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## **WORKING DOCUMENT**

### **Draft guide concerning the decision-making process regarding medical treatment in end-of-life situations**

Document prepared by the Drafting Group on the decision-making process regarding medical treatment in end-of-life situations

This text is a working document that has been made public under the responsibility of the Drafting Group on the decision-making process regarding medical treatment in end-of-life situations.

At its 2<sup>nd</sup> plenary meeting (December 2012), the Committee on Bioethics (DH-BIO) of the Council of Europe made comments on a draft preliminary text and instructed the Drafting Group to revise it in the light of those comments. The DH-BIO, which has agreed to this publication, has not yet examined the revised version of the text.

This document has been made public for consultation so as, in particular, to elicit comments from the fields directly concerned (such as patients, doctors, other carers, families, bodies/persons likely to be involved in the decision-making process on medical treatment at the end of life), which will be taken into account when finalising the draft guide for subsequent submission to the DH-BIO for adoption.

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## **I – Introduction**

1. Progress in the health field and advances in medicine – particularly developments in medical technology – enable life to be prolonged and increase prospects of survival. By making what used to be regarded as acute illnesses into chronic illnesses, they give rise to complex situations and are unquestionably rekindling the debate on the end of life and the framework in which decisions are taken on medical treatment in end-of-life situations.
2. The end of life and the questions it raises in terms of dignity of the person is one of the current social concerns of all the Council of Europe member States. It leads in particular to queries about how the principles established by the 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 can be applied to these situations. These principles do, however, form the legal framework for any discussion or any medical practice relating to an end of life situation.
3. The fact is that the purpose of the Council of Europe<sup>1</sup> is described as safeguarding and fostering the ideals and principles which are its member states' common heritage: democracy, human rights and the rule of law. In this context, the member states endeavour to find common, co-ordinated responses to the questions which arise in society, with the aim of ensuring that human dignity is protected. The European Convention on Human Rights is the main reference text and provides a legal framework based on shared values, one of whose aims is to strike the necessary balance between medical and scientific progress and the protection of human beings and human dignity. These texts provide benchmarks for discussions on the end of life.
4. Medical and scientific progress has, however, made more specific answers necessary. It was for this purpose that the Convention on Human Rights and Biomedicine was adopted in 1996 and opened for signature in Oviedo (Spain) in April 1997. These provisions can be applied to end-of-life situations dealt with through medical care and health systems and some even provide direct responses to such situations.

### **The purpose of this document**

5. It was considered worth preparing an informative summary document presenting the principles that can be applied to the decision-making process regarding medical treatment in specific end-of-life situations. The intention is for these principles to be applied regardless of the distinct legal framework pertaining in each state. The document is aimed primarily at the health care professionals concerned but it is also a potential source of information and a basis for discussion for patients, their family and relatives, all other persons providing support, and associations dealing with end-of-life situations. Some items in this document could also serve as material for the many debates sparked by end of life issues.

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<sup>1</sup> An intergovernmental organisation currently comprising 47 member states including the 27 European Union states.

6. The aims of this document are as follows:
- **to propose reference points** for the implementation of the decision-making process regarding medical treatment in end-of-life situations. Among other things these should make it possible to identify the different stages of the process, the factual elements that influence decisions and the parties involved in the process;
  - **to bring together both normative and deontological reference works** and elements relating to good medical practice which will be useful for health professionals dealing with the implementation of the decision-making process regarding medical treatment in end-of-life situations. The document may also provide reference points for patients and their relatives, families or representatives to help them to understand the issues at stake and hence to take the appropriate part in the process;
  - **to contribute, through the clarification it provides, to the overall discussion** on the decision-making process in end-of-life situations, particularly the complex circumstances encountered in this context, as it creates an opportunity to outline a number of issues and debates to which the different European countries sometimes provide a diverse range of responses.
7. Its aim is not to take a position on the relevance or legitimacy of one decision or another in a given clinical situation. There is no doubt, however, that the weight of the expected decision adds to the complexity of the situation.
8. It is true that decisions on medical treatment in end-of-life situations may hasten the onset of death or delay it. At the end of life, the main purpose of any medical treatment is to improve quality of life or, at the least, to try to control symptoms that are liable to impair the quality of the end of people's lives.
9. Furthermore, while the main thread of any discussion on decisions regarding medical treatment should be respect for individuals and their autonomy, clinical experience shows that at the end of life it is often difficult for patients to express opinions when they are made vulnerable by illness. In addition, decisions are sometimes taken when patients are no longer able to express their wishes.
10. At all events, in uncertain and complex situations like those generated by the end of life, decisions should be the culmination of a proactive, collective process designed firstly to avoid the biases of inevitable subjectivity and secondly to allow as far as possible for treatment to be adjusted in line with the patient's changing state.

### **The scope of the document**

11. The discussion below focuses very specifically on the following points:
- the **decision-making process** and not the content of decisions (where certain types of decision are presented, it is simply to illustrate arguments relating to the process);

- the decision-making process as it applies to **end-of-life situations**;

**For the purposes of this work, end-of-life situations are understood as those in which the evolution of a disease or a severe deterioration in health threatens the life of a person irreversibly in the near future.**

- the decision-making process regarding **medical treatment**, including its implementation, modification, adaptation, limitation or withdrawal.

The document therefore does not address the issues of euthanasia or assisted suicide, which cannot be defined as medical treatment.

12. The elements described below apply – with the necessary adjustments – whatever the place and the conditions in which the end of life situation is being dealt with, whether in hospital, in a medico-social establishment such as a retirement home, or at home, and irrespective of the department or ward in which the person is being treated (emergency, intensive care, cancer or any other). The principles outlined in the description of the decision-making process can be taken into account once the adjustments needed for each situation have been made. For example, the question of time scales is a key one and the process cannot be organised in the same way in an emergency situation as it would in the context of an anticipated end of life situation.

Nonetheless, due regard must always be shown for the principle that patients' opinions should always be sought in the light of the treatment options available and collective discussion processes become essential where patients are unwilling or unable to take part directly in the decision-making process.

The authors of this document also recognise that specific features can make some end-of-life situations particularly complex. It would be worth looking at some of these situations in isolation so that the necessary adjustments to the process can be singled out (for example end-of-life situations in the neonatal field).

## **II - The ethical and legal frames of reference for the decision-making process**

13. Where intervention on the human person is concerned, the issue of the decision-making process regarding medical treatment in end-of-life situations raises questions concerning the three main principles which are internationally acknowledged to form the core of medical ethics, namely **autonomy, beneficence/non-maleficence and justice**. These principles form part of the fundamental rights enshrined in the European Convention on Human Rights and transposed into the field of medicine and biology by the Convention on Human Rights and Biomedicine (the Oviedo Convention).

### **A. The principle of personal autonomy**

14. Respect for autonomy begins with recognition of the legitimate right and the capacity of a person to make personal choices. The principle of autonomy is exercised in particular through the **process of free and informed consent**, which may be withdrawn at any time without detriment to the person concerned.

15. Information is an essential contributing factor to autonomy. For people to take informed **decisions**, they must have access to appropriate and full information which they can understand. Patients must be notified of the purposes and the potential risks and benefits of treatment. The information they are provided with must be understandable, meaning that the manner and form in which it is supplied are particularly important. Lastly, it is important to be satisfied that the information provided has really been understood.

Consent must be free, which means that the person concerned must not be subject to any constraints or pressure.

16. The right to respect for private life enshrined in Article 8 of the European Convention on Human Rights encompasses the principle of autonomy, in other words free and informed consent prior to any intervention on a person.

17. The principle of free and informed consent and the right to withdraw consent at any time are enshrined in Article 5 of the Convention on Human Rights and Biomedicine. Furthermore, Article 6 of this Convention sets out the provisions designed to ensure that vulnerable people who are those not able to consent, are protected.

18. More specifically and connected directly with end-of-life situations, Article 9 of the Convention on Human Rights and Biomedicine provides for the possibility of people expressing their wishes concerning the end of their lives in advance, in case they are no longer able to do so at the time, and the duty of doctors to take account of these wishes when assessing the situation (see paragraphs 45 to 51 below).

19. Any end of life situation will represent one of the highest degrees of vulnerability in a human's life and can have a profound impact on the patient's ability to exercise autonomy and give free and informed consent. Assessing the extent of patients' autonomy and hence their ability to be involved in decision-making is therefore one of the main issues in the end of life decision-making process. Inquiring into patients' desires or previously expressed wishes is an indispensable part of the decision-making process, particularly among patients whose functional capacities have declined to such an extent that their ability to take part in the process is restricted.

20. Autonomy should not, however, be confused with a right to absolute self-determination as health decisions are the result of a reconciliation between the will of the patient and a professional who is subject to obligations arising from the principles of beneficence and non-maleficence.

### **B. The principles of beneficence and non-maleficence**

21. The principles of beneficence and non-maleficence refer to the doctor's dual obligation to seek to maximise the potential benefit and to limit as much as possible any harm that might arise from an intervention. The balance between benefits and risks of harm is a key aspect of medical ethics. The potential harm may not only be physical but could also be psychological for example, or even take the form of an infringement of privacy.

22. On a normative level, these principles are reflected in the right to life enshrined in Article 2 of the European Convention on Human Rights and the right to protection from inhuman and degrading treatment established in its Article 3. They also form the basis

for the assertion of the primacy of the human being over the sole interest of society or science in Article 2 of the Convention on Human Rights and Biomedicine and, more precisely, the obligation to comply with professional obligations and standards laid down in Article 4 of this Convention.

23. More specifically, doctors should not dispense treatment which serves no purpose or is disproportionate in view of the risks and constraints it entails. In other words, they must provide patients with treatment that is proportionate and suited to their situation while showing due regard for professional standards and obligations. They also have a duty to relieve suffering and support their patients.

### **What is meant by the words “treatment” and “care”?**

24. Under the heading of care in its broadest sense a distinction can be made between treatment and care from a technical view point.

- **Treatment:** this covers interventions requiring medical skill and involving medical procedures, whose aim is to improve a patient's state of health by acting on the causes of the illness or condition. The goal of such treatment is to cure patients of an illness or to act on its causes in order to reduce its impact on the patient's health. Treatment also covers interventions which have no bearing on the aetiology of the main illness from which the patient is suffering but on the symptoms (for example analgesic treatment) or which are a response to a physiological deficiency connected with the patient's state of health (such as dialysis).
- **Care:** the purpose of care is to satisfy patients' everyday needs and it does not require any particular medical skill (for instance, improving personal hygiene and comfort).

25. It may be decided to withdraw or limit treatment which does not provide any benefit or has become disproportionate. Limitation of “treatment” can mean both progressively withdrawing it and reducing the doses administered so as to limit side effects and increase beneficial effects. Treatment of pain on the other hand must not be called into question.

26. It is also important to bear in mind that, while the question of limiting or withdrawing treatment can be raised in end-of-life situations, there should be no question of discontinuing “care”, as this is always necessary, embodying respect for the human person in medical practice. The same applies to the continuation of palliative care and treatment. In addition to its technical features, care includes attention paid by health professionals to any person made vulnerable by illness or by an infringement of physical integrity.

## **Disputed issues**

### **The question of artificial hydration and nutrition**

Food and drink given to patients who are still able to eat and drink themselves are external contributions meeting physiological needs, which should always be satisfied. They are essential elements of care.

Artificial “nutrition” and “hydration” are the response to a medical indication and imply choices concerning medical procedures and devices.

For this reason artificial nutrition and hydration are regarded in many countries as forms of treatment, which may therefore be limited or withdrawn. In some other countries, however, it is considered that they are not treatment but a form of care meeting the individual’s basic needs, which cannot therefore be withdrawn, at least if the patient is not in the terminal phase of an end of life situation.

### **What are the implications of the obligation to provide appropriate treatment?**

27. The implementation or continuation of any treatment requires a medical indication. However, other aspects must be taken into account when assessing whether a form of treatment is appropriate in view of the particular situation of the patient concerned. The issues that need to be addressed are as follows:

- the benefits, risks and drawbacks of medical treatment depending on the anticipated effects on the patient’s health;
- their appraisal in view of the expectations of the person concerned. This results in an assessment of the “overall benefit”, which takes account of the benefit in terms not only of the results of the treatment of the illness or the symptoms but also of the patient’s quality of life, psychological and spiritual well-being, etc.

28. In some cases, this appraisal leads to the conclusion that the treatment is disproportionate when the risks and/or the scale of the constraints and the resources required to implement it are compared with the anticipated benefits. In this case, the doctor is justified in not implementing it or withdrawing it. In English-speaking countries in particular, the treatment concerned in such cases is described as “futile”.

29. There is no obvious means that would apply to all individual situations, of measuring whether treatment is disproportionate. Even though there are medical criteria (from evidence-based medicine) to evaluate risks and benefits, which make it possible to assess whether treatment is proportionate, the suitability of treatment will always be assessed in the light of the patient’s situation as a whole. The answer to this question derives from the relationship of trust between doctors, carers and patients. In many cases, the disproportionate nature of treatment will tend to be defined according to the development of the illness and the patient’s reaction to the treatment, which will determine whether the medical indication needs to be called into question. In other circumstances, it is in the course of the discussion between doctors, carers and patients about the purpose and the expected benefits and potential risks of treatment that a possible disproportionality may emerge.

30. When, in a given situation, the treatment that is being contemplated or implemented will not yield or no longer yields any benefits, or is regarded as being clearly disproportionate, beginning or continuing to implement it can be described as “therapeutic obstinacy” (or unreasonable obstinacy). Doctors faced with such situations have a duty not to implement treatment or to withdraw it.

31. In end-of-life situations, assessing “overall benefit” has a key part to play in determining the suitability of treatment whose purpose may change (shifting from a curative to a palliative purpose for example). The prolonging of life must not in itself be the sole aim of medical practice, which should attempt just as much to relieve suffering. The difficulty of any medical decision at the end of life is that of ensuring that the patient’s dignity is respected and that the balance is struck between the protection of life and the person’s right to be relieved of suffering if possible.

### **C. The principle of equitable access to health care (the principle of justice)**

32. The right of equitable access to health care of appropriate quality is enshrined in Article 3 of the Convention on Human Rights and Biomedicine. The principle implies that available resources should be distributed fairly.

33. It is now generally accepted that palliative care is an integral part of health care, as asserted in Recommendation (2003) 24 of the Committee of Ministers of the Council of Europe to the member states on the organisation of palliative care. In this connection, it is therefore for governments to guarantee equitable access to palliative care for anyone who needs it.

34. The same Recommendation also points out that doctors are not required to continue treatment that clearly serves no purpose and is too stringent for the patient, and the patient may refuse such treatment. The aim of palliative care therefore is to provide the best possible quality of life for the patients. Patients must be offered both active care designed to control pain and other symptoms and provide the necessary psychological, social and spiritual support.

35. To meet the challenges posed by end-of-life situations, one of the priorities is most certainly to broaden access to palliative care regardless of how it is organised. Steps should be taken at least to foster a palliative approach within health care establishments so that everyone’s suffering can be dealt with satisfactorily without discrimination and that, over and above access to palliative care, respect is shown for human rights, especially each individual’s right to choose the place and the conditions of their end of life.

### **III – The parties involved in the decision-making process and their role**

36. The two main players in the process are the patient and the doctor. Other parties may be involved however, some to stand in for the patient where there are no clear previously expressed wishes, to pass on such wishes when they have been expressed or to support a patient who has become vulnerable, others to help frame the decision. It is important to clarify on what footing the various parties concerned will be involved in the decision-making process and define their respective roles in the various situations encountered in order to avoid sources of conflict.

#### **A. Patients, their representatives and their families**

##### **1. Patients**

###### **a. Patients capable of taking part in decision-making**

37. If patients are able to draw up a care plan with the doctor and the medical team, they take their decision on the basis of the information and guidance provided by the doctor in the context of the relationship of trust which they have built up, and on no account can there be any intervention without the patient's consent; doctors must accept clearly expressed refusals of treatment, but may suggest, where possible, that the patient takes time to think and/or consult other people.

38. Patients may themselves express the desire for other people to be consulted. Furthermore, in some especially complex situations, such as a request from the patient for a continuation or withdrawal of treatment which may have a negative impact on the quality of the final phase of life, it may be suggested that he or she should take other people's advice and, in particular, consult other health professionals before taking his or her decision.

39. Lastly, patients who are capable of deciding for themselves may wish nonetheless to be guided and supported in their decision and may ask on their own initiative for a collective procedure to be put into place for assistance in their decision.

40. At all events, it may seem appropriate to allow a time for patients to think matters through before taking their decision.

###### **b. Patients in respect of whom there is some doubt as to their ability to take part in decision-making: assessing their ability**

41. The patient's ability to participate in the decision-making process must be assessed. As far as possible, what patients say must be listened to and taken into account. Depending on the circumstances, however, the patient's state may call for the implementation of a system of decision-making by a third party (see below), which guarantees that the decision-making process will be a collective one with all the parties involved. There should be a written record of the assessment of the patient's ability to exercise his or her full autonomy.

## Review of the issues involved in:

### **Assessing the patient's autonomy**

There are four component parts of the power of discernment which need to be present for a patient to be deemed capable of discernment.

- **Ability to understand:** Patients must be able to understand information connected with the diagnosis and the related treatment and be capable of showing that they understand.
- **Ability to appraise:** Patients must be able to appraise the situation in which they find themselves, recognise the problem and evaluate the consequences of treatment in their own situation in relation to their own scale of values or view of things.
- **Ability to reason:** Patients must be able to reason, compare options and weigh up their risks and benefits. This skill depends on the ability to absorb, analyse and handle information rationally.
- **Ability to state and stand by a choice:** patients must be able to express their desires, state a choice and stand by it. They must be able to communicate their decision freely and resist any pressure brought to bear on them by outsiders.

42. Even where patients do not seem capable of expressing free and informed wishes, it is necessary to view them as persons in the fullest sense, who are capable of partly perceiving or understanding what is said to them. It is recommended therefore to spell out as clearly as possible to them what the issues and the potential courses of action are. Any opinions that they may communicate and the expressions and reactions they may have at this point should be taken into account and guide the decision to be taken as much as possible.

### **c. Patients who cannot or can no longer participate in the decision-making process**

43. Where patients cannot or can no longer take part in the decision-making process (due to a coma, brain damage or an advanced-stage degenerative disease, etc.), the decision will be taken by a third party according to the procedures laid down in the relevant legislation and under conditions offering guarantees of objectivity, taking account of the benefit for the patient and respect for his or her dignity. Such situations call for a collective decision-making process.

44. The patients' wishes will be incorporated into the process through advance directives, surrogates, etc. (see sections below on legal representatives, surrogates, family and relatives).

### **Previously expressed wishes**

45. Although unable to express their wishes concerning the arrangements for the end of their lives at the time that the decision must be taken, patients can be involved in the decision-making process nonetheless by means of their previously expressed and formally stated wishes. This expression of the patient's wishes in advance can take various forms including advance directives, a living will or a power of attorney. The

patient may also have confided his or her intentions to a surrogate, appointed as such so that he or she can bear witness to the patient's wishes. A formal written statement of the patient's wishes is undoubtedly the most reliable form. Otherwise, the surrogate designated by the patient can state what the patient's wishes would be (see below).

46. Whatever form they take, previously expressed wishes can help patients to take part in the decision-making process regarding medical treatment in end-of-life situations "without being present". As a result it is important that, however legally binding they are, such arrangements are brought to the notice of any user of the health system.

### **Review of the issue of:**

#### **Previously expressed wishes**

*Formal statements* (or "advance directives", which are sometimes referred to as "living wills") are written documents drawn up by competent persons (who have attained majority and possess legal capacity) containing provisions relating to medical treatment in the event these persons are no longer in a position to take a decision.

*Powers of attorney on health-care questions* ("procuration" in French) enable persons known as granters to appoint persons known as attorneys to express on their behalf their wishes concerning the medical treatment to be given to them if they are no longer capable of taking part in the relevant decision. In French, these powers are sometimes referred to as "*mandat de protection future*" ("powers of future protection"). Any suitable person may be appointed including a family doctor, a family member, a relative or a surrogate, etc. He or she may also clarify ambiguous provisions of formal statements or provide clarification concerning other situations not mentioned in them or arising as the illness progresses. Attorneys must always act in accordance with their powers and in the granter's interest.

47. Written **advance directives** are probably the method that most directly reflects patients' wishes. Accordingly, they should take precedence over any other non-medical opinion expressed (by a surrogate, a family member or a relative, etc.) during the decision-making process.

48. Bearing in mind their importance in the decision-making process as a means of ensuring that the patient's wishes are carried out, special attention should be paid to directives when organising the health system and asserting patients' rights:

- the persons concerned should be systematically provided with information about the fact that the possibility of drawing up such directives exists, the requirements for them to be valid and their scope;
- provision should be made for health professionals to help citizens to draw up such documents to ensure that they are effective;
- appropriate measures should be taken as regards storage of and access to advance directives (for example by including them in medical records or creating a register).

49. The attention of health professionals, particularly doctors, should be brought to this tool for dialogue with the patient. When drawn up in advance and with the assistance of a doctor, they make it possible to anticipate the decisions to be made, bearing in mind the evolution of the illness and the various options which will arise. Their value, both for patients and for doctors, is obvious in certain chronic and degenerative illnesses.

50. Under Article 9 of the Convention on Human Rights and Biomedicine, doctors must always "take into account" previously expressed wishes and this implies that they have a duty to seek out any that exist once the decision-making process begins. In some legal systems, advance directives are legally binding, meaning that doctors are obliged to comply with them. In others, they do not have any binding force and are considered only as indicators of the person's wishes which doctors "take into account" in this light, without being bound by them; they retain some discretion in the light of the actual situation and the potential advances in medical knowledge by the time the decision must be taken.

51. Regardless, moreover, of the applicable legal system, in order to be taken into account and be effective, advance directives must meet certain conditions in order to be valid (means of authenticating the author, legal capacity of the author, precise content, etc.). Another question that needs to be resolved is the length of their validity and the arrangements for them to be redrafted so that they can be kept as closely in line as possible with current developments. Lastly, they must be made accessible to doctors in good time, which requires some thought to be given to the way in which they are kept (see box).

**Disputed issues**

**Advance directives and their weight in the decision-making process**

**I – The legal status of advance directives varies considerably according to each countries' relevant statutory provisions.**

In the framework of the Council of Europe, the Convention on Human Rights and Biomedicine requires doctors to "take [them] into account" and states have the choice whether or not to give them binding force. The Committee of Ministers attaches major importance to them and in Recommendation (2009)<sup>11</sup> on principles concerning continuing powers of attorney and advance directives for incapacity, it recommends that member States "promote self-determination for capable adults in the event of their future incapacity, by means of continuing powers of attorney and advance directives". It also states that "States should decide to what extent advance directives should have binding effect" and points out that "advance directives which do not have binding effect should be treated as statements of wishes to be given due respect".

In the debate on the extent to which advance directives should be binding, some argue that giving them binding force places all the responsibility for the decision on the patient whereas under arrangements in which they are not binding, doctors retain some discretion and assume responsibility for the decision. Others argue that advance directives reflect the will of the person at the time that they are written and cannot anticipate how this may change as the illness develops – changes of mind of this sort are seen in people who are still capable of expressing their views.

**II – Other aspects of the debate on advance directives**

• **Limits and contents of advance directives**

Can advance directives relate to a request to limit or cease treatment in certain predetermined situations or should they relate only to choices of types of treatment to be implemented? Besides treatment, should they address other questions relating to the organisation of care and the patient's living conditions? More generally, must they be specific and precise, or general in scope? Both propositions have pitfalls: if they are too precise, they leave no room for any medical interpretation with a view to adaptation, whereas if they are too general, they make it

impossible to be certain that the wish expressed will have anything to do with the situation. Advance directives may, however, only relate to possibilities authorised by the law.

- **Length of validity and periodic renewal**

Depending on the patient's condition, the answers may differ on this point. Periodic renewal of directives and limits on their validity make it possible to keep up with practical developments. However, with neurodegenerative diseases, it must be possible to refer to wishes expressed well in advance, before the patient's mental condition deteriorates to the point that valid restatement of his/her wishes becomes impossible. At all events, everyone accepts that it should be possible to revoke advance directives.

- **Assessment of the capacity or "incompetence" of the patient**

- **When advance directives are drawn up**

If they are drawn up out of context and in the abstract, when the person is still in possession of all his/her faculties, what is their value? If, however, they are drawn up while the patient is in a position to grasp the consequences of his/her illness but his/her faculties may already be affected by it, what is their value?

The situations that have to be catered for are extremely varied. They include chronic illnesses in which the illness can be apprehended at each stage, accidents with unforeseeable circumstances, neurodegenerative diseases affecting cognitive faculties in a fluctuating manner over time and mental illnesses such as severe depression, which affect patients' will, etc.

- **When the advance directive is consulted and implemented**

Patients are not always unconscious. Their will may simply be impaired by the illness. Should advance directives take precedence over direct expressions of will which may be impaired? Should they be consulted in order to complement other views? Who is to assess their relevance and according to what criteria: the doctor, the judge, or a board?

- **The need for formalism**

The need for a written document seems to be widely acknowledged. Furthermore, the more binding advance directives are considered to be, the stricter the formal requirements become, including formalities such as validation by the doctor (attesting to the patient's mental state and the reliability of the instructions) and countersignature by two witnesses. Another issue is the arrangements for keeping the document. Should it be kept by the patient or entrusted to the doctor in attendance, the hospital authorities, a legal professional (such as a solicitor) or the patient's surrogate, and should it be recorded in a national register?

Therefore, from a formal viewpoint, either advance directives are seen as a clinical tool, stemming from the doctor-patient relationship and contributing to a decision-making process which shows respect for patients, or they are viewed as an "administrative" document which, provided the validity criteria are met, is binding on the doctor. Between these two schematic viewpoints, there is a whole range of intermediate situations. Advance directives might be regarded as an instrument conducive to dialogue between the patient and the doctor or the medical team; this would make them a substantial contributing factor to the framing of the decision in the context of the collective discussion process.

Although advance directives seem to be an obvious means of allowing patients to be given their place in the end of life decision-making process and creating a link between doctor and patient, they encounter a major pitfall in the difficulty for all individuals to imagine their future life as a patient, and their dependence and their death, and hence to anticipate this situation lucidly and pertinently.

## **2. Legal representatives**

52. When the patient is an adult benefiting from legal protection who is recognised as not being able to consent, or is a minor, he or she is generally supported by a legal representative, whose nature (person, institution, authority) and role are determined by national law.

53. In some legal systems, legal representatives have a decision-making role. Authorisation to carry out an intervention on a legally protected patient is given for example by a judge or by a designated representative. Sometimes, the legal representative is a member of the family (e.g. spouse, child's parents).

54. Whatever the legal system, in accordance with the principle of respect for the patient's dignity, if the patient, despite lacking legal capacity, is able to participate him/herself in the decision-making process, the presence of a legal representative should not exempt the doctor from involving the patient in the decision relating to him or her. The legal representative's place in the decision-making process will also have to be defined vis-à-vis the surrogate or the attorney, if they are different.

## **3. Attorneys**

55. It has been possible to entrust the patient's previously expressed wishes to a third party under a power of attorney. The attorney acts on behalf of the patient in accordance with the powers assigned to him or her.

## **4. Surrogates**

56. The definition of a "surrogate" may vary according to national legislation. However, surrogates must be differentiated from legal representatives and attorneys. Indeed, a priori, they do not speak "on the patient's behalf", but help and support the patient when he/she is still able to participate in the decision-making process, or bear witness to what his/her wishes would be as from the moment that the latter no longer has the capacity to express him or herself. Surrogates may also be entrusted with advance directives. The surrogate's role may therefore vary depending on the situation and the relevant legislation. This role in the decision-making process will have to be defined in relation to that of legal representatives, attorneys or relatives and family. Surrogates may of course be selected from among legal representatives or family members and this makes it all the more important to clarify their role.

## **5. Family, relatives and voluntary or other support providers**

57. With respect more specifically to the family, attention should be paid to the place which should be given to it, not only in the social sphere in certain countries but also from a legal viewpoint (e.g. a child's parents are his or her legal representatives, or the spouse may be the guardian of the other member of the couple). The place of the family and relatives may also vary depending on the place where the patient is cared for (e.g. at home). Even where they have no legally-defined role in the decision-making process, consultation with family and relatives, albeit subject in principle to the patient's consent, is especially important in view of their emotional ties and intimacy with the patient.

58. As to the various other support providers (such as members of associations), in principle, over and above the support that they provide to the person, these parties, who are not members of the group providing care, even in the broad sense, do not intervene in the collective decision-making process. However, these different support providers may possess information (on existing advance directives, on the patient's wishes, about his/her living environment, etc.). As such, they may be considered as witnesses to the patient's wishes or as a source of information and it is certainly useful and sometimes essential to consult them. Their presence often makes it possible to offer patients human or even spiritual support, which should not be neglected at this moment in their lives.

### **B. Carers**

#### **1. The doctor**

59. Doctors have the necessary knowledge to appraise the patient's situation from a medical viewpoint. They have a major, not to say prime, role in the decision-making process. They provide patients with the necessary information and, where the patient is capable of expressing free and informed wishes, they can help him or her to take decisions. Where patients are not able to express their wishes, doctors are the persons who, ultimately, at the end of the collective decision-making process, will take the final decision, having taken note of all the determining arguments arising from the collective process. They are the ones to ensure that the decision-making process is properly conducted and, in particular, that any wishes expressed previously by the patient are taken into account and any disproportionate treatment is avoided.

**2. The healthcare team** and, more generally the team taking care of the patient (including, for example, nurses, carers and, where appropriate, paramedical professions such as physiotherapists, psychologists, etc.).

60. Its role in the decision-making process may vary according to the country. In any case, these elements must be determined in the framework of the decision-making process. These professionals, who take care of the patient on a daily basis and are often close to him or her, contribute not only medical information but also crucial details concerning patients to the decision-making process, such as information on their environment, their background and their beliefs.

## **IV - The decision-making process**

61. For the purposes of the discussion, this chapter takes the highly schematic approach of identifying a number of phases, taking into account the nature and aims of the activities being carried out, the parties involved and the location in which the end of life situation occurs (home, hospital or elsewhere).

62. This succession of phases does not necessarily represent a chronological sequence, which it is absolutely essential to follow. The main point is to make it possible to identify the key components of the decision-making process while also taking account of the time constraints that can exist in some specific clinical situations.

NB: The subject of this section is the decision-making process. As pointed out at the beginning of the document, the aim is not to discuss the content, the relevance or the legitimacy of the decision which will ultimately be taken in a given clinical situation.

### **A. Preliminary remarks**

63. Before looking at the various phases of the decision-making process in detail, we should reiterate the following points:

64. **The patient should always be the focus of any decision-making process.** This holds true whatever the patient's legal capacity or his or her *de facto* ability to take the decision or participate in it. In principle, patients are the parties who must decide on and make choices concerning the end of their lives. Their direct involvement may vary, however, depending on their personal situation, which can be affected to varying degrees by their state of health, in which case the decision-making process can be adjusted accordingly.

65. **The decision-making process takes on a collective dimension when the patient is not willing or able to participate in it directly.** Where patients cannot or are no longer able to take part in the decision-making process or express the need to be assisted in the process themselves, a collective decision-making process:

- provides safeguards when the decision is taken by a third party;
- is suited to the situations and complex choices to which an end of life situation gives rise.

66. **In principle, the collective decision-making process in end-of-life situations is made up of three main stages:**

- an **individual** stage, in which each party to the process constructs his or her argument;
- a **collective** stage, involving exchange and discussion between the various parties, providing different perspectives and complementary viewpoints;
- a **concluding** stage, when the actual decision is taken.

67. **Patients and, where appropriate, any other people concerned, must always have access to the information corresponding to their role in the decision-making process.** Unless they specify otherwise, patients must always be given the requisite information on their state of health (diagnosis, prognosis), the therapeutic indications and possible types of medical provision. Where appropriate, their representatives,

attorneys and surrogates or even their family and relatives must be given the information appropriate to their role in the decision-making process.

### **B. Different phases of the decision-making processes in end-of-life situations: description and analysis**

#### **1. The starting point of the process**

68. The starting point of the process is the same as for any other situation requiring a medical decision on therapeutic options and is based on general principles of good clinical practice. This approach requires a medical indication to be defined and a balance to be struck between the risks and benefits of the treatment concerned. Irrespective of the curative or palliative nature of the care plan, it is essential therefore to assess regularly whether:

- any treatment already set up or planned meets the requirement of being of benefit to the patient (for example, relieving or reducing suffering) and not harming him or her (for example, prolonging the process of dying);
- any comment or complaint made by the patient, his or her representative or surrogate, a family member or another person providing support raises questions about the care plan set up;
- any of the members of the healthcare team has doubts about the therapeutic approach adopted or planned in view of the patient's specific situation.

#### **2. Definition of the problem**

69. In order to weigh up the benefits of and possible problems raised by a given type of treatment, it can be useful in some cases to see whether any of the care team or the patient (or his or her surrogate, family or any other person who is close to him or her) have any concerns about the care and/or the support being provided. If this is the case, it is important to clarify the underlying questions, to determine where the problem lies and to elucidate the reasons in the patient's particular situation.

70. Questions can relate to any of the following matters:

- the appropriateness of the implementation or continuation or, conversely, the limitation or withdrawal of treatment which is likely to have an impact on the quality of the patient's life in its very last phase or on the process of dying;
- the meaning of a complaint or request (for example, pain-related complaints or requests for pain relief);
- differing opinions among the parties concerned about quality of life, the need to control certain symptoms or other matters.

#### **3. Developing a line of argument**

71. This phase is important in the framework of a collective process where the patient cannot take part in the decision or has requested help with it. In principle, the doctor and the healthcare team in a broad sense intervene in the decision-making process and, where appropriate, the patient's legal representative. Previously expressed wishes (such as advance directives and powers of attorney) are of course sought out and taken into account. Family members, relatives and other support providers are consulted, unless a prior objection has been expressed by the patient.

### **a. Establishing an individual line of argument**

72. Each party must be aware of his/her role and in which capacity he/she intervenes in the process. Every professional involved in this process takes responsibility for his/her actions.

73. Each party must analyse his/her motivations (in the light of his/her professional practice) and try to bear in mind that some of his/her reasoning may be subjective (deriving from personal experience, ideas and outlooks) as well as being influenced by his/her personal points of reference (ethical, philosophical, religious, etc.).

74. Each party must base his/her arguments on factual elements when analysing the issues. The factual elements of the argument are to be sought at a minimum of three levels concerning:

- the disease and medical condition: diagnosis, prognosis, emergency, treatment plan, possibility of improvement, etc.;
- the patient's situation: assessment of his/her capacity to participate in the decision-making process; his/her legal status; sources of information about his/her wishes; his/her quality of life and personal points of reference; the people/environment around him/her; his/her living conditions;
- health care provision, what kind of care the health care system can provide.

### **b. Collective discussion**

75. While there can be no standard model since arrangements vary, in particular according to the location of care (hospital or home), the following steps are recommended prior to discussion:

- defining the practical arrangements for the discussion (venue, number of participants, number of meetings planned, etc.);
- setting a time frame while catering for an emergency response where necessary;
- choosing who will take part in the discussion, specifying their role and obligations (decision-maker, rapporteur, minute-taker, coordinator/moderator, etc.).
- drawing the attention of all the participants to the fact that they must be prepared to change their mind when they have heard the views of the other people taking part in the discussion. In addition, everyone must be aware that the final view or opinion will not necessarily be in accordance with his or her own.

N.B. While there is no obvious scale of values among the various opinions expressed, the nature of the arguments will lead to a hierarchical order facilitating the decision making.

76. Sometimes, where positions diverge significantly or the question is highly complex or specific, there may be a need to make provision to consult third parties (for example ethics committee, consultant, ombudsperson) either to contribute to the debate, to overcome a problem or to resolve a conflict. At the end of the collective discussion, agreement must be reached. This agreement is often found where the different opinions intersect. A conclusion or an opinion must be validated collectively and formalised in writing.

#### 4. Taking a decision

77. In all cases, prior identification of the person who takes the decision is necessary.

78. If the person deciding is the patient who, despite being able to take an autonomous decision, has nevertheless expressed the wish for a collective discussion:

- the conclusions of this collective discussion must be presented to him or her in accordance with ethical and deontological principles and showing tact and restraint;
- patients must be allowed enough time to reach a decision.

NB: These factors are also relevant if the decision is taken by the legal representative or the patient's attorney.

79. If the decision is taken by the doctor in charge of the patient, it is taken on the basis of the conclusions of the collective discussion and will be announced:

- to the patient in accordance with ethical and deontological principles;
- to the surrogate and/or family and friends if the patient has so requested or is not able to express his/her will;
- to the medical team that took part in the discussion and cares for the patient;
- to third parties concerned who have taken part in the process in any capacity.

80. Once reached, the decision must be:

- formalised (a written summary of the justifications agreed);
- kept in an identified place;
- easily accessible (patient's medical records, elsewhere).

At all events, data kept in this way are covered by medical confidentiality.

NB: The effect of the decision will need to be anticipated by considering in particular what additional measures to take in case the decision taken has an unexpected result.

#### **Disputed issues**

##### **Decision on sedation for distress in the terminal phase**

Sedation seeks, by means of medication, to reduce awareness to a degree which may extend to loss of consciousness. Its aim is to alleviate or remove the patient's perception of an unbearable situation when every available treatment adapted to this situation has been offered and/or dispensed but has failed to bring the expected relief.

One effect of sedation, over and above the expected relief of suffering, can be to shorten the time left to live.

For some, this result in itself poses a problem, particularly if the person cannot participate in the decision-making process (for example, some people with brain damage).

For others, the decision is acceptable provided that the main intention is not to hasten the onset of the end of life but to relieve suffering.

#### 5. Evaluation of the decision-making process after application

81. Ex-post evaluation is one of the general principles of good practice. Evaluation of the decision-making process and the way it took place is particularly important in that it allows the medical team, based on its experience, to progress and better respond to similar situations.

82. For this purpose, keeping a concise yet accurate written record of the way in which the decision-making process was conducted in the case in question may be very useful to the team concerned. The aim is not, of course, to establish an instrument to monitor decision-making retrospectively. However, it is important for every party involved to be able to read and analyse the various arguments exchanged during the decision-making process, together with the terms of the agreement reached within the medical team at the end of the discussion and, broadly speaking, how the decision was arrived at. This ex-post review of the implementation of the decision-making process should enable all of the parties involved and the team as a whole to understand on what basis the medical decision was taken and what the contentious issues were and to enhance its own understanding of such situations in the future.

### **V - Conclusions**

83. Paying particular attention to the decision-making process regarding medical treatment at the end of life is a form of quality procedure, the main aim of which is to guarantee respect for patients made vulnerable by their serious illness.

84. In this context, it is essential to promote any measure that makes it possible to adhere as closely as possible to the patient's wishes, such as advance directives.

85. The collective discussion process relates to the complex clinical situations in which patients find themselves at the end of life. In such situations, in which many ethical issues are raised, there is a need to discuss and compare arguments to enrich the response and formulate a decision that is geared to the situation and shows due respect for the patient.

86. The above-mentioned Recommendation (2003) 24 on the organisation of palliative care alerts states to the need to provide information and training, and conduct research. These requirements should also be applied to all other issues relating to the end of life.

87. The decision-making process should in itself be the subject of:

- **information** for users of the health system, including their representatives from associations and their families. This information should relate to the tools enabling or facilitating dialogue between patients and doctors such as advance directives, the appointment of a surrogate and to everyone's place and responsibility in the discussion process surrounding end of life decisions;
- **training** for health professionals. In addition to specific end of life-related questions, training in the construction of individual thought processes and collective discussion is necessary so that each health professional can deal with the increasing frequency of complex situations involving ethical issues in

clinical practice. In both initial and in-service training contexts, the focus should be on the importance of learning such collective processes.

88. In addition, **research** in the end of life field should be encouraged. The complexity and singularity of the situations encountered, which are often the result of advances in medicine and medical techniques, are so marked that they should be the subject of specific research programmes. This research, particularly research on decision-making processes, should favour interdisciplinary approaches combining human sciences and medicine.

The purpose of this guide is to serve as a useful tool for public information and professional training. It is aimed at health professionals, patients, their families, and all those who face problematic decisions with regard to medical treatment in end-of-life situations, and provides help for the development of practices. The guide is also a source of material for any discussion held within our societies on the decision-making process regarding medical treatment in end-of-life situations in that it proposes benchmarks relating both to the practices and the principles that can be applied in this context.