Review Article

Advance directives in therapeutic intervention: a review of the Italian bioethical juridical debate

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Abstract

The authors present a review of the Italian bioethical and juridical debate about advance directives. The relevant points of difference between desistence from therapy and euthanasia and of the definition of the concept of therapy are also examined. The Italian Senate has passed a bill in which the value of advance health-care directives is affirmed. However, it is also affirmed that in conditions of emergency or when the subject's life is at immediate risk, the advance health-care directives should not be applied and that artificial nutrition and hydration cannot be included in advance directives. In fact, these practices are thought to be of vital support and physiologically aimed at alleviating suffering until the end of life. Therefore, they cannot be the object of advance health-care directives. It is the authors' view that it is not at all desirable to trust legislative choices about a subject which continually varies in relation to the scientific and clinical knowledge, options and alternatives. The physician is rather asked for a behaviour inspired by the value of the dignity and autonomy of the persons involved, by the respect of wills previously expressed or, in any case, objectively proved.

Med Sci Law 2011; **00**: 1–4. DOI: 10.1258/msl.2010.010201

Introduction

In Italy, as in many other countries,[1] patients have a statutory right to refuse treatment. Before some recent rulings, Italian jurisprudence had never pondered so specifically about this matter. Therefore, clear conclusions had never been reached before, not only on the issue of the right of patients, in full possession of their mental faculties, to express a refusal of so-called 'lifesaving treatments', but also regarding the possible value of the patient's previously expressed will. Moving on to analyse some recent Italian rulings, it is convenient to retrace the Italian constitutional, legal and ethical contexts in which the physician finds himself having to act.

The Italian code of medical ethics (2006), faces the issue of therapeutic obstinacy:

> 'The physician, also taking into account the patient's wills, when these are expressed, must abstain himself from persisting in diagnostic and therapeutic procedures from which it is not possible to reasonably expect a benefit for the patient's health and/or an improvement of the quality of life' (art. 16).

Such ethical tenets match the official stance expressed on a national (National Bioethics Committee [NBC][2,3]) and European[4] level, which is founded on the medical duty to the utmost attention to the person's will, even if this is trusted to advance directives.

The NBC had pronounced on the same line, drawing up conclusive bioethical recommendations which were giving full legitimacy to public advance statements, redacted in written form, devoid of any prospect of euthanasia, compiled with the help of a physician, as much specific and personalized as possible and by which the physician has to abide even if not compulsorily. The Italian medical code underlines the strong meaning of advance directives from a patient currently incompetent, affirming the medical duty either not to elude a will previously expressed or to abstain from treatments from which it is not possible to reasonably expect a benefit for the patient's health and/or an improvement of the quality of life. Q2

The Italian jurisprudence

The recent response of Italian jurisprudence seems to be placed on a full valorization of the patient's will, even if negative and even if previously expressed. The ruling by the Italian Supreme Court (Englaro case, October 2007) concerns the case of a young woman who was in a persistent vegetative state since 1992. Her father, in the capacity of her tutor, had solicited a judicial regulation to authorize the interruption of artificial nutrition and hydration which kept her alive.[5]

The Supreme Court emanated a sentence which deserves to be carefully examined in its fundamental principles.

(a) The physician-patient relationship is founded more on the rights of the latter and on the freedom of self-determination, than on the duties of the physician; (b) the informed consent of patients in possession of their mental faculties constitutes legitimacy and foundation of the medical treatment; therefore medical intervention without a previous valid consent is surely illicit, even when effected in the assumption of the patient's interest; (c) the criterion which regulates the physician-patient relationship is that of a complete autonomy of choices, which can involve also the sacrifice of life, and that must always be respected by the physician; (d) the physician will surely have to verify, whether a refusal is informed, authentic and current. The physician can always try to persuade the patient to undergo the treatment; but, if the refusal stance persists, he will only be able to acknowledge it; (e) the refusal of life saving treatments cannot be confused with euthanasia.

A relevant passage of the Supreme Court dwells on the difference between desistence from therapy and euthanasia. This difference is not irrelevant.[6–10] Whereas the Italian ethical code openly and strongly invites the physician to desist from therapy, with as much strength and authority states that 'The physician, even on request by the patient, must neither effect nor foster treatments aiming to cause the patient's death' (art. 17). Also the NBC[2,3] has pronounced, emphasizing the existing difference between the concept of euthanasia and the choice of the patient who, expressing his/her own personal autonomy, demands not to be helped to die, but simply not to be (further) subjected to undesired treatments, so accepting that his/her disease follows its natural course, even to the extreme consequences.

In this perspective, the NBC deems it essential to eliminate any ambiguity and emphasizes that the right proposed – the right of patients to influence, by means of advance wills, 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. It is, rather, a right to ask physicians to interrupt or to not 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 they capable of so doing. Examples are practices whose effectiveness is not properly proven, or which involve serious risks, which are not proportionate to the actual clinical condition of the patient, which are extremely invasive or would seriously affect the serenity of the dying process.

However, the positions about these issues emerged within the NBC are really differentiated.

We firmly believe that to acknowledge the right to refuse therapy does not identify with acknowledging the right to die, but must be understood as acknowledging a voluntary acceptation of one's own clinical condition matured in the (informed) knowledge of the meaning and of the consequences of such decision. It is not so much up to the physician to prevent death as to cure in the way and in the measure according to which the cure might result of some clinical usefulness and, most of all, within the limits in which this cure, whatever it is, is accepted and allowed by the patient.

A previously expressed judgement (the Welby case which referred to a competent patient who, for pathological reasons, was not able to express his wills any more)[11] had underlined the deep difference between interrupting treatments and euthanasia:

> 'the action of interrupting a therapy can not in any case conceptually be assimilated to the fulfilment of 'a treatment aimed to cause the death' of the patient, because the first is the simple termination of a previously administered therapy while the second is the ex novo activation of a therapeutic intervention aimed to the patient's demise'. Also the difference between interrupting treatments and 'assisted suicide' should not be overlooked: 'It can not be defined suicide the behaviour of the person who, by now aware of the immediate imminence and inevitability of his/her death, decides the time and the way of decease'.

However, it should be underlined how in the Italian cultural debate[12,13] some obscure issues are still now present which still require satisfying and, as much as possible, definitive conclusions.

The first point concerns, inevitably, the true concept of therapy. In Italy this issue is quite debated. The NBC (2005, *Artificial nutrition and hydration in persistent vegetative state*), with a majority opinion, has stated that practices as artificial nutrition and hydration represent actually the due 'ordinary basic supply indispensable to guarantee the basic physiological conditions for life'. In particular, it can be noticed that, in the opinion of NBC, such procedures would constitute 'assistance practices' and 'basic vital supports' and not medical acts, also because they lack any therapeutic aim. Therefore, the conclusion is that 'the decision to not perform or to interrupt artificial nutrition and hydration is not disciplined by the principles regulating medical acts'.

Q3

Also the recent rulings of Italian jurisprudence attempt to provide a definition of the concept of therapy.

In the Welby case the roman Judge wrote:

> 'it can not be denied that assisted ventilation is a kind of therapy only because pertaining "to support vital functions", because otherwise also cardiac surgery, even if extremely complex, could not be qualified as therapeutic intervention, inasmuch as it also is effected to support a vital function, namely, without doubt, the one performed by the cardiac muscle. Instead, it should be surely qualified as therapy, or anyway as medical treatment, the activity of mechanical ventilation… In fact, this consists in the artificial induction of respiration by means of a machine… Therefore, the above mentioned subject, asking to be detached from the artificial lung, has actually exercised his right to interrupt a medical treatment, as individuated by the constitutional rule, as the artificial induction of respiration is not otherwise qualifiable'.

A few months later, the Judges of the Supreme Court categorically comprised the practices of artificial nutrition and hydration in the all-inclusive definition of medical treatment: 'There is no doubt that artificial nutrition and hydration constitutes a medical treatment'.

The debate about this issue, however, persists and it is also confirmed by the numerous bills on living will presented in the Italian Parliament during the past legislatures. Some of these assimilate the procedures to support the vital functions to sanitary treatments, whereas others expressly exclude it, not considering them belonging, as a consequence, to the possible contents of advance wills.

Personally, we feel like sharing the vision of the judges who include in the whole of therapeutic activity also the support of vital functions (artificial nutrition and hydration) and mechanical ventilation. Hypothetically, if the idea was accepted that 'water and food do not become a medical therapy only because they are administered in an artificial way and that nutrition and hydration are due acts inasmuch as basic vital supports, since they allow the subject to survive', then, paradoxically, from this could derive that also a blood transfusion might not be considered a therapy only because blood (basic vital support inasmuch as it allows the individual to survive) is administered artificially. Artificial nutrition and hydration are not basic interventions that can be administered by anyone, as food and water are. Artificial nutrition and hydration are a medical therapy administered for a medical indication by means of technical procedures.

Conclusively, we think that therapy comprises every act, notwithstanding its nature, directed to protect the health of the individual and there is no doubt that also artificial hydration and nutrition have as ultimate purpose that of safeguarding someway the health of the person.

The Italian debate

A relevant part of the decision by the Supreme Court deals with the issue of the so-called advance directives, which still today is lacking normative references in our legal system and is object of a lively and persisting debate.[14–17] Many bills have been drafted and presented for approval to the Italian Parliament during past legislatures, in particular regarding the requirements for validity and the possible contents of the wills previously manifested by the patient and also regarding their potential binding character for the physician who finds himself to be their receiver. In the absence of a comprehensive legislative regulation, the principles of deontological codification and of the aforementioned document by the NBC, which postulate the duty, for the Italian physician, to respect the patient's wills, even if previously expressed, emerge with strength.

The value at stake is essentially the right to freely dispose of their health by the persons concerned, in full possession of their mental faculties. This right presents itself in a different way when the adult subject is not able to manifest his/her will due to his/her condition of total incapacity and when he/she, prior to falling into such condition, when in full possession of his/her mental capacities, has not specifically indicated, by means of statements of advance wills, which therapies he/she would have liked to receive and which on the contrary he/she would have refused in the case of finding himself /herself in a condition of unconsciousness.

The roman Judge (Welby case) had dealt with the problem of the topicality and validity of the wills expressed by a subject who, for pathological reasons, is not able to express such wills any more. According to the Judge's verdict, what is relevant is the predictability of the event, namely the demonstration of the fact that the patient stands by his decision even knowing what he is going to face and that what is actually going to happen is what had been foreseen by the patient himself.

In the Englaro case, in the absence of any clear and explicit formulation of 'declarations of advance wills', the Judges venture in the definition of the limits of the intervention by the legal representative. The very personal character of the right to health of the incompetent person entails that the legal representative does not have an unconditioned power to decide on the health of the same incompetent patient, but is instead subject to two kinds of obligations: the duty to act 'in the exclusive interest of the incompetent patient' and the duty to look for his best interest. He has to decide neither 'in the place' of the patient nor 'for' the patient, but 'with' the patient, therefore reconstructing the alleged wills of the unconscious patient, taking into account the wishes previously expressed prior to the loss of consciousness or, in the absence of any declaration, inferring those wills from his personality, his life style, his inclinations, his reference values, his ethical, religious, cultural and philosophical beliefs.

The choice of the tutor must be in favour of the incompetent subject and therefore aimed to protect his life. However, the tutor cannot neglect the idea of the person's dignity, of the quality of life and of death, expressed by the same incompetent subject prior to falling into a condition of unconsciousness. The law must guarantee to the patients the possibility to make their own voice heard through the legal representative. The patients' wills, manifested in an explicit form or through their beliefs, their life style and their reference values, must be respected. The research of the presumed wills of a person in a condition of unconsciousness, reconstructed on the basis of clear, univocal and convincing elements of evidence, not only on the basis of previously expressed declarations of wills, but also of life style, assures that the choice under question is not expression of the judgement about the quality of life by the tutor but by the patient.

The Judges had therefore enounced the principle of law according to which, in the condition of a persistent vegetative state in which survival is determined by artificial nutrition and hydration realized with nasogastric tube, the judge can authorize (on request of the tutor representing the patient) 'the deactivation of this sanitary presidium'. When this condition is missing, the judge must deny the authorization, since in these cases unconditioned prevalence must be given to the right to life, disregarding the degree of health, autonomy and mental faculties of the subject concerned and the perception that others may have of the quality of life itself.

Moving from these principles the Court of Appeal of Milan (July 2008), after having once again and autonomously verified the young woman's clinical conditions, has authorized the request to suspend artificial nutrition and hydration. The General Prosecutor's Office of Milan has then lodged an appeal to the Supreme Court against this sentence. Finally, on 13 November 2008, the Supreme Court has declared inadmissible the appeal putting an end to the legal matter.[18] Eluana Englaro died on 9 February 2009 and this event came close to provoking a constitutional crisis in Italy. Following Eluana's death, in March 2009, the

Italian Senate has passed a bill on the matter of therapeutic alliance, informed consent and advance health-care directives which has to be approved by the Chamber of Deputies. In this bill, on one hand the value of advance health-care directives is affirmed, on the other hand, paradoxically and in open contrast with the principles animating the Italian Constitution, it is affirmed that in conditions of emergency or when the subject's life is at immediate risk, the advance health-care directives should not be applied. Also, the bill appears strongly debatable on the matter of the contents of the advance directives, in which the subject may render explicit the refusal to any or to some particular form of medical treatment in as much as of disproportionate or experimental kind, but not to artificial nutrition and hydration. In fact, these are thought to be of vital support and physiologically aimed to alleviate the sufferings till the end of life and therefore, they cannot be object of advance health-care directives. As stated in the bill, the physician is to take into consideration the wills expressed by the patient and to note down in the clinical record the reasons according to which he thinks to follow or not to follow them. The physician cannot take into consideration indications directed to cause the patient's death or which are anyway in contrast with the juridical rules or the medical ethical code.

Discussion

Several questions though remain unsolved, namely those regarding the limitations on advance directives. An advanced directive may allow an individual to specify in advance that under certain circumstances (i.e. when the prognosis is hopeless) he/she would withhold or withdraw a medical intervention (informed refusal). However, according to the current Italian proposed bill, a person is not allowed to state that under these circumstances he/she would wish to not receive life supporting interventions such as artificial nutrition and hydration.

The current decision by the Italian legislator to exclude artificial nutrition and hydration from the field of application of advance directives cannot be subscribed at all. For advance directives to really reflect a person's wishes, their contents should include a range of care issues in the settings of terminal illness, persistent vegetative state or end-stage illness, including the person's preferences about artificial nutrition and hydration.

This approach is based on the existence of a community consensus regarding certain treatments, such as artificial nutrition and hydration in case of permanent unconsciousness, that, actually, does not exist in the Italian cultural debate. The issue inevitably raises ethical questions and traditional moralists refer to medically administered nutrition and hydration as a 'natural means of preserving life' and, therefore, as ordinary and morally obligatory means.

We strongly believe that there is no medical, legal or ethical mandate to provide artificial nutrition and hydration to a dying patient or a persistent vegetative state patient when the burden/risk of feeding the patient outweighs the benefit; ordinary food and fluids could be forgone if they fail to provide a proportionate hope of benefit or impose excessive burden. Artificial nutrition and hydration are a medical treatment and therefore can be requested or refused by the patient.[19]

Decisions regarding artificial nutrition and hydration can be challenging for practitioners, patients and families of those incapable patients affected by progressive and potentially terminal illnesses. The decision whether or not to provide artificial nutrition and hydration often evokes a powerful emotional response. Even in the unquestionable criticality of the issue under question, we do not agree with the ones who, in the ethical, deontological and juridical debate, quite lively in Italy at present, invoke a rigid regulatory intervention by the legislator. The law will help ensure that patients' existing advance directives are made available to health-care providers.

The physician is asked for a behaviour inspired by the value of dignity and autonomy of the persons involved, by the respect of wills previously expressed or, in any case, objectively proved, which values the ethical responsibility of the same physician.

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