

# ITALIAN NATIONAL BIOETHICS COMMITTEE

## ADVANCED TREATMENT STATEMENTS

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## *1. Introduction.*

This document concerns advance treatment directives, the importance of which has grown constantly in recent years and which are frequently referred to in the national and international literature on bioethics with the expression *living will*. Other expressions used include biological will, life will, prior treatment wishes, etc. These expressions all refer to a document through which individuals, in full possession of their mental faculties, express their wishes regarding the treatments that they would or would not want to undergo to in the event that, in the course of an illness or as a result of sudden trauma, they were no longer able to express their informed consent or dissent. The different forms that an advance treatment directive can take (some of which have been legally recognised in a number of countries) have been discussed in the literature.

To give these documents public (although not necessarily legal) status, they are required to be drawn up in writing in such a way that there can be no doubt as to the identity and capacity of the person signing them, their authenticity and the date of signing. They should if possible be countersigned by a physician, who should guarantee that the signer has been fully informed of the possible consequences of the decisions he is taking in the document. It is desirable for the signer to indicate a date for the confirmation and/or renewal of the directive, without prejudice to their right at any time to withdraw or amend the instructions it contains. The person drawing up these documents is considered to be responsible for establishing the arrangements for their safe-keeping and the number of authentic copies to be produced, and for selecting the persons to whom the documents should be entrusted for safe keeping and who, if and when the needed arises, should present and use them. For those who so request, lawmakers should establish a procedure for these documents to be deposited and/or registered with a public institution. Signers should also establish, in the event that these documents are actually used, whether their content can be made public.

## *2. Reference texts*

The Italian National Bioethics Committee (NBC) has not previously devoted any single document specifically to the question of living wills.

However, useful reference material can be found in previous documents produced by the Committee on related subjects, for example in the document *Information and Consent to Medical Procedures*. Of particular relevance is the third chapter of the document entitled *Bioethical Questions on the End of Human Life*, approved by the NBC on 14 July 1995. This will be referred to in the present document, for example to identify which points it will be examining in greater detail in the light of the most recent thinking in bioethics and significant new developments in the bio-legal field.

Of these, particularly worthy of mention is the European Union's *Charter of Fundamental Rights*, which establishes that the patient's free and informed consent to medical procedures must no longer be seen merely as a requirement for the treatment to be considered lawful, but should be considered first and foremost as an actual *fundamental right of European citizens*, pertaining to the more general *right to the integrity of the person* (Chapter I *Dignity*, Article 3 *Right to the integrity of the person*). With specific regard to the issue under consideration, it should be borne in mind that the Italian Parliament has ratified the *Convention on Human Rights and Biomedicine* (through Law 145 of 28 March 2001), which was signed in Oviedo on 4 April 1997. Underscoring the centrality of the protection of the dignity and identity of all human beings, Article 9 of the Convention attributes particular significance to the patient's *previously expressed wishes*, and establishes that these shall be *taken into account*.<sup>(1)</sup>.

It can also be observed that even before approving the law ratifying the Convention, the principle expressed by Article 9 had already been espoused in Italy, in 1998, by the *Italian Code of Medical Ethics*. Article 3 of the Code, under the heading *Autonomy of the Citizen*, establishes that: "Physicians are required to follow, in full respect for the principles of dignity, freedom and professional independence, the wishes freely expressed by individuals regarding their treatment. If patients are not able to express their preferences in cases where their lives are in grave danger, the physician must take into account the wishes previously expressed by patients". It should also be borne in mind that this code of ethics states, at Article 36, that "the physician, including at the patient's request, must not carry out or facilitate treatment intended to cause the patient's death" and at Article 35 entitles the physician to take action in

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<sup>1</sup>) 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. In the French version: Les souhaits précédemment exprimés au sujet d'une intervention médicale par un patient qui, au moment de l'intervention, n'est pas en état d'exprimer sa volonté seront pris en compte.

the form of assistance and indispensable treatment in emergency situations and in cases where the patient's life is in danger ("in the event of an emergency or of danger to the life of the person, who is unable at that time to express his or her wishes to the contrary, the physician must provide assistance and any indispensable treatment"). It follows that for the National Federation for the Orders of Physicians and Dentists (FNOMCeO), any previous expression of the patient's wishes will be applied to the case at hand.

### 3. *Advance directives in the light of Article 9 of the Convention on Human Rights and Biomedicine.*

The social issue that has prompted the need to engage in an in-depth discussion not just of the bioethical aspects but also of the *bio-legal* aspects of advance directives to the top of the agenda is, therefore, the need to fully and consistently implement the spirit of the *Convention on Human Rights and Biomedicine*. In doing so, we also need to ensure that the dignity and integrity of the individual is accorded the maximum protection possible in all situations where the increased opportunities created by advances in medicine might give rise to doubts, not just of a scientific but above all of an ethical nature, on the type of treatment to be adopted in the presence of reliable declarations of intent formulated by the patient before losing their natural capacity to express their desires. With the intention of respecting the provisions of the Convention as faithfully as possible, the NBC has decided to adopt the expression *advance treatment directives* in the present document to indicate the various forms of self-determination that might derive from a deed that is compatible with the ethical and legal model expressed by Article 9 of the Convention.

As the NBC has stated previously, the "fullest possible participation by citizens in decisions that concern them" applies throughout the entire treatment process and is especially necessary when the patient might be deprived of their cognitive faculties and even of consciousness, and thus be completely dependent on the will of others. Such situations are particularly dramatic when the action might put the patient's life or quality of life at risk. Advance treatment directives tend to foster the "socialisation" of the most dramatic moments of our existence and to avoid situations where the incapacity of a patient might lead physicians to consider that individual, perhaps unconsciously and against their best intentions, no longer as a person with whom the best possible treatment programme can be discussed and agreed upon, but merely as a body to be subjected to anonymous treatment. For this purpose it would be advisable to provide physicians, healthcare personnel and patient's relatives with information to help them make decisions that, where possible, are in keeping with the wishes and preferences of the person to be treated. It can therefore be said - as the NBC observed in its document on the end of human life - that the various forms of advance directive "are part of a positive process of adapting our concept of medical procedures to the principles of decision-making autonomy on the part of the patient".

In actual fact, advance directives cannot be considered merely as an extension of the society that has introduced the informed consent model to the physician-patient relationship; they also have the much more sensitive and complex task of making it possible to establish a *personal* relationship between the physician and the patient in those extreme situations where it does not seem that any link might exist between the solitude of the person who is unable to communicate and the solitude of the person who has to take the decision. The fundamental aim of the directives is therefore to provide an instrument that can be used to recover as fully as possible, in situations where the patient is incapable of making decisions, the role that is ordinarily played by the informed dialogue between the patient and physician. This dialogue enables the former, through a process whose outcome is an expression of consent (or dissent), to acquaint the physician with all information judged to be significant for the purpose of ensuring that the rights connected with the protection of health and, more in general, the overall good of the individual, are respected.

In a sense, such advance directives make it possible for the physician-patient dialogue to continue even when the patient is no longer able to take part consciously. In saying this, the NBC also means to emphasise that while the assessment task that the physician and medical personnel have to perform as a result of advance directives is made all the more complex by the fact that it is impossible to interact with the patient, this same task also enhances their professional autonomy (including the humanistic dimension). It also seeks to emphasise that advance directives should not in any way be seen as a practice that can lead to or facilitate "therapeutic abandonment", even indirectly: indeed, the instructions provided by the patient, even when expressed (as is to some extent inevitable) in a general and standardised form, should never be applied bureaucratically and obtusely but always need to be inserted into the specific circumstances of each individual patient and his or her actual clinical situation.

One final consideration on this point is that although advance directives raise numerous and complex bioethical questions, from the ethical point of view they do not give rise to any fundamental objections of principle, even though different ethical theories may well have formulated different reasons and grounds in support of their respective positions. The literature subsequent to 1995 has not brought any new developments on this point, and the NBC concurs in confirming the topical relevance of the opinion set forth in its 1995 document.

Against this consensus in principle, it is however possible, as we have just mentioned, to advance a number of doubts and reservations with respect to the structure and conditions of implementation of advance directives, which inevitably come to assume a significant, but diverse, ethical relevance. Without claiming to cover the entire range of problems that have emerged in a debate that has been running for over thirty years, in this document we examine four themes that need to be analysed if an acceptable procedure is to be introduced. These can be summed up as follows:

- A) How can we avoid the "abstract" nature of advance directives and the inevitable "ambiguities" arising from the language in which they are formulated, especially when the patient does not seek the help of a physician or other expert when preparing them?
- B) What operational instructions need to be included in these documents?
- C) How reliable should these documents be deemed to be? How binding should they be on physicians, from the ethical and legal points of view?
- D) What instruments should be used to implement advance directives, should this be deemed desirable?

#### *4. Abstraction and ambiguity in advance directives.*

One of the most frequent objections to advance directives or similar documents concerns their inevitably abstract nature. This abstract and generic quality is a consequence of the psychological and temporal distance between the situation in which the declaration is drawn up and the situation of actual illness in which it has to be applied. The grounds for this objection are stronger if we consider that in many respects it might actually be desirable for advance directives to be drafted at a time when the person is not only in full possession of their decision-making faculties but also in good health and free from the stress caused by the onset of illness and/or admission to hospital. In this way, the decision to draw up (or not to draw up) an advance directive - which is obviously not considered merely as a bureaucratic act - can provide an important opportunity for reflection on the individual's own values and view of life and on the meaning of death as a sign of human finiteness, and thus help to avoid the "repression of death" that many stigmatise as one of the negative features of our era and culture.

However, even if it is clearly not possible to establish in abstract terms the best time to draft an advance directive, concerns over the abstract nature of these documents prompted by this distance in time and circumstances can be mitigated if it is envisaged that the person may at any time withdraw their previous wishes or amend them in response to changes in the way they perceive their personal circumstances as a result of their actual experience of illness. In this latter case - and independently of previous drafts - advance directives might usefully take the form known as "advanced healthcare planning" or "advanced treatment planning". Hard questions regarding therapy and treatment decisions can undoubtedly be, if not resolved, then at least facilitated by this type of document, if they are formulated during the early stages of the illness and applied specifically to certain slowly developing conditions (AIDS, Alzheimer's, cancer). The typical progress of these conditions is sufficiently well known and, on the basis of current medical knowledge, there are a range of diagnostic-therapeutic options available for them, none of which prevails in absolute terms over the others, but each has its own specific benefits and related burdens. The overall effects of each treatment therefore need to be weighed up, a task which, at least in the first instance, should be the responsibility of the patient himself.

It is clear that while a carefully considered and informed drafting of advance directives can significantly reduce their abstract nature, it is not however possible to eliminate this in full. This is just one (but certainly not the only) decisive argument against viewing advance directives as rigidly binding instruments, since, even if drafted with extreme care, they could in the event fail to match the patient's actual condition closely enough.

### *5. The proxy*

Another objection that is often raised in the debate on advance directives concerns their language and scope. Since, commentators observe, it is difficult for patients to correctly define the clinical situations to which they intend their declarations to apply, this situation can give rise to ambiguity in their instructions and, as a result, to doubts when the time comes to follow them. This objection touches on a particularly thorny question and, if it is taken to its extreme conclusion - that is, if it is used to argue that advance directives should only be acceptable if the language in which they are drafted is absolutely precise or the person drafting them is fully capable of predicting the details of the situation in question - would in itself deprive the directives of any bioethical and above all practical value. However, this would be an overly drastic conclusion, which if applied,

by analogy, to the major ethical issues of information and consent, could empty them of all meaning. And no one should forget Aristotle's advice to the effect that we should never search for a greater degree of precision than that which the nature of the subject admits.

Another serious problem, which is very similar to but does not fully overlap with the former, is that of the actual form that the physician's decision on treatment would have once a patient's directives had been observed. If this were to consist of a cold and formal decision to follow the wishes expressed in the declarations to the letter, an automatic mechanism would be created which, since there is no dialogue, would weaken, if not entirely undermine, the ethical and medical-therapeutic value of the medical procedures while exacerbating their bureaucratic nature.

The strategy adopted to resolve these difficulties has been for the drafter of the advance directive to appoint a proxy or agent. This figure is included in many of the model directives proposed in Italy and abroad, some of which have already been legally recognised in a number of countries. In the United States in particular, the proxy mandate (Durable Power of Attorney for Health Care in the State of California; Health Care Representative in the State of Oregon; Patient Advocate for Health Care in the State of Michigan) is the cornerstone of these documents, while the directives themselves are formulated in terms of limits placed by the patient on the action of their proxy or agent.

A large variety of responsibilities can be attributed to the proxy, but all of them are linked to the very general task of acting, always and solely in accordance with the legitimate intentions expressed by the patient in their advance directive, to make these wishes and intentions known and to carry them out. The physician should inform the proxy of the therapeutic strategies that he intends to adopt for the patient, and demonstrate that these are compatible with the patient's advance directive or - if applicable - properly justify why he considers it to be his *duty* (and not merely *opportune*) to depart from them. One of the principal tasks of the proxy is to guard against the very real possibility of the patient, especially if terminally ill, being abandoned by the physicians and health structures regardless - obviously - of whether abandonment has been specifically mentioned in the directives.

In this framework, the role of the proxy appears to be much fuller than that of power of attorney and fairly close to the role that family members already play, or should play, in these situations. The essential

difference here is that - in the light of the explicit mandate contained in the advance directive - the proxy has a full right-duty to act as the physician's point of reference with respect to the treatments applied to the patient. In short, the task of the proxy is to comprehensively protect patients (starting with the directives they have drawn up) rather than simply overseeing the correct and formal execution of the procedure through which the directives are expressed (naturally, however, there should not be any difficulty in principle in reconciling these two commitments).

Of course, the figure of the proxy can create subtle problems, which must be pointed out. To start with, the proxy appears to be modelled on the legislative paradigm currently used to govern the protection of rights and interests of legally incapacitated adults. This reference is, however, both unsatisfactory and inadequate since the protective measures (disqualification followed by the appointment of a guardian) envisaged by the legislation for such persons reflects an approach that focuses more on the protection of property rights and the interests of family members and third parties than on the rights and needs (not just property-related) of the incompetent person.

This explains the insistence of those who maintain that a law is absolutely necessary to introduce the new figure of the proxy or agent to the Italian legal system. The previous tendency to differentiate clearly between the sector of property interests, dominated by issues of transferability, and that of personal interests, which refer to the state and capacity of the person, would in fact be reversed. It is of course within the framework of this change that this new figure of the proxy could be set, as the actor formally entrusted with the task of protecting the interests of a person who has become mentally incapacitated in the event of any doubts arising as to the interpretation of their wishes.

Recognition of legitimacy, and for some of the advisability, of appointing a proxy still leaves the question of the precise ethical-legal significance of their function unanswered. While there is no doubt that the decisions taken by the proxy regarding the treatment of a patient who has become incompetent acquire an ethical value through the very fact that the author of the advance directive has entrusted such a very delicate task solely to this person, it would not be appropriate for these decisions to have binding legal force. As for any other bioethical evaluation, the proxy's opinion should aspire to true *authoritativeness*, rather than to a legally sanctioned *authority*, and his tasks should be limited, in an on-going

dialogue and debate with the physicians in charge of the case, to identifying the best interests of the patient based on the instructions laid down in the advance directive. The proxy would also have the task of ensuring that the physician did not fall into the temptation to practice any form of heroic treatment and of agreeing with him or her on the actual course of action to be followed in those cases where different, equally legitimate diagnostic and therapeutic options are available. There is, however, no question of the proxy being able to take decisions that could not have been legitimately taken by the patient himself in their advance directives (<sup>2</sup>).

#### 6. *The content of advance directives.*

While advance directives are connected with the consolidation of a bioethical culture that has already taken effective action to introduce the informed consent model in physician-patient relations and to overcome medical paternalism, their sphere of impact coincides with that in which a conscious patient can validly express their consent or dissent with the treatments proposed. The general principle that should inspire the content of advance directives can be formulated as follows: *each individual has the right to express his or her wishes, including in advance, with respect to any therapeutic treatment or medical procedure about which they can legitimately express their current wishes.*

From this definition, it appears immediately evident (but should be underscored) that this principle precludes any chance of a situation arising where advance directives might contradict positive law, good clinical practice or medical ethics, or might seek to actively impose practices on physicians that they find unacceptable in terms of science or conscience. It should be remembered that the Italian legal system includes constitutional, civil and criminal laws that recognise the principle of the inalienable nature of human life. As a consequence, the patient cannot be legitimised through advance directives to request or obtain medical action that implies euthanasia. Moreover, in some countries the ambiguity of laws legally recognising advance directives, or the unacceptably broad interpretation of these laws by the courts, makes any proper analysis of

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<sup>2</sup> ) According to Prof. Renata Gaddini, lawmakers should place a strong emphasis on the legal status of the proxy (if possible a physician, especially the patient's own or family physician) and make it obligatory for his or her identity to be recorded in a document specifically designed for this purpose. The right of the proxy to evaluate, along with the person in charge of treatment, the arguments for or against the implementation of the advance directives, should be formally recognised (where, obviously, patients are no longer able to express their own *current* preferences in person).

the point in question extremely complex and has fostered the idea with many that the recognition of the validity of advance directives is equivalent to legalising euthanasia.

It is for this reason that the NBC deems it essential to eliminate any ambiguity and emphasises that the right being proposed - for patients to influence the treatment to which they might be subjected in the event of their being considered incompetent - *is not a right to euthanasia*, or a right to die which the patient can invoke in their relations with physicians (exemplary in this regard is the European Court of Human Rights ruling of 29.4. 2002, *Pretty v. the United Kingdom*). It is, rather, a right solely to ask physicians to interrupt or not to undertake therapeutic actions even in the most extreme, tragic cases of life support, practices which patients would have the full moral and legal right to refuse where capable of so doing. Examples are practices whose effectiveness is not properly proven, or which involve serious risks, are not proportionate to the effective clinical condition of the patient, are extremely invasive or would seriously affect the serenity of the dying process<sup>(3)</sup>.

Taking all this as given, we need to focus on various types of treatment and procedures which, in principle, are encompassed by the above principle. Without necessarily carrying out a complete comparative analysis of the content of the existing models of advance treatment directives, we can however highlight some elements:

1. directives on religious care, the intention to donate (or not) organs for transplant, the use of the body or parts of it for research and/or teaching purposes;
2. directives regarding ways of humanising death (palliative treatments, request to be treated at home or in hospital, etc.);
3. directives that reflect the individual's preferences regarding the range of diagnostic-therapeutic options that might be available during the course of the illness;
4. directives on the implementation of palliative treatments, following the recommendations made by the NBC in its document of 14 July 1995 on *Bioethical Questions on the End of Human Life*;
5. directives intended to formally request the non-activation of any form of heroic treatment, i.e., of life support treatment that appears to be disproportionate or unjustified;

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<sup>3</sup> ) Prof. Silvio Ferrari argues that the document should also mention the patient's right to refuse treatment that is not compatible with his or her religious beliefs.

6. directives requesting the non-activation or the suspension of life support treatment which, in the case at hand, does not necessarily constitute heroic treatment;
7. directives requesting the suspension of artificial feeding and hydration.

The first two types of directives do not pose any particular problem, and may be formulated with a sufficient degree of precision to ensure that those who are called upon to put them into effect are not faced with doubts or difficult choices. The third type of directive does not raise great difficulties either, especially when it consists of the advance planning of treatment and stays within the ambit of the diagnostic-therapeutic options that may be applied during the course of a given disease. The fourth and the fifth directives do not give rise to moral dilemmas, given the unanimity of belief in the desirability of making palliative treatment as widely available as possible and unanimous censure of excessive treatment.

The last two directives, however, are highly controversial; the last most of all, especially if we consider the symbolic significance that attaches itself to feeding and hydration, even if by artificial means. Some members of the NBC believe patients, for motives that will vary but relate to people's most intimate and unassailable convictions, should be accorded the right to express in advance their wish to accept or refuse *any* type of treatment, and to indicate the conditions in which their wish must be put into effect. Those that favour this view stress the necessity of ensuring that advance directives are drawn up, or at least discussed, within the context of a physician-patient relationship, so that the patient is fully aware of the consequences of the enactment of his or her wish. Other members of the NCB, however, believe the patient's power to issue directives should be limited exclusively to those treatments that, in varying degrees, include forms of invasive procedures, on the grounds that they may be disproportionate or even futile. On this view, the patient's right to issue instructions should not refer to non-extraordinary medical intervention in support of life, nor to artificial feeding or hydration which, unless they cause the patient suffering, are ethically and morally mandatory, because, if proportionate to the clinical condition of the patient, they contribute to eliminating the suffering of a terminally ill person, and their omission would constitute passive euthanasia.

### *7. The reliability of advance directives*

Assuming that the issues mentioned above have been resolved, there is widespread consensus that advance directives have great moral force. The same cannot be said, however, about the value of such directives in relation to medical ethics and the law. Above, we touched on two closely connected yet distinct points, which we shall now look at in more detail:

a) the issue of the *reliability* of the choices made in advance of the time of their implementation;

b) the issue of whether such choices should be considered binding on the physician or merely indicative.

In relation to the first issue, advance directives protract the effects of a patient's choice over a period of time, but clearly do not assure that the choice remains current in time, i.e., the wish expressed is not *contemporaneous* with the moment in which conditions are such that the physician is obliged to act. For this reason, the criminal law literature often looks askance at advance directives on the grounds that they cannot guarantee that the *real* wishes of the patient are being realised. The physician can never be certain that declarations made under prejudicial circumstances and particular personal conditions, often when in a state of full psychological and physical health, truly correspond to the wish that the patient would express if of sound mind at the moment it becomes necessary to apply the medical procedure or treatment. The risk for patients is that, on the basis of a choice that was legally improvident, they will be deprived of indispensable assistance that they might have good reason to want if only they could take stock of the realities of the situation, in which new scientific knowledge or therapeutic techniques capable of curing an illness previously considered incurable may have been developed, or, at any rate, in which *different* cures from what they had originally expected may be available.

Two counter-arguments can be advanced against this.

The first is that if a person has been properly warned of the need to take the risks mentioned above into account, and recognises that all advance decisions relating to treatment must inevitably carry an element of hazard, contingency and uncertainty, yet firmly resolves to impart directives nonetheless, that person's signature is an unequivocal attestation of his or her intention to take personal and full ethical responsibility for the risk. If the person in question is an adult, autonomous, informed and of sound mind, and firm in his or her intention to impart advance directives, it is hard to see why the risk that the person has consciously elected to take should render the directives invalid.

The second counter-argument is that if we insist that the manifestation of consent or refusal can only be valid if concurrent with the moment in which the medical act is to be executed, the logical implication is that the patient's will deserves to be respected for as long as he or she is fully conscious and capable of expressing his or her wishes without reservation. This causes no difficulty for what is likely to remain the majority of patients, those who sincerely wish to commit themselves entirely to the competence and wisdom of the physician if they themselves should become incompetent, and therefore to the physician's subsequent unquestionable decisions. This principle, however, causes significant and

paradoxical difficulties when the patients, having signed a document giving advance directives, have, through the exercise of their autonomy, given explicit proof of their wish to guide the medical procedures visited upon them after they are no longer competent. For these patients *and for them alone*, the problem is one of *medical paternalism*, which they consider unacceptable and contrary to contemporary bioethical thinking, which favours the autonomy of patients and the centrality of the individual. In other words, in an effort to avoid the indubitably considerable risk of a mismatch between the substance of a patient's wish and the realities of the situation in which it is to be implemented, we run into the equally serious risk of failing to give due recognition of the patient's autonomy. The only way out of this difficulty is to understand that the requirement that a wish should be current does not refer merely to chronological time. Italian law (for example, the 1999 law referring to organ transplants) has already breached the concept, albeit in reference to a different, though analogous, concept, that legal recognition may be given to a wish expressed by the person while alive, even if the wish was expressed by silence.

As with any form of expression that gives voice to a person's will or, more generally, preference, an advance directive is contingent on the principle that a person retains the right to withdraw consent or change position, right up to the final moment of losing consciousness. It must, however, be accepted that at that point, the known wish of the patient that has been implicitly or explicitly confirmed is to be considered the *final valid wish*, and no one has the right to make conjectures about whether the patient might have changed his or her mind after the loss of consciousness. In any case, given that the decision whether to intervene or not has to be made, it is preferable to follow the indications given by the patient when still in full possession of his or her faculties, since these indications will presumably accord with the person's conception of life, rather than ignore them on the strength of a presumed and unprovable change of will after the loss of consciousness.

On the basis of this reasoning, therefore, we have good reason for arguing that if a patient gives or withholds consent at a time other than the moment of decision proper, the patient's wish should be accorded the same respect that is due to a wish expressed concurrently with the medical intervention. A number of other conditions also apply, and we shall define them in detail below.

### *8. The binding nature of advance directives*

Let us now consider the question of whether advance directives should be considered as (absolutely) binding or (merely) indicative. This

theme, too, has been widely explored in national and international forums, which has inevitably given rise to a wide range of opinion and divergent views. Even so, as the adverbs in parentheses preceding the adjectives "binding" and "indicative" above demonstrate, it is the NCB's view that the disagreement is more conceptual than ethical. The issues at stake have been posed in an improper manner that neither corresponds to the spirit of Article 9 of the Convention on Human Rights and Biomedicine, nor to the interests and needs that, presumably, prompt a person to draw up advance directives. The starting point of the argument must necessarily be a sense of respect for "general good of the human person" and the *therapeutic alliance* between physician and patient, which is a necessary corollary of the first condition. We can make a case for saying that when a person composes and signs an advance directive, the person is not just giving clear indication of a desire to have his or her wishes honoured but is also indicating, with equal clarity, that he or she does not intend these wishes to be absolutely binding in a deterministic and mechanical sense, regardless of the situation.

This is why Article 9 of the Convention uses the French and English words *souhais* and *wishes*, which refer to *what is desired* rather than *what is imposed by third parties*. A person asks that his or her wishes be *respected*, but also asks that they retain their current validity, i.e. that the conditions that the patient intended actually exist. Indeed, it is reasonable to assume that no patient intends to encourage an attitude leading to the abandonment of treatment that would deprive him or her of the possibility of enjoying the benefits of methods of treatment that might become available when he or she is no longer capable of expression. To consider a patient's wishes as neither (absolutely) binding nor (merely) indicative is not a violation of patient autonomy, which, on the contrary, is thus given full expression. Nor does it constitute, as some fear, a violation of the autonomy of the physician and medical professionals. In fact, this approach leaves room for physicians to exercise their independent judgement, without having to respect the patient's wishes mechanically. Rather, the physician has the obligation to assess the currency of previously articulated wishes with reference to the patient's clinical state and any advances in medical technology or pharmaceutical treatment that may have taken place in the meantime, or of which the patient was evidently unaware. This, moreover, is the most accurate interpretation of the meaning of Article 9 of the Convention, as may be seen quite clearly from point 62 of the *Explanatory Report* which we transcribe here:

"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."

It is worth observing that a previous version of the Convention had defined the patient's wishes as "decisive", an adjective that gave rise to considerable misgivings in many quarters, including the NCB. In the first place, the adjective seemed to constitute a violation of the professional autonomy of the physician; secondly, it did not even appear to correspond to the real motives for which, as we have seen above, a patient formulates advance directives. The change in the wording from "decisive" to "taken into account" should not, however, be taken to indicate a shift from treating wishes as (absolutely) binding to (merely) indicative. If it is right to rule out the first formulation, the second, too, should also be ruled out *whenever it is construed in so weak a sense as to amount to the restitution of full decision-making and operational liberty to the physician*, because this is the equivalent of granting the physician inappropriate *paternalistic* power, with the result that very idea of patient directives is emptied of all meaning.

These observations should help take some of the sting out of the controversy over the degree to which advance directives should be considered binding. The ethical value of these declarations depends exclusively on their retaining their relevance during the physician's autonomous assessment of whether the precise conditions indicated by the patient actually obtain. It follows that if the physician, on the basis of his or her knowledge and conscience, is firmly convinced that the patient's wishes were not only *legitimate* but remain *current*, then honouring the wishes not only fulfils the compact made with the patient, but also becomes a matter of ethical duty. If the circumstances have not changed, doing the opposite to the patient's wishes would be a very strange way indeed of taking them into account. Just as obvious is the point that if physicians, acting autonomously, should come to a different decision, they are bound to *provide an exhaustive explanation and justification* so as to allow whoever is acting as the patient's proxy or agent to take action.

### *9. How to implement advance directives*

The issue of implementing advance directives can be considered from two perspectives. Some bioethicists believe that, in light of the growing complexities of situations involving terminal cases, *all* or *most citizens* should make use of advance directives. Those that hold this view feel that

it is important not only to decide upon the most accurate forms of directive and the limits that should be imposed, but also to take action in society to encourage people to prepare directives, in a manner similar to the campaign inviting citizens to make their organs available for post-mortem transplant.

It is also possible, however, to say that equal bioethical respect should be given both to those prepared to draft such directives and to those who are utterly repelled by the idea. Statistical data demonstrates that even in those countries where the possibility of imparting advance directives has been legally formalised for some time, only a very small number of people have wanted to use them. Further, certain practices by which people are pressured into preparing directives are, beyond doubt, highly repugnant. Once such example is a famous London hospital that, when taking in very old people (i.e. more than 75 years) requests (or requires?) the patients, who are particularly fragile both physically and, above all, psychologically, to sign a declaration renouncing their right to life-sustaining therapies if, in the course of treatment, unfortunate, though not extreme, mishaps (such as sight or mobility loss) should occur.

At the present stage of bioethical thought, it seems reasonable to recommend that advance directives should be implemented, but with a view to ensuring only that they are correctly formulated for and applied to those that intend to use them. This avoids the risk that, on the pretext of carrying out previous wishes, a surreptitious attempt will be made to inculcate among patients, especially the more elderly, an attitude of *surrender* in the face of death, which would transform the care of the terminally ill into an appalling and undignified bureaucratic acceleration of the process of dying.

Once we accept, within the limits set out above, that advance directives may be implemented, we need to bear in mind that Article 3.1 of the law ratifying the Convention on Human Rights and Biomedicine delegates the Government the power "to adopt, within six months of the coming into force of the present law, one or more legislative decrees containing further necessary measures for adapting the Italian legal system to the principles and rules of the Convention and the Protocol referred to in Article 1." The question that arises here is whether, for the sake of giving practical effect to the principle outlined in Article 9 of the Convention, we should wish to see the enactment of formal legislation to put advance directives on a legal footing.

It is a question that touches on many different issues and is open to many interpretations. It has been quite rightly pointed out that if the law is to be framed correctly, the legal classification of patient directives should be preceded by an adequate set of rules to address the very general

and fundamental problem of what legal weight should be given to the patients' wishes in relation to the power of medicine to cure, and set down the limits, faculties and obligations inherent in this power (i.e. the scope and content of what is commonly referred to now as the physician's "guarantee role"). Once these issues have been taken into consideration, the legal recognition of advance directives may be justified in full only if it forms part of a more general set of rules referring to the importance of patients' wishes in relation to medical and surgical treatment, which is something that medical science, the medical profession and the law have needed for some time. A remedy is needed for the current situation, which leaves too many legal grey areas.

Another important observation that has been made is that the real bioethical difficulties relating to advance directives are practical and operational, not doctrinal. The achievement and consolidation of correct practice in this area is more a cultural than a legal challenge. Although we must take the principles set forth in the Convention as definitively acquired and shared (for how could we do otherwise?), the very fact that so much effort had to be made to frame the principles and then formally and authoritatively proclaim them suggests that they cannot be taken as obvious or self-evident. It is therefore legitimate to argue that much time will have to pass before they shape the general beliefs of physicians, patients, and the public at large. Given that this is the case, one of the most advanced principles of the Convention, that referring to the value of advance directives, should not be treated as if it represented a clear and unproblematic resolution of a broad debate in bioethics and biopolitics, but, rather, as one of the intricate, complex and occasionally contradictory premises that will always be in need of further painstaking clarification, as part of the unending attempt to make respect for the dignity of patients the cardinal point of all healthcare practice. If we do not start out by being aware of this, we risk reducing the struggle for the promotion and defence of bioethical values in general and advance directives in particular to a purely formalistic battle. The experience acquired over the years shows that, for example, the obtaining of informed consent has, in most cases, been diminished until it consists of no more than the signing by the patient of a document that is often written using terminology that is extremely remote from common understanding of the phenomena involved. If this is the case, then we must not delude ourselves that legislative action to formalise the legal grounds by which advance directives may be considered valid can on its own produce an outcome any different from the inevitably and intrinsically formal results that the law is already capable of providing. Without wishing to deny the usefulness of legal provisions to give effect to the principles of the Convention, the NCB is nonetheless adamant

that a prior effort has to be made to extract all the ethical resources that are implicit in Article 9, so that full value may be given to the physician-patient relationship, not only when a directive is being formulated but also at the rather more traumatic moment when it is being put into effect.

Advance directives should act as a powerful reminder to physicians of their professional duties and offer an opportunity for inaugurating a new model of healthcare for situations of extreme difficulty (except, of course, in those welcome cases where new practices have already been put in place). Healthcare should be regarded as a dynamic structure of relations, not as a static system of procedure. Article 9 should be treated for what it is: the simplest means available for guaranteeing the best possible ethical result with the smallest possible number of rules. We should support an open-ended and flexible approach to legislation whenever the situations that need to be regulated are ethically controversial or social expectations are extremely uncertain. With a view to this, it is to be hoped that any law dealing with advance directives will *accompany and not precede* far-reaching efforts (which should be extended to medical schools, hospitals and civil society in general) to inculcate awareness of the bioethical complexities of the issue.

Some members of the NCB welcome the opportunity of rapidly eliminating the *legal uncertainty* that is such a torment for many healthcare workers and leads many citizens, who are firmly persuaded of the utility and necessity of preparing advance directives, to conclude that the current legal framework provides few guarantees that their wishes will be heeded. In the area of advance directives, many simple but also essential questions can only be given uncertain and imprecise answers. For instance, do patients have to express their wishes in writing, or will an oral declaration do? In either case, how is it done? Who is responsible for the taking and safekeeping of such directives? Should mention be made of them in medical records? How can a physician be sure that the advance directives that he or she has received were not withdrawn or substituted? How can the physician be sure they were made by persons genuinely competent to do so? If the patient has named someone to act as their representative, what are the consequences of the appointed person refusing to accept the responsibility? Clearly, these and other questions that arise time and again in the debate are not answered by the Convention, nor by the Code of Medical Ethics. Yet, without comprehensive and unequivocal answers, the risk is that the principle of respecting previously expressed wishes will not be observed in practice.

To conclude, in addition to raising cultural awareness, it is also necessary to ensure that legislative action is wide-ranging, exhaustive, able to resolve many of the outstanding questions relating to medical-legal

responsibility, provides legal support for advance directives and regulates the procedures for their implementation. This would give physicians clear guarantees for their professional practice, especially for extreme situations. Legislation would also give patients a reasonable certainty that their wishes will be carried out. Only precisely-worded regulations that unequivocally define the contents and limits of the *guarantee role* that healthcare professionals play in their dealings with patients can restore the equanimity of professionals who are called upon to make decisions, and can help them through legal and professional dilemmas that would otherwise be insoluble. In some instances, insoluble dilemmas have led healthcare professionals to conduct themselves in a manner that they regard as morally right and justifiable, yet, in the absence of clear and explicit regulations, leave them open to legal challenge, with possibly dire consequences for their private and professional lives. In an even greater number of cases, however, the absence of legislation induces them to adopt the practice of "maximum caution", not for any ethical or professional reasons, but rather to protect themselves against the legal repercussions of actions they might take. In the aforementioned document from 1995, the NCB advised physicians to conduct themselves in this way, for the sake of prudence rather than for bioethical motives, given the "disappointing" and "insidiously flawed" nature of Italian legislation relating to the "principles of personal autonomy in the exercise of the right to health."

#### *10. Concluding recommendations*

Briefly stated, the NCB believes that advance directives are bioethically *legitimate*, provided that they comply with the following general criteria:

- A. they are *public*, i.e. include a date, are *made in written form only and never orally* by adequately informed persons of adult age, sound mind, who are autonomous and not subject to any family, social or environmental pressure;
- B. they do not contain any instructions whose intent is to obtain euthanasia, or that violate the law, the rules of medical practice or professional ethics. In no case may physicians be forced to do anything that conflicts with their science or conscience;
- C. to ensure that they are prepared properly and in compliance with point B above, directives should be compiled with the assistance of a physician, who may countersign them;
- D. they should be as personalised an expression as possible of the wishes of the future patient, and should therefore not consist of the mere addition of a signature to a pre-printed form or document; they

should not be written in generic terms that might leave room for misinterpretation of their content, and should be as clear as possible about the clinical situations that should obtain before they are taken into consideration.

The NCB also recommends:

- a) that lawmakers act in this specific area to give effect to the directives of the Convention on Human Rights and Biomedicine, and to prepare the way for the future introduction of general legislation referring to bioethics and the health professions, for whose preparation the NCB can offer its contribution;
- b) that the law will oblige physicians to take advance directives into account, but also expressly specify that the directives are not binding, and will compel *both those who carry out directives and those who do not* to provide *formal and adequate* explanation of their decision in the medical records;
- c) that advance directives may appoint one or more *proxies*, whom the physicians must consult when taking decisions relating to patients who have become incapable of comprehension or communication;
- d) that in the very possible event of advance directives containing sensitive and private information, the law will lay down the procedures that must be followed for preserving and consulting them.