi editore, 2018.

[119] Leader of the worldwide movement of persons with disabilities, who lived with the permanent aid of an artificial respirator. *The World Became My Room,* by Kalle Könkkölä and Heini Saraste (1996) and *The World Became My Room: Part II* by Konkkola K. and Saraste H. (2014).

[120] The national conference on disability held in Turin (2-3 October 2009) set up a working group on the issue of "Vegetative states as paradigm of extreme disability". See the final document on the website of the Italian Ministry of Labour and Social Policies and the Italian *Guidelines for the care of people in a vegetative state and minimally conscious state*, http://www.salute.gov.it/imgs/C_17_pubblicazioni_1535_allegato.pdf. To explain this position, we recall the definition of disability in the CRPD preamble: "*disability results from the interaction between persons with impairments and attitudinal and environmental barriers that hinders their full and effective participation in society on an equal basis with others*".

order to survive, those affected by it require treatment based on biomedical equipment and artificial hydration and nutrition.

Finally, another aspect worthy of consideration is awareness of the processes of multi-discrimination in the form of unjustifiably different treatment from the common one in relation to conditions not necessarily associated with physical or mental disability, but with the fact of belonging to minority or socially weaker groups in terms of age, ethnicity, religion, legal status or sexual orientation[121].

Therefore, a first fundamental bioethical element to be respected in relation to the end of life of persons with disabilities is the need to remove the aura of negativity that surrounds the issue of how such persons live and often unconsciously conditions the individual and collective choices concerning them.

CONTEXTUAL ELEMENTS WITH WHICH PERSONS WITH DISABILITIES RELATE

The end-of-life issue, which is extremely delicate and deeply controversial, can be properly addressed if it is put in relation to the different conceptions in different societies of the quality of life and their interpretation of the support opportunities available to them. Indeed, persons with significant functional limitations of a similar degree may perceive their dignity and quality of life differently in relation to the presence or absence of adequate family or social support, good human relations and good quality of care.

These factors often significantly influence end-of-life decisions. Indeed, the choices can be considerably influenced by the presence of territorial services capable of guaranteeing adequate levels of assistance in terms of both home-based services and reception centres[122]. In the absence of the latter, the burden of care falls on the family and, in end-of-life choices, it is difficult to distinguish the reasons of the family from those of the patient, each geared to different objectives. These reasons must therefore be assessed separately, with the interests of persons with disabilities being identified as paramount.

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[121] *The Specific Risks of Discrimination against Persons in Situation of Major Dependence or with Complex Needs. Report of a European study*. Vol.1: Policy recommendations. Brussels, 2010.
https://disability-studies.leends.ac.uk/wp-content/uploads/sites/40/library/inclusion-europe-Inclusion-Europe-1.pdf.

[122] For example, hospices, relief centres, etc. See, for example, the concluding document of the "National Day of Awakenings" promoted by the Association *"Gli Amici di Luca"* in Bologna, 7 October 2012 (http://www.amicidiluca.it/).

INFORMED CONSENT

Therapeutic acts involve providing persons undergoing treatment with all necessary and specific information, so that they can make a free decision by giving their free and informed consent. This issue has been covered in a specific chapter, therefore there is no need to repeat widely assimilated concepts.

A particularly complex situation is when informed consent is to be provided by persons with intellectual and relational disabilities, both for treatment under ordinary clinical practice and for end-of-life care. In this case, the bioethical approach requires the use of all available instruments (facilitated writing, support by experts in specific communication, activities to support self-determination), in order to ensure that the consent reflects in any case the will of persons who have received information proportional to their understanding abilities, even when the consent has been provided by the legal representative (Articles 12 and 15 of the CRPD)[123].

END-OF-LIFE SUPPORT

The preceding chapters have examined in depth both the issue of interventions aimed at supporting end-of-life-patients and any bioethical positions that might emerge regarding this specific topic.

The debate on artificial nutrition and hydration also arises for persons with disabilities. In this regard, the main reference is the CRPD, which includes two specific articles: Article 25 "Health" (paragraph f), according to which States must *"prevent discriminatory denial of health care or health services or food and fluids on the basis of disability"*, and Article 15 on *"Freedom from torture or cruel, inhuman or degrading treatment or punishment".*

RECOMMENDATIONS

On the basis of the above considerations, the CSB recommends:

- To counter negative perceptions of how persons with disabilities live, promoting the richness of human diversity and preventing discriminatory treatment that violates the human rights of persons with disabilities;
- To promote action to ensure that human diversity is enhanced and not eliminated on the basis of discriminatory assessments on the quality of life, which lead to euthanasia, infanticide and death due to lack of therapeutic intervention;
- To establish univocal diagnostic criteria for defining end-of-life conditions and standardised therapeutic procedures;
- To include people diagnosed with VS, MCS and severe acquired brain injury in the category of extreme disability conditions requiring more intensive support;

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[123] Some ISTAT data on suicides due to pathological conditions can be found at https://blog.openpolis.it/2017/03/27/testamento-biologico-temi-fine-vita/14740.

- To regulate, in accordance with the principles of protection of human rights, and functionally and quantitatively enhance reception facilities for persons with extreme disabilities;

- To train health and legal professionals on the issue of respect for the human rights of persons with disabilities.

PREVIOUSLY EXPRESSED WISHES RELATING TO HEALTH CARE

BIOETHICAL RELEVANCE AND BIO-LEGAL CONTEXT

Reflection on the delicate and complex issue of wishes relating to health care can only be considered from a bio-legal perspective, in compliance with international bioethical Charters and San Marino legal system.

The bioethical assessment is set in a precise supranational reference context, from the Oviedo Convention[124] and the UN Convention on the Rights of Persons with Disabilities[125], to the most recent international guidelines on decision-making processes at the end of life of the Hastings Center[126] and of the Council of Europe[127], and San Marino and Italian Codes of Ethics to which San Marino doctors refer[128].

It is appropriate to examine the legal framework starting from the legislation currently in force in the Republic of San Marino, which recognises the Declaration on the Citizens' Rights and Fundamental Principles of San Marino Constitutional Order[129] as its first source of law. Moreover, the provisions contained in the international Declarations on human rights and fundamental freedoms are an integral part of its legal system and San Marino complies with them[130].

The affirmations contained in the international Treaties and Conventions, recognised and ratified by the Republic, reveal the fundamental general principles of San Marino ordinary law[131], which provide for the

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[124] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine,* Oviedo, 4 April 1997 (ratified by San Marino on 20/03/1998) Art. 9, **"Previously expressed wishes"**: "The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.".

[125] *UN Convention on the Rights of Persons with Disabilities* (adopted by the UN General Assembly on 13 December 2006 and ratified by San Marino on 22 February 2008): Art. 25, "**Health":** *"States Parties recognize that persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability. States Parties shall take all appropriate measures to ensure access for persons with disabilities to health services that are gender-sensitive, including health-related rehabilitation. In particular, States Parties shall: (...) Prevent discriminatory denial of health care or health services or food and fluids on the basis of disability".*

[126] Berlinger N, Jennings B, Wolf SM, *The Hastings Center Guidelines for Decisions on Life-Sustaining Treatment and Care near the End of Life,* Oxford University Press, Revised and Expanded Second Edition, 2013.

[127] Council of Europe, *Guide on the decision-making process regarding medical treatment in end-of-life situations,* 2014.

[128] FNOMCeO, *Code of Conduct for Doctors and Dentists, 2014,* rev. 2018, Title IV: "Information and Communication. Consent and Dissent"; AIS (San Marino Nursing Association), *Code of Ethics for Nurses,* 2017, Chapter III: "The nurse and the person cared for".

[129] *Declaration on the Citizens' Rights and Fundamental Principles of San Marino Constitutional Order*, Law no. 59 of 8 July 1974, with subsequent amendments resulting from Law no. 95 of 19 September 2000 and Law no. 36 of 26 February 2002.

[130] Id, Art. 1: *"The Republic of San Marino receives generally recognised rules of international law as integral part of its constitutional order, to which it shall conform its acts and conduct. It conforms to the provisions contained in international declarations on human rights and fundamental freedoms ... San Marino legal system recognises, guarantees and enforces the rights and fundamental freedoms set forth by the European Convention for the Protection of Human Rights and Fundamental Freedoms. Regularly signed and implemented international agreements on the protection of human rights and freedoms shall prevail over domestic legislation in case of conflict."*

[131] The following is a non-exhaustive but highly representative list, in hierarchical order of importance:

- *Universal Declaration of Human Rights* (UN General Assembly, 1948, ratified by San Marino on 9 March 1989): Art. 3 *"Everyone has the right to life, liberty and security of person"*; Art 25 *"Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in* recognition of the right to life and health, understood as the right to treatment and therapies aimed not only at healing, but also, where this is not possible, at improving the quality of life and preserving the dignity of the patient.

Therefore, the central element of the CSB's reflections is the need to find an element harmonising two different perspectives on the treatments and therapies that may be proposed if the patient becomes incapable to consent: the point of view of the doctor and that of the patient, whose will may not initially coincide with that of the doctor and therefore may not be oriented towards consent.

Indeed, it should be borne in mind that wishes relating to health care can be expressed previously in a document through which, in anticipation of a possible situation of inability to make decisions, patients declare their reference framework of values and classify as desirable or undesirable the treatments that they might receive.

It is useful to note that these wishes become effective after the loss of decision-making capacity, but they certainly do not replace any decisions possibly adopted by the person concerned at the time of the specific choice, in case the latter is able to consent[132].

The CSB considers that these wishes have a profound bioethical value in the care relationship between the patient and the doctor, as a particular form of long-term informed consent: *"It is as if, thanks to previously expressed wishes relating to health care, the dialogue between doctor and patient ideally continues even when the patient can no longer consciously take part in it"*[133].

Therefore, the bioethical meaning of the drafting of this document lies precisely in the continuation over time of the therapeutic alliance, even when all forms of dialogue are precluded. This alliance aims at a choice that ensures the necessary balance among three fundamental rights: *inviolability of personal freedom, protection of health and decision-making autonomy* (both personal - of the patient - and professional - of the doctor and the treatment team).

Therefore, the final decision cannot be the result of a rigid and bureaucratic application of the above-mentioned wishes but must take into account the wishes previously expressed by the patient and the

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circumstances beyond his control. Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection".

- European Convention for the Protection of Human rights and Fundamental Freedoms (Council of Europe, 1950, ratified by San Marino on 9 March 1989): Art. 2 "**Right to life:** *1. Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law. 2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary: (a) in defence of any person from unlawful violence; (b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained; (c) in action lawfully taken for the purpose of quelling a riot or insurrection."*
- Oviedo Convention (Council of Europe, 1997, ratified by San Marino on 24 February 1998)*:* Art. 2 ***"The interests and welfare of the human being shall prevail over the sole interest of society or science"*;** Art. 9 **"Previously expressed wishes"** (see note 2).
- Convention on the Rights of Persons with Disabilities (UN General Assembly, 2006, ratified by San Marino on 29 January 2008)*:* Art. 10 "**Right to life**: States Parties reaffirm that every human being has the inherent right to life and shall take all necessary measures to ensure its effective enjoyment by persons with disabilities on an equal basis with others." Art. 25 "**Health"** (see note 4).

[132] Berlinger N, Jennings B, Wolf SM, *The Hastings Center Guidelines…,* cit.

[133] Italian Committee for Bioethics, *Advanced treatment statements,* 2003

expertise and scientific knowledge available at that precise moment, in order to identify the most appropriate treatment for a specific clinical situation and guarantee the rights connected with the health and overall well-being of the patient.

BIO-LEGAL ISSUES

The CSB considers it necessary to reflect on the main bio-legal issues that could arise with regard to the form and content of the above-mentioned wishes.

The first element of complexity is intrinsic to any previously expressed wishes relating to health care, which are obviously generic and asynchronous. Any truly informed choice must derive from a consent expressed on the basis of comprehensible, complete and detailed information on the nature and method of the intervention and its interruption, as well as on the risks, benefits and therapeutic alternatives.

However, such information, although essential to consent to any forthcoming therapeutic choice, cannot always be available to adopt decisions on any hypothetical future situations.

If the person expressing such advance wishes is not ill, it is clearly difficult to consciously foresee a hypothetical disease and to rationally provide the related information. Indeed, dramatic situations are often difficult to reconcile with rational decisions and there is no absolute certainty that the wishes previously expressed coincide with those adopted in the actual situation[134]. Similarly, the doctor, although in the presence of family members or trusted persons, may experience real difficulties in fully understanding the meaning and current relevance of the wishes previously expressed by the person who has become incapacitated in the meantime.

In this regard, it should be emphasised that, in the bio-legal field, informed consent is of paramount importance and, in order to be valid, it must be current, i.e. lasting over time until the moment of the fact-event affecting the person concerned. It follows that the person can always withdraw consent with immediate effect.

When wishes are previously expressed relating to health care, it is therefore essential to identify the validity and characteristics of the consent obtained or refused, since San Marino law requires that the latter be not only valid, but also "expressed", and not presumed, by the person *"entitled thereto"*[135].

To this end, it is necessary that consent to the possible treatments be given on the basis of scientifically reliable information received from the doctor in a comprehensible form, and that the patient, at the time the wishes are drawn up, is aware and free from coercion, i.e. is recognised as being capable of *"giving content"*[136].

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[134] Tagliabracci A, Borgia LM: *Consenso alle cure e trattamenti sanitari obbligatori (TSO); I trattamenti in liminae vitae*, in AA. VV., "Elementi di Medicina Legale", Monduzzi Editore, 2010. Noceto (Parma).

[135] Art. 39 of San Marino Criminal Code: "*Anyone damaging or endangering a property with the validly expressed consent of the person entitled to dispose thereof shall not be punished. The consent shall not valid if extorted by violence or given by an easily recognisable mistake, obtained by deception or expressed by a minor aged less than 18 or by an incapable person*".

[136] Ibidem.

The greatest difficulty is encountered when previously expressed wishes contain the <u>refusal of treatments</u> and the unrelated, uninformed, generic and abstract nature barely meets the requirements of case law in qualifying the will in a care relationship and, in particular, when the suspension or omission of treatment has potential harmful consequences or causes the death of the patient[137].

Another bio-legal issue, closely related to those mentioned above, concerns how binding the previously expressed wishes are, i.e., whether the wishes contained in such document should be binding on the doctor or the treatment team.

In order to unravel the complexity of these issues, it is necessary to refer to the International Bioethical Charters, to Codes of Ethics and to some previously mentioned International Declarations which, as they have been ratified by the Republic of San Marino, have become an integral part of its legal system.

In all documents, starting from the most important bioethical reference text, namely the Oviedo Convention, the term wishes (souhaits in the French version) is used: *"The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account"*[138].

This expression is based on the concept of desired option, not of a choice imposed on others, whereby the person asks for his/her wishes to be respected, provided that the conditions indicated by him/her continue to apply.

For a correct interpretation of this Article of the Oviedo Convention, it is useful to refer to point 62 of the Explanatory Report[139], according to which the **principle of autonomy** should be equally respected for the patient (whose wishes are in no way binding, but not even merely indicative) and for the doctor, who is obliged to carefully check that the patient's wishes correspond to the current clinical situation and any scientific and pharmacological developments that have taken place in the meantime.

The FNOMCeO Code of Conduct, to which San Marino doctors refer, states that *"when taking into account previously expressed wishes relating to health care, the doctor shall verify their logical and clinical consistency with the patient's current condition and shall inspire his/her conduct to respect for the patient's dignity and quality of life, clearly expressing this in health documents"*[140].

The recent International Bioethical Guidelines of the Hastings Center and the Council of Europe on end-of-life decision-making processes[141] focus in particular on the patient's request to suspend or abandon

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[137] Id, Art. 24: *"The offence shall be committed when the event of damage or danger envisaged by the law occurs as a consequence of the commission or omission of the act by the offender. The event shall also be the consequence of an omission when the person has a legal obligation to prevent it"*.

[138] Oviedo Convention, Art. 9 **"Previously expressed wishes"**.

[139] *"The article lays down that when persons have previously expressed their wishes, these shall be taken into account. Nevertheless, taking previously expressed wishes into account does not mean that they should necessarily be followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion. The practitioner should thus, as far as possible, be satisfied that the wishes of the patient apply to the present situation and are still valid, taking account in particular of technical progress in medicine"*.

[140] FNOMCeO, *Code of Conduct for Doctors and Dentists,* cit., Art. 38 **"Previously expressed wishes relating to health care".**

[141] See note 5 and note 6.

treatment. The Hastings Centre document reinforces the role of the patient by proposing an advance care planning that envisages both the appointment of a trusted person - who will take on the role of "therapeutic representative" when the person becomes incapacitated - and the obligation for healthcare professionals to explore the reasons for any repeated requests for suspension or withdrawal by the patient by addressing a specific board, as well as to allow treatment to be suspended only in the event of the patient's persistent firm intention to do so. However, according to this document, no patient may make requests *contra legem*, and no doctor is obliged to agree to requests contrary to his/her conscience.

The Council of Europe Guide provides more detailed indications on previously expressed wishes, urging the drafting of a treatment plan shared with healthcare professionals while the patient is still aware. They suggest periodic renewal of declarations and specify that, if the patient is incapacitated, any expressions of will must be taken into account, provided they are written or authenticated, relevant to the specific situation and preferably drawn up when the pathological process had already begun.

Finally, the Grand Chamber of the European Court of Human Rights has established both the fundamental importance of the patient's wishes in decision-making processes and the State's decision-making autonomy with regard to balancing the protection of the patient's right to life against the protection of the patient's right to respect for his/her private life and autonomy[142].

Therefore, these documents also reaffirm the **principle of autonomy,** under which neither the doctor nor the legislator are obliged to scrupulously respect the patient's previously expressed wishes, since *"there is broad acceptance that there may be certain reasons authorising doctors not to follow the patient's wishes. For example, when they have been formulated several years before the onset of the incapacity or where there have been significant medical advances since the date when the advance directives were drawn up which have a direct impact on their content"*[143].

Doctors play a fundamental role, as they are responsible for correctly informing patients at every stage of the disease, especially at the end of their life, and for supporting them in their decision. It is not by chance that the Council of Europe Guide stresses the need for specific training of the doctor and the treatment team on the management of problems pertaining to end-of-life situations.

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[142] Lambert V. France, 5 June 2015.

[143] Council of Europe, *Guide on the decision-making…,* cit.

What has been said so far identifies wishes relating to health care as a document that cannot be compared to testamentary wills, since the latter express the will to dispose of material goods, which, as such, are in one's possession, whereas wishes relating to health care lawfully express wishes for therapeutic treatments that do not translate into acts of disposition of life as a good.

It follows that such wishes must exclude requests that conflict with positive law, medical ethics and the rules of good clinical practice. In this regard, patients may draw up a document containing wishes on the donation of their organs, the possibility of donating their body or parts thereof for educational or research purposes[144], spiritual assistance and the place where they can receive treatment and be supported until death, their preferences in relation to the diagnostic and therapeutic possibilities known at the time of drawing up the document, and the suspension or non-initiation of therapeutic treatments which, at that particular moment, are futile, burdensome for the patient and clinically inappropriate.

On the other hand, the multiplicity of clinical situations, the specificity of each person and the continuous medical and scientific developments over time are not compatible with a standard that claims to be exhaustive for each of them.

In the light of the above, the CSB reiterates that the basis of previously expressed wishes relating to health care must be the therapeutic and relational alliance between the patient and the doctor/treatment team, namely a balance between a paternalistic model that is no longer sustainable and a diametrically opposed model that attributes to the doctor the role of mere executor of the patient's wishes.

The legitimate expectation not to be subjected to futile and disproportionate treatment (so-called “futility”) and the equally legitimate proposal of therapeutic interruption by the doctor and the treatment team should be the subject of a careful clinical assessment on a case-by-case basis, taking into account the appropriateness of the therapeutic intervention and in relation to each different stage of the disease. Indeed, as already said in the previous chapter on artificial nutrition and hydration, the CSB emphasises that each therapeutic intervention can be considered both an ordinary means of treatment (and therefore necessary for end-of-life support in the control of pain and suffering) and a therapy (and therefore lawfully rejectable if it no longer meets the criteria of appropriateness and takes the form of futile medical care).

Therefore, the CSB believes that wishes relating to health care can be a valuable support for free and informed decisions, especially if expressed at the beginning or in the presence of a disease for which it is possible to agree on an advanced treatment plan in relation to the evolution of the condition and on the basis of available scientific knowledge.

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[144] On this subject, see the previous CSB document *“Body and body part donation for therapeutic or scientific purposes”* (15 February 2016) and the opinion *“Answer to the requested opinion on relevant ethical issues using anatomical parts derived from corpses”* (8 October 2014).

In such cases, the CSB considers it desirable for the wishes to be updated over time and included in the medical record, so that they are immediately available to the treatment team.

Because of their high bioethical value in the therapeutic relationship, the CSB considers the drafting of wishes to be a fundamental moment in the relationship of trust with the general practitioner or other specialist treating the patient. It is desirable that a doctor should be able to assess the patient's capacity to consent and be prepared to provide scientifically sound answers to his/her questions about present or potential diseases on the basis of knowledge of the patient's specific clinical condition and socio-family context. In this way, an in-depth conversation will develop between the patient and the doctor, which will lead to the drafting of a document that is as informed as possible, in the presence of a third-party witness. The procedure described above, free of bureaucratic obstacles, can facilitate the drafting of previously expressed wishes, including it in the most appropriate context of the care relationship.

The CSB considers that this handwritten document, duly signed in full and dated on each page, should be updated in the event of a change of general practitioner or specialist treating the patient, or in the event of the onset of a new disease. In the latter case, the care plan shared with health professionals, or advance care planning, indicated in international bioethical documents, would be implemented.

The CSB also hopes that wishes relating to health care will be included in the health card of the citizen who has freely expressed them, so that they can also be immediately available in case of clinical emergencies.

TRUSTED PERSON

This term refers to a person chosen and expressly designated by the patient, generally different from legal representatives and proxies, whose role is to assist and support the patient during his/her disease.

When a patient is no longer in a position to express his/her wishes, this can be done by a trusted person, whose task is to *"provide all-around protection of the patient"*[145], always in accordance with the patient's legitimate intentions previously expressed, in a constant dialogue with the doctor and the treatment team, by virtue of the authority conferred on him/her by the patient.

Although the trusted person cannot in any event take decisions that the patient would not legitimately have taken in his/her previously expressed wishes, he/she is nevertheless the point of reference for the therapeutic strategies undertaken by the doctor and the treatment team at the appropriate time[146].

In line with the above-mentioned international documents, in the event of disagreements between the doctor or the treatment team and the trusted person, or of any unresolved tensions between the patient's loved ones or within the treatment team that could lead to conflicts in the decision-making process, the CSB believes that the reasons lie primarily in inadequate communication regarding clinical information and the compatibility of treatment options with the previously expressed wishes. For this reason, where possible, it is highly desirable to take therapeutic action after all possible attempts have

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[145] Italian Committee for Bioethics, *Advanced treatment statements...,* cit.

[146] Council of Europe, *Guide on the decision-making process..,* cit.

been made to resolve conflicts by exploring their reasons through appropriate communication processes including ethical consultation. It is also necessary that any decisions deviating from previously expressed wishes relating to health care be clearly justified in the medical record.

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END-OF-LIFE PHARMACOLOGICAL SUPPORT: PALLIATIVE SEDATION

Once any prospect of a cure has been abandoned, in chronic and progressive diseases the patient must be guaranteed quality of residual life through prevention and relief of suffering. This objective must also be pursued by controlling present symptoms through the appropriate use of symptomatic drugs.

In addition, it is important to ensure that end-of-life patients are assisted by highly skilled professionals applying individual care plans and avoiding the conditioning of rigid protocols[147]. Once the end-of-life condition has been recognised[148], the delicate phase of communication has been correctly implemented, hydration has been maintained (if possible) and constant hygiene and care of the oral cavity and lips has been ensured, clinically appropriate drug therapy should be considered, mainly aimed at managing symptoms (primarily: pain, shortness of breath, anorexia, nausea and vomiting, constipation, anxiety with delirium and agitation, noisy respiratory secretions)[149].

In the literature, major studies with statistically significant results[150] show that the last phase of life can present symptoms that are difficult to control therapeutically. Any symptom that is “resistant” to usual pharmacological treatment and that, despite the use of all available treatments by a specialised Palliative Care team, is not satisfactorily relieved is defined as “refractory symptom”[151]. The burden imposed by the treatment must be bearable, taking into account the individual's situation and the stage of the disease, and the symptom must be alleviated within an appropriate period of time having regard to the patient's life expectancy[152]. Consequently, the absolute necessity of ensuring the patient the best quality of residual life, free from particularly invasive and uncontrollable symptoms, imposes “sedation” in serious cases as the deepest pharmacological treatment aimed at suppressing consciousness. In Palliative Care practice, the use of sedation to control refractory symptoms in the terminal phases of neoplastic and, more rarely, non-neoplastic diseases is now well established.

DEFINITION

Sedation has a wide range of implications with possible discretionary powers and has for some time generated a lively debate on its various definitions. Indeed, several adjectives have been proposed for the term “sedation” (“terminal”, “deep”, “continuous”, etc.), none of which, however, for various reasons, seems to be exhaustively suited to this procedure. By convention, the term “palliative sedation” (PS) will be appropriately used here. PS can be defined as the *“intentional reduction of vigilance by pharmacological means up to the point of the complete loss of consciousness with the aim of reducing or abolishing the perception of a symptom that would otherwise be intolerable for the patient despite the*

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[147] Cartabellotta A, Varani S, Pannuti R. *Linee guida per l’assistenza agli adulti nel fine vita.* Evidence. 2016, 8 (6): 1-4.

[148] *Care of dying adults in the last days of life*. National Institute for Health and Care Excellence (USA). 2015.

[149] *Treatment and care towards the end of life: good practice in decision making.* General Medical Council. 2010.

[150] *Paziente terminale.* MSD Manual. 2018.

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[152] *Intensive medicine measures. ASSM medical and ethical guidelines.* 2013 (5):4.

implementation of the most adequate means aimed at controlling the symptom itself, which is therefore to be considered refractory”[153].

In order for this definition to be correctly applied to the therapeutic action of sedation, a number of essential elements must be recognised: its *palliative* significance (i.e., oriented towards reducing the patient's pain and/or suffering in the presence of “refractory” symptoms), its *depth* nature (i.e., aimed at completely suppressing consciousness, by inducing a state similar to deep anaesthesia or pharmacological coma), the *imminence of death* and the availability of *valid informed consent.* As regards the time required for its implementation, PS may be *continuous*, when it is intended to continue until death, or *intermittent*, when it is recognised that it is appropriate to interrupt it, for justified reasons, taking advantage of the reversibility of this therapeutic intervention.

INDICATIONS

In clinical practice, the indications for initiating PS refer either to situations of progressive worsening until the symptom is completely refractory to the best possible treatment, or to the onset of acute events involving a situation of imminent death. This is the case of aggravating respiratory distress, characterised by the sensation of imminent death by suffocation, especially if accompanied by an agonising panic crisis, or of massive bleeding judged not to be amenable to surgery or other means, especially external and visible, mainly of the digestive and respiratory tracts. In such cases, PS may be an emergency treatment because of the inevitability of death and the extreme psychophysical suffering of the patient.

The refractory symptoms, identified as the most frequent indications for PS in oncology, are dyspnoea, delirium, pain, incoercible vomiting, and status epilepticus. These symptoms are reported with varying incidence and prevalence by different authors[154]. Other studies show that psychomotor restlessness and anxiety in the terminal phase are recognised as indications for SP in 20% of patients admitted to hospices[155]. Nausea and incoercible vomiting in case of intestinal obstruction are present in 25% of cases. One element reported in the literature, which is probably little known and, in some respects, unexpected is that refractory pain is a symptom for which PS is rarely and inconsistently indicated (5%)[156].

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[153] Cherny NI, Portenoy RK, *Sedation in the teatment of refractory symptoms: guidelines for evaluation and treatment.* J Palliat Care 1994; 10; Morita T, Tsuneto S, Shima Y, *Definition of sedation for symptom relief: a systematic literature review and a proposal for operational criteria*. J Pain Sympt Manage 2002; 24: 447-453.

[154] Schildmann E, Pörnbacher S, Kalies H, Bausewein C. *'Palliative sedation'? A retrospective cohort study on the use and labelling of continuously administered sedatives on a palliative care unit.* Palliat Med. 2018 Mar 1:269216318764095. doi: 10.1177/0269216318764095. [Epub ahead of print] PMID: 29557260.

[155] Cowan JD, Walsh D. *Terminal sedation in palliative care medicine.* Support Care Cancer 2001; 9: 403-407. 10; Sykes N, Thorns A. *Sedative use in the last week of life and the implications for the end-of-life decision making*. Arch Inter Med 2003; 163:341-344.

[156] Fainsinger R, De Moissac D, Mancini I, Oneschuk D. *Sedation for delirium and other symptoms in terminally ill patients in Edmonton.* J Pall Care 2000; 16: 5-10; Caraceni A, Zecca E, Martini C, Gorni G, Galbiati A, De Conno F. *Terminal sedation a retrospective survey of a three-year experience,* 2nd Congress of the EAPC Research Network. Lyon (France), Eur J Pall Care www.eapcnet.org, 2002, pp 4.

In order to initiate PS, the refractory symptom must be present at the moment when the doctor, in agreement with the other members of the treatment team, estimates the patient's life expectancy to be within a range of a few hours to a few days.

Worth mentioning is the condition generally referred to as “existential pain”, since it is difficult to classify in objective terms and its characteristics make it eligible for PS. On the one hand, there is an obvious need for sedation if, in the eyes of caregivers, psychophysical and spiritual suffering threatens the integrity of the patient, in keeping with the most dignified and humanly compassionate vision of how to deal with death. However, on the other hand, such an assessment can be extremely subjective and exposed to the risk of error.

SEDATION TECHNIQUE AND DRUGS USED

The careful choice of drugs and modes of administration is a key aspect of PS and must take many interrelated factors into account. The main general factors include the place were sedation is implemented (home, hospice, hospital, socio-health facility, other), the possibility of monitoring the dynamics of the level of sedation and any changes in the treatment plan, as well as the experience of the treating doctors. Other factors are instead mainly of clinical relevance: the age of the patient, current therapies (e.g. opioid analgesics and psychotropic drugs), general condition at the time of sedation, renal and hepatic function and feasible routes of administration. Finally, some factors pertaining more strictly to management should be considered, such as the progressive evaluation of pharmacological response and side effects, the gradual increase of dosages until the desired level of sedation is reached, when there are no acute clinical situations with a risk of imminent death, the reassessment of the degree of sedation and any relative changes in therapy, and the use of a sedation scale to assess the degree of symptom control.

The choice of drugs to be used depends to a large extent on the experience and training of the team and does not enjoy univocal consensus. The literature shows that midazolam is the most commonly used benzodiazepine and that, in any case, PS should preferably be implemented with sedatives and not with haloperidol or opioids. Since this is not the right place to go into technical details, we will only mention here a few drugs supported in the literature[157] as valid alternatives: levomepromazine, chlorpromazine or barbiturates, but also lorazepam, diazepam, clonazepam, flunitrazepam. Higher doses are administered to young patients, but also in case of absence of jaundice, of previous use of midazolam and of prolonged sedation (due to probable tolerance). Opioids must be administered as drugs to control pain and dyspnoea, not as sedatives; the most used opioid in such cases is morphine[158]. Initially, sedation

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[157] Morita T, Tsuneto S,Shima Y. *Definition of sedation for symptom relief: a systematic literature review and a proposal of operational criteria.* J Pain Symptom Manage 2002; 24:447-453; Morita T., Chinone Y, Ikenaga M et al. *Efficacy and safety of palliative sedation therapy: a multicenter, prospective, observational study conducted on specialized palliative care units in Japan*. J Pain Symptom Manage 2005; 30: 320-328.

[158] Some sedatives and opioids other than midazolam and morphine are considered as alternatives in cases where the latter are not indicated or do not adequately achieve their purpose. The literature also reports on the use of propofol, remifentanil, fentanyl and sufentanil, which, according to international guidelines, should be prescribed and administered by personnel trained in the use of anaesthetic drugs. Haloperidol should not be used as main drug for sedation because of its weak sedative effects, except in cases of delirium, where it should be considered as the drug of choice. Alternatively, more sedative neuroleptics such as

is implemented at low doses, which are progressively increased until the degree of control of the physical or psychological symptoms for which sedation has been decided is achieved, with the exception of acute clinical conditions where the risk of death is imminent. The indicated route of administration is subcutaneous or intravenous (midazolam, morphine and haloperidol can be administered subcutaneously).

As a rule, a data collection form is used to record the degree of symptom control achieved, the level of effective sedation for symptom control (assessed using appropriate scales), the safety of sedation in relation to the achievement of the desired depth (verified by recording vital parameters), the doses of drugs used and any increase in such doses. Once the optimal level has been reached, sedation should be reassessed for any necessary changes, possibly several times a day. Each assessment is reported on the form used.

According to the literature, the weighted average duration of the PS intervention is 2.8 days[159]. It is important to emphasise that survival of sedated terminally ill patients does not differ from that of non-sedated patients. Some studies[160] indicate that patients sedated for more than a week before death survive longer than those not sedated.

BIOETHICAL ASPECTS

The clinical contexts in which PS can be applied, the delicate choices involved and the obvious consequences of this therapeutic intervention call for some bioethical considerations. In particular, the apparent similarity of the practice of sedation to that of euthanasia has long characterised the debate on its lawfulness, fearing that these two practices could be confused.

Therefore, the CSB deems it appropriate to clarify that such a risk does not exist, and that there is a substantial difference between what is done with the exclusive intention of drastically alleviating suffering, as in the case of PS, and what can, instead, happen by suppressing life, albeit with the same aim, as is the case with euthanasia.

Some bioethical positions justify the morality of any therapeutic intervention on the basis of respect for the sole duty of preserving the quality of the patient's life, expressed only by the person concerned, the judgement of third parties not being ethically acceptable. The bioethical **principle of beneficence**, although present, is subordinated to that of **autonomy**. The latter is achieved by direct expression on the part of the person concerned and by recourse to the standards of ethical decision-making, such as informed consent and previously expressed wishes. According to this approach, the lawfulness of therapeutic PS, when considered appropriate and in agreement with all persons involved, is in no way called into question.

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chlorpromazine may be used. Antihistamines, especially promethazine, are strongly sedative and their use in combination with opioids and benzodiazepines or neuroleptics may be useful to enhance the sedative effect and complement it.

[159] Sykes N, Thorns A. *The use of opiods and sedatives at the end of life.* Lancet Oncology 2003; 4: 312-318.

[160] Ibidem.

Other positions include an absolute ban on interfering with the intrinsic finality of human life, which is considered an inalienable good: the morality of actions is judged on the basis of compliance with this ban. Therefore, the **principle of beneficence** prevails over that of **autonomy**. However, PS is ethically justified also in this case, since it is traditionally based on the doctrine of "double effect"[161]. In summary, according to this view, PS is morally lawful if the possible anticipation of death is foreseen but not intended and if there is proportionality between the foreseeable negative effect and the desired positive effect (control of refractory symptoms). In this bioethical perspective, it is the terminal disease and not the PS that ultimately determines the patient's death. In further support of this view, worth recalling is that, should therapeutic PS shorten survival - a possibility, as mentioned above, substantially refuted by current scientific evidence - the moral legitimacy would remain unaltered, due to the high significance of closeness and respect for human life, in the higher perspective of individual belief and not of mere biological survival.

In summary, it can be said that therapeutic PS is substantially different from the practice of euthanasia, medically assisted suicide and, obviously, from any homicidal intent, in that it is absolutely distant and distinguishable from the latter actions, and is therefore morally lawful and in line with any bioethical vision.

CONCLUSIONS

On the basis of the above considerations, the CSB believes that the decision to implement PS understandably represents the last act of an entire clinical and human process. Although it occurs in a minority of cases, it nevertheless constitutes a therapeutic action of excellence within Palliative Care plans, both because of the specific and complex professional skills required for its implementation and because of the critical human aspects that characterise it.

Indeed, its correct application requires preparation in a welcoming and sympathetic relational environment, a possibly serene sharing of choices among the persons involved and full acceptance of the relevant consequences. For this reason, worth reiterating is the importance, in the operators, of the

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[161] The doctrine of “double effect” was developed by St Thomas Aquinas and concerns the justification of killing in self-defence. This doctrine considers the mixture of good and evil as a consequence of human action. It must be established to what extent, by always fulfilling our duties, we can cause not only good but also evil. When a good action also has bad, unwanted consequences, we can either choose not to perform the action or, after taking stock of the consequences, to perform the action if the positive consequences outweigh the negative ones. This is a typical example of a consequentialist or teleological approach and includes four conditions:

1. The action must be morally good or at least indifferent;
2. The good effect must be directly achieved, the bad effect must only be expected or tolerated, but not directly intended;
3. The bad effect must not be the means to achieve the good one;
4. The good effect must be proportionately greater than the bad one.

In the case of PS, it is morally permissible to implement a treatment that has a positive effect (alleviation of suffering) and a possible or foreseeable negative effect (hypothetical shortening of life), provided that the latter is not intentional. This doctrine involves three further conditions for lawfulness, which refer to: the absence of therapeutic alternatives (objective not otherwise pursuable), proportionality between positive and negative effect (in the comparison between treatment and severity of symptoms, the positive effect must prevail over the negative effect) and the distinction between means and effects (the negative effect, the possible anticipation of death, must not be the means to achieve the positive effect).

simultaneous involvement of appropriate professional and technical skills and more strictly human qualities, recognising solidarity, compassion and closeness as essential values to be offered to those who suffer, as they approach death.

HUMAN-ANIMAL RELATIONSHIP AT THE END OF LIFE

HUMAN-ANIMAL RELATIONSHIP

The innate human predisposition to interspecific relations has characterised our species for millennia.

This inclination leads us to establish relationships with animals, which are so deep that they are considered an integral part of the lives of those who have chosen them. This is an important component of affection and a source of well-being and gratification.

The predisposition of the human species to interspecific *adoptions* is the basis of the domestication process. This process assigns to our species historical responsibilities towards the animal, commits it to the protection and promotion of the animal's well-being and to the definition of ethical boundaries necessary to guide behaviour.

The two parties to the relationship receive, propose and return, while creating a dialogical entity in which they find their position and recognise each other. Therefore, the relationship, and not the animal, is the source of mutual satisfaction and well-being. It is possible that the owners of animals wish that the effects of the relationship extend beyond their lifetime. Providing indications on the future of the animal and its well-being is a way of continuing the relationship beyond life, as well as simply addressing a concern.

HUMAN-ANIMAL RELATIONSHIP AT THE END OF LIFE

Animals are therefore parties to an important relationship, which can positively influence the life of the person they accompany.

Over the years there have been numerous studies aimed at demonstrating what and how many benefits a human being going through a period of frailty, such as disease and an end-of-life situation, can obtain from being close to and interacting with an animal, in terms of improved quality of life[162].

The presence of the animal as part of the family is a factor that promotes well-being, relieves stress, favours relaxation and offers acceptance. Therefore, no constraints should be placed on the continuation of the relationship even after transfer to residential facilities such as hospices.

However, the presence of an animal in the family, sometimes even the only other member of the family, raises questions and concerns for the responsible owner who wonders what life will be like for his companion after his death.

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[162] Among the most significant studies are: Italian Committee for Bioethics, *Bioethical problems concerning the use of animals in activities linked to human health and well-being*, 2005; Italian Veterinary Bioethics Committee, *Le Procedure per una Decisione Clinica Informata e Responsabile: Riflessioni Critiche sul così detto "Consenso Informato" in Veterinaria,* 2000.

There are many cases of bequests of money to take care of animals. These are often hastily attributed to eccentricity but reveal instead concern for the future of the animals by those responsible for them.

Pets cannot be beneficiaries of bequests. On the contrary, like other kinds of property, animals can become the property of heirs, who will be more or less willing or suitable for adoption, and not always able to guarantee their psychophysical well-being, or to meet the expectations of the preceding owner.

In the light of these considerations, the CSB would like to offer a reflection on the opportunity for owners of family pets to declare their wishes regarding the future thereof. In the Republic of San Marino, owned animals orphaned by their owners' death, in the absence of relatives able to take care of them, are currently kept in the shelter managed by an animal welfare association[163], which takes care of them while waiting for adoption.

Expressions of will are intended to be a reconciliation of duties, rights and legal responsibilities at the end of life. It is therefore plausible to assume by extension that, in the fulfilment of a person's wishes, human moral obligations and animal well-being, which are not regulated or cannot be regulated otherwise, can be affirmed within the expressions of will in relation to freedom, respect for the will and the dignity of dying.

CONCLUSIONS

The CSB believes that:

- It is highly desirable to support the continuity of the human-animal relationship in all care and residential facilities;
- It is legitimate to have animals at every stage of one's life;
- Animal ownership should be responsible, in terms of continuity and quality of care and relationship, albeit with the variations that life may impose on the owner/responsible person;
- The way of living with an animal can vary greatly in relation to the lifestyle choices of the owner/responsible person, but should respect the conditions of adequate well-being and continuity of the relationship;
- Since no one can know when they will no longer be able to provide for themselves and others, it is desirable to be concerned with the future condition of survivors, including animals;
- Devoting resources to the future life of an animal, when one is no longer able to do so personally, is a necessary concern and should be disseminated;

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[163] APAS (San Marino Association for the Protection of Animals). A fact sheet on this Association can be found in the appendix to this document.

- Expressions of will concerning animal care are also useful and desirable.

Similarly, the CSB considers it appropriate that there is a professional able to help the owner/responsible person make complex choices regarding the medical treatment and lifestyle of the animal in relation to the various personal ethical views. The case of expressions of will in veterinary medicine seems to specifically call for the involvement of the **clinical veterinary bioethicist**, in order to allocate resources taking into account human ethical choices and actual animal interests, in relation to effective foreseeable future needs[164].

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[164] AMNVI (National Association of Italian Veterinarians) Seminar, *Veterinary Clinical Bioethics*. Cremona, June 2017.

CONCLUSIONS AND RECOMMENDATIONS

Because of the complexity and wide-ranging scope of the topics covered in this document, the CSB has decided to include conclusions and recommendations at the end of each chapter.

Therefore, this chapter contains only the elements characterising the entire document, which is based on the concept of the centrality of the person, whose dignity requires respect: guaranteeing the implementation of the fundamental **bioethical principles of beneficence/non-maleficence, autonomy and justice** means recognising everyone's status of person in every condition.

In the delicate end-of-life situation, respect for dignity means allowing each person to live a *good death*, through the precious instrument of Palliative Care, which guarantees the control of pain and suffering, in the deep awareness that the life of a seriously ill and incurable person never loses its intrinsic value nor the right to be supported and protected.

Indeed, there is a substantial difference between the two distinct and related concepts of “incurable” and “untreatable”: a person suffering from an “incurable” disease never becomes also “untreatable” but, precisely because he/she is more vulnerable, this patient is entitled to seek and obtain assistance and treatment. This statement **is a cornerstone of the ethics of care**, in which the human face of medicine is represented.

Therefore, the CSB recognises the essential role played by Palliative Care, because of its respect for the rights of the patient. The latter’s well-being must be guaranteed by the social system at all stages of existence, through facilities organised as a network, where staff with specific skills operates.

The decision-making process in end-of-life care can only lead to a therapeutic pact, understood as the result of a project and a process shared by all stakeholders (the patient, the treatment team and the family members) and based on the following elements:

- **A correct and constant flow of information** among all those involved;
- **Ongoing training of health professionals**, to enable them to deal adequately, in clinical practice, with the ethical aspects of complex end-of-life situations;
- **Specific studies** that take into account the complexity of end-of-life situations, closely linked to advances in medicine and technology, and that encourage interdisciplinary approaches by combining the humanities and medicine.

Such a therapeutic pact makes it possible to adopt shared therapeutic choices based on the criteria of **appropriateness** and **proportionality** of treatment.

The CSB recognises these criteria as essential ethical and deontological references. They arise from a careful assessment of the risks and limitations related to each therapeutic intervention, in the awareness that a patient’s “overall benefit” involves not only the results of the treatment, but also the patient's quality of life, psychological well-being and spiritual needs.

The CSB believes that, in the context of this therapeutic relational alliance between the patient and the doctor or treatment team, wishes relating to health care can be a valuable support for free and informed decisions, especially if expressed at the beginning or in the presence of a disease for which it is possible to agree on an advanced treatment plan in relation to the evolution of the condition and on the basis of available scientific knowledge.

The CSB considers it desirable for the wishes to be updated over time and included in the medical record, so that they are immediately available to the treatment team.

The CSB recognises the complex and specific needs of particularly vulnerable persons, such as children, the elderly and persons with disabilities, for which it is necessary to have ad hoc skills related to analysis, exchange of views, communication and teamwork, focusing on the various specific problems of each category of persons.

The CSB also believes that, in a condition characterised by frailty, such as disease and an end-of-life situation, patients can obtain benefits, in terms of improved quality of life, also from being close to and interacting with their pet. Therefore, the CSB hopes that:

a) it will be possible to support the continuity of the human-animal relationship in all care and residential facilities;
b) in expressing their wishes relating to health care, the owners of animals will be able to declare their will concerning the future of their animals.

Therefore, the CSB hopes that, precisely because of the centrality of the patient and the family, the health system will evolve from a model centred on the hospital and the disease to a model centred on the person’s needs.

GLOSSARY

The following are some of the most recurring terms in this document.

PALLIATIVE CARE

A set of therapeutic, diagnostic and care interventions, aimed at both the patient and the latter's family, and intended to the active and total care of patients whose underlying disease, characterised by an unstoppable evolution and an ominous prognosis, no longer responds to specific treatments.

According to the World Health Organization (WHO, 1990, modified by the Ministerial Palliative Care Commission in 1999), Palliative Care is the active and total care of patients suffering from a disease, which no longer responds to specific treatments and whose direct consequence is death. In this situation, the control of pain, other symptoms and psychological, social and spiritual aspects is of paramount importance. The aim of Palliative Care is to achieve the best possible quality of life for patients and families. In particular, Palliative Care affirms life and regards dying as a natural event, does not hasten or delay death, provides relief from pain and other ailments, integrates the psychological and spiritual aspects of care, helps patients to live actively until death, and supports the family throughout the disease and bereavement.

EARLY AND SIMULTANEOUS PALLIATIVE CARE

Simultaneous/early care for patients in an advanced phase of disease is an organisational model aimed at guaranteeing global care of the patient through continuous, integrated and progressive assistance between therapies aimed at the underlying disease and Palliative Care when the objective is not primarily the survival of the patient. It aims at optimising the quality of life at every stage of the disease, from diagnosis onwards, through meticulous attention to the multiple clinical, psychological, spiritual and social needs of the patient and the family. Ensuring continuity of care by managing patients and their needs in a flexible way is also a key aim of this approach, which includes appropriate objectives in each individual situation and is achieved through assessment, planning, coordination, monitoring and selection of options and services. Finally, a specific aim of early care is also to avoid feelings of abandonment in the advanced and terminal phase.

The integration of specific oncological therapies and Palliative Care in the continuum of care is essential for chronically ill patients as the disease progresses and in end-of-life support.

The modern implementation of a Palliative Care programme usually differentiates among:

- HOME PALLIATIVE CARE. It is the most widespread model of Palliative Care. It follows the general organisational framework of integrated home care, a system of health care interventions and services offered at the patient's home characterised by the integration of the services offered, linked to the nature and needs involved. Originally conceived as an alternative to hospitalisation, which is more costly and traumatic for the patient - who, on admission, is often disoriented and not sufficiently surrounded by the comfort of his/her family - this form of care is more and more implemented in modern health systems. The operational organisation is based on teamwork, which involves the harmonised intervention of various professionals, including the family doctor, with the (family reference) caregiver also playing an active role. The other stakeholders in the overall economy of the care process are specialists who, from time to time, act on the basis of the specific needs of each individual case. These include, in most models, the Palliative Care doctor. The latter acts as a reference point for the other members of the team and intervenes above all in the most intensive care situations, and therefore, often, though not always, in the most advanced and terminal phases of the disease. Palliative Care doctors initially play the role of consultants, working alongside, but not replacing, family doctors. However, as the clinical condition progresses, they often take on a more important role. Nurses also play a key role in care, not least because of the fact that, in common parlance and also according to Cicely Saunders, the founding nurse of Palliative Care, such care has always been considered to have a purely nursing nature.

The method is also based on the harmonisation of interventions designed and managed by multidisciplinary professionals. The continuity of care provided by the plans jointly developed by the professionals involved (health professionals, social workers, physiotherapists, pharmacists, psychologists, etc.) guarantees the sharing of objectives and responsibilities and establishes the means and resources needed to achieve health results. Home care, a component of regional and local welfare, is divided into various types of intervention, which differ according to their greater or lesser intensity, the number and specific professional competence of the operators involved, the profile of the person to whom they are directed, the working methods of the operators and the territorial and integrated operational level involved. The provision of home care services is based on economic considerations and the specific characteristics of the patient.

In the light of what has been described so far, the system of home-based interventions and services is a valid alternative to hospitalisation, as it is able to meet the needs, mostly of a health nature, of the elderly, persons with disabilities and patients suffering from chronic degenerative diseases in a stabilised phase or with varying degrees of non-self-sufficiency (temporary/permanent, partial/total).

- RESIDENTIAL PALLIATIVE CARE: THE HOSPICE. This is quantitatively second to home care, although the geographical distribution of the two forms of care is rather uneven. Indeed, residential Palliative Care is more implemented where social disaggregation is due to a more fragmented family environment, while in territories where family aggregation is stronger and more significant, the home remains the most requested and reliable solution. The hospice is detached from the idea of a “hospital ward”, as it is structured in a less medicalised way and focuses rather on the comfort of the environment, which, respecting family reunion, promotes social relations between guests (patients) and families.
- HOSPITAL PALLIATIVE CARE. It is the least implemented form of care for patients in the advanced and terminal stages of the disease. In addition to doctors, several professionals with accredited Palliative Care backgrounds and training are also involved. These professionals, distributed in various ways

among the operating staff, have the mandate to adopt a special approach toward patients who, while responding less and less to therapies aimed at curing and/or stabilising their disease, have an ever-increasing need for care aimed above all at minimising suffering and providing the best possible end-of-life support.

LIFE-LIMITING/LIFE THREATENING

A "life-limiting disease" is defined as a disease that results in certain early death. The field is paediatrics. An emblematic example is Duchenne muscular dystrophy, but there are many other conditions that fall under this definition. The appropriate treatment, currently excluding the possibility of recovery, is Palliative Care. "Life-threatening diseases", on the other hand, are serious diseases, such as neoplasms or the aftermath of severe trauma, which have a chance of being cured but which, if curative treatment fails, could lead to early death.

BEST PRACTICE

Best practice refers to the set of experiences, procedures and actions, which have been accredited as the most valid or which, in any case, have led to the best results in relation to various contexts and proposed objectives. This term is used in medicine, but is borrowed from business management, software engineering, corporate or governmental organisations.

PERSISTENT/PERMANENT VEGETATIVE STATE

The condition of "coma", i.e. the deep state of unconsciousness caused by intoxication, metabolic changes or damage to and disease of the central nervous system, can evolve into the so-called "vegetative state", characterised by the resumption of wakefulness but without consciousness and awareness of self and surroundings. It is defined as "persistent" if it is prolonged in time and "permanent" when it is presumed to be irreversible. Because of the difficult nosographic classification of the latter condition, experts, supported by the many medical and legal controversies on irreversibility, do not recognise the existence of a real, clear-cut difference between persistent and permanent vegetative state.

REFRACTORY SYMPTOM

According to the definition by Cherny and Portenoy (1994), symptoms are refractory when they *"cannot be adequately controlled despite aggressive efforts to identify and utilize a therapy that does not compromise consciousness".* In Palliative Care, the relevance of identifying "refractory" symptoms lies in the need to address and resolve in any case all forms of suffering, by resorting to the technique of "palliative sedation". "Refractory" conditions that most frequently occur in the terminal stage of a disease and require this last treatment include dyspnoea, delirium and severe haemorrhage. Pain, although present, is not among the "refractory" symptoms most commonly mentioned.

SURPRISE QUESTION

Much has been written about the importance of timing in the implementation of Palliative and End-of-Life Care. However, once this is established in the abstract, it is *de facto* necessary to identify on a patient-by-patient basis the right time to start PC with sufficient prognostic accuracy. To this end, the *surprise question* tool was created in the nephrological field and then transferred to the oncology specialist field: “Would you be surprised if this patient died within the next 12 months?” Available studies have shown that the proposed system is effective and is also psychologically preferable to a prognostic formulation in numerical terms, even though specialists tend to overestimate the prognosis of their patients.

ANH

ANH stands for “Artificial Nutrition and Hydration”. Clinical conditions in which functions related to oral nutrition are temporarily or permanently impaired can benefit from these therapeutic methods. A distinction is made between the “enteral” administration, in which food is administered by placing a tube into the patient's digestive system via nasal or percutaneous access, and the “parenteral” administration, in which nutrients are administered directly via venous access, i.e., bypassin the digestive system.

NGT

This acronym stands for “naso-gastric tube”, namely a long catheter that is gently introduced into a nostril until it reaches the stomach. It is used in the clinic practice to bypass the first part of the digestive tract (from the oral cavity to the oesophagus-gastric hiatus) if food transit here is compromised. Indeed, this means is often used for the so-called “enteral artificial nutrition”. The direct communication of the gastric lumen with the external environment by means of this device is also used for other conditions, such as vomiting resistant to drug therapy or drainage of enteric secretions that cannot otherwise be eliminated.

The permanence *in situ* of this device is limited in time, due to the risk of decubitus affecting the enteric mucous membranes in contact with it or deterioration of the material of this device. The use of the NGT is also conditioned by complications, such as, for example, the possibility of displacement and, above all, psychological acceptance by the patient, which is not always ensured. The NGT is not used for long time, i.e. no more than a few weeks, and often precedes the application of another device that serves the same purpose, namely PEG.

PEG

PEG stands for “Percutaneous Endoscopic Gastrostomy”, a technique which, like the naso-gastric tube, is used for enteral nutrition. This type of nutrition is necessary in patients who are unable to feed themselves by mouth due to neurological disorders and/or physical disorders in the upper digestive tract. It has the same advantages as parenteral nutrition and also allows maintenance of intestinal function and easier management of the patient at home. PEG is usually used in patients who require enteral nutrition for a long period of time. It is better tolerated than the naso-gastric tube but, according to recent studies, it does not lead to a significant improvement in quality of life or a reduction in complications (e.g., regurgitation and aspiration). For this reason, its use should only be reserved for selected patients with a life expectancy of more than 6 months.

FUTILE MEDICAL CARE

It is represented by the obstinate continuation of any diagnostic or therapeutic treatment of proven ineffectiveness and uselessness, which is excessively disproportionate to the objective of treating the patient because of the risks involved, its limited chance of success and the prevalence of risks and disadvantages over benefits, both in clinical terms and in terms of quality of life.

FUTILITY

Synonymous with inadequacy in producing a result or achieving the required objective and with ineffectiveness, this term defines a medical intervention that is useless for the good of the patient in relation to the evolution of the disease. If the treatment is burdensome, it is an act of maleficence.

THERAPEUTIC INTERRUPTION

This choice means abstaining from all forms of futile medical care, suspending or stopping treatments which, in the light of the lack of benefit and the inappropriate nature of treatments, have the sole consequence of painfully and needlessly prolonging the agony of the end-of-life patient. The decision to withdraw treatment should not be considered euthanasia, since the death of the patient, if occurring, is neither desired nor sought, but is the end of an irreversible process.

THERAPEUTIC ABANDONMENT

It is an action or omission which, by its nature or by intention, actually causes death for the purpose of eliminating all suffering.

ANNEX 1: REFERENCE LEGISLATION AND DOCUMENTS

REPUBLIC OF SAN MARINO

Delegated Decree no. 21 of 24 February 2016, ratifying Delegated Decree no. 1 of 13 January 2016 "*Measures in favour of the elderly and of persons with disabilities who are not self-sufficient and rely on continued assistance*".

Declaration on the Citizens' Rights and Fundamental Principles of San Marino Constitutional Order, Law no. 59 of 8 July 1974, with subsequent amendments resulting from Law no. 95 of 19 September 2000 and Law no. 36 of 26 February 2002.

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ANNEX 2: THE POSITION OF MONOTHEISTIC RELIGIONS

CATHOLICISM

The starting point of any moral discourse within the Catholic Church is the encounter with God, which takes place in Jesus of Nazareth, the Christ. This event is the foundation of every experience of faith. The Magisterium of the Church is an indispensable element of the reflections that have been made on the experience of faith throughout the history. The Magisterium of the Church has the task of preaching the faith to be believed and practised in life. This task also extends to the specific prescriptions of natural law, because their observance is necessary for salvation. The Magisterium of the Church has always intervened in the field of bioethics. The Second Vatican Council invited all the faithful to "*let them blend new sciences and theories and the understanding of the most recent discoveries with Christian morality and the teaching of Christian doctrine, so that their religious culture and morality may keep pace with scientific knowledge and with the constantly progressing technology*"[165].

For the Christian, "*the decisive answer to every one of man's questions is given by Jesus Christ, or rather is Jesus Christ himself*"[166]. Therefore, Christian morality does not derive from a doctrine but is that inner dynamism that comes from God and attributes a divine purpose to natural ethical action.

Another characteristic element of Catholic morality is conscience. Conscience is the judgement of reason, by which man assesses whether the action he is about to perform, or has already performed, is good or bad. It is through conscience that man verifies whether the action he is about to perform or has performed is consistent with the Law, which requires him to live according to reason. This is where man's personal identity is realised consistently with natural law. *"Conscience is not the source of good and evil; it is the call to conformity that an action must have with regard to a man's intrinsic need, so that man can be true and perfect. It is the subjective and immediate intimation of a law, which we must call natural, despite the fact that today many no longer want to hear about natural law"*[167].

Conscience, law and freedom are not opposed to each other, but together they contribute to the realisation of the person according to righteousness and to the promotion of collective justice. We can therefore define conscience as the attitude and act of knowledge and discernment aimed at evaluating moral actions.

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[165] Second Vatican Council, *Pastoral Constitution "Gaudium et Spes"*, 62

[166] Pope John Paul II, *Encyclical Letter Veritatis Splendor* (6 August 1993), no. 2.

[167] See Pope Paul VI, *Allocution of 12 February 1969*.

Living will

It is considered a form of expression of the last will. In addition to indicating one's preferences as to how one wishes to be treated in the event of being in a state of serious suffering or living conditions deemed to be poor, and one cannot decide for him/herself, this term also refers to the fact of authorising family members, medical staff or a specific person, in the event he/she cannot decide autonomously, to intervene in the decision-making process. In principle, such expression of will, even if drawn up in a document, would not be unlawful, since patients are entitled to be the protagonists of the clinical choices that affect them, and their legitimate wishes must be binding on the doctors' actions. If living wills are understood as the expression of a desire not to be subjected to futile medical care, they are absolutely legitimate and also testify to the desire to humanely live one’s passage to death. However, any exercise of autonomy aimed at defining what should or should not be done with respect to oneself, if and when one is not able to express oneself, should be respected only for that part consistent with the integral good of that person, which could not coincide with what he/she may have decided at an earlier time. The patient's wishes, possibly even expressed in writing, are certainly important to bear in mind, as an expression of his/her religious or moral conscience. However, they cannot be binding on the doctor and the decision-maker in the precise circumstances that have arisen and that can hardly be foreseen by a person not involved in the situation experienced. It is common experience that convictions can change over the years and that a disease can completely change an individual's choices compared to when he/she was healthy.

Euthanasia

Euthanasia means any action or omission aimed at putting an end to the life of an incurable or terminally ill person, an elderly person or a person with a disability, in order to avoid physical or mental suffering. Catholic bioethics literature refers to direct and indirect euthanasia. Direct euthanasia means any intervention that, in itself or in the intention behind it, tends to hasten or cause death. Indirect euthanasia means any act that may hasten or cause the death of a patient, but without this being intended by the acting person. To avoid confusion, in this case the term euthanasia is usually avoided. As regards the means by which euthanasia is achieved, a distinction is made between active euthanasia, when death occurs as a result of an act, and passive euthanasia, when death occurs as a result of the omission of an essential act or intervention. Voluntary euthanasia is defined as euthanasia requested by the person concerned, which would correspond to assisted suicide. Non-voluntary euthanasia is defined as euthanasia practised without the consent of the person concerned or practised on human beings no longer capable of expressing their will.

The Catholic Church's moral assessment has always been clear and unchanged against euthanasia as a principle and as a practice. Euthanasia is opposed to the principle of the sacredness of life, which is a good in itself and cannot be disposed of by a person for moral, religious and social reasons. For the Catholic Church, no one can make an attempt on the life of an innocent man without opposing God's love for him, without violating a fundamental, inadmissible and inalienable right, and therefore without committing an extremely serious crime[168]. Euthanasia is considered and assessed as an intrinsically bad act because it radically contradicts the fundamental, intangible and inalienable value of human life as a sacred good. Therefore, any form of euthanasia, whether active or passive, voluntary or on-voluntary, is ethically unacceptable. The main documents with which the Magisterium of the Church has clearly and distinctly expressed its opinion are: the *Declaration on Euthanasia* and, solemnly, the *Encyclical Letter Evangelium Vitae*, in which John Paul II states that: *"In harmony with the Magisterium of my Predecessors, and in communion with the Bishops of the Catholic Church, I confirm that euthanasia is a grave violation of the law of God, since it is the deliberate and morally unacceptable killing of a human person: this doctrine is based upon the natural law and upon the written Word of God, is transmitted by the church's tradition and taught by the ordinary and universal Magisterium"*[169]. Even more explicitly, in declaring euthanasia immoral and unlawful, the Congregation for the Doctrine of the Faith states that *"nothing and no one can in any way permit the killing of an innocent human being, whether a foetus or an embryo, an infant or an adult, an old person, or one suffering from an incurable disease, or a person who is dying. Furthermore, no one is permitted to ask for this act of killing, either for himself or herself or for another person entrusted to his or her care, nor can he or she consent to it, either explicitly or implicitly. Nor can any authority legitimately recommend or permit such an action. For it is a question of the violation of the divine law, an offence against the dignity of the human person, a crime against life, and an attack on humanity"*[170].

Futile medical care

Both futile medical care and therapeutic abandonment of a terminally ill patient are considered unlawful and immoral. The Church recognises the fundamental right of every person, including terminally ill patients, *"to die peacefully with human and Christian dignity"*[171]. Therefore, the use of the means that today's medicine provides, which can artificially delay death, without the patient receiving any real benefit, are also considered unlawful. All those interventions that are insistent, burdensome and useless, or at least disproportionate, effectively condemn the patient to artificially prolonged agony. On the contrary, patients must always be ensured the so-called routine care, i.e., nutrition and hydration, analgesia and nursing.

Palliative Care

Palliative and symptomatic care, which, while not eliminating the causes of the disease, attenuates the violent manifestation of its symptoms, aims at taking care of end-of-life patients and seeks to comprehensively meet their physical, psychological and spiritual needs. While respecting life and dying as a natural process, Palliative Care does not hasten or delay death, but protects the best possible quality

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[168] See Congregation for the Doctrine of the Faith, *Declaration on Euthanasia*, (5 May 1980), II.

[169] Pope John Paul II, *Encyclical Letter Evangelium Vitae* (25 March 1995), no. 65.

[170] Congregation for the Doctrine of the Faith, *Declaration on Euthanasia* (5 May 1980) II.

[171] *Ibidem*.

of life even in the last moments before death. Palliative Care is considered by the Magisterium of the Catholic Church to be a supreme experience of mercy, which agrees to takecare of the suffering person in his/her last moments of life, even when, from the point of view of healing, there is nothing more to be done. The Catechism of the Catholic Church states that *"Palliative Care is a special form of disinterested charity"*[172]. Among Palliative Care, also the Catholic Church attributes a prominent role to pain therapy, where pain is understood in all its facets. Indeed, the Charter for Health Care Workers states that painkillers, *"which help to make the course of the illness less dramatic, contribute to the humanization and acceptance of death"*[173]. Indeed, since the physical and psychological devastation caused by the pain that accompanies many fatal diseases is one of the main reasons for requesting euthanasia, appropriate pain therapy must be considered one of the cornerstones of comprehensive and integrated care of the person-patient. Pius XII already stated that the use of analgesics is lawful, even if they cause semi-consciousness or reduced lucidity in the patient as an unintended secondary effect. Indeed, it is also lawful to cause deep or palliative sedation in extreme cases through appropriate drugs. In particular, Pius XII stated that *"it is not right to deprive the dying person of consciousness without a serious reason"*[174]. In conclusion, according to the authoritative teaching of the Magisterium, it is permissible to use analgesics to alleviate physical suffering, even if this is expected to lead more rapidly to death, if the sole purpose of this intervention is to make the pain more bearable, if death is neither sought nor intended in any way, and if the pain is of such intensity as to justify the risk[175].

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[172] Catechism of the Catholic Church, 1993, no. 2279.

[173] Pontifical Council for Pastoral Assistance to Health Care Workers, *The Charter for Health Care Workers*, Vatican City 1995, no. 122.

[174] Pius XII, *To an international assembly of doctors and surgeons*(24/2/1957) in AAS 49 (1957) 145; see Pontifical Council "Cor Unum", *Questions of ethics regarding the fatally ill and the dying,* in *Enchiridion Vaticanum, 7. Official documents of the Holy See 1980-1981*, EDB, Bologna 1985, p. 1153, no. 4.

[175] See Pontifical Council for Pastoral Assistance to Health Care Workers, *The Charter for Health Care Workers*, Vatican City 1995, nos. 122-124.

JUDAISM

The Jewish tradition has always combined ethical requirements with the evolution of research.

Judaism does not reject *a priori* scientific evolution. It encourages it while not indiscriminately accepting its results, which must be subject to precise limits, including regulatory principles and constant ethical control.

It must also be taken into account that today Jews do not have an unanimously recognised central authority. Therefore, the solution to individual problems is left to qualified experts, who must assess each situation on a case-by-case basis, starting from the teachings that stem from the biblical text (the Torah) and the interpretations developed over the centuries by the masters of tradition (oral Law).

There is no substantial difference between ethics and legislation. Both are part of the biblical teaching that regulates the relations among men and between man and the Creator, starting from the consideration that the biblical message is aimed at making every human behaviour and every act sacred, even the most insignificant ones.

Today, in the field of bioethics, extremely delicate issues arise, with implications that entail risks and need profound changes to be made to the way of considering the essence of man's existence, and that can challenge the mental categories acquired in the past.

This is a challenge that we have to face with intelligence and humility, considering the opening up of new horizons and the discovery of forces that need to be controlled.

There are cases where Jewish law and some aspects of bioethical applications may conflict (Sabbath observance, dietary rules, etc.), or there are more specific and complex issues such as fertility, its establishment, fertilisation, genetics, abortion, euthanasia, organ transplantation, determination of the time of death and autopsy, to name but a few.

In addressing these issues, the Jewish tradition, while leaving room for the individual decision-maker to assess each case in its specificity, starts from general principles, without forgetting that principles are fundamental, but what matters is their application.

First and foremost, the absolute value of life: *"Humanity was created from a single individual to teach that whoever saves one life, saves the world entire, and whoever kills a man is liable for his blood and for that of his descendants for all eternity".* This is a well-known Talmudic statement.

Human life is an immeasurable and inalienable value. The protection of all human lives is an imperative that goes beyond almost all biblical rules.

In Judaism there is no exaltation of martyrdom.

The obligation to protect life, but also one's own health, concerns the individual and the community.

Particular attention must be paid to environmental protection.

However, the patient must never give up on treatment.

There is an obligation on doctors to perform their work to the best of their ability. They cannot refrain from providing their services and must always regard themselves as an instrument of the divine will.

All individuals have an obligation to procreation. *"Be fruitful and multiply"* is the imperative of Genesis and *"the world was created to be inhabited"* (Isaiah 45:18).

Some specific rules prohibit the destruction of male semen.

A strict regulation prohibits adultery and incest.

The determination of the moment when life begins, with all its implications, is important for the solution of bioethical issues. Equally important is the determination of the time of death, which is considered to be the complete, definitive and certified interruption of cardio-respiratory functions.

It shall be prohibited to perform any act that hastens or causes death, but delaying the death of a terminally ill person by artificial means is not tolerated.

Organ transplantation is a separate issue, which must be addressed in the light of the ban on remaining inactive in case of real or presumed serious danger to the life of a human being. However, it must also be taken into account that it is forbidden to take a life in order to save another.

Complex issues concern the legal position of the embryo, the treatment of infertility, artificial insemination, pain and terminally ill patients.

The question arises as to whether it is lawful to intervene in the human genetic heritage. Whether it is permissible to intervene in the work of Creation. According to the great doctor, philosopher and jurist Moses Maimonides (12th century): *“Man's actions are not predetermined by the Creator. This is an indisputable truth, so a reward is given to those who are on the right path and a punishment if they are not. All man’s actions must be guided by the "fear of God". This is the fundamental principle of the Torah. Both the teaching of the Torah and that of the Greek philosophers show that man can decide his own behaviour without constraint”.*

Therefore, according to Maimonides, we must always keep the “fear of God” in mind when facing any problem that comes our way.

The masters of the Mishnah had already stated the following: *"Keep three things in mind and you will not incur sin. Know where you come from, where you are going and to whom you will be accountable.*

Where do you come from? From a putrid drop. Where are you going? To a place of worms. To whom will you be accountable? To the King of kings the Holy Blessed One”. (Avot III,1).

Living will

In Muslim law, the term *al-wasiyah* means last will and, by extension, also testament. It has been regulated starting from Koran 5.106.

The living will cannot be included in a testament (*wasiyah*) since what is in it will only be executed after the death of the testator. Conversely, the content of the living will refers to what to do in the phases prior to death. Consequently, if a Muslim signs a living will it should be considered to have no legal value.

Alternatively, the believer may draw up a non-binding living will in which, for example, the following requests could be contained:

a) Request to interrupt treatment if it does not improve the patient's quality of life. In this case one simply refuses excessive treatment. However, hygiene care and artificial nutrition should be maintained. This last aspect can be interpreted in various ways, resulting in different clinical options;
b) Instructions for disconnecting life-support equipment after brain death has been diagnosed;
c) Inclusion of the will to donate organs based on the principle of public benefit (*maslaha*) and altruism towards others (*al-ithar*);
d) It is useful to appoint a representative (ar. *wakalah*) who is morally obliged to communicate the dying person's wishes to family members and doctors.

In several North-Western countries, Islamic medical associations recommend living wills. The usefulness of such documents (which are also very different from each other) is evident in geographical areas marked by immigration, where the autonomy of the patient is more respected and where there is a strong fear of a technological postponement of death.

In Muslim States, living wills are largely absent while the *“do not resuscitate orders”* are more widespread in hospitals.

Euthanasia

Human life is sacred but can be taken for a “just reason” in accordance with the Sharia (e.g. Koran 17:33). “Just reasons” include: execution of a legal sentence; just war; self-defence. Killing a terminally ill patient (regardless of the manner) would not fall under the “just reasons”.

A judge at the Supreme Court in Jeddah (Saudi Arabia) ruled against any kind of euthanasia: *"There is no difference ... whether the death of the patient is caused by disconnecting life-support equipment, the withdrawal of life-sustaining treatment, or the administration of drugs that lead to death. All these procedures are unlawful. They cannot be performed by anyone, nor can anyone consent to them”.*

However, within the unanimous condemnation of euthanasia in principle, different positions can be identified in case of some specific clinical situations. This is facilitated by the application of the criterion of "futility-uselessness", which appears to be very arbitrary in its use and very undefined at a conceptual level. In addition, several documents seem uncertain about the value to be attributed to artificial nutrition and hydration. This results in different attitudes about the willingness to disconnect equipment in some critical situations. Finally, in Western countries, the debate on euthanasia focuses on the need to respect the patient's will if he/she refuses “treatment”, and on the duty not to kill. In Islamic countries, the importance of the former need appears to be less perceived than the latter duty. This translates into less autonomy for the individual, less individualism, but also less propensity to grant the individual some rights to be invoked against the dominant values and customs in the community.

Regarding deaths in intensive care units in North America and Europe, decisions to refrain from using or withdraw from life-sustaining treatment (LST) are the most frequent causes of death in intensive care units, accounting for 60-80% of deaths. Such decisions by doctors and/or relatives depend on social, cultural, moral and religious factors. Limited to a comparison only with the Middle East, the evidently lower frequency (about 50% of deaths) is due to the fact that doctors seem reluctant to suspend or withdraw from treatment in critically ill patients, and such behaviour is often interpreted as euthanasia. Moreover, the delay in making such decisions is frequently linked to the families' desire to continue “caring” for the patient. There seems to be a widespread tendency to take the patient home to die when his/her situation is compromised, with the aim of favouring a rapid and comfortable death.

There are also some diversified positions by Islamic jurists and doctors, who explicitly refuse, in specific cases, to maintain artificial nutrition and hydration aor other life-sustaining treatments. According to some experts, artificially prolonging the vegetative state of a permanently unconscious patient (PVS) is unlawful since it is consciousness that makes an individual responsible. Such artificial prolongation would violate human dignity, as well as divine will. According to others, withdrawing from the use of unnecessary or non-beneficial drugs and life-sustaining treatments respects the principle of non-maleficence rooted in Islamic medical ethics. According to others again, Sharia punishes the doctor who actively and unilaterally helps the patient to die. However, Islamic law allows the patient to refuse treatment that delays certain death, or allows the doctor - after consultation with the patient, family members, etc. - to interrupt futile treatment.

Nevertheless, the majority of testimonies and documents refer to the duty to maintain artificial nutrition and hydration in certain circumstances. Some case studies confirm that the refusal of assistance (nutrition, oxygenation, drugs, etc.) by a terminally ill or very seriously ill patient can be ignored on the grounds that his/her psycho-physical balance is impaired by the disease.

State laws basically reject euthanasia. Despite this, it is difficult to assess the actual practice in individual Muslim countries. Euthanasia is present but not interpreted or considered as such.

Palliative Care

Apart from exceptions often limited to socially advantaged contexts, the perception and dissemination of Palliative Care in the very diverse Muslim States is problematic for a variety of cultural and organisational reasons. These include: the general lack of awareness of the importance of Palliative Care; the general lack of preparation of doctors, nurses, patients, etc., with the associated fear that such care will interfere with the patient's religious duties; the widespread belief that opioid analgesics are contrary to the principles of Islam; and the reluctance to address the problems of death and dying openly with the patient and/or family members.

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ANNEX 3: SAN MARINO ASSOCIATION FOR THE PROTECTION OF ANIMALS (APAS)

San Marino Association for the Protection of Animals[176], founded in the Republic of San Marino in September 1986, is a non-profit organisation that runs a shelter where abandoned dogs and cats and some small courtyard animals are hosted.

APAS strives to help improve the condition of animals through its volunteers, by promoting animal protection laws, carrying out educational and awareness raising activities and working with public and private institutions on specific projects aimed at facilitating a harmonious relationship between man and other animals.

The commitment of APAS has led to the adoption of important laws, such as that on the prevention of straying (Law no. 54 of 23 April 1991), the prohibition of animal abandonment and mistreatment (Law no. 101 of 25 July 2003), the prohibition of animal testing (Law no. 108 of 3 October 2007), and the protection of pets (Law no. 101 of 30 July 2012).

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[176] http://www.apasrsm.org/