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ΒΙΟΗΘΙΚΑ

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Ανασκόπηση - Review

Advanced healthcare directives: an analysis of the ethical and legal related issues, and a current comparison among EU Members states

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Abstract

This paper deals with the never-enough-discussed topic of the end of life advanced decisions, focusing on the instructional advanced directives and other kinds of advance healthcare planning (like the appointment of a proxy), as forms of autonomy on own health and life – that is the right to self-determine in advance about whether to submit or not to some medical treatments, even the life-saving ones, in case of the future inability or unconsciousness at the moment they are required. This work aims to provide an overview of the current state of the art of the subject matter, starting from the reconstruction of the route that led to the achievement of such an important legal common framework as the informed consent principle (implemented at a European level by the Oviedo Convention of 1997), to get to the analysis of five EU Members States' national regulations, comparing for the purpose the related similarities and differences, the strengths and the weaknesses; that is the Acts of Belgium, France, Germany, Spain, until the most recent at the moment, the Italian law on informed consent and advanced directives of the late 2017. The report highlights how there is not still a common view of the matter, particularly talking about the legal bindingness of the advanced directives; and even where it is provided, margins of inefficiency or ineffectiveness are more than a possibility, as many concrete cases continue to show, due to some gaps of the system.

A lot of work still needs to be done at all levels, from the EU institutions to the national Parliaments, from the Courts to the hospitals wards, to enhance and grant the advanced will of the most weak among the patients, the unable ones to currently express their wishes; patients thatnevertheless, and even more so, deserve their personal liberty and their dignity to be respected.

Keywords: Advanced healthcare directives, end of life, self-determination, living will, proxy.

Προγενέστερες οδηγίες: ανάληση των ηθικών και νομικών ζητημάτων, και σύγκριση των πρακτικών ευθανασίας των χωρών της Ευρωπαϊκής Ένωσης

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Περίληψη

Το θέμα της συγκεκριμένης εργασίας είναι πολυσυζητημένο και αφορά τις προγενέστερες αποφάσεις για το τέλος της ζωής, εστιάζοντας στις καθοδηγητικές προγενέστερες οδηγίες αλλά και στην προσπάθεια προγραμματισμού προηγμένων υπηρεσιών υγείας, (όπως για παράδειγμα ο διορισμός νόμιμου αντιπροσώπου/δικαστικού συμπαραστάτη), ως έκφραση της αυτονομίας του ατόμου για την υγεία και τη ζωή• αυτό απορρέει από το δικαίωμα του αυτοκαθορισμού εκ προοιμίου, σχετικά με την επιθυμία κάποιου να υποβληθεί ή όχι σε ορισμένες ιατρικές θεραπείες, ακόμη και κι αν αυτές μπορεί να αποβούν σωτήριες, υπό την προϋπόθεση της μελλοντικής ανικανότητας ή έλλειψης συνείδησης τη στιγμή που θα απαιτηθεί. Στόχος της παρούσας εργασίας είναι η παροχή μιας επισκόπησης για την τρέχουσα κατάσταση του υπό συζήτηση θέματος, έχοντας ως εφαλτήριο την ανακατασκευή της πορείας που οδήγησε στην επίτευξη ενός τέτοιου σημαντικού κοινού νομικού πλαισίου, όπως η αρχή της συναίνεσης κατόπιν ενημέρωσης / της ενήμερης συγκατάθεσης (που εφαρμόστηκε σε Ευρωπαϊκό επίπεδο από τη Σύμβαση του Οβιέδο το 1997), καθώς επίσης και η ανάλυση της εθνικής νομοθεσίας πέντε Κρατών-μελών της ΕΕ, συγκρίνοντας τις σχετικές ομοιότητες και διαφορές, τα πλεονεκτήματα και τις αδυναμίες. Πιο συγκεκριμένα, είναι η νομοθεσία του Βελγίου, της Γαλλίας, της Γερμανίας, της Ισπανίας, έως της πιο πρόσφατης αυτή τη στιγμή νομοθεσίας της Ιταλίας στα τέλη του 2017, όσον αφορά τη συναίνεση κατόπιν ενημέρωσης και τις προγενέστερες οδηγίες. Ωστόσο, στην εργασία επισημαίνεται ότι δεν υπάρχει κοινή τοποθέτηση σε αυτό το ζήτημα, ειδικά όταν γίνεται αναφορά στη νομική δεσμευτικότητα των προγενέστερων οδηγιών ακόμα και στις περιπτώσεις που προβλέπεται, τα περιθώρια ανεπάρκειας και αναποτελεσματικότητας είναι πολύ περισσότερα από μία πιθανότητα, καθώς πολλές ιδιαίτερες περιπτώσεις εμφανίζονται διαρκώς εξαιτίας των κενών στο σύστημα.

Είναι αναγκαίο να καταβληθεί μεγάλη προσπάθεια σε όλα τα επίπεδα, από τα θεσμικά όργανα της ΕΕ μέχρι τα εθνικά κοινοβούλια, καθώς κι από τα δικαστήρια μέχρι τα τμήματα/πτέρυγες των νοσοκομείων (νοσοκομειακά τμήματα), για την ενσωμάτωση και την ικανοποίηση των προγενέστερων επιθυμιών ακόμα και των πιο αδύναμων από τους ασθενείς, αυτών που δεν μπορούν επί του παρόντος να εκφράσουν τις επιθυμίες τους• των ασθενών που, παρά των συνθηκών, αλλά και κυρίως εξαιτίας αυτών, δικαιούνται το σεβασμό της προσωπικής τους ελευθερίας και της αξιοπρέπειά τους.

Λέξεις-κλειδιά: Προγενέστερες οδηγίες, τέλος ζωής, αυτοκαθορισμός, διαθήκη ζωής, πληρεξούσιος, νόμιμος αντιπρόσωπος.

1. A necessary introduction

1.1 The achievement of the informed consent principles

Even if informed consent principle, talking about medical treatments, seems now to be accepted and shared by the whole EU community, there is still a great distance and a variety of views and regulations on a closely related issue: the Advance healthcare planning.

The informed consent finds its roots in many national constitutions, in particular, as they state the right to health and the one to personal freedom. The first one, in fact, provides the right to go for treatment, as well as the right to not to do so, according to each person own will and self-determination and, as a consequence, the right of refusing any unwanted medical treatment; the second one provides the bodily integrity, and the right to self-determine in general.

Although this could seem obvious today, the informed consent principle and its protection are a quite recent achievement: it was just in 1997, in fact, that the Convention on Human Rights and Biomedicine (better known as Oviedo Convention) made European countries acquire a common legal background on the field, in the sense of the patients' autonomy enhancing.

For many decades before that, the doctor-patient relationship had been unbalanced and dominated by a sort of paternalism, according to which the doctors had the full control over the choices and the decisions involving medical treatments, the patient being just submitted to his will, as the absolute authority on health and on life protection; in a sense, that was the case regardless of the patient's will and even in conflict with it, when necessary.

This conflict was deeper and very excruciating, when it regarded life-saving medical treatments, as the artificial hydration or nutrition, strictly necessary for the prosecution of the patient's life. According to the duty of care (deontologically), and to the sanctity of life (ideologically), and consequently to its unavailability, the doctor's will always prevailed, and the patient's one, possibly addressed to refuse (or to give up) the treatments, could legitimately be ignored (medically as well as legally), convicting him to a body-prison that, thanks to the technological progress, could last for many suffering years — artificially and indefinitely extending his dying process, against his will.

It's evident how a conflict like this represented a crossroads of ethical, legal, medical, scientific, religious, deontological and philosophical issues, the fulcrum of which is something as hard to define as the value of life: whether life should be considered a value and a (unavailable) sacred good, always decent in itself, and always to be protected, whether efficient or less, conscious or less, wanted or less, and regardless of the subject's wishes; or instead, if the value of life, its dignity and at the end its *sense* should be rather estimated by each man, since life, which belongs to the whole mankind, belongs at the same time (and maybe first) to each one, personal and unique as it is.

Coming back from ethics to medicine, this last view, if followed, was able to legitimate the refusal of an unwanted medical treatment, even a vital one, since own life is here seen as available.

The great debate about theseissuesthat involved politicians, philosophers, lawyers and the public opinion in general, was powered by some heavy dramatic cases, widespread by media: cases of people forced to some life-saving perpetual medical treatment against their will, people that preferred by far death to that kind of living; in this sense, they claimed the right to giving up the treatments, according to their freedom, their autonomy and their self-determination.[1]

[1] One of the most relevant cases known is that of PiergiorgioWelby in Italy: he was totally paralyzed and submitted to an artificial ventilator for more than nine years, due to a degenerative disease. He finally found a doctor who agreed to stop the treatment in 2006; the doctor went to trial for consensual homicide, but it was later cleared as he acted to fulfill a duty (Tribunale di Roma n. 2049/2007, in *www.dirittoegiustizia.it*)

It progressively came to a subjectification of the ill and his health, giving him back the right to choose and self-determine, and redrawing the doctor-patient relationship as an alliance (*therapeutic alliance*). According to this, the doctor can submit the patient only to wished treatments, after informing him about all the treatments related issues; otherwise, he cannot do anything but stopin front of a current, capable and informed dissent, under penalty of acting illegally. Even if it goes under the patient's best interest, or if it can lead to his death, the ill's wishes prevail, and he can always legitimately refuse any medical treatments, or give up the already submitted one: consequently, he must be informed and he must express his consent to any medical treatment before its submission.

The informed consent is then able to be used as an instrument of self-governed reappropriation, as well as a reaffirmationand protection of personal dignity.

The consent had been yet linked to dignityto protect the human body from some forms of utilization and trialin the International Covenant on Civil and Political Rights adopted by the United Nations General Assembly in 1966; talking about European Countries, a common framework was stated by the Convention on Human Rights and Biomedicine(mentioned above), stipulated in 1997: its important Article 5 provides that "*An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time*."

Likewise, the Charter of Fundamental Rights of the EU, which regulation is binding for all the Countries as the Treaties one[2], provides: "*In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law* […]".

As a consequence, the national Courts, as well as the Medical Codes of ethics, implemented and protected these principles.

But what happens when the patient is unable to express his consent/dissent, due to his current unconsciousness or inability?

1.2 Liberty/Dignity

The personal freedom and the availability of own body are strictly related to the human dignity; many rights have been achieved in the name of these values, to affirm, to promote and to protect the individual dignity and identity.

We can already find the dignity as a principle of law just after the end of the WWII, that is after a period in which dignity had been abused and violated hard: the emphatic Preamble of the Universal Declaration of Human Rights of the United Nations (1948) significantly states that "*Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world.*"

At the same time, the human dignity as a fundamental value (and right) raised into the national laws: for example, the Article 1 of the German Constitution, as a *Grundnorm* of the system, provides that "*Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority.*"

Moreover, these respect and protection are highly enhanced in the European field, as we can find it in the Oviedo Convention (1997), starting from its full title "*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*",as well as in the Charter of Fundamental Rights of European Union (2000), and in the Article 2 of the Treaty of European Union, according to which the human dignity is the first among the founding values of the EU.
In the light of the above, human dignity has become a key-word of the modern laws, in particular of biolaws. But what is dignity?

[2] As stated by the Treaty of Lisbon of 2007.

It's important to frame it, since no definition of dignity can be found in legal texts; and the risk is that it could descend to a hollow formula.

At first sight, dignity can play two differentroles: if it can be generally related to the mankind essence, being a column of its inherent value, it can play, on one hand, in a personal and subjective perspective, as a principle to affirm freedom and to claim rights and autonomy (in particular from the authorities); on the other hand, it can be as a limit to these same values, in the name of the dignity as universally and objectively seen, that is the dignity of the whole of mankind.[3]

In this dichotomy lies a potential conflict between personal dignity, as a source of rights, and human dignity, as a source of duties: each person, in fact, is morally - and often even legally – required not to cross with his acts the borders which protect the dignity of the mankind that as a human he must respect so; in a mutual respect of the individual dignities, each person is required to be balanced and in parallel with the collective respect of the abstract and absolute dignity (although able to update its boarders in time) of the whole humanity.

Personal freedom, as expression of personal dignity, can be limited in the name of a higher interest: the protection of the human dignity cannot be put at risk by the extremism of a single person, and neither by the *amoral* technological and scientific development.[4]

The human dignity, then, represents a threshold, un-crossable even by the free consent, since this would involve an unavailable good: the even consensual violation of own dignity would be an indirect violation of the human dignity that each person has inside him, as he belongs to humanity, following the famous Kantian approach according to which each man is an expression of the whole mankindand the humanity inside each man must be always treated as an end, never as a means.

However, this compression of liberty leads to a conflict that becomes bigger as we think that the human dignity is a pre-positive concept, determined by a third partyand that it's something that may be highly influenced, in its concrete specification, by the dominant moral common ground, which likely suffers from a metaphysical view and a religious feeling that can be shared more or less by the subject, but to which he will be forced to submit, though.

A law who defends the individual from himself, and warrants the respect of each one's nature by themselves, overcoming the personal will, cannot justify this role but in the name of insuperable duties that each person has to him or herself. Moreover, it sometimes justifies the duties, or the restriction, arguing about an abstract party who could be offended by the agent's self-acts, the subject's class, the community, the humanity, as appropriate.

Dignity is like an impregnable fortress, inherent to human beings in all of their degrees, granted from the pre-natal status of embryos to the after-death status of dead bodies.

But what about the end of life matters?
It is a field that is highly involved by the conflict we are talking about, between personal dignity and humankind dignity. Let us think of the

[3] About the double-face of the principle of dignity, Beyleveld – Brownsword, *Human dignity in bioethics and biolaw*, Oxford, Oxford University Press, 2001. The authors relate the two mentioned concepts of "*dignity as empowerment*" (the subjective dignity, aimed at the individual rights and liberties enhancing) and of "*dignity as constraint*" (the objective dignity as a limit to self-determination) to two different periods: the first one, to the post-war period of conventions and national constitutionalisations; the second one, to the more recent period of the "*new bioethics*", also as an answer to the new instances and issues raised by the technological progress.

[4] Andorno warns against this threat in *Human dignity and human rights as a common ground for a global bioethics*, in *Journal of Medicine and Philosophy* 34, 2009.

euthanasia for a moment: it is claimed by its supporters as the right to a *decent* end, or as the right to put an end to a life not *decent* anymore, an expression of freedom and self-determination. However, it is strongly opposed by the opponent, who supports the unavailability of life, and of the right to define it as decent or not, since in their opinion it always is.

According to this last opinion, the self-determination is heavily restricted, the freedom is denied, the dignity is imposed, on the basis of hetero-determined criteria and close ties between ethics and law, being the paradigm of dignity used without any references to objective, concrete and positive parameters.

Personal dignity (that is related to the liberty of choice and self-availability) and human dignity, however, are not in a necessary adversarial relationship, according to which the one cannot but exclude the other one: dignity is a universal value, and all of its form can be viewed as the other side of the same coin.

In this sense, the Article 3 of the Charter of Fundamental rights of EU provides and protect the informed consent principle, that is an expression of individual dignity as freedom-enhancing, as long as "*the prohibition on making the human body and its parts as such a source of financial gain*", as a limit to individual actions, and as a protection of the human dignity.

Balancing these values is a delicate, but necessary task. The respect to the moral and personal autonomy and the one to the humankind value can move in the same direction, as they can also come into conflict. In this case the public authorities must warrant the human dignity, as the value that the first Article of the Charter of Nice requires to "respect" and "protect".

2. Advance care planning

2.1 Ethical and legal issues; the framework at the European level

If the informed consent principle is, by now, a shared paradigm,heterogeneous solutions are still given by the EU Countries to a related issue: what to do if the patient is actually unable to express his or her current free will about a medical treatment he must be submitted to, because of his/her permanent or temporary unconsciousness or inability.

In such cases, in fact, the potential conflict between the doctors' duty of care and the patient's right to self-determine (and to refuse the unwanted cares) is at its highest, since the ill cannot even make his choice, in the form of informed consent or dissent.

As long as the required treatments are life-saving, the conflict becomes crucial, especially as we consider that nowadays the scientificand technological development could artificially prolong lifeand avoid the natural occurring of death, for an indefinite time.

It should be strongly taken into account, then, the possibility that a patient, if able to, would rather die than live, for instance, in a permanent vegetative state, submitted to an artificial ventilator or to artificial nutrition and hydration.

If the informed consent principle, as we have seen above, enables the patient to refuse any care, even a vital one, and oblige the physician to respect his will, the lack of consciousness or ability willmake his current will unknowable, and the doctors consequently usually follow the maxim "*in dubio pro vita*": that is, according to the duty to provide care stated by their Code of ethics.

There is the chance, though, that the patient had expressed his will in advance, in some forms, properly planning the care he wished or did not wish to submit to, in case of an actual state of unconsciousness or inability: this is what is called, in general, an advance care plan.

The best known forms of advance healthcare plan are the living will and the durable power of attorney for healthcare, but the category also includes other documents as: the Do-not-resuscitate-order (DNR), the Do-not-intubate-order (DNI), the Physician – or Medical – orders for life-sustaining treatments (POLST and the MOLST, mostly used in the USA).

An important distinction must be underlined, though, to avoid easy confusions: if all of these acts represent a form of advance care *planning*, the living will (or some other specific orders, like the DNR or the DNI) just falls under

the subcategory of the advanced *directives*, as a document that a person drafts to express his will in advance to prevent to be forced to unwanted cares – that is the wishes or the directives about the medical treatment he could face being in a state of inability. When this kind of acts is drafted, an agent eventually appointed by the subject will just control and supervise the respect of the stated will, representing the patient before the doctors and excluding any other people (like the relatives) from getting involved in the matter; but he will not have any actual right to decide by himself.

By a durable power of attorney, instead, a person appoints a proxy not just to represent him or her, in the same hypothesis of lack of consciousness, but in this case, even mandating him to make medical decisions on his or her behalf, as a full surrogate of himself, according to the situation; obviously trying to decide as the patient would have done if conscious, because of his values and his convictions, is what the proxy is supposed to know well.

The big issue that divides the European Countries is to define which forms of ACP are legally valid and, moreover, if they are binding for the doctors, or can be legitimately ignored by them (and in this case, when).

The difficulties about a regulation concern at least two different, but related, problems: the lack of a stringent common framework at the EU level and the hard conflicts at the bottom of some legal and ethical issues.

There is an undeniable, unbridgeable gap between an informed consent and an advanced healthcare plan (in particular focusing on the *instructional* kind of plan, i.e. properly the advanced *directives*).

While an informed consent to be valid, must be (precisely) either informed, conscious, concrete or mostly *current*, the advanced directives are quite the opposite: abstract, (more or less) general, uninformed and mostly, by their definition, *advanced.*

To recognize a binding value to an advanced healthcare plan means to act on the basis of a presumption: the presumption is that, meanwhile, the patient has not changed his mind about the wishes he drafted (a long time before getting sick, possibly in a totally different state of mind); moreover, and it is a sort of *probatio diabolica*, we should presume that he wouldn't have changed his mind about the *current* and *specific* medical treatments he needs, if he was conscious and able to be informed, and he could choose at the moment. For example, he might choose differently because of some developments in the therapeutic field, unknown when he drafted his will or simply because of a stepped in will to fight the disease, instead of just giving up; and certainly, it is not an invincible presumption.[5]

That could be really crucial, as long as we think that respecting a living will could lead to not artificially prolong the unconscious patient's life as stated by him (by chance) — that is letting him die; on the contrary, ignoring his advanced directives could represent a heavy violation of his rights and of his self-determination.[6] Moreover, the Law usually gives the presumptions a probative value, not a decisive one; the decisions are rather to be taken *beyond any reasonable doubt*.

As anticipated, all of these conflicts have not been solved at the EU level (and probably they simply could not) by the though important Convention on Human Rights and Biomedicine of 1997, which chose a "minimalist approach"

[5] Some national legislations actually know some kinds of advanced will, expressed "now for then", for example talking about the organ donation; but none of them can determine a life-or-death choice.

[6] For example, probably because of the abstraction, vagueness and uncurrent time of the dissent, a medical staff in Italy refused to respect the "No blood" card that an unconscious patient (a Jehovah's Witness) had with him, submitting him to a blood transfusion that saved his life. When they went on trial, the doctors argued that they could not assume that the patient's wishes could be clearly also related to a great and imminent danger for the life itself. They won the trial (Cass., 15/9/08, n. 23676, in *Nuovagiur. civ. comm.*, 2009, I, p. 170), although (in confirmation of the hard conflict in this field) the same Supreme Court had stated in a previous judgment that "It must be excluded that the right to self-determination of the patient may be limited if it leads to the sacrifice of his life" (Cass. n. 21748/2007, in Foro it., 2007, I, 3025).

because of "*both substantive and practical reasons, that is, for the need to respect the cultural specificities of each country, and for the impossibility of a deeper consensus*".[7]

That's why the Article 9 of the Convention, "Previously expressed wishes", does not set any common frame either about the minimal formal requirements for the validity of advance directives or about the legal effect of advance directives; yet, it *only* provides that: "*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 order to interpret this vague provision, we must consider it as a compromise formula, provided as a starting point, not an ending one, for a regulation on this delicate field; at the same time it marks the first recognition of the legal value of advance directives in a European binding document.

However, the expression "*taken into account*" clearly leaves open the problem whether the advanced directives should be considered as just indicatory or mandatory, and when they could be disregarded; thus, it leaves to the national legislations the burden to specifically regulate the issue, but it gives the Countries (the ones which ratified the Convention, of course) a common standard ground, according to which, the advanced directives shall *at least* be taken into account.

Although it must be noted how the Oviedo Convention does not deal with the durable power of attorney but just with the advanced *instructional* directives as the living will, still it represents an important achievement, since it seems to provide that "*doctors cannot act arbitrarily and need good reasons to disregard the patient's previously expressed wishes*"[8], for example: "*when they have been expressed a long time before the intervention, or when medical technology has made significant progress since the time when the advanced directive was signed and it can be reasonably assumed that, in the present circumstances, the will of the patient would have been different*".[9]

The next document related to the field at a European level was a soft-law instrument, the Recommendation (2009) 11, that tried: to fill the gaps of the Oviedo Convention, to go deeper in the AD's regulation and deal with the Power of attorney.

According to the Principle 2.3, the advanced directives are defined as "*instructions given or wishes made* […]", being the two different words used in reference to both legally binding or merely advisory advanced statements[10] (still not solving the problem of their legal force by itself, then); but the advance directives which do not have binding effect should, according to the Principle 15, be treated as statements of wishes to be given "*due respect*", that seems to be something stronger than just taking them *into account*, as provided by the previous Article 9 of the Oviedo Convention.[11]

By the way, the recommendation goes a step further by explicitly recognizing for the first time the validity of a binding advance directive.

It also deals with the formal requirements of the AD's, providing that the States should consider whether all or certain types of advance directives should be made or recorded in writing if intended to have binding effect (Principle 16.1). Moreover, according to the Principle 16.2 "*If a directive is about health issues, it is advisable that the adult receives guidance from a*

[7] Andorno, *Regulating advance directives at the Council of Europe*an Negri, *Self-Determination, Dignity and End-of-Life Care. Regulating Advance Directives in International and Comparative Perspective*, Leiden-Boston, MartinusNijhoff, 2011.

[8] Andorno, *ibidem*.

[9] Explanatory Report to the Convention on Human Rights and Biomedicine, paragraph 62.

[10] Explanatory Memorandum to Rec (2009) 11, paragraph 178.

[11] Andorno, *ibidem*.

lawyer, a notary or a medical doctor in order to ensure that the directive is clear and that the adult is aware of the consequences of the choice"[12]; that is something reaffirmed and reinforced next by the Resolution 1859 (2012), which provides, by its point 7.2, that "*Advance directives, living wills and/or continuing powers of attorney should, in principle, be made in writing and be fully taken into account when properly validated and registered (ideally in state registries)*".

In the next paragraphs of this paper, we will make a comparison among the regulations, in the field of the advance healthcare plan, implemented by some EU Member States.

2.2 The EU Member States national regulation

Among the 28 EU Member States, the most of them (17), but not all of them have ratified the Oviedo Convention; the most of them (18), but not all of them have a specific legislation on the advance healthcare plan field, whether they have ratified or not the Convention. This gap leads to some different kinds and levels of regulations, which reflect the different views of the Countries on this matter.

The table below may help to frame the current situation:

EU MEMBER STATE	CONVENTION RATIFIED	SPECIFIC LEGISLATION
Austria	No	Yes (2006)
Belgium	No	Yes (2002)
Bulgaria	Yes (2003)	No
Croatia	Yes (2004)	No
Cyprus	Yes (2002)	No
Czech Republic	Yes (2001)	Yes (2011)
Denmark	Yes (1999)	Yes (1998)
Estonia	Yes (2002)	Yes (2001)
Finland	Yes (2010)	Yes (2005)
France	Yes (2012)	Yes (2005)
Germany	No	Yes (2009)
Greece	Yes (1999)	No
Hungary	Yes (2002)	Yes (2009)
Ireland	No	Yes (2015)
Italy	Signed but not ratified	Yes (2017)
Latvia	Yes (2010)	Yes (2009)
Lithuania	Yes (2003)	No
Luxembourg	Signed but not ratified	Yes (2009)
Malta	No	No
Netherlands	Signed but not ratified	Yes (1994)
Poland	Signed but not ratified	No
Portugal	Yes (2001)	Yes (2012)
Romania	Yes (2001)	No
Slovakia	Yes (1999)	No
Slovenia	Yes (1999)	Yes (2007)
Spain	Yes (2000)	Yes (2002)
Sweden	Signed but not ratified	No
United Kingdom	No	Yes (2005)

[12] Explanatory Memorandum to Rec (2009) 11, paragraph 183.

As can be seen from the table, it seems that the attention paid by the EU Member states is progressively increasing, the great majority of the relating laws having been implemented from 2005 onwards; this is a sign of the rise of the advance healthcare plan as a current, hot topic, although some States which have not regulated the matter yet, have not even started to discuss about that.

However, the Oviedo Convention (with its Article 9 that is interpreted as self-executing, in the sense that an internal law to actually implement it is not required) has significantly reduced the distances among all the ratifying Countries: whether they have or have not implemented a specific regulation about the AD's (recognizing them as legally binding), these shall at least be *taken into account*, being them legally *valid*, if not *binding*; this is the result of the common ground provided by the Convention and a minimum standard to respect.

In the Countries where ADs are provided as legally binding, but they don't accidentally fulfill the legal requirements, we could say that the more they fulfill the requirements of a binding AD, the more they shall be taken into account for the establishment of the patient's will.

Moreover, the Advanced Directives are not forbidden in any EU Country, even in those who have neither ratified the Convention nor implemented an internal law.

Before ending this paper, we will compare five legislations among those mentioned above, as an example; specifically, these are the laws implemented by Belgium, France, Germany, Italy and Spain.

2.2.1 Belgium: Law on the rights of patients (2002)

Belgium is one of the most advanced European Countries in the field of the end-of-life, since it is the one, just together with Netherlands, Luxembourg and, outside from EU, Switzerland, in which the active euthanasia is legal (even for the minors, in the first two cited states).

According to the law on the rights of patients, the patients have the right to refuse or withdraw their consent for any intervention (Article 8, 4°, §1 of the law on patient rights).

If the patient has made a written statement refusing a specific medical intervention at the time when he was still capable of asserting the rights covered in the law, this refusal shall be respected as long as the patient does not revoke it in a period when he or she is competent to exercise his or her rights (Article 8, 4°, §4).

Although the notion "*advance directive*" is not used by the law, it clearly envisages this. Positive advance directives (that is directives lead to accept or allow a medical treatment) are not covered by this law.

Advanced directives validity and bindingness

The law requires the refusal of a specific medical intervention in order that the advance directive has to be respected. Otherwise it must just be taken into account.

In order to be legally binding, the advance refusal has to be in a written form. That is the only formal requirement.

To draft an advance directive, the person must be able to assert the rights of the patient. Neither an evaluation of the capacity at the moment of drafting the advance directive nor an obligation to be counseled by a physician is provided for.

The law does not provide for a limitation of the validity in time. In principle the advance directive is valid irrespective of when it has been written. However, as time passes, although the law does not allow physicians explicitly not to follow an advance directive when the circumstances have been changed, in practice this may be the case for older advance directives; since it is possible that they currently exist some medical alternatives for the specific medical intervention refused in an advance directive, unknown at the time of the draft.

At the request of the patient, the health professionals add any documents supplied by the patient to his medical records (Article 9, 1°, §2, for instance a living will drafted by the patient).

There is not any official registration system. It is up to the patient and/or his surrogate to assure that the advance directive is known and available to the treating physicians. In an

emergency situation a physician will not often have enough time to verify this and his duty to provide assistance will take precedence (Article 8, §5).

Other kind of Advance healthcare plan provided

The rights of adult patients who are not currently conscious or able to exercise their rights as a patient are possibly exercised by the person previously designated by the patients to act on their behalf when and for as long as they are unable to exercise these rights themselves (as a proxy).

This act must have the form of a specific written mandate, and it must be dated and signed by both the patient and the agent.

The mandate can be revoked by both parts at any time (Article 14, §1).

2.2.2 France: Law on patients' rights and end of life (2005)

Advanced directives validity and bindingness

In France the Advanced directives, even if they are provided, are not legally binding.

The Law 370/2005 on the rights of patients and the end of life has created the legal basis for advance directives by introducing section L 1111-11 in the Code of Public Health. It provides:

"*Every adult person may draft advance directives in case he is no longer capable to express his will. These advance directives indicate the wishes of the person concerning the conditions to limit or stop treatment at the end of life. They may be revoked at any time. On the condition that they have been made up three years before the person became unconscious the physician takes them into account before taking a decision to diagnose, intervene or treat*".

Although the law attributes them a validity of only three years, it should be noted that the spirit of earlier wishes endures, in particular when no new advance directives have been written after three years.

According to the decree 119/2006, advance directives must be drafted in a written form, as long as they are dated and signed.

There is no registration system for advance directives, but they must be kept in the medical file of the patient under his request.

Other kind of Advance healthcare plan provided

Article L.1111-6 of the Code of Public Health, about the possibility to design a "personne de confiance", provides:

"*Any adult may designate a person of confidence who can be a relative, a friend or a doctor, and who will be consulted should the person concerned be unable to express his wishes and to receive information necessary for this purpose. The designation is done in writing. It can be revoked at any time. If it is the wish of the patient the person of confidence accompanies him at every step and is present at medical appointments to help him reach decisions*."

To encourage people to appoint health care proxies, the law demands that in the event of hospitalization, the health care facility must suggest that the patient appoints a person of confidence for the duration of the hospital stay. The patient is free to refuse or agree to choose a healthcare proxy. The person of confidence does not have the power to decide in the place of the patient.

Moreover, by creating a "*mandat de protection future*", the law 308/2007 reforming the legal protection of adults introduced a durable power of attorney in health care. This mandate allows any competent person to designate, in view of a time when he will no longer be able to manage his own life alone, one or several other people to act as his representative(s) in all personal matters, including health care. The written advance directives, if drafted, do not prevent consulting the proxy, but they prevail over the latter's view.

The close relatives of an incompetent patient have no legal right to represent him. In the past the jurisprudence recognized their role as "*natural protectors*" and required their consent for a medical intervention but this obligation seems now to be replaced by just an

obligation to inform or consult them in certain hypotheses.

Implementation and data[13]

In 2012, a study of the consultations conducted in relation to advance directives, also taking into consideration ageing conditions and death, showed that nearly 20% of interviewed people aged over 75 expect their will to be respected[14]. They also insist on the paramount importance of exercising their autonomous and free choice concerning their end-of-life decisions.

French physicians consider it difficult to ask patients to draft their advance directives. Another study, published in 2012, concluded that only 2.5% of deceased patients had drafted their advance directives.[15]

Such data are convergent with those published by the preceding study showing that 83% of persons aged over 75 were not willing to draft advance directives;[16] 42% considered it "too early", 36% thought them "useless" and 22% refused to anticipate death or discuss it. Over half of them preferred to talk about their remaining life-time or about their life-quality rather than anticipate on their conditions of death.

Currently, advance directives are unheeded in France, rarely suggested and generally uneasy for patients to draft. When implemented, physicians consider that they have been an important element for 72% of their medical decisions in end-of-life situations. That survey, based on 5217 questionnaires supports the view that advance directives genuinely help doctors take decisions for end-of-life patients.[17]

2.2.3 Germany: Law on advance directives (2009)

Advanced directives validity and bindingness

According to article 1901a of the German Civil Code, an advance directive has to be specific and related to a well determined medical intervention, and this has important practical consequences.

General formulations or guidelines for a future, as well as not well-described medical treatments cannot be considered as an advance directive; but the vagueness of the concepts of "*generic*" or "*specific*" formulations might lead to hardly compress the right of the patients to self-determine, since their directives could potentially always be judged as not specific enough.[18]

However, like verbal expressions of the will, these general statements may have a certain significance (they shall be *taken into account*, as we have seen).

With regard to their binding force, neither the patient nor his healthcare attorney can enforce a medically non indicated intervention from the treating physician, so a positive advance directive has no binding force.

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[13] Based on LeDivenah, Bril, David, *Advance Directives in Palliative Care: The French Case*, in *www.omicsonline.org*.

[14] Fournier, Berthiau, Kempf, D'Haussy, *Are advance directives useful for doctors and what for*, Presse Med, 2013.

[15] Pennec, Monnier, Pontone, Aubry,*Population and societies. Monthly newsletter of the National Institute of Demographic Studies*, 2012.

[16] Fournier, Berthiau, Kempf, D'Haussy, *ibidem.*

[17] Pennec, Monnier, Pontone, Aubry, *ibidem*.

[18] For example, in a recent, much criticized, judgment of 2016 (XII ZB 61/16), the German Federal Court of Justice (Bundesgerichtshof) held that the statement in a patient's living will: "I do not wish to receive life-prolonging treatments" was not sufficient to legally bind a patient's representative to authorize removal of an artificial feeding tube. The Court also separately found that an authorized representative of a patient can only consent to or prohibit medical interventions in life-threatening situations if the written power of attorney sufficiently describes the measures and states whether the representative is empowered to consent to them or not.

Article 1901a, section 3 GCC provides that an advance directive is valid whatever the nature and the stage of the disease the patient is suffering from. This means that the validity of an advance directive does not require a terminal illness that will irreversibly cause the death of the patient. Any restriction would violate the right to physical integrity guaranteed by the German Constitution, because it would force incompetent patients to undergo medical treatments against their will.

According to Article 1901a, section 1 GCC, a valid and binding advance directive has to be drafted by an adult capable of giving consent and exercising his rights as a patient. It must be written and signed; there are not any additional formal requirements.

The AD can be revoked at any time, without formal requirements; they have no expiry date.

The act has not provided a formal system for the registration of advanced directives. The doctors are not under a legal obligation to check whether an incompetent patient has made up an advance directive, and that might represent a potential gap of the whole system.

Other kind of Advance healthcare plan provided

There are no specific rules that govern health care attorneys for incompetent patients. The general rules of the GCC on representation and mandate also apply to the healthcare proxy.

When an incompetent patient has not made an advance directive or his advance directive does not match his actual living and health situation, the attorney has to ascertain his presumed will. The agent should then decide whether or not giving the consent to the intervention proposed by the treating physician. The presumed will of the incompetent patient may be deduced from concrete indications, like verbal or written declarations of the patient, his ethical or religious convictions and other personal value opinions.

Even though the notion of presumed will is subjected to criticism, this has not prevented the legislature from attributing binding force to the presumed will of an incompetent patient. When there is a consensus between the attorney and the treating physician regarding the presumed will of the patient, it has to be respected and no intervention of the guardianship court is required.

The Act does not regulate the case of an incompetent patient who has not made an advance directive while it is also impossible to construe his presumed will, although this is not an exceptional situation. The Civil Senate of this Court judged that the welfare of the patient should be the decisive criterion; this means that in cases of doubt, doctors have to give priority to the life of the patient (*in dubio pro vita* principle, mentioned above).

German legislation does not leave room for informal representation by relatives of the incompetent patient.

Implementation and data

More than 700,000 advance directives have been registered on a voluntary basis in the central advance directive register of the Federal Chamber of notaries[19]; however, 82.2% of the people interviewed in 2009 declared not to dispose of an advance directive.[20]

2.2.4 Italy: Law on informed consent and advanced directives (2017)

Italy has implemented a specific regulation of the matter after an almost fifteen years heated public debate, and particularly after some dramatic famous cases (as the one of PiergiorgioWelby, Eluana Englaro and, recently, DJ Fabo), which had made the end-of-life issues popular, and urgent.

[19] Dhien and Rebhan, *Vorsorgevolmacht und Patientenverfügung*, NeueJuristischeWochenschrift, 2010, p. 326.

[20] Beckman, *Patientenverfügung: Entscheidungswegenach der gesetzlichenRegelung*, MedizinRecht, 2009, p. 586.

The law provides, *inter alia*, that artificial nutrition and hydration (the most controversial medical treatments, because of their life-saving function) are treatments, and consequently they can be legitimately refused by the patient according to his or her will, with a legally binding effect.

Advanced directives validity and bindingness

Article 4 of the law allows any person of age, who is able to understand and will, to express his or her advanced directives for the case of future unconsciousness or inability to self-determine about the wished or unwished medical treatments; that is any medical treatment, including AHN.

The ADs are legally binding when drafted in writing, in the form of a public actor private agreement bearing the patient's signature, which must be certified by a notary; alternatively, they may be expressed in an official public or private agreement that is personally delivered by the patient to the municipal registry office (to be implemented, at the time of this paper). In the case of particular physical impairment, ADs (as prescribed for informed consent) can be expressed through video recording or devices that allow the patient to communicate. In the same ways, ADs can be renewed, amended or revoked at any time.

The law does not place any time limit on the binding force of ADs, nor are particular requirements requested during the patient's life, like medical counseling or update of ADs.

The patient can appoint a trustee (of age, and able to understand and will) to represent him or her before the doctors (but the appointment is not required to make the ADs valid, nor binding).

According to Article 4.5, the advanced directives are legally binding for the physicians, but they can be disregarded in whole or in part by the agreement of both doctor and trustee, when they are "*clearly incongruous or do not correspond to the patient's true clinical picture*" (an expression which certainly is able to generate some conflicts, because of the lack of more specific indications) or when new therapies become available, that could not be foreseen at the time of the signing of the advanced directives.

If doctor and trustee disagree and cannot solve the conflict, the decision will be up to the Court.

Other kind of Advance healthcare plan provided

The law does not provide a durable power of attorney. However, the patient can appoint a trustee, as we have seen, to represent him and supervise the respect of advanced directives by the physicians.

The law does not apply to patients who have not draft their living will; in their case, the doctors will try to trace it back to their presumed wishes, deduced by their personal ethical and religious convictions, opinions and way of living. In the (probable) lack or difficulty to solve the issue, the doctors will fulfill the duty care provided by their Code of ethics, still applying the cited important, as well as controversial, "*In dubio pro vita*" principle, potentially able to compel someone to undefined, unwanted cares that he is just not able to refuse.

2.2.4 Spain: Patients Rights Law (2002)

The protection of patient autonomy as a right in Spain began with the Spanish Constitution of 1978. This does not provide neither a right to autonomy nor a general right of liberty, nor a right to informed consent either.

Furthermore, the Spanish Constitution, like almost every modern one, provides many rights and liberties that are strictly related to their condition as patients for sure: right to health, right to life, freedom of conscience, and in general the protection of human dignity and the development of the personality.

The Law of 2002 particularly regulates the patient autonomy, the rights and obligations regarding clinical information and documentation.

Nevertheless, besides the State regulation, applicable on the entire Spanish territory, all Autonomous Communities possess their own regulation of advance directives (which even preceded the national one), resulting in a huge normative body which contains diverse

institutions of advance care planning. That could lead to a confused system; there are laws that appropriately guide the clinical decision-making, as well as imprecise, confused and also contradictory laws. Moreover, the legal accuracy and the terminology are varied: just as an example, the ADs are named "Preliminary instructions", "Advance will", "Advanced statement of will", "Preliminary will", "Advance expression of will" or "Advance living will", according to the different regional regulations.

These differences of the legal denominations are able to generate legal uncertainty and insecurity. However, since the variety of terminology does not imply conceptual or semantic variety, the different denominations must be understood as different ways to formulate the same concept.

Advanced directives validity and bindingness

Article 11 of the Patients Rights Law provides:

"*For the advance directives document, a person who is of age, competent and free states in advance his or her will regarding healthcare and treatments or, after his or her death, the destination of his or her body or organs, with the aim that his or her will will be complied when he or she is no longer competent to express them personally*[…]".

Despite this provision, some regional legal norms set exceptions to being a person of age, and allow certain minors to issue advance directive documents: a mature minor, an over 16 years old who has intellectual and emotional competence to understand the purpose and consequences of the intervention (Article 9.3.c) Act 41/2002), and the under 16 years old minor who is emancipated by his legal parents or by a judicial decision (articles 314-321 Civil Code), or the minor from the age of 14 when emancipated through marriage (articles 46 and 48 Civil Code), as applicable.

The legal age and the capability apart, the written form is another formal requirement; the document must be drafted before a notary, or before three witnesses (competent and of age), or before the person in charge of the Registry of advance directives, according to the Autonomous Community specific regulation.

Advanced directives are invalid if they are incompatible with the legal order and the *lex artis*; moreover, some Autonomous Communities add two other questionable limits, as the professional or medical ethics and the conscientious objection. The latter, in particular, makes no sense as a general limit, since it should work as an objection to a specific, concrete situation, not to an aprioristic one.

The law does not provide an expiry date, but the ADs can be renewed, amended or revoked at any time, in writing; but an old time, not renewed draft could impact the effect of the ADs in some cases, for example if the healthcare professional discern a great lack of correspondence between the advance directives statement and the current situation.

National and Autonomous Communities' Registries of advance directives were created to ensure the efficacy of advance directives. Registration is not a requirement of validity although it influences the efficacy of advance directives, as the registries are accessible by the healthcare professional.

Just like the Italian recent law (cited above) provides, Advance directives can include the designation of a proxy to act as an interlocutor with healthcare professionals, helping them to interpret patient's wishes and guaranteeing the respect of values and the compliance of instructions included in the advance directives document.

Other kind of Advance healthcare plan provided

Almost simultaneously to advance directives, self-guardianship (*autotutela*) was introduced into the state legal system (article 223 Civil Code).

Although both the institutions act in the sense of the enhancing of the individual's autonomy and self-determination regarding own life and health, self-guardianship acts on a wider personal area, not limited to health matters, and also on the patrimonial area, banned from advance directives. It allows some decisions of the competent person to forecast future

incapacitation and not mere incompetence, which is the case of advance directives. Amongst such decisions is the designation of a guardian, whilst advance directives refer to the possible designation of a proxy.

Another option of advance care planning is preventive powers of attorney, whose aim is the appointment of someone who voluntarily acts when a person's incompetence occurs or worsens.

Moreover, the Life Support Preferences Questionnaire (LSPQ) is a clinical tool provided to improve communication between healthcare professionals and patients (and, when appropriate, their proxies) regarding life support measures. The LSPQ aims to clarify a patient's preferences for the final stages of life, overcoming the difficulty of reliably and accurately documenting a patient's wishes regarding care and treatment during this period, and improving the identification and interpretation of his or her true will in the clinical decision-making process.

Finally, when a patient is not capable of taking decisions and if he lacks ADs as any legal representation, the consent has to be granted by people having ties to the patient by virtue of family or *de facto* reasons (article 9.3, Patients Rights Law).

Implementation and data

According to the National Register for Advanced Decisions, the implementation of the AD in Spain is very low, with a global incidence of 4.52 per 1000 inhabitants, with implementation increasing in parallel to age.

Data apart, "*Generally speaking, most professionals do not know if the patient for whom they are responsible has an AD. Moreover, some professionals, despite knowing, would not observe it in the event of a life-threatening emergency, hence the undeniable need for greater training in this regard. The involvement of administrations, patients, relatives and, above all, doctors is necessary in order to improve the penetration of this type of document within the group*". [21]

Conclusions

The advance care planning, particularly in the form of the advanced directives, is an essential tool to allow the people to self-determine about the crucial end-of-life medical decisions, and in a sense, it is anything but the fair transposition of the fundamental informed consent principle to the case of inability or unconsciousness of the patient to express it at the time.

Having some universal, or at least European uniform legal standards is still an open challenge at the moment, because of the lack of a shared consensus among the countries; but achieving a common efficient implementation of the advanced directives is a desirable goal that could possibly bridge the current great and chaotic gap among the national regulations (even still lacking somewhere, as we have seen) of the validity, the bindingness, the formal requirements, the recording and the accessibility of these documents.

Moreover, it is highly advisable that this common path goes towards recognizing the people the full fundamental right to self-determine about their own health, and to see their personal freedom and autonomy respected by the doctors, as well as by the Courts at all levels.

[21] Manso, Aragones-Rodriguez, Gomez-Duran, Galceran, *The living will or advanced directives.Medicolegal considerations and analysis of the status of implementation in Spain*, in www.elsevier.es